Bioethics Track

BIOS 782  Interdisciplinary Issues in Bioethics: Law and Policy

Course Description

This is the third of five required courses in the Bioethics track of the Bioscience doctoral program. The course is interdisciplinary, and its goal is to introduce students to the interdependency of ethics and policy, legal and economic principles, and the media and public opinion in bioethics and bioscience. The course accomplishes this by presenting readings and featured speakers, exposing students to different players and perspectives in the bioscience and bioethics fields across a range of issues from genetic modification to issues of personhood.

The course builds on the foundation in the legislative process introduced in Bioethics Foundation II, examining in more detail how issues in biology and bioethics are identified by the legislature for legislation, and then the process by which the legislature creates laws that regulate in these areas. International and non-traditional topics will be integrated into this part of the course to expose students to a broad and culturally diverse perspective. The course will go on to examine the impact of legislation on the health and biotechnology industry, as well as on individual practitioners in the fields. To illustrate these relationships, property rights (including, intellectual property) in biological materials (e.g., genes, genetic information, tissues and organs) will be presented. The course will conclude with a discussion of bioethics in the public eye, including critiques of bioscience and bioethics, how the media exploits bioscience and bioethics, and public perception of ethics and the law.

Course Rationale

As a field, bioethics addresses the moral dilemmas and choices that face society in matters that involve bioscience. The framework for analyzing these issues has been introduced in the earlier required courses in the Bioethics track. The Foundations III course builds on this foundation by examining how ethical choices are codified into regulations and laws, and the impact these have on industry and practitioners. Acquiring an understanding of these relationships is a critical step in the training of both bioethicists and bioscientists to assist them in navigating through the regulatory framework, how to influence it, and how it affects the practice of bioscience in the academic and commercial worlds. To show these issues close up, speakers will be brought in from different fields to present their different perspective and the policies that drive it.
Course Goals:

1) To understand the basic legislative process through which choices in bioethics are codified into laws

2) To understand the interdependency of the marketplace (e.g., biotechnology and health care) and the laws which regulate it

3) To become acquainted with leading issues in bioethics

4) To gain awareness of the diverse spectrum of voices and perspectives in bioscience and bioethics

5) To become acquainted with different career tracks in bioethics

6) To gain critical skills in identifying issues in bioscience that benefit from ethical analysis

7) To develop a basic foundation in principles of property and ownership, especially how it relates to intellectual property and biological materials

Course Objectives:

This course has several key objectives: (1) to introduce course participants to bioethics practice by having invited speakers lecture the class about questions and concerns faced in a “real world” environment (e.g., of current interest and importance), and in this context (2) to examine issues across a variety of disciplines that involve science, ethics, and the law.

Course Schedule:

The course meets once a week for a three-hour session. There are seven modules. Each module covers a two-week period and includes a speaker, readings, lecture, and class discussion.

1. Legislative policy
   Speaker: Congressional aide or lawyer who describe the process of lawmaking, from hearings to enactment of a statute

2. International bioethics
Speaker: Scholar/practitioner who discusses relevant topic in international bioethics, and contrasts with the policies in the United States.

3. Perspective in health care and research
   Speaker: Clinical researcher who describes issues facing physicians/nurses who treat patients in a clinical research setting

4. Biocommerce
   There is a well-established market in the commerce of human tissues. For example, self-replicating tissues, such as sperm, ova, and blood, are bought and sold in specialized markets for human tissue. We will address the legal and ethical issues that arise when body parts become an object of trade, including state and federal laws regulating commerce in biological products.
   Speaker: GIVF personnel who describes how donors are solicited and screened
   Readings: Federal and state statutes which regulate human tissues, organs, and other biological materials; legal cases involving sale of tissue and liability for tainted blood

5. Biotechnology and the environment
   Genetically modified (“GM”) crops, such as corn and soybean, are widely used in the agricultural industry. Many products for human consumption contain GM ingredients. A number of ethical questions about GM foods are currently being debated, including, whether GM foods should be labeled as such, the risks to human health by the consumption of GM foods, and the impact of GM crops on the environment.
   Speaker: USDA scientist or policymaker

   Identification of genes associated with disease, disease predisposition, and behavior is at the forefront of biomedical research. Genetic information is of particular interest to employers and health insurance companies as predictors of disease susceptibility and job performance. This topic examines current and proposed legislation which protects and regulates the dissemination of genetic information. We will look broadly at the issue of privacy and genetic discrimination.
   Speaker: Congressional policymaker
   Readings: Proposed statutes protecting genetic information

   Human genes have become a currency of the biotechnology industry. The primary strategy to secure rights in human genes is the patent system. There is much public controversy over the ethics of patenting human genes. We will examine fundamentals in patent law as applied to genes. As a case study, we will study a lawsuit filed by a patients’ rights group challenging a patent covering a disease gene isolated from their tissues.
   Speaker: Intellectual attorney
8. Personhood and ethics.
   At the heart of many legal and ethical issues today is the definition of what is a person. There are a variety of contexts in which it arises, including embryo and animal research, and, in death and dying cases. We will address the significance of personhood from an ethical, legal, and cultural viewpoint, and examine different definitions of it.
   Speaker: Religious scholar
   Readings: Legal cases, including The Dred Scott Case and The Right to Die cases

9. Venture capital in biotechnology
   Speaker: Venture capital manager or biotech company chief executive officer or financial officer

10. Bioethics in the public eye
    Speaker: Newspaper, radio, or internet journalist
    Readings: Lay articles on bioscience and bioethics

Readings

Course packet, including selections from legal cases, law review articles, specialty journal articles (e.g., from bioethics journals, business journals, medical journals), and federal and state regulations and statutes.

Assignments

Four 3-5-page papers:
1. Viewpoint Paper: Identify an issue being debated in bioethics, and describe at least two different sides of the debate. Analyze the basic differences between the positions.


3. Legal analysis Paper: Analysis of a statute regulating bioscience (e.g., stem cell law; patent law; organ transplantation law), and its effect on biotechnology

4. Policy Paper: Identify an issue in bioscience, summarize a policy, and propose a plan for implementing that policy.

Grading:
Papers: 20% each x 4 = 80%
Class Participation 20%

100%