BIOTECHNOLOGY AND LAW SYLLABUS
VERSION 1-19-2015
(LAW 5367-19040-Spring, 2015)
Prof. Evans
UNIVERSITY OF HOUSTON LAW CENTER
Course areas: Health Law, IPIL, and EENR
First Day's Assignment is on page 4 in the Reading List

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Office Hours:
T Th 4 – 5
and by appointment--email me to set up a time that works

CLASS TIME T Th 2:30 – 4 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 (see Profs. Weaver or Bray for details).

COURSE MATERIALS **The estimated cost of materials for this course is $14.00.**

1. This course uses the paperback version of Eric Topol's Creative Destruction of Medicine (Basic Books, 2012) Paperback version is: ISBN 978-0-465-06183-9.
2. Most of the course materials will be provided for free via the UH Electronic Blackboard, because there simply isn't a good, current casebook available in this field.
3. In this class, we will do a lot of in-class problem solving and discussion, using problem sets I have developed and will provide to you.

COURSE OVERVIEW This introductory course requires no prerequisites other than completion of the general 1L curriculum. No science background is required. This course can be taken as an elective by people who simply are interested in the latest controversies with genetically modified food and advanced medical technologies and human enhancement, or as a way to gain serious practice-oriented skills if you wish to pursue a career in Houston's growing life-sciences and biotechnology industry. This course is covers four major topical areas:

Unit I	Helping clients navigate the relevant health-and-safety and economic regulatory frameworks to commercialize their technologies: Basics of FDA, CLIA, CMS Regulation
Unit II	Regulation in the face of radical uncertainty about health and environmental impacts
Unit III	Access to critical resources for biotechnology innovation: data and biospecmens
Unit IV	Special concerns in protecting and commercializing biotechnology discoveries

COURSE REQUIREMENTS

Attendance: The usual Law Center attendance rules apply. I reserve the right to adjust a student's final grade downward for poor attendance or habitual lateness. That said, I understand that illness can strike or there may be other situations such as job interviews that force you to be away.

You are not required to contact me to explain your first two absences from class, but I am always glad to hear from you because I like to know if you are coping with difficult situations so that I can save you a copy of any class handouts if you have to be away. I'll also be happy to get you caught back up after an illness.

Class participation: This is not a good class to take if you want to sit back and passively monitor the proceedings and then cram at the end just to get ready for the final. You will not be cloaked in anonymity in my classroom. I enjoy getting to know all my students and I will quickly learn your name; thereafter, I shall call on everybody all the time. My aim in calling on you is not to intimidate or embarrass you, but simply to make sure we engage all minds in a lively debate. We will be discussing some very serious and unresolved regulatory problems. This is an area where a law student can play a nationally important policy-setting role if he or she figures out a promising way to address the difficult problems that Washington's policymakers are struggling to resolve. I'll teach you how to file citizen's petitions and file comments in open regulatory proceedings so that you can enter your proposed solutions into the national debate. Everybody in our classroom will be drawn into the conversation. At my discretion, a student's final grade may be adjusted upward or downward by one "notch" (e.g., from B+ to A-, or from B- to C+) in recognition of classroom contributions or lack thereof.

Cell phones/pagers: Of course you should set your electronic devices to silent mode! I confess that the only time I ever had a cell phone go off in my classroom, it was my own cell phone. Thus I appreciate how hard it can be to remember this rule, but please try.

Use of computers: I strongly support the use of computers in the classroom. It is the professor's task to make him- or herself more interesting than your computer screen. Unless otherwise announced in class, you may use your computers to take notes and look up statutes, regulations, and administrative materials that we are discussing. But please, I ask that you not record or "film" class proceedings without my express permission, because I want our classroom to be a "safe" environment where students feel free to speculate and speak their minds freely and even speculatively, without fearing that what they say is being recorded to haunt them later when they are nominated for a position on the Supreme Court.

During class, I would like to see your computers being used only for course-related purposes. Non-course-related use of e-mail and the Internet is strongly discouraged. The point where I would get fierce is if you were using your computer or other

communication devices in ways that were distracting or disturbing your fellow students. Sanctions for violating these provisions can include adjusting a student's final course grade downward or suspending a student's right to use a computer in this class, and such sanctions may be imposed without warning at my sole discretion.

EXAMINATIONS AND GRADING

Ungraded thought pieces. During the semester, there will be several times when I ask you to prepare a brief, one- or two-page "thought piece" reflecting on topics covered in our readings and discussions. **These short papers will not be graded, so you should turn them in using your name rather than exam number**. These will be announced ahead of time and will be due on the date specified, with no late papers accepted. If you anticipate being away, you should make arrangements to turn in your thought pieces ahead of the specified due dates.

In-class midterm (30% of course grade). This class covers a large amount of meaty, practice-oriented material. Students in past years have indicated they would have preferred to have a midterm that completes the testing of topics covered early in the course, before moving on to later topics. Accordingly, I plan this year to schedule a seventy-minute-long midterm exam which will be administered ***with clear prior notice***. **Topics covered on the midterm will not be tested again on the final.**

Final exam (70% of course grade). The final exam will be 1 hour, 50 minutes long and will count for 70% of your final grade in the course. **It will be open-book, open-notes and will address topics covered in the latter part of the course that were not covered on the midterm examination.**

Current Events presentations: Each student will be asked to present at least one brief (not to exceed 7 minutes) class presentation related to biotechnology and law, and to provide a brief written summation of your remarks (which can be in the form of a written summary, outline, or powerpoint slides that show the key sources to which you referred). This written summary, which should be provided in handout form, is not a graded assignment but, instead, is intended to help your fellow students absorb and retain the key points you discovered while preparing your presentation.

COURSE OUTLINE & READING LIST

In 2015, I am reordering the sections of the class to focus first on Food and Drug Administration issues first. Some very important FDA proceedings are actively underway now that will affect the future of genomic medicine, and I want you to know the basics of FDA regulation early in the semester so that you can be a knowledgeable observer/participant in these fascinating proceedings. So I have moved what used to be Unit II into the Unit I position.

Unit I Helping clients navigate the relevant health-and-safety and economic regulatory frameworks to commercialize their technologies: Basics of Food and Drug Administration Law

The first major topic is regulation of genetic 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. Both these regulatory frameworks are the subject of major turmoil, with amendments being worked out in 2014-2015. This section provides an extremely compact, practical, and efficient introduction to the current frameworks and it will highlight the points of dispute in the proceedings that are underway to revise the regulations. 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.

R-Intro The reading assignment for Day 1 is posted on the course web site:

First Day's Assignment: Read: (1) in Topol book: Introduction, pages v - xi; (2) Joshua Sharfstein, JAMA Viewpoint, (3) James P. Evans and Michael Watson, JAMA Viewpoint

R1-IntroA – Sharfstein Viewpoint
R1-IntroB – JP Evans/M Watson Viewpoint

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

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

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

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

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

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

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

R-18 Lewin Group, The Value of Diagnostics (Excerpts)
Reimbursement for Diagnostics/Genetic Tests

R-18SUPP: The current proceedings to revise the regulations, and how to have an active voice in them.

Javitt & Corner-FDA Regulation of Next Generation Sequencing

Deverka-Insurance Reimbursement of Genomic Testing

FDA Draft Guidance on Framework for Oversight of Laboratory-Developed Tests

FDA Draft Guidance on Notification and Reporting for Laboratory-Developed Tests

FDA Discussion Paper on Regulation of Next-Generation Sequencing

Unit II Regulation in the face of radical uncertainty about health and environmental impacts

This section will focus on agricultural biotechnologies that rely on recombinant DNA technology including genetically modified organisms (GMOs) such as genetically modified salmon and "biopharming" that induces plants to express proteins for use in pharmaceutical manufacturing. Innovators seeking to develop and commercialize these technologies face difficult challenges to protect their intellectual property and they must run the gamut of multiple, overlapping state and federal agencies that fund, approve open-air testing, regulate environmental impacts including impacts on fish and wildlife, and approve human consumption of these products. Topics include decision-making under conditions of radical uncertainty (unknown and ultimately unquantifiable risks); major differences between U.S. and rest-of-the-world approaches to regulating these

technologies; the National Institute of Health's evolving framework for oversight of recombinant DNA technologies; environmental and human safety regulation under major frameworks that protect the environment, fish and wildlife, and safety of the human food supply. This course examines how the First Amendment constrains regulation of these technologies. It also explores how ineffective litigation has been as a tool for challenging lax regulatory oversight of these technologies.

R-1A Katharine Van Tassel, excerpts from *The Introduction of Biotech Foods to the Tort System: Creating a New Duty to Indentify*, 72 U. Cin. L. Rev. 1645 (2004).

R-1B *International Dairy Foods Ass'n v. Amestoy*

R-2A When are scientifically uncertain statements about health impacts or environmental impacts "misleading" for purposes of *Central Hudson* analysis?

R-2B *Stauber v. Shalala*

R-2C Instructions for filing a Citizen's Petition to challenge action by the Food and Drug Adminisration: 21 C.F.R. §§ 10.25, 10.30, 10.45

R-3 *Alliance for Bio-Integrity v. Shalala*

R-4 Daniel A. Farber, excerpts from *Uncertainty*, 99 Geo. L. J. 901 (2011).

R-5 *Foundation on Economic Trends v. Thomas*

R-6 Learning to use Institute of Medicine resources: You will learn how to access IOM resources and we'll discuss selected readings from the recent IOM report on regulation of recombinant DNA research
http://www.nap.edu/catalog.php?record_id=18577

R-7 *Foundation on Economic Trends v. Heckler*

R-8 Getting familiar with the National Institutes of Health's Office for Biotechnology Activities (OBA): You will learn to access information available on OBA's web site, http://oba.od.nih.gov/rdna/nih_guidelines_oba.html
and we will discuss select issues in the Current Guidelines for Recombinant DNA Research,
http://oba.od.nih.gov/oba/rac/Guidelines/NIH_Guidelines.htm#_Toc351276401

R-9 *Foundation on Economic Trends v. Bowen*

R-10 *Center for Food Safety v. Johanns*

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

The third major topic is ownership, control, and access to data and biospecimens (samples of human, animal, or plant tissues that can be studied to reveal genetic and other important information). Biotechnology is analogous to an extractive industry (mining or petroleum) that extracts value from critical natural resources, and the resources are data and biospecimens. Like the "petroleum landmen" of the past, attorneys that can navigate privacy regulations and help their clients access data and biospecimens are key players who affect the pace of discovery and commercialization of modern biotechnologies.

This course will not overlap coverage of these topics you may have had in Health Industry Basics and will focus specifically on how to apply these regulations in research settings (as opposed to hospital/healthcare settings). It provides sufficient detail about the basic regulations to allow those who have not had Health Industry Basics to gain a full understanding of how to apply these regulations in the research setting.

This unit covers the major regulations affecting data access, including the HIPAA Privacy Rule; the Federal Policy that protects human subjects of biomedical research (the "Common Rule"); the FDA regulations affecting access to and use of biospecimens; and the role of state privacy laws. The course takes a practical approach and will teach you how to navigate the loopholes to achieve lawful access to data and biospecimens for your client. We will explore access to data and biospecimens for biomedical research as well as for other applications including studies of the impact of environmental toxins on human health.

R-19 Sample exam questions and exercises

R-20 Learning objectives and regulatory summary for use in class

R-21 Supplement- types of scientific evidence used in the regulatory process

R-22 How to navigate key federal regulations to gain access to data and biospecimens for research: the Common Rule 45 C.F.R. pt. 46, subpt. A; the FDA framework at 21 C.F.R. pts. 50, 56; and the HIPAA Privacy Rule at 45 C.F.R. pts. 160, 164.

R-23 Regulatory supplement: the Common Rule 45 C.F.R. pt. 46, subpt. A

R-24 Office for Human Research Protections (OHRP) guidance on the use of coded data and biospecimens in research

R-25 FDA guidance for research sponsors and IRBs on informed consent for the use of biospecimens in research

R25-A Beyond consent and IRB review: the complete FDA framework for regulation of medical device research: Investigational Device Exemptions. Reading: Evans-

Limits of FDA's Authority to Regulate Genome Sequencing Research

R25-B Regulatory supplement: 21 C.F.R. part 812 (Investigational Device Exemptions)

R-26 Note: This reading may change if there is further progress in the regulatory proceeding to amend the Common Rule: Advance Notice of Proposed Rulemaking (or proposed regulations if such have been issued by the time we cover this topic in class)

R-27 Learning to submit and access comments on pending regulatory proceedings: Link to Reguations.gov comments on the Common Rule ANPRM

R-28 Abuse of consent in research that uses data or biospecimens: Arizona's Broken Arrow

R-30 The absence of private rights of action under key federal regulations: Tilousi v. Arizona State

R-31 Regulatory supplement: excerpts from the HIPAA Privacy Rule

R-32 2013 amendments to the HIPAA Privacy Rule

R-33 Managing the human genome as a natural resource after Association for Molecular Pathology v. Myriad Genetics

R-34 Antitrust issues in genomic data access: Evans: Economic Regulation of Next Generation Sequencing

Unit IV Special concerns in protecting and commercializing biotechnology discoveries: To capture the most recent developments, topics for this section of the course will be announced later in the Spring.

The fourth major topic is a set of concerns relating to protection and commercialization of discoveries. This course does not duplicate coverage provided in your I.P. courses, but it explores certain angles that are especially important in the biotechnology arena. These topics include bioprospecting and CRADAs (collaborative research and development agreements private parties can enter with the U.S. government); the Bayh-Dole amendment that allows universities and research institutions to patent discoveries made during federally-funded research; "march-in" rights under the Bayh-Dole amendments; advising clients on how to choose a business strategy for commercializing their genetic discoveries after the recent *Myriad* and *Mayo v. Prometheus* Supreme Court decisions; and important things lawyers need to know about the potential for their clients to commit fraud when announcing discoveries and business plans in the biotechnology area; how to protect yourself and clients from inadvertently committing fraud.