## Week 1: Introduction to Biotechnology & Law

### Objectives

Upon completion of this module, students will be able to:

1. Appreciate the enabling tools and resulting applications of biotechnology
2. Assess the scope of federal administrative agency oversight of biotechnology in agriculture, industry, and health care
3. Interpret relevant statutes, case law, and regulations pertaining to biotechnology
4. Assess incentives for innovation, such as federal funding, licensing, and patents
5. Analyze biotechnology case studies, including problems raised by synthetic biology and rDNA in agriculture
6. Evaluate broad ethical considerations and mechanisms for bioethical assessment of biotechnology
7. Identify legal and policy issues resulting from “dual use” research

### Requirements

**Readings:**


2. Yali Friedman, Applications, Ch. 6 Click for more options in BUILDING BIOTECHNOLOGY 4th Ed. (Logos Press 2014), p. 57-88.

**Video Presentation:**

1. View the video presentation by Monday of this week.

**Activities:**

- Activity # 1: Tutorial Questions
- Activity # 2: Discussion Questions
Tutorial Questions for Week 1

The Tutorial Questions are designed to ensure that you have an accurate understanding of the key points in the readings. Answers to these questions can be any length. Your goal should be to accurately state the relevant points of law as concisely as possible. Your professor will provide feedback and guidance on your responses. Answers are due by 11:59PM on Wednesday.

TQ 1.1: Sutton: What types of legal issues has biotechnology already begun to raise in the courtroom? What does Justice Kennedy say about the role of science in the courtroom? What are the range of technologies that enable biotechnology? What was the early role of the Food and Drug Administration in overseeing products utilizing biological processes?

TQ 1.2: Friedman: What are the three general categories of applications of biotechnology? What are some of the examples described of each category? How do products differ from services? What is golden rice and how is it an example of biotechnology? What types of applications seem the most futuristic, and why?
Discussion Questions for Week 1

A "threaded discussion" is a discussion forum that allows students to respond to questions posted by the professor (original responses), which can then be read by other users who add their own comments in response (secondary postings). Unlike chat rooms and other "real-time" interaction forums, threaded discussions do not require different users to be logged on at the same time.

Discussion questions are assigned each week. Original responses to these questions must be posted by Thursday at 11:59PM. Original responses must be at least 250 words and must incorporate concepts from the lectures and assigned readings.

Secondary Responses/Postings: Each student must post two or more secondary responses to other students’ postings for each discussion question. Secondary responses are due by 11:59PM on the Monday following the week in which the questions were assigned. They must be a minimum of 150 words and, like original responses, should incorporate concepts from the lectures and assigned readings. Students are encouraged to embark on interactive discussions that go beyond the minimum number of secondary postings.

Although the discussion board is expected to be student-driven, professors will be participating in the discussions as well.

DO 1.1: Researchers predict that, within the next two decades, almost 90% of human body parts will be replaceable with organs grown in the laboratory using biotechnology techniques. In fact, British scientists recently reported the growth of a complete and functional mouse thymus, an organ located near the heart that acts as a vital immune system nerve center. Identify and discuss some potential risks and benefits of such a shift in transplantation norms from human organ donors to biotechnology-derived organs.

DO 1.2: Because biotechnology consists of a spectrum of disciplines and technologies, there is no "biotechnology law" in the sense that there is environmental law or criminal law. Many traditional legal realms have an impact on biotechnology. Identify 2-3 areas of the law that you believe are most implicated by developments in biotechnology, given the readings and your own experience. How do you think developments in biotechnology will affect these areas of law? What specific dilemmas will courts and legislatures be forced to confront?