Biotechnology and the Law

HLTH 9529

Course Description
This course will examine a variety of legal, policy, scientific, social, and ethical issues in the realm of biotechnology. Biotechnology crosses many scientific disciplines: biology, cell biology, molecular biology, immunology, microbiology, chemical engineering, genetics, chemistry, biochemistry, physics, computer science, and mathematics. Course topics will include examination of foundational technologies such as recombinant DNA technology; current applications, including nanobiotechnology and synthetic biology; research and development; funding; academic-industry relationships; human subjects research and institutional review of clinical trials; regulatory oversight by federal agencies; and protection of intellectual property.

Readings
All readings for this course are available in a custom-made textbook published by XanEdu.

Weekly Schedule

Week 1 Topic: Introduction to Biotechnology & Law
Week 2 Topic: Early Challenges to Biotechnology -- rDNA in Agriculture
Week 3 Topic: The Bayh-Dole Act and its Impact on Innovation
Week 5 Topic: Regulatory Basics – The Who, What, and When
Week 6 Topic: Regulatory Case Study – Synthetic Biology
Week 7 Topic: Bioethics, Human Subject Research Protections & the “RAC"
Week 8 Topic: Dual-Use Research Concerns

Course Outcomes
Upon completion of the course, students will be able to:

CO 1. Examine the history and development of the field of biotechnology
CO 2. Appreciate the enabling tools and resulting applications of biotechnology
CO 3. Assess the scope of federal administrative agency oversight of biotechnology in agriculture, industry, and health care
CO 4. Interpret relevant statutes, case law, and regulations pertaining to biotechnology
CO 5. Assess incentives for innovation, such as federal funding, licensing, and patents
CO 6. Analyze biotechnology case studies, including problems raised by synthetic biology and rDNA in agriculture
CO 7. Evaluate broad ethical considerations and mechanisms for bioethical assessment of biotechnology
CO 8. Identify legal and policy issues resulting from “dual use” research
Activity #1: Tutorial Questions
The Tutorial Questions are weekly assignments 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.

Tutorial Questions for week 1 are available with the first week’s assignments. Tutorial Questions for the remaining weeks of the course are available on the Blackboard course site.

Activity #2: Discussion Questions

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. For weeks one through seven, all secondary responses are due by Monday night at 11:59PM. However, all secondary responses for week eight are due by Saturday night at 11:59PM when the course ends. 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.

Discussion Questions for week 1 are available with the first week’s assignments. Discussion Questions for the remaining weeks of the course are available on the Blackboard course site.

Activity #3 – Interpreting a State Labeling Law
This activity is due on Saturday of Week 2. Further information is available on the Blackboard course site.

Activity #4 – Presentation on the BRAIN Initiative
This activity is due on Saturday of Week 4. Further information is available on the Blackboard course site.

Activity #5 – Intellectual Property Approaches
This activity is due on Saturday of Week 6. Further information is available on the Blackboard course site.

Activity #6 – Performing Dual Use Review
This activity is due on Saturday of Week 8. Further information is available on the Blackboard course site.
Grading

**ACTIVITIES** | **% OF FINAL GRADE**
--- | ---
Activity #1: Tutorial Questions | 25%
Activity #2: Discussion Questions | 25%
Activity #3: Interpreting a State Labeling Law | 12.5%
Activity #4: Presentation on the BRAIN Initiative | 12.5%
Activity #5: Intellectual Property Approaches | 12.5%
Activity #6: Performing Dual Use Review | 12.5%

Responses to the Tutorial Questions and Discussion Questions will be graded. At the end of the course, the lowest grade you receive for the Tutorial Questions and for the Discussion Questions will be dropped and will not be counted towards your final grade for the course. The purpose of this policy is to accommodate unanticipated professional or personal scheduling conflicts that may arise during the course.

**IMPORTANT:** You are required to post a minimum of one 250-word main post plus two 150-word secondary posts to each weekly discussion thread/topic. Your weekly discussion board grade will be based upon the quantity and overall quality of your postings.

**Late Activities:** For purposes of grading, activities and assignments that are submitted late will be treated as not having been submitted at all. The professor may make exceptions to this policy for true emergencies, such as serious illness. Requests for exceptions should be made in advance of the deadline, if possible. The professor’s decision to grant or deny a request for an exception is final and unreviewable.

The following grade scale will be used to calculate final grades. The following is an explanation of how points equate to grades, based on a 4.33-point scale:

<table>
<thead>
<tr>
<th>Grade</th>
<th>Quantitative</th>
<th>Qualitative</th>
<th>Definition</th>
</tr>
</thead>
<tbody>
<tr>
<td>A+</td>
<td>4.33</td>
<td>Excellent</td>
<td>Superior understanding of the content and method of the course, extraordinary ability to recognize relationships between concepts, initiative in doing work in which quality consistently surpasses that required.</td>
</tr>
<tr>
<td>A</td>
<td>4.00</td>
<td></td>
<td>Good understanding of the content and method of the course, demonstrated ability to recognize relationships between concepts, substantial achievement of course objectives and fulfillment of course requirements.</td>
</tr>
<tr>
<td>A-</td>
<td>3.67</td>
<td></td>
<td>Good understanding of the content and method of the course, limited recognition of relationships between concepts, basic but incomplete achievement of course objectives and requirements.</td>
</tr>
<tr>
<td>B+</td>
<td>3.33</td>
<td>Good</td>
<td>Rudimentary understanding of the content and method of the course, limited recognition of relationships between concepts, basic but incomplete achievement of course objectives and requirements.</td>
</tr>
<tr>
<td>B</td>
<td>3.00</td>
<td></td>
<td>Little understanding of the content and method of the course, inability to demonstrate minimum recognition of relationships between concepts, unsatisfactory achievement of course objectives and requirements.</td>
</tr>
<tr>
<td>B-</td>
<td>2.67</td>
<td>Unsatisfactory</td>
<td>Lack of understanding of the content and method of the course, failure to achieve objectives and/or complete requirements of the course.</td>
</tr>
<tr>
<td>C+</td>
<td>2.33</td>
<td>Fair</td>
<td>Superior understanding of the content and method of the course, extraordinary ability to recognize relationships between concepts, initiative in doing work in which quality consistently surpasses that required.</td>
</tr>
<tr>
<td>C</td>
<td>2.00</td>
<td></td>
<td>Good understanding of the content and method of the course, demonstrated ability to recognize relationships between concepts, substantial achievement of course objectives and fulfillment of course requirements.</td>
</tr>
<tr>
<td>C-</td>
<td>1.67</td>
<td>Unsatisfactory</td>
<td>Good understanding of the content and method of the course, limited recognition of relationships between concepts, basic but incomplete achievement of course objectives and requirements.</td>
</tr>
<tr>
<td>D+</td>
<td>1.33</td>
<td>Unsatisfactory</td>
<td>Rudimentary understanding of the content and method of the course, limited recognition of relationships between concepts, basic but incomplete achievement of course objectives and requirements.</td>
</tr>
<tr>
<td>D</td>
<td>1.00</td>
<td></td>
<td>Little understanding of the content and method of the course, inability to demonstrate minimum recognition of relationships between concepts, unsatisfactory achievement of course objectives and requirements.</td>
</tr>
<tr>
<td>F</td>
<td>0.00</td>
<td>Failure</td>
<td>Lack of understanding of the content and method of the course, failure to achieve objectives and/or complete requirements of the course.</td>
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Grades are based strictly on individual performance, not on any external factors (e.g., tuition reimbursement policies at your place of employment). Any questions about grades must be made in writing.