Syllabus v3 – March 20, 2020

**REGISTRATION NUMBER FOR LAW STUDENTS:**

**5397 Regulating Disruptive Innovation: Biomedicine & Beyond – 28201**

**REGISTRATION NUMBER FOR ENGINEERING STUDENTS:  
6397 ECE Medical Devices Law, Regulation, and Ethics – 25251**

Spring 2020

Class time: T Th 4 – 5:30 pm Central. Room TU-II 215.

**Professor Barbara Evans, Ph.D., J.D. Office Hours:**

**Office UH Law Center BLB-214 Th after class and other times**

**(713) 743-2993 office ; (713) 446-7576 (cell) by appointment: email me**

**E-mail:** [**bjevans@central.uh.edu**](mailto:bjevans@central.uh.edu) **set up a time that works**

**Course Materials.** See list of assigned readings starting on Page 5. Assignments for the period after Spring Break start on page 11. This course uses:

(i) Clayton M. Christenson, Jerome H. Grossman, and Jason Hwang, The Innovator’s Prescription: A Disruptive Solution for Health Care (available in paperback for about $12.00)

(ii) National Academies of Science, Engineering & Medicine, Preparing for Future Products of Biotechnology (2017) (provided in electronic form at no cost)

(iii) Institute of Medicine, Medical Devices and the Public’s Health (2011) (provided in electronic form at no cost)

(iv) Other materials provided in electronic form at no cost

(v) Links within this Syllabus to regulatory agency materials. Accessing regulatory agency materials on-line, using the URL links in this Syllabus, is the best way to read them, because many regulatory documents have embedded links that make it easy for you to refer to relevant background material by clicking on the links.

(vi) Supplements delivered via e-mail. This course presumes you monitor your e-mail address regularly.

**Summary of What Has Been Updated in This Syllabus:** Please read pages 1 – 4 of this new Syllabus carefully. These pages contain information related to our shift to remote learning at UH as of March 23, 2020. As per President Khator’s letter to students on March 19, our classes will be offered remotely (online or alternative format) for the duration of the semester.

The assignments remain largely consistent with what was included in our January 2020 syllabus. The introduction/overview of the course and other basic information in that syllabus are not repeated here. The changes are as follows:

1. Information about how to access classes via Zoom video and the Law Center rules and expectations concerning student participation in online format courses.

2. In the “Assignments for After Spring Break” section starting on page 11, there are some changes to course content to reflect the loss of one week of classes (March 16-20) and to update content to highlight some recent hot topics that are relevant to our course (e.g., introduction of VALID Act legislation in Congress that proposes to modernize regulation of clinical laboratory tests; timely issues such as COVID test regulation that have emerged during the recent pandemic; privacy concerns with proposed public heath tracking software).

3. Changes to the testing schedule and evaluation methods for this course.

**Procedures for Conducting Our Classes (post March 23)**

Unless otherwise agreed in class (and confirmed by email follow up), our class will meet regularly on Tuesdays and Thursdays at the usual time (4 – 5:15 pm), at the following link:

**Join Zoom Meeting**

[**https://zoom.us/j/713862427**](https://zoom.us/j/713862427)

**Meeting ID: 713 862 427**

It can be really boring to use Zoom simply to go over Powerpoints or to hear somebody give a lecture. When I have a Powerpoint presentation or a lecture I want you to see, I may make a recording showing the Powerpoints and giving a narrative description of the slides. I will email you a link to view that video on your own (“asynchronously”) ahead of class. You should review these materials before class begins. Then, we can use our “synchronous” time when we are all together on Zoom for active discussion, comments, and Q&A. Thus, for example, if I send you a 20-minute recording to view before class, our Zoom class would be shortened accordingly (e.g., to 55 minutes, equaling 75 minutes minus the 20 minutes you spent watching the video).

For some sessions involving work on your individual class papers/projects, I may either talk to you one-on-one by phone, or else set up a conference call-in number allowing a group of students to phone in simultaneously. I will provide instructions to you via e-mail.

**Expectations for participation in Zoom synchronous digital education (SDE).** To be counted “present” in a Zoom class session, there are a number of requirements you must meet:

(i) you must be connected to the internet videoconference when class starts;

(ii) your computer must have a working video camera and quality audio capability; joining by audio only due to your lack of video capability will be treated as an absence (you may need an external mic or headset for sufficient audio quality);

(iii) if your computer is a laptop, you must not be distracted by traveling or other activities when you join the internet videoconference;

(iv) you may not join the class internet videoconference from a phone;

(v) you must listen closely and speak loud and clear, as hearing students speak in the classroom and classmates ability to hear the SDE student may not be optimal;

(vi) you must identify yourself with your class roll name in the internet videoconferencing software;

(vii) you must present your face and upper body area professionally in the video stream; eating “on-camera” is not a professional presentation;

(viii) you must be able to fulfill your responsibilities if called on to discuss a case or course materials; and

(ix) you must manage the “mute button” when remote to keep a professional demeanor.

**Class Recording**. The Law Center will record Zoom class sessions for the sole and limited educational purpose of allowing students to stream the recorded sessions for review or to enable students who missed a class to hear the class presentation. Students may not listen to recorded class sessions to avoid an absence. Any recordings created will be deleted and destroyed shortly after the final exam for the class. There is a chance that your contributions to class discussion, whether voluntary or while on call, may be included in the recording. Your continued registration in this class indicates your acquiescence to any such incidental recording for the purposes described above.

**Evaluation Methods and Participation Requirements**. Because of the loss of momentum caused by our extended Spring break, we no longer will have two quizzes during the semester (one of which was to have occurred immediately after the Spring break).

Instead, we will have a single exam, to occur in mid-to-late April on a date we will schedule. It will count as 70% of your grade. You will continue to have the choice of doing either a written paper or an in-class presentation for your class project, which will count for 30% of your grade.

The exam will be administered to law students using our regular Electronic Blue Book software, which enables anonymous grading as is required and keeps track of timing. Engineering students will receive their exam questions and return their responses via email during a mutually agreed time window.

Each student (or collaborative teams of students, with permission of Prof. Evans) will complete a research project. Results can be reported either as a short project paper (3,000 – 6,000 words, for sole-authored submissions) or as an in-class presentation. Students making a presentation should document it as a Powerpoint file or as a set of written notes, with references, to provide a durable product for members of the audience. Students electing to submit their written thought piece as a short paper will turn their paper in during the final exam period (specific date to be clarified). Students making in-class presentations will work with Prof. Evans to schedule the date. The research project will count 30% of the final grade.

Students also are expected to have read assigned materials prior to class and to participate actively in class discussions.

(i) JD Law students (including JD/LLM students who have not yet completed 90 semester hours of credit) are subject to the usual Law Center class average grading practices for 2L and 3L classes, as adapted by the Associate Dean’s office for the circumstances of this semester.

(ii) LLM students are subject to the customary Law Center LLM grading practices, as adapted by the Associate Dean’s office for this semester.

(iii) Engineering graduate students are graded on a separate scale consistent with engineering departmental norms.

**Message from the University**: Counseling and Psychological Services (CAPS) can help students who are having difficulties managing stress, adjusting to the demands of a professional program, or feeling sad and hopeless. You can reach CAPS (www.uh.edu/caps) by calling 713-743-5454 during and after business hours for routine appointments or if you or someone you know is in crisis. No appointment is necessary for the “Let's Talk” program, a drop-in consultation service at convenient locations and hours around campus. [http://www.uh.edu/caps/outreach/lets\_talk.html](https://legacy.central.uh.edu/owa/redir.aspx?REF=U6yyHPdkPNWwWtD3c87rFd3x3CEgZldaKvGvavOzhaKzYNvyYePUCAFodHRwOi8vd3d3LnVoLmVkdS9jYXBzL291dHJlYWNoL2xldHNfdGFsay5odG1s).

**Naming and pronoun preferences.** I go by Professor Evans or Barbara and I use she/they, hers/theirs, you/y’all as my pronouns. Please reach out to me in person, by e-mail, or by phone if you have preferred pronouns you would like for me to use or if you prefer “Dr.” or “Mx.” to “Mr.” or “Ms.” I’ll try my best to honor your preferences. Please attribute any lapses to failings of memory and do not feel embarrassed to correct me if I make any mistakes.

My cell phone is listed on page 1. If you are having any problems related to the switch to on-line learning or just want to talk to me, feel free to call me. If you text me at that number, please be sure to identify yourself in the text, in case I do not already have you in my phone’s directory.

**Continue to Reading List on Page 5**

**Pages 5- 10 are the things we covered before Spring Break. There are no changes here. Proceed to page 11 for our post-Spring-Break readings**

**Assigned Readings**

**“CGH” refers to the Christensen, Grossman, and Hwang *Innovator’s* *Prescription* book in the reading list below**

**“NASEM Biotech” refers to Preparing for Future Products of Biotechnology**

**“IOM Devices” IOM, Medical Devices and the Public’s Health**

**Other readings provided in electronic form or via links to regulatory web sites**

**First Day’s Assignment**

Before class, read any four of the following short articles and come to class prepared to discuss them.

1. **AI software could displace 47% of workers**: Pham et al, “The Impact of Robotics and Automation on Working Conditions and Employment,” IEEE Robotics and Automation Magazine (June 2018) – See reading Intro1 electronic file

2. **Lawyers and other skilled workers are not safe from AI-related job loss**: Kevin Finneran, “Overdetermined,” Issues in Science & Technology (Vol. xxv, Fall 2018), at <https://issues.org/overdetermined/>

3. **Non-transparency of AI Software**: Cliff Kuang, Can AI be Taught to Explain Itself? New York Times (Nov. 21, 2017) *available at:* <https://www.nytimes.com/2017/11/21/magazine/can-ai-be-taught-to-explain-itself.html>

4. **Is anybody regulating this stuff? Gene-edited and synthesized food falls into regulatory gaps**: Dan Charles, “Will Gene-Edited Food be Government Regulated?” NPR (May 10, 2019), at <https://www.npr.org/sections/thesalt/2019/05/10/717273970/will-gene-edited-food-be-government-regulated>

5. **Gene editing offers medical miracles for patients who can pay millions of dollars**: Carolyn Y. Johnson & Brady Dennis, “Gene Therapies offer dramatic promise but shocking costs,” The Washington Post (Nov. 14/15, 2015), See reading Intro 5 electronic file or see

[https://www.washingtonpost.com/business/economy/gene-therapies-offer-dramatic-promise-but-shocking-costs/2015/11/11/01f11cf0-824b-11e5-9afb-0c971f713d0c\_story.html](https://www.washingtonpost.com/business/economy/gene-therapies-offer-dramatic-promise-but-shocking-costs/2015/11/11/01f11cf0-824b-11e5-9afb-0c971f713d0c_story.html )

6. **Gene editing has unresolved safety risks**: Sharon Begley, “Potential DNA damage from CRISPR has been seriously underestimated, study finds,” StatNews (July 6, 2018), at <https://www.statnews.com/2018/07/16/crispr-potential-dna-damage-underestimated/>

7. **Human rights impacts of AI and big data**: Molly Galvin, “Human Rights in the Age of Social Media, Big Data, and AI,” National Academies of Science, Engineering, and Medicine News (Sept. 23, 2019), at <http://www8.nationalacademies.org/onpinews/newsitem.aspx?RecordID=9302019>

8. **Ultrapersonalized medicine**: Gina Kolata, “Scientists Designed a Drug for Just One Patient. Her name is Mila,” New York Times (Oct. 9, 2019), at <https://www.nytimes.com/2019/10/09/health/mila-makovec-drug.html?action=click&module=Editors%20Picks&pgtype=Homepage>

**Unit I. Introduction - Business Models for Disruptive Innovation**

**Learning objectives.** Inventing a great technology will not, by itself, bring about transformative change. Other required elements sometimes include developing an innovative business model and creating a value network that lets the new technology to be delivered safely and at a price that works for both the consumers and the developers. After this unit, you will be able to: (1) define and recognize three distinct business models: the solution shop, the value-added process business, and the facilitated network, and which pricing options work for each; (2) analyze how particular technological innovations can help shift existing businesses (such as healthcare or agriculture) from one business model to another one.

**Class 2.**

**Read I.C (Topol reading) and come prepared to identify concerning practical, ethical, economic, or regulatory issues you spotted. Simply bring the handouts in I.A and I.B with you to class. You don’t need to look at them before class.**

I.A Basic definitions to get us started

- Categories of products that FDA Regulates

- 21st Century Cures Act provisions on FDA regulation of software

I.B U.S. Coordinated Framework agencies and major statutes

I.C Eric Topol, “High Performance Medicine: The Convergence of Human and Artificial Intelligence,” Nature Medicine 25, 44-56 (2019)

**Questions for discussion**: How does AI medical software fit into the business model(s) of modern healthcare? What ethical concerns do you have about the types of software Topol describes?

**Class 3. Read I.D**

I.D CGH, “The Role of Disruptive Technology and Business Model Innovation in Making Products and Services Accessible and Affordable,” pages 1 – 33.

**Questions for discussion**: How do advanced diagnostics, medical software, gene therapy, and emerging neurotechnology devices enable disruption of healthcare? Try to identify some recently emerging technologies that have been in the news that you regard as potentially disruptive and be ready to discuss your examples in class.

**Class 4. Read I.E. Bring a copy of the slides in I.F to class if you would like to have it to help take notes. You don’t need to look at the slides before class.**

I.E Daniel Grushkin, Todd Kuiken & Piers Millet, “Seven Myths and Realities about Do-it-Yourself Biology”

**Questions for discussion**: Where does DIY Bio fit into the spectrum of business models CGH discuss? What is its potential to bring about disruptive change? Is it dangerous? Does it need to be regulated? How?

I.F Powerpoint slides for use in class: Discussion Example - The Regulatory Challenge of DIY Genomics – Moral and Regulatory Limits of Self-Harm

**Class 5. Read I.G**

I.G CGH, “The Technological Enablers of Disruption [in biomedicine]” pages 37 – 66.

**Sign up for informal class reports on other chapters in CGH:**

* Ch.3 Disrupting hospitals
* Ch.4 Disrupting physicians
* Ch.5 Disrupting chronic disease
* Ch.6 Integrating
* Ch.7 Reimbursement
* Ch.8 Pharma
* Ch.9 Medical devices/diagnostics
* Ch.10 Medical education
* Ch.11 Regulatory reform

**Unit II. Introduction to Consumer Safety Regulation.**

**Learning objectives**: Most researchers understand that their publications and speeches can affect their ability to claim patent protection for new products. Less well understood is the fact that their communications also affect whether FDA will regulate their products and what the specific regulatory requirements will be. After this unit, you will be able to:(1)recognize and define various categories of products that FDA regulates (e.g., drug, device, biological product, combination product, food, food additive, dietary supplement, cosmetic, tobacco product, etc.); (2) apply the factors that FDA looks at when deciding whether an innovative product falls under FDA’s regulations; (3) understand that things researchers and inventors say, write, and publish can affect whether and how FDA will regulate their inventions; (4) manage communications to optimize regulatory pathways; and (5) understand how the choice of business model also may affect whether you (or your client) will be regulated by FDA.

**Bring the charts in I.A above with you to class throughout this Unit II.**

**Topic. The American regulatory experiment.** Distinctive features of the American model of biotech safety regulation. What principles does it rest on? What does it cost and does it even keep consumers safe? Overview of reforms implemented and being considered.

**Readings: Before class, read II.A, II.B, II.C**

II.A Daniel A. Farber, *Uncertainty*, 99 Georgetown Law Journal 901 (2011) – excerpts

Bring to class: I.B. The U.S. Coordinated Framework agencies and major statutes

II.B Alliance for Bio Integrity v. Shalala, 116 F.Supp.2d 166 (2000) – excerpts

II.C Int’l Dairy Foods Ass’n v. Amestoy, 92 F.3d 67 (1996)

Supplements/Class Handouts

II.D Deference to Federal Agencies - Chevron-Mead Supplement

II.E Paternalism and the Moral Basis of Consumer-safety Regulation

**Topic. What causes a technology to fall under FDA regulation?** FDA’s wide (but not unlimited) power to decide which product category a new technology falls into.

Readings. Read II.F, II.G before class

II.F Excerpts from cases: U.S. v Bacto-Unidisk 394 U.S. 784 (1969)

Nutrilab, Inc. v. Schweiker, 713 F.2d 335 (7th. Cir 1983)

National Nutritional Foods Ass’n v. Mathews, 557 F.2d. 325 (2d Cir. 1977)

II.G Bradley Merrill Thompson, Strategies for Technology Companies Entering the Health Care Internet of Things, Bloomberg Health IT Law & Industry Report, Vol. 9, No. 4 (January 16, 2017).

**Topic. Be careful what you say!** FDA’s algorithm for deciding whether researchers, product developers, manufacturers, and distributors have the “intent” that allows FDA to regulate them.

II.H 21 C.F.R. § 801.4: the regulatory “intent” algorithm

* FDA’s failed attempt to shift to a “totality of circumstances” standard and the industry pushback: Excerpts from FDA, “Clarification of When Products Made or Derived From Tobacco Are Regulated as Drugs, Devices, or Combination Products; Amendments to Regulations Regarding ``Intended Uses'' 82 Fed. Reg. 2193 – 2217 (January 9, 2017)
* U.S. v. Travia 180 F.Supp. 2d 115 (D.D.C. 2001) - excerpts

**II.I What constitutes a label, labeling, and advertising?**

* FFDCA §§ 201(k), 201(m): definitions of label and labeling
* Kordel v. U.S., 335 U.S. 345 (1948) - excerpts
* U.S. v. Urbuteit, 335 U.S. 355 (1948) - excerpts
* U.S. v. 24 Bottles of “Sterling Vinegar & Honey”, 338 F.2d 157 (2d. Cir. 1964)-excerpts

**II.J** **Basics of First Amendment Commercial Speech Doctrine.** When is a scientific publication or conference presentation just free speech, and when does it become “labeling” that affects how FDA will regulate you and your product?

**II.K** Nathan Cortez, *Can Speech by FDA-Regulated Firms Ever Be Noncommercial?*, 37 Am. J.L. & Med. 388, 397 (2011) - excerpts

**II.L**  **How the choice of business model can affect regulatory jurisdiction**

* **Example for class discussion**: CRISPR gene-editing – is it an FDA-regulated drug, device, or a biological product, or is it practice of medicine? Could it be any of the above? What did FDA decide?
* **NASEM Biotech Book (provided in electronic form) pages 27 – 40** (discussing technical drivers that are restructuring biotech manufacturing, leading to emergence for four new business models. These drivers include, for example, standard biological parts, contract laboratories and community laboratories; new software platforms; the changing scale of manufacturing activities, and changing sources of funding for R&D (including crowdsourced funding).

**III. Basics of Medical Device Regulation:**

General framework of FDA’s device oversight; regulation of genomic testing and diagnostics as devices and under the Clinical Laboratory Improvement Amendments; regulation of software under FDA’s device framework

**Learning objectives.** After completing this unit, students will be able to: (1) describe the major features of FDA’s medical device regulatory process, including both premarket and postmarket controls; (2) develop plans for positioning a new product for the most favorable regulatory treatment and obtaining an FDA investigational device exemption, clearance and/or premarket approval and then complying with FDA’s postmarketing controls; (3) explain how FDA’s device regulations (and other major federal regulatory frameworks such as the Clinical Laboratory Improvement Amendments of 1988) affect genomic tests and other advanced diagnostics and software; (4) contribute to the debate about key policy issues that FDA has not yet been able to resolve, such as how to determine whether AI software is sufficiently “explainable” that physicians and other healthcare professionals can use it safely.

III.A **Intro to the Medical Device Industry**. Medicare Payment Advisory Commission – June 2017 Report to Congress, Ch. 7, “An Overview of the Medical Device Industry” Read 207 – 214 (stop before “Unique Device Identifier”)

III.B Powerpoints (to be provided via e-mail): The shifting mix of premarket to postmarket evidence collection to establish safety and effectiveness. FDA’s new evidentiary paradigm after the Food and Drug Administration Amendments Act of 2007

III.C Excerpts from **Institute of Medicine, Medical Devices and the Public’s Health: The FDA 510(k) Clearance Process at 35 Years (2011)**, electronic copy of this book is provided. It is also available for free PDF download at <http://nationalacademies.org/hmd/reports/2011/medical-devices-and-the-publics-health-the-fda-510k-clearance-process-at-35-years.aspx?_ga=2.39970402.1981029323.1512495203-886719148.1512334659>

**Supplemental resource**

FDA Device Advice – Comprehensive Regulatory Assistance <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/default.htm> Scroll down to “More in Device: Comprehensive Regulatory Assistance” and read the links on: “Overview of Medical Device Regulation” at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/Overview/default.htm> and “How to Study and Market Your Device” at <https://www.fda.gov/MedicalDevices/DeviceRegulationandGuidance/HowtoMarketYourDevice/default.htm>

III.D Emerging device regulatory challenges: genomics and advanced diagnostics; software as a medical device.

D.1 LawSeq Quality Task Force, “How Can Law and Policy Advance Quality in Genomic Analysis and Interpretation for Clinical Care?” (2020 forthcoming)

D.2 Nathan Cortez, excerpts from “Regulating Disruptive Innovation,” 29 Berkeley Tech. L. J. 175 (2014)

D.3 FDA, “Developing Software Precertification Program: A Working Model” (v0.2, June 2018), at <https://www.fda.gov/media/113802/download>

D.4 21 C.F.R. Part 812 - FDA’s Investigational Device Exemption (IDE) Regulation

**Assignments for After Spring Break**

Reading E.2 was your assigned reading for our first class session following Spring Break, which now will be March 24. Please come to class ready to discuss the strengths and weaknesses of FDA’s proposed policy.

III.E Understanding FDA’s new software-related guidance documents (published on September 26, 2019)

E.2 Draft guidance titled [Clinical Decision Support Software](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/clinical-and-patient-decision-support-software) describing FDA’s regulatory approach to clinical decision support software functions (replacing the 2017 draft guidance entitled *Clinical and Patient Decision Support Software)*.

E.3 **In-class exercise:** How to access, use, and file public comments in an FDA regulatory proceeding. This exercise will explore comments filed on the new Clinical Decisions Support Draft Guidance, at [www.regulations.gov](http://www.regulations.gov/) under docket number FDA-2017-D-6569. The comment period closed Dec. 26, 2019.

**Unassigned supplemental links.** The following are not assigned readings, but links are provided in case they may be relevant to your chosen paper topics:

1. Final guidance, [Changes to Existing Medical Software Policies Resulting from Section 3060 of the 21st Century Cures Act](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/changes-existing-medical-software-policies-resulting-section-3060-21st-century-cures-act). This guidance details the changes to existing guidance documents that relate to the regulation of the software functions.

2. Updates to conform past guidances to the above documents:

- [Policy for Device Software Functions and Mobile Medical Applications](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/mobile-medical-applications) *(originally titled Mobile Medical Applications)*

- [General Wellness: Policy for Low Risk Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/general-wellness-policy-low-risk-devices)

- [Off-The-Shelf Software Use in Medical Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/shelf-software-use-medical-devices)

- [Medical Device Data Systems, Medical Image Storage Devices, and Medical Image Communications Devices](https://www.fda.gov/regulatory-information/search-fda-guidance-documents/medical-device-data-systems-medical-image-storage-devices-and-medical-image-communications-devices)

3. FDA, Artificial Intelligence and Machine Learning in Software as a Medical Device (April 2019), at https://www.fda.gov/medical-devices/software-medical-device-samd/artificial-intelligence-and-machine-learning-software-medical-device

4. FDA, “[Proposed Regulatory Framework for Modifications to Artificial Intelligence/Machine Learning (AI/ML)-Based Software as a Medical Device (SaMD) - Discussion Paper and Request for Feedback](https://www.fda.gov/media/122535/download)” (April 2, 2019) at <https://www.fda.gov/media/122535/download>

5. FDA’s long-term [Digital Health Innovation Action Plan](https://www.fda.gov/media/106331/download)

**IV. REVISED – Hot Topics Arising Since March 2020**

**I will email you reading materials that you can download add to your electronic readings collection.**

**IV.A New legislation introduced in early March for regulation of in vitro diagnostic tests: The VALID Act**

**IV.B Articles about the VALID Act and about its sponsors**

**IV.C Student research and discussion: What went wrong with the COVID-19 tests? Would better legislation have helped?**

**Combination Products, Biological Products, and Biotech Cosmetics:**

**(Advanced Cellular, Tissue, and Tissue-Based Products; Gene Therapy Products; and Advanced Biotech Cosmetics and Enhancement Products)**

**To make up for time we lost due to the extended Spring Break, we will “divide and conquer” this material. Students will divide up into groups to cover one of the topics below, with each group preparing some slides or a written summary of key points to present to the class. I’ll work with the groups as you prepare your reports.**

**Objectives:** Biological drugs (e.g., penicillin) date back decades and FDA has a longstanding paradigm for regulating them under the Public Health Service Act and the Food, Drug, and Cosmetic Act. Today’s challenging regulatory issues relate to novel biotech products that are difficult to fit into that old paradigm. Examples include human gene editing tools; engineered tissues such as genetically synthesized knee cartilage or transplant organs; biotech cosmetics such as synthetic scalp tissue able to grow hair and eliminate baldness; biologically-based and biocompatible computing equipment to enhance human performance. After this unit, students will understand key safety challenges and be able to participate in the policy debate to resolve unsettled problems in how to regulate these products.

V.A FDA, Combination Products, at <https://www.fda.gov/combination-products>

V.B FDA “Combination Product Classification Again Struck Down by DC Court,”  
Policy & Medicine (May 6, 2018), at <https://www.policymed.com/2014/12/fda-combination-product-classification-again-struck-down-by-dc-court.html>

V.C FDA, Principles of Premarket Pathways for Combination Products: Draft Guidance (February 2019), at <https://www.fda.gov/media/119958/download>

V.D U.S. National Academies of Science, Engineering, and Medicine, Human Genome Editing: Science, Ethics, and Governance (2017) - excerpts

V.E FDA, Cellular and Gene Therapy Products, at <https://www.fda.gov/vaccines-blood-biologics/cellular-gene-therapy-products> [Students will form teams to report on unresolved issues in the key guidance documents listed on this web page]

V.F National Academies of Science, Engineering, and Medicine, “The Current Biotechnology Regulatory System/Biotechnology-based Cosmetics” (2017)

**VI. Beyond Biomedicine: Agricultural Technologies; Genetically Modified and Synthesized Food; Animal Gene Editing**

**Learning Objectives.** This unit acquaints students with the interplay of regulatory oversight among FDA, the Centers for Disease Control, the U.S. Department of Agriculture, and the Environmental Protection Agency. We use the examples of genetically modified plants and animals, genetically modified food and synthesized food, and open-release products that might have unintended environmental impacts.

VI.A Evan Fraser and Silvain Charlebois, Automated Farming: Good News for Food Security, Bad News for Job Security,” The Guardian (Feb. 18, 2016), at <https://www.theguardian.com/sustainable-business/2016/feb/18/automated-farming-food-security-rural-jobs-unemployment-technology>

VI.B Ashley P. Taylor, “Gene Editing Meets the Food Supply: The New World of Custom-Designed Crops, Milken Institute Review (July 29, 2019), at <https://www.milkenreview.org/articles/gene-editing-meets-the-food-supply>

VI.C Jennifer Kuzma, “Regulating Gene-Edited Crops, “ Issues in Science & Technology (Vol. xxxv, Fall, 2018), at <https://issues.org/regulating-gene-edited-crops/>

VI.D National Academies of Science, Engineering, and Medicine, “The Current Biotechnology Regulatory System/Biotechnology Foods, Food Additives, and Dietery Supplements” (2017), pages 80 – 85.

VI.E Open-release research and production of genetically modified agricultural products: excerpts from case law.

VI.F Point for discussion - ethical and human safety problems with genetic modification of animals: Can FDA, CDC, USDA, and EPA effectively regulate DIY and professional biotechnology that aims to modify animals—for example, to produce ultra-beautiful showcats, glowing fish, ultra-aggressive animals for dog-fighting, or de-extincted Wooly Mammoths?

**Unit VII. Unaffordable Miracles:**

**The Challenge of Making Innovative Biomedical Technologies Accessible to**

**People Who Need Them**

**Here, we will adopt a “divide and conquer” strategy, as described above, to cover this material. We will divide into working groups to present the materials.**

**Learning objectives.** This unit introduces economic factors that can interfere with commercialization of innovative medical technologies, using examples from diagnostics, gene therapies, and rehabilitation devices. These themes are revisted throughout the course. The objective here is simply to emphasize that value network innovation is as crucial as –and sometimes more challenging than – techonology innovation.

VII.A Medicare Payment Advisory Commission – June 2017 Report to Congress. See pages 219 – 231 (stop before “Ramifications of bundling…”

VII.B Gregory Daniel, Nick Leschley, Jeff Marrazzo & Mark McClellan, “Advancing Gene Therapies and Curative Health Care Through Value-Based Payment Reform,” Health Affairs Blog (Oct. 30, 2017)

VII.C Institute for Clinical & Economic Review, “Gene Therapy: Understanding the Science, Assessing the Evidence, and Paying for Value” (March 2017) – selected excerpts.

VII.D Cornelia Henschke & Rita F. Redberg, “Medical Device Price Differentials in the U.S. and Europe – Rethinking Price Regulation,” Health Affairs Blog (Dec. 7, 2018), available at <https://www.healthaffairs.org/do/10.1377/hblog20181206.716970/full/>

VII.E Brian Buntz, “Why Medical Technology Is So Expensive in the United States,” Medical Device & Diagnostic Industry (Aug 6, 2013), at <https://www.mddionline.com/why-medical-technology-so-expensive-united-states>

VII.F Patricia A. Deverka and Jennifer C. Dreyfus, “Clinical Integration of Next Generation Sequencing – Coverage and Reimbursement Challenges” J. Law, Med. & Ethics Supp (Fall 2014) 22 – 38 – selected excerpts

VII.G Michelle Mello and Rebecca E. Wolitz, Legal Strategies for Reigning in Unconscionable Prices of Prescription Drugs (Nw. U. L. Rev. 2020 forthcoming) – selected excerpts

**In-class discussion**: Basics of Medicare and private insurer coverage and reimbursement approvals – what innovators have to do to get a new technology to be covered.

VIII. Broader Social and Ethical Impacts of the Sharing Economy, DTC and DIY Technologies, Neurotechnology, and Knowledge Commons

VIII.A Andrea Wiggins & John Wilbanks. The Rise of Citizen Science in Health and Biomedical Research. Am. J. Bioethics (2019).

VIII. B Lisa Ikemoto: DIY Bio: Hacking Life in Biotech’s Backyard,51 UC Davis L. Rev. 539 (2017).

VIII.C Kellen Zale, When Everything is Small: The Regulatory Challenge of Scale in the Sharing Economy, 53 San Diego L. Rev. 949,(2016).

VIII.D Excerpts from National Academies of Science, Engineering, and Medicine, “Preparing for Future Products of Biotechnology” – non-medical biotechnologies.

VIII.E Cook-Deegan et al., Trade Secret Protection of Data/Data Hoarding/Antitrust Issues.

VIII.F Aas & Wasserman: Ethical Issues with Brain-Computer Interfaces.