Antonin Scalia Law School at George Mason University

FDA LAW AND POLICY

Fall 2023

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

Professor: Barrett Tenbarge
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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

As a general matter, 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. Don't fret: you will never be punished for being wrong.

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%

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). The first class session will feature voting, including on the "Wildcard" class options below. 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**
Monday, August 21	• Course Introduction and Voting • Writing Tips • History of the FDA • Structure of the FDA • The FDA Research "Ladder"	• *Politics and the English Language* by George Orwell (focus on the six rules) • *Symposium on Regulating Medical Innovation: The Architecture of Government Regulation of Medical Products,* Richard A. Merrill (82 Va. L. Rev. 1753 - 1777 (1996). • *Promoting Safe & Effective Drugs for 100 Years*, FDA o 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	• Brief Biography (template available on Blackboard)
Monday, August 28	• Background on the Food, Drug, and Cosmetic Act and Public Health Service Act • Key Statutory Definitions • Concept of Intended Use • FDA Jurisdiction	• Statutory and Regulatory Provisions o FDCA: ▪ 201(f), (g), (h), (i), (p), (ff), (rr) ▪ 1006 o PHSA: 42 U.S.C. 262(i) o Regulations: 21 C.F.R. 201.28, 801.4 o FDA guidance, *Classification of Products as Drugs and Devices & Additional Considerations* (Sept. 2017) • Cases on Key Definitions o *Nutrilab, Inc. v. Schweiker*, 713 F.2d 335 (7th Cir. 1983). o *Genus Med. Techs. LLC v. United States FDA*, 994 F.3d 631. • Cases on FDA Jurisdiction o *FDA v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 131 – 143 (2000). o *Gonzales v. Raich*, 545 U.S. 22 - 33, 39 - 42 (2005)	• Answers to 8/21 questions.

		○ *United States v. Regenerative Scis., LLC*, 741 F.3d 1314 (D.C. Cir. 2014)	
Monday, September 11	• Drug Development and Approval ○ Investigational New Drug applications (INDs) ○ Clinical Trials ○ Application Review ○ (b)(1) vs. (b)(2) New Drug Applications • Expedited Programs • Prescription Drug User Fee Amendments (PDUFA) ○ Fees ○ Application Review and Timeline	• 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 read for key concepts) ○ https://www.cbo.gov/publication/57126 • The Entrepreneur's Guide to a Biotech Startup, 4th Edition – Chapter on Clinical Drug Development (pgs. 62 – 69) (Can read for key concepts) • 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 (Can read for key concepts) • FDA's *Demonstrating Substantial Equivalence of Effectiveness for Human Drug and Biological Products* guidance (Can read for key concepts) • FDA's *Expedited Programs for Serious Conditions* guidance (Can read for key concepts) • Congressional Research Service, *FDA Human Medical Product User Fee Programs* (pgs. 1 – 5 – through the PDUFA section)	• Answers to 8/28 questions • Note that this class has extra reading, in light of no class for Labor Day.

Monday, September 18	• Post-approval Requirements
	  ○ Post-marketing requirements and commitments
	  ○ Risk Evaluation and Mitigation Strategies (REMS)
	  ○ Good Manufacturing Practices
	• Advertising and Promotion
	• Controlled Substances Act
		• Statutory Provisions
		  ○ FDCA: 505(p); 505-1
		• 10-K Filing for AcelRx Pharmaceuticals (filed March 31, 2023)
		  ○ Sufentanil Sublingual Products section (pg. 8)
		  ○ 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
		• *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)
		• Congressional Research Service, *The Controlled Substances Act (CSA): A Legal Overview for the 118th Congress* (pgs. 1 – 17)
			• Answers to 9/11 questions

Monday, September 25	• Follow-On Products
	• Exclusivities
	• Hatch-Waxman Framework
	• BPCIA Patent Dance
	• GDUFA and BsUFA
		• 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).
		• *Aaipharma, Inc. v. Thompson*, 296 F.3d 227 (4th Cir. 2002)
		• *Caraco Pharmaceutical Laboratories, Ltd. v. Novo Nordisk A/S*, 566 U.S. 399 (2012)
		• 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/
			• Answers to 9/18 questions

		• Congressional Research Service, *FDA Human Medical Product User Fee Programs* (pgs. 7 -10 – through the GDUFA and BsUFA)	

Monday, October 2	• **Wildcard**:
	  ○ Opioids; or
	  ○ Public Health Emergency (focus on COVID vaccines)
		• TBD	• Answers to 9/25 questions

Tuesday, October 10	• No Class (Work on Client Memo)		

Monday, October 16	• 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. 23, 2023)
		  ○ "Government Regulation" section, stopping at "Foreign Regulation"
		• 10-K Filing for Prometheus Bioscience (filed X, 2023)
		  ○ "Government Regulation" section, stopping at "U.S. Regulation of Drugs and Biologics"
		  ○ https://ir.prometheusbiosciences.com/static-files/c8f3c0fa-4bd1-4e8a-bb13-065491a656ea
		• *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008)
		• Congressional Research Service, *FDA Human Medical Product User Fee Programs* (MDUFA section)
			Client Memo Due

Monday, October 23	• Combination Products
	• **Wildcard**:
	  ○ Digital Health; or
	  ○ Diagnostic Tests
		• Statutory Provisions
		  ○ FDCA: 503(g), 563
		• FDA guidance, *Principles of Premarket Pathways for Combination Products* (Jan. 2022)
		• *Prevor v. Food and Drug Administration*, 895 F. Supp.2d 90, X (D.D.C. 2012)
		• Wildcard: TBD
			• Answers to 10/16 questions

Monday, October 30	• Foods
	• Dietary Supplements
		• FDA, Label Claims for Conventional Foods and Dietary Supplements
		  ○ https://www.fda.gov/food/food-labeling-nutrition/label-claims-conventional-foods-and-dietary-supplements
		• FDA Guidance for Industry, *Food Labeling Guide* (pgs. 4 - 6, 72 – 86)
		• Congressional Research Service, *Regulation of Dietary Supplements: Background and Issues for Congress*
		• FDA Press Release (and related materials), *FDA approves soy leghemoglobin as a color additive* (July 31, 2019)
		  ○ https://www.fda.gov/news-events/fda-brief/fda-brief-fda-approves-soy-leghemoglobin-color-additive
			• Answers to 10/23 questions

Monday, November 6	• **Wildcard** – Pick 2:
	  ○ CBD
	  ○ Tobacco
	  ○ Cosmetics
		• TBD	• Answers to 10/30 questions

Monday, November 13	• Leftover Topic from Wild Card vote • Enforcement • Issue Spotting (antitrust, product liability, etc.)	• TBD • 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* (January 2023) (read for key concepts)	• Answers to 11/6 questions
Monday, November 20	• How Congress Works • Practice Pointers • Exam Prep	• 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 11/13 questions