BIOTECHNOLOGY AND LAW SYLLABUS
VERSION January 6, 2017
(Spring, 2017)
Prof. Evans
UNIVERSITY OF HOUSTON LAW CENTER
Course areas: Health Law, IPIL, and EENR

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Office Hours:
W after class and other times
by appointment: email
me to set up a time that works

CLASS TIME M,W 10:30 – 12 pm

NOTE This course qualifies for credit in IPIL, EENR, and Health Law. Because of technical constraints in the UH catalogue software, it could only be displayed under IPIL and Health Law. But students taking this course also may count it toward EENR studies.

COURSE MATERIALS

1. Course reading materials will be provided for free via the UH Electronic Blackboard, because there simply isn't a good, up-to-date casebook available in this field.
2. In this class, we will do a lot of practice-oriented, in-class problem solving and discussion, using problem sets I have developed and will provide to you.

GRADING: This course has an in-class midterm that will count for 50% of students' grades, and a take-home final that counts for 50%. Material covered on the midterm will not be tested again on the take-home final. The specific date for the midterm will be set in class by consensus to minimize scheduling conflicts. However, in the event a student has a scheduling conflict or is ill on the date of the midterm, it can be rescheduled on the same basis that a final exam could be rescheduled: that is, students with a bona-fide school or work-related conflict or illness on the date of the midterm may work with the Office for Student Services to reschedule the midterm to an alternative day *within one week* of the regularly scheduled time.

NO PREREQUISITES This introductory course requires no prerequisites other than completion of the general 1L curriculum. No science background is required. The course does not overlap law and genetics and students are encouraged to take both courses in either order. This course can be taken as an elective by people who simply are interested in the latest controversies in biotechnology law and policy, or as a way to gain practice-oriented skills if you wish to pursue a career in Houston's growing life-sciences and biotechnology industry.

COURSE CONTENT This course provides a practice-oriented survey of major regulatory frameworks for commercializing new biotechnology products and protecting consumers and workers from the risks these products pose. This year's course has been updated to add coverage of important legal and policy developments during the past 12 months.

Unit 1: Introduction and Overview: The Biotech Regulatory Challenge

The course starts off with a quick introduction--in terms accessible to students with no scientific background—to the profusion of new technologies and biotech products expected to enter the market and change our world during the next 5 – 15 years. Future biotech products go far beyond the familiar categories of medical products and genetically modified foods. Products already available or in development include at-home gene editing kits that will rupture the tightly controlled research and development pathways of the past and confront regulators with a wave of citizen science and small-scale, do-it-yourself manufacturing; artificially intelligent biological robots that may soon compete with you for a job; bioprinted sheets of new skin and scalp that may keep today's law students looking young for as long as you live; DNA-based memory devices capable of storing the cumulative knowledge of mankind in a teaspoon and wireless machine/brain interfaces that will put that knowledge at your disposal (but, sadly, not in time for the take-home final in this course!); designer pets (pink dogs?) and babies and de-extincted species; biotech industrial processes that can generate limitless quantities of spices, fruits, eggs, and meat but which threaten to displace millions of agricultural workers; and new sources of climate-change-neutral energy.

FIRST DAY'S ASSIGNMENT: Available on course electronic Blackboard and on the course web site. I also e-mailed copies to students registered for the course.

Please read the following short case studies and come to class prepared to discuss what concerns you feel about these technologies and whether you feel the regulatory oversight framework described is sufficient.

Intro 1: Navigating the Regulatory Landscape: Biopesticide Case Study
Intro 2: Navigating the Regulatory Landscape: Oxitec Case Study
Intro 3: Navigating the Regulatory Landscape: Genetically Modified Plant Case Study
Intro 4: Navigating the Regulatory Landscape: Synthetic Squalene (Cosmetics) Case Study
Intro 5: Navigating the Regulatory Landscape: Biomining Case Study

SECOND DAY'S ASSIGNMENT: With profound scientific advances on the near-term horizon, the White House Office for Science & Technology Policy, in July 2015, launched a major overhaul of the U.S. Coordinated Framework for Regulation of Biotechnology, last modernized in 1992. The White House issued the Updated Coordinated Framework on January 4, 2017. Prof. Evans, who has been closely involved in these efforts, will introduce the key regulatory frameworks you need to know to work in the biotech sector (FDA, EPA, USDA, consumer and occupational safety, and privacy regulations), and press you to help conceive solutions to the profound social, economic, and policy challenges regulators will face as a profusion of new biotech products comes on stream in the next 5 – 15 years.

READING: 1/4/2017 Coordinated Framework document, READ PAGES 1 – 20.

Unit II Regulating key health-related biotechnologies: precision medicine, genomic testing, and human gene editing. Basics of FDA, CLIA, and CMS regulation of biotechnologies.

Unit II introduces regulation of precision medicine and genome-related technologies by the Food and Drug Administration (FDA) and under the Clinical Laboratories Improvement Amendments of 1988 (CLIA), and reimbursement approvals that affect whether, and at what price, an innovation can be sold to consumers. These regulatory frameworks are the subject of ongoing turmoil, with major reform initiatives under debate. This section provides an extremely compact, practical, and efficient introduction to the current frameworks and it will highlight key points of dispute. This section aims to equip students to advise clients on key regulatory opportunities and pitfalls lurking in these regulations. Topics include strategic choices clients must make, even during their earliest upstream research and when they are first protecting their IP, that may affect the client's subsequent ability to commercialize technologies that require FDA approvals; strategic choices among alternative commercialization pathways that let clients opt into lighter regulatory oversight in return for greater capital commitment and operational involvement by the client; regulatory strategies that allow clients to accept greater federal regulation in return for greater preemption of state tort causes of action. The course also introduces the process − all-important to your client's ultimate financial success − of qualifying a new biomedical technology for reimbursement by Medicare and insurers.

All materials are on the class Blackboard

R-11 **The Traditional FDA Regulatory System and Its Problems**
Institute of Medicine, Future of Drug Safety (Excerpts)

FDA INTRO SLIDES: print and bring to class if you want a hard copy to refer to

R-12 **Efthimios Parasidis: Patients over Politics (Excerpts)**

SLIDES: BASIC FDA DRUG REGULATION

REVIEW QUESTIONS ON R11-R12

R-13 **Statutory Reading Exercise: Key Elements of FDAAA Reforms**
21 U.S.C. §§ 355(k)(3), 355(p), 355(r), 355-1

STUDY QUESTIONS TO GO WITH R13 STATUTORY READING EXERCISE

R-14 **Postmarketing regulation under the Food and Drug Administration Amendments Act of 2007, excerpts from Evans, Seven Pillars of a New Evidentiary Paradigm**

SUPPLEMENT: TYPES OF SCIENTIFIC EVIDENCE

R-15 **Lewin Group, The Value of Diagnostics (Excerpts)**
Introduction to the Diagnostics/Genetic Testing Industry and its Regulation

SLIDES: INTRO TO REGULATION OF DIAGNOSTICS

LINKS TO CLASS REPORTS ON PERSONAL GENOMICS CONTROVERSIES

R-16 **Jessica Palmer, Direct-to-Consumer Genetic Tests**

IN-CLASS HANDOUT

R-17 **Institute of Medicine, Medical Devices and the Public's Health (Excerpts)**

FDA IVD PRODUCT DEFINITION AND INTENDED USE

READING GUIDE TO GO WITH R-17

SUPPLEMENTS FOR MENTION IN CLASS
- ASR GUIDANCE
- HUMANITARIAN USE DEVICES
- CUSTOM DEVICE GUIDANCE

FDA EXAMPLE PROBLEMS (MIDTERM PREP TO WORK IN CLASS)

R-18SUPP: Now that you know the basics, we will read selections from the latest debates at the time. These may include materials from the Dec. 1-3 International Summit on Human Gene Editing, a technology that makes it possible actually to alter a person's genome, or materials related to the ongoing debate about FDA regulation of genomic technologies, including a discussion paper FDA just issued in January 2017. The following readings are subject to revision, depending on how events develop:
R-18 Lewing Group: The value of Diagnostics (Excerpts)
Reimbursement for Diagnostics/Genetic Tests
R18-A – Sharfstein Viewpoint
R18-B – JP Evans/M Watson Viewpoint
Javitt & Corner-FDA Regulation of Next Generation Sequencing
Deverka-Insurance Reimbursement of Genomic Testing
FDA Discussion Paper on Framework for Oversight of Laboratory-Developed Tests

THE MIDTERM WILL ONLY COVER MATERIAL THROUGH THE END OF UNIT II

The precise content of Units III and IV will depend on two key events: (1) timing of the release of a major National Academies of Science, Engineering, and Medicine report that is currently expected to be released in February, 2017, and (2) whether the Obama Administration finalizes revisions to the major research regulation known as the Common Rule prior to the inauguration, and whether the incoming Administration allows the revised rule to stand. These matters should become clear by Feb. and the syllabus will be filled out based on what happens.

Unit III **Intro to Agricultural and Industrial Biotech**

Genetically modified and synthetic foods: basics of USDA/EPA/FDA oversight of traditional genetically engineered plants and animals and foodstuffs generated using an array of new food-synthesis technologies. Social impacts of restructuring in the agriculture sector.

New horizons in biotech consumer products: the consumer-safety challenge of novel trends such as do-it-yourself gene editing kits and citizen science, biological robots, modified gut microbiomes, biotech cosmetics, and genetically engineered pets. Public safety challenges and concerns about bioterrorism.

Unit IV **Access to critical resources for biotechnology innovation: data and biospecmens**