Antonin Scalia Law School at George Mason University

FDA LAW AND POLICY

Fall 2024

Mondays – 6:05pm – 8:05pm ET
2 Credit Hours

Professor: Barrett Tenbarge
btenbarg@gmu.edu

Office Hours: Email me to schedule a meeting, which may be before or after a class, or virtual.

Attendance Expectations: This course will be held in-person. There may be 1-2 classes held by Zoom if I have conflicts come up.

You are expected to complete the assigned readings in advance of each class, arrive at class on time, attend and participate in class discussions, and be respectful of all other class members. Because this class is small, it is important for everyone to be present and well prepared. If you cannot attend a class session for any reason, please contact me by email with an explanation as far in advance of the session as you can.

If a student is absent for any reason for more than 20 percent of the sessions of a course (i.e., a maximum of 3 class sessions), the student is not eligible for credit in that course. A student who is not present for at least 75 percent of a session of the course is absent from that session.

Course Overview

The U.S. Food and Drug Administration (FDA) regulates products that account for approximately 25% of the U.S. Gross Domestic Product (GDP). This course will explore the legal and policy issues that shape the development and commercialization of FDA-regulated products. The course will focus on medical products (drugs, biologics, and medical devices), but will also include information related to foods, dietary supplements, cosmetics, and tobacco.

Learning Expectations

The primary goals of this course are three-fold:

- First, students will be able to demonstrate knowledge of basic black-letter law of the statutes and regulations that FDA implements, and be able to identify critical categories in the FDA framework that determine fundamental legal obligations;
- Second, students will be able to conduct the research needed to inform the work of advising clients on FDA legal questions, and provide written analyses of such legal issues to clients; and
- Third, students will be able to understand and reflect on the policy goals of such laws, and FDA's broader role in our society to protect American patients and consumers.

Preparing for Class

My goal is to prepare you to practice law, and more specifically, to practice FDA law. Therefore, to the extent practicable, I will aim to have this course simulate such practice.

- Be proactive – FDA law is complicated, and you will need to learn how to research concepts, references, and terms that you don't know. Because of the complexity of the FDA framework, the

most important skill to take away from this class is not the ability to *know* an answer, but the ability to *find* an answer.
- Come to class ready to discuss and debate. Class participation is crucial. I will be tracking class participation, and such contributions may inform your final grade (either positively or negatively). You will be assessed on thoughtful, respectful interactions that reflect a good-faith grappling with the course material and relevant issues.

Course Materials

Because practicing lawyers rely on publicly available materials, this course will not have a textbook. We will use the same open-source materials that you will use in practice: statutes, regulations, guidance, regulatory preambles, case law, and articles and other resources written by third parties.

Grades

Your course grade will be calculated in the following way:
- Final Exam: 60%
- Client Memo: 30%
- Written Responses and Class Participation: 10%

Depending on course enrollment, the standard grading curve will apply.

Assignments: Client Memo + Written Responses to Questions

One of the primary assignments for this course will be a memo written to respond to questions raised by a "client" regarding their proposed drug development program. You will be expected to write this memo as the client's attorney, incorporating the substantive knowledge and research skills that you will have learned through the first several weeks of class.

At the end of every class session, I will provide questions that relate to the material that we covered during that session. You will prepare written responses to those questions and we will spend the first several minutes of the next class session discussing your responses. This will serve to recap and reinforce the material learned during the previous session. During the course, I will collect three written responses (chosen randomly, though I may provide hints as to which ones will get collected). For many of these question sets, the questions will fall outside of the direct material we cover in class (though will be within the broader topics we covered). You will have to dig into the relevant statutes, regulations, and guidance to find the answer, just like you will be asked to do in your future practice.

Course Schedule

Please note that the readings and assignments are subject to change based on class pacing, developments in the law, and other considerations. I will try to give at least one week's notice for such changes.

Class Voting: In an effort to make this course as valuable as possible, I want to focus the course on areas that are of highest interest to the class (balanced against needing to cover core topics). During the first class session, we will discuss topics that may be of particular interest to students in the class. Based on that discussion, the syllabus (especially for sessions later in the semester) may change. Please come to the first class session with thoughts on what you would like to get out of this course.

Date	Topics	Reading	Assignment Due
Mon., August 26	• N/A	• No class, as I will be traveling. • With no class this first session, please use this time to get ahead on reading – the reading for class on 9/9 is long.	

Wed., Sept. 4	• Course Introduction and Voting
	• Background on the FDA
	• Background on the Food, Drug, and Cosmetic Act and Public Health Service Act
	• The FDA Research "Ladder"
	• Key Statutory Definitions
	• Concept of Intended Use
		• *Promoting Safe & Effective Drugs for 100 Years*, FDA
		  ○ https://www.fda.gov/about-fda/histories-product-regulation/promoting-safe-effective-drugs-100-years
		
		• *The Food and Drug Administration (FDA) Budget: Fact Sheet*, Congressional Research Service
		
		• Statutory and Regulatory Provisions
		  ○ FDCA:
		  ▪ 201(f), (g), (h), (i), (m), (n), (p), (ff), (rr)
		  ▪ 1006
		  ○ PHSA: 42 U.S.C. 262(i)
		  ○ Regulations: 21 C.F.R. 201.128, 801.4
		  ○ FDA guidance, *Classification of Products as Drugs and Devices & Additional Considerations* (Sept. 2017)
		
		• Cases on Key Definitions
		  ○ *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335 (7th Cir. 1983).
		  ○ *Genus Med. Techs. LLC v. United States FDA*, 994 F.3d 631 – 635, 637 - 644.
			• Come to class ready to explain the importance of these three people:
			  ○ Upton Sinclair
			  ○ Frances Kelsey
			  ○ Estes Kefauver
			• Note that this class is on Wed. 9/4, per the school calendar.

Mon., Sept. 9	• FDA Jurisdiction
	• Drug Development and Approval
	  ○ Investigational New Drug applications (INDs)
		• Cases on FDA Jurisdiction
		  ○ *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 131 – 143 (2000).
		  ○ *Gonzales v. Raich*, 545 U.S. 22 - 33, 39 - 42 (2005)
		  ○ *United States v. Regenerative Scis., LLC*, 741 F.3d 1317- 1322 (D.C. Cir. 2014)
			• Answers to 9/4 questions

	○ Clinical Trials ○ Application Review ○ (b)(1) vs. (b)(2) New Drug Applications • Expedited Programs	• Congressional Research Service, *How FDA Approves Drugs and Regulates Their Safety and Effectiveness* (pgs. 1 – 16) • Congressional Budget Office, *Research and Development in the Pharmaceutical Industry* (April 2021) (Can skim for industry background) ○ https://www.cbo.gov/publication/57126 • S-1 Filing for Kaleido Biosciences, Inc. (filed in January 2019) ○ Prospectus Summary (up until "Corporate history") ○ Risks related to our business, technology, and industry (focused on risk factors that mention FDA regulatory issues) ○ Risks related to government regulation (focused on risk factors that mention FDA regulatory issues) ○ Government regulation (up until "Other regulatory matters") • FDA Warning Letter to Kaleido Biosciences (issued on August 26, 2021) • Statutory and Regulatory Provisions ○ FDCA: 505(d) ○ CFR: 21 C.F.R. 314.26 • FDA's *Benefit-Risk Assessment for New Drug and Biological Products* guidance (Focus on pgs. 1 - 12) • FDA's *Demonstrating Substantial Equivalence of Effectiveness for Human Drug and Biological Products* guidance (Focus on pgs. 1 - 13) • FDA's *Expedited Programs for Serious Conditions* guidance (Read for key concepts)	
Mon., Sept. 16	• Prescription Drug User Fee Amendments (PDUFA) ○ Fees ○ Application Review and Timeline	• Congressional Research Service, *FDA Human Medical Product User Fee Programs* (pgs. 1 – 5 – through the PDUFA section) • Statutory Provisions ○ FDCA: 505(p); 505-1 • 10-K Filing for AcelRx Pharmaceuticals (filed March 31, 2023) ○ Sufentanil Sublingual Products section (pg. 8)	• Answers to 9/9 questions • Prepare for "debate" on opioids review standard

	• Post-approval Requirements
	  ○ Post-marketing requirements/ commitments
	  ○ Risk Evaluation and Mitigation Strategies (REMS)
	  ○ GMPs
	
	• Controlled Substances Act
		○ Government Regulation (pgs. 13 – 14)
		
		• FDA's website: Risk Evaluation and Mitigation Strategies
		  ○ https://www.fda.gov/drugs/drug-safety-and-availability/risk-evaluation-and-mitigation-strategies-rems
		
		• External Review of FDA Regulation of Opioid Analgesics – Final Report (pgs. 7 – 23; 34 – 38)
		
		• Congressional Research Service, *The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress* (pgs. 1 – 17)	

Mon., Sept. 23	• Advertising and Promotion • Catch-up Time	• *United States v. Caronia*, 703 F.3d 149 (2d Cir. 2012) • Opinion and Order, *Amarin Pharma, Inc. et al. v. FDA et al.*, No. 15-3588 (S.D.N.Y. Aug. 7, 2015) • FDA's *Addressing Misinformation About Medical Devices and Prescription Drugs* guidance (focus on questions 1, 2, and 3) • Time for general catch-up Q&A on topics covered so far	• Answers to 9/16 questions

Monday, Sept. 30	• Follow-On Products
	• Exclusivities
	• Hatch-Waxman Framework
	• GDUFA
		• Statutory Provisions
		  ○ FDCA: 505(b)(2), 505(j)
		  ○ PHSA: 42 U.S.C. 262(k)
		
		• Congressional Research Service, *Drug Prices: The Role of Patents and Regulatory Exclusivities* (focus on pgs. 7 – 18, 28 – 37)
		
		• *Catalyst Pharmaceuticals, Inc. v. Becerra*, No. 20-13922 (11th Cir. 2021) (Focus on Sections I.A and III).
		
		• *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012)
		
		• Congressional Research Service, *FDA Human Medical Product User Fee Programs* (pgs. 7 -10 – through the GDUFA and BsUFA)
			• Answers to 9/23 questions

Mon., October 7	• BPCIA Patent Dance
	• BsUFA
	
	• Public Health Emergencies (focus on COVID vaccines)
		• Statutory Provisions
		  ○ PHSA: 42 U.S.C. 262(k)
		
		• Sandoz v. Amgen 137 S. Ct. 1664 (2017)
		
		• Fish & Richardson, *How Biosimilars Are Approved and Litigated: Patent Dance Timeline*
		  ○ https://www.fr.com/insights/ip-law-essentials/how-biosimilars-approved-litigated-patent-dance-timeline/
		
		• Statutory Provisions
		  ○ FDCA: 564, 565
		
		• Congressional Research Service, *Development and Regulation of Medical Countermeasures for COVID-19 (Vaccines, Diagnostics, and Treatments): Frequently Asked Questions* (June 25, 2020)
		
		• GAO, *Operation Warp Speed: Accelerated COVID-19 Vaccine Development Status and Efforts to Address Manufacturing Challenges* (Feb. 11, 2021)
			• Answers to 9/23 questions

Monday, Oct. 14		• No class (Fall Break) • Please use this time to work on your client memo and get ahead on reading, because the reading for the next two classes is long (esp. For 10/28).	

Monday, Oct. 21	• Medical Devices
	• MDUFA
		• Statutory Provisions
		  ○ FDCA: 513, 515(a), 520(e)-(g), 522
		
		• Congressional Research Service, *FDA Regulation of Medical Devices*
		
		• 10-K Filing for Inspire Medical Systems, Inc. (filed Feb. 9, 2024)
		  ○ "Government Regulation" section, stopping at "Foreign Regulation"
		
		• 10-K Filing for Owlet (filed March 8, 2024)
		  ○ "Regulatory Interactions" and "U.S. Regulation" sections
		
		• Congressional Research Service, *FDA Human Medical Product User Fee Programs* (MDUFA section)
			Client Memo Due

Monday, Oct. 28	• Combination Products • Digital Health/AI	• Statutory Provisions ○ FDCA: 503(g), 563	• Answers to 10/16 questions

	• Diagnostic Tests	• FDA guidance, *Principles of Premarket Pathways for Combination Products* (Jan. 2022)
		
		• *Prevor v. Food and Drug Administration*, 895 F. Supp.2d 90 (D.D.C. 2012)
		
		• Statutory Provisions
		  ○ FDCA: 515C, 520(o), 524B
		
		• 10-K Filing for Dexcom (filed Feb. 8, 2024)
		  ○ "FDA Regulation" section
		
		• FDA's guidance:
		  ○ *Clinical Decision Support Software* (focus on the examples)
		  ○ *Policy for Device Software Functions and Mobile Medical Applications* (pgs. 1- 15)
		
		• HHS Legal Memo on the Status of Laboratory Developed Tests (focus on pgs. 1-5, 15-17 – skim the other parts)
		  ○ https://www.thefdalawblog.com/wp-content/uploads/2021/11/HHS-Legal-Memo-on-LDTs-by-Charrow-00864663.pdf
		
		• Hogan Lovells, HHS again permits FDA review of LDTs, updates EUA policy for laboratory developed tests
		  ○ https://www.jdsupra.com/legalnews/hhs-again-permits-fda-review-of-ldts-3772110/
		
		• Covington & Burling, Client Alert series on LDTs rule:
		  ○ https://www.cov.com/en/news-and-insights/insights/2023/10/inside-fdas-proposed-rule-to-regulate-laboratory-developed-tests-ldts-key-takeaways-and-open-issues
		  ○ https://www.cov.com/en/news-and-insights/insights/2024/05/unpacking-fdas-final-rule-to-regulate-laboratory-developed-testing-services-as-medical-devices	

Monday, Nov. 4	• **Wildcard** – Pick 2:
	  ○ Foods and Dietary Supplements
	  ○ CBD
	  ○ Cosmetics
	  ○ Tobacco
		• TBD	• Answers to 10/28 questions
			• Election predictions!

Monday, Nov. 11	• Enforcement • Issue Spotting (antitrust, etc.)	• Statutory Provisions ○ FDCA: 301, 303, 304 • *Heckler v. Chaney*, 470 U.S. 821 – 828, 835 – 839 (1985) (focus on the decision; skim the dissent) • FDA Regulatory Procedures Manual, Chapters 4 and 5 (read for key concepts) • Federal Trade Commission, *Overview of FTC Actions in Pharmaceutical Products and Distribution* (July 2024) (read for key concepts)	• Answers to 11/6 questions
Monday, Nov. 18	• How Congress Works • Practice Pointers	• FDALawBlog, Summary of the Food and Drug Omnibus Reform Act (FDORA) ○ https://www.thefdalawblog.com/2023/01/fdora-enacted-hpm-issues-detailed-summary-and-analysis/	• Answers to 11/11 questions
Thurs., Nov. 21	• Final Exam Prep	• Class Q&A ahead of the final exam.	