

# Vaccine Law Spring 2026 (5397/20628)

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Office Hours: By appointment

## General Information

### Course Description and Purpose

Welcome to one of the most fascinating areas of law, **Vaccine Law!** This course covers the confluence of numerous areas of law that bend towards the long-established public policy of having a population that is as fully vaccinated as possible against infectious disease—particularly in the time of a pandemic.

Topics will include: development, regulation and licensure of vaccines; equitable distribution and administration issues; public and private vaccination mandates, exemptions, exclusions, and accommodations; the National Vaccine Injury Compensation System and other means of compensation for vaccine adverse events; legal responses to antivaccination activism; bioterrorism and pandemic response; and international and comparative issues in vaccine law.

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### Course Objectives

Upon completing this course, students will be able to:

1. Identify the legal standards for the evaluation of proposed new vaccines for licensure, and the circumstances under which an emergency may be deemed to exist justifying authorization to use an unlicensed product.
2. Articulate the intellectual property and market access issues peculiar to vaccines.
3. Explain how vaccines are funded, distributed, and promoted.
4. Identify the constitutional basis for vaccination mandates, and the common practices employed in imposing or limiting vaccination mandates.
5. Evaluate assertions that an individual or group should be exempt from vaccination mandates based on their physical condition or beliefs.
6. Differentiate the various regimes for seeking compensation for injuries attributed to vaccines, and the limitations on liability for manufacturers and administrators of vaccines.
7. Explain what legally can and cannot be done with respect to antivaccine activism, and specifically with respect to asserted misinformation.
8. Explain international legal structures for the distribution of vaccines, and identify specific patterns common to other countries in their vaccine laws.

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## Textbook and Course Materials

The primary resources for this class are:

- Abramson, et al., *Vaccine, Vaccination, and Immunization Law* (Bloomberg/AHLA 2018 [2023 update]; hereinafter *VVIL*), which is available electronically via UH's subscription to Bloomberg Law. **It is not necessary to buy the print edition of the book**; the edition available electronically is substantially expanded and has differences in arrangement. And it's free.
- Reiss & Yang, *Vaccine Law and Policy* (Springer, 2023), ISBN:3031369882; hereinafter *VLP*.

Cases and additional materials for the class are generally available online; those that are not will be made available to all enrolled students by the professor.

**PLEASE NOTE: there is a lot of reading for this class; do not be intimidated by this.**

**The instructor does not expect that every student will pore over every word of the instructor's densely-constructed treatise. The idea is to get an overall sense of what is going on in the readings and in the cases.**

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## Expectations of this Course

This is an online course, which means most (if not all) of the course work will be conducted online. Expectations for performance in an online course are the same as a traditional course. In fact, online courses require a degree of self-motivation, self-discipline, and technology skills which can make these courses more demanding for some students.

- Students are expected to:
  - **review the getting started page** located in the course modules;
  - **introduce yourself to the class** during the first week by posting a self-introduction in the appropriate discussion;
  - **interact** online with instructor and peers;
  - **review** and follow the course calendar and weekly outlines;
  - **respond** to discussions by the due date specified. **No late work will be accepted**;
  - **respond to emails** within a reasonable time;
  - **submit** assignments by the corresponding deadline.

The instructor will:

- log in to the course multiple times per week;
  - respond to discussion postings within **three days of posting, subject to delays for previously indicated travel**;
  - respond to **emails** within **48 hours, subject to delays for previously indicated travel**;
  - grade assignments within **ten days** of the assignment deadline.
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## Assignments

- - There will be two primary written assignments. The first will be:
    - An individual class paper of not less than 15 pages (excluding cover pages) and not more than 25 pages (double-spaced, twelve-point Times New Roman font, one-inch margins), substantively addressing some area of Vaccine Law.
    - The topic of this final paper must be **approved by the professor**, and must be submitted for approval by the **fifth week of class**. If, after obtaining approval, you wish to change the topic, that will be allowed within reason.
    - This final paper will be due the last week of class. If at some point you think you may have trouble finishing a paper on that schedule, try to tackle it early. There is no rule prohibiting handing in the paper early (though you will certainly want to wait until you have gained enough substance from the class to write thoroughly on your chosen topic).
  - The second written assignment will be:
    - A profile of the vaccine laws of an individual country selected from a list of countries *not* already covered by *VVIL*, addressing (to the extent that information is available) how vaccines are approved for use in that country; whether there are vaccination mandates for various groups (students, healthcare workers, workers in other professions, the general population); and how asserted vaccine injuries are compensated, if at all.
    - Based on the size of the class, if students would prefer, this may be made into a group assignment, with students being placed in groups of not more than three.
  - Assignments are to be submitted to me by email or through Canvas.

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## Grading

Grades will be based on participation, quizzes, the country profile, and the class paper.

Students who participate in discussions are expected to be prepared for class, not just by having read the materials, but in being prepared to take and defend positions in discussion of contentious questions of law.

Please contact me if you foresee an issue with participation.

## Course Calendar

### TOPICS AND READINGS:

Weeks 1-2 January 21, 26, 28

### Objectives:

- Explain what vaccines are and how they are legally defined, how they are intended to work, and why that matters to the law.
- Understand the alphabet soup of entities and rules involved in vaccine approval: FDA, NDA, BLA, IRB, CDC
- Explain how clinical trials for vaccines differ from those for other pharmaceutical products, and how the FDA evaluates the evidence to determine whether vaccines are safe and effective to use.
- Articulate the standards for allowing a vaccine to be used under an Emergency Use Authorization, and under normal FDA licensure.
- Describe how the FDA polices the quality of products once licensed, and prosecutes efforts to distribute unlicensed or counterfeit products.
- Explain FDA requirements for advertising of pharmaceutical products.
- Identify the limitations on individuals seeking to oppose FDA determinations.
- Identify the limitations on state efforts to regulate FDA-approved pharmaceutical products.

### Readings:

- *VVIL* Chapter I: *Introduction* (read lightly)
- *VVIL* Chapter II: *Vaccine Regulation*, Part I and Part II, Section A (read lightly)
- *VLP* Chapters 1-3
- *Coalition for Mercury-Free Drugs v. Sebelius*, 671 F.3d 1275 (D.C. Cir. 2012)
- *Rempfer v. Von Eschenbach*, 535 F. Supp. 2d 99 (D.D.C. 2008)

- *Griswold v. Connecticut*, 381 U.S. 479 (1965)
  - *Eisenstadt v. Baird*, 405 U.S. 438 (1972)
  - DOJ Announcement, [Doctor, Clinic Owner and Staff Charged with Falsifying Clinical Trial Data \(Links to an external site.\)](#) (March 8, 2020)
  - DOJ Announcement, *Department of Justice Enforcement Actions Related to COVID-19*, available at [https://en.wikisource.org/wiki/Department\\_of\\_Justice\\_Enforcement\\_Actions\\_Related\\_to\\_COVID-19\\_\(Links\\_to\\_an\\_external\\_site.\)](https://en.wikisource.org/wiki/Department_of_Justice_Enforcement_Actions_Related_to_COVID-19_(Links_to_an_external_site.))(March 24, 2020)
  - DOJ Announcement, *Department of Justice Files Its First Enforcement Action Against COVID-19 Fraud*, available at [https://www.justice.gov/opa/pr/justice-department-files-its-first-enforcement-action-against-covid-19-fraud\\_\(Links\\_to\\_an\\_external\\_site.\)](https://www.justice.gov/opa/pr/justice-department-files-its-first-enforcement-action-against-covid-19-fraud_(Links_to_an_external_site.)) (March 22, 2020)
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Week 3      February 2, 4

**Objectives:**

- Enumerate the legal standards are for issuance of a patent, and describe how questions about the patentability of vaccine-related technology have been resolved.
- Describe how other intellectual property regimes such as trademark, copyright, and trade secrets, apply (or do not apply) to vaccines.
- Explain the continuing role of FDA in extending exclusive rights to market a vaccine under the BPCIA
- Discuss the feasibility of proposals to waive vaccine patents in the face of a pandemic.
- Describe how the market for vaccines circumscribes the availability of antitrust claims arising from actions in connection with the development and marketing of vaccines.

**Readings:**

- *VVIL* Chapter II: *Vaccine Regulation*, Part II, Section E, and Part III
- *VVIL* Chapter III-IV: *Vaccine Patents* (optional, read lightly)
- *VVIL* Chapter V: Other Intellectual Property Issues
- *VLP* Chapter IV
- *Diamond v. Chakrabarty*, 447 U.S. 303 (1980)
- Copyright Office, *Affirmance of Refusal for Registration (re: Prancer DNA Sequence)*, available at [https://en.wikisource.org/wiki/Copyright\\_Office\\_letter\\_affirming\\_refusal\\_t](https://en.wikisource.org/wiki/Copyright_Office_letter_affirming_refusal_t)

[o register the "Prancer DNA Sequence" \(Links to an external site.\)](#) (February 11, 2014)

- *US v. Martin*, 228 F.3d 1 (1st Cir. 2000)
  - *Barton & Pittinos, Inc. v. SmithKline Beecham Corp.*, 118 F.3d 178 (3d Cir. 1997)
  - *United States ex rel. Krahl v. Merck & Co.*, 44 F. Supp. 3d 581 (E.D. Pa. 2014)
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Week 4      February 9, 11

**Objectives:**

- Describe the funding, distribution, access, and administration of vaccines
- Identify different parties able to prescribe and administer vaccines, and the arguments for designating such ability.
- Identify the various means by which minors are able to consent to vaccination if their parents object, and the arguments for and against such means.
- Identify the goals of government agencies in rationing and prioritization of vaccine recipients during a shortage.

**Readings:**

- *VVIL Chapter VI: Vaccination Funding, Payment, and Access Issues*, Parts II, III, and V (Part III can be read lightly)
- *VLP Chapters 8-11*
- *Braidwood v. Becerra* (TBD; Fifth Circuit Decision pending)
- *Mazer v. DC Dep't of Health*, No. 1:21-cv-01782 (TNM) (March 18, 2022)
- *In the Matter of Dr. Paul Thomas*, Oregon Health Authority (July 12, 2019) (will be provided)

Weeks 5-6      February 16, 18, 23, 25

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**Objectives:**

Introduction to public vaccination mandates

- Identify the sources of authority for states to mandate vaccination.
- Discuss whether the police power to impose mandates diminishes as advances in medical technology make infectious disease less threatening.
- Discuss whether the United States federal government has the power to mandate vaccination – and whether it should.

## Vaccination and Family Law

- Understand the role a parent's views on vaccination may play in determining child custody.

### Readings:

- *VVIL* Chapter VII: *Vaccination Mandates*, Parts I and II, III.C., and V through VII
- *VVIL* Chapter VII: *Vaccination Mandates*, Parts III.B.2 and III.B.3
- *VLP* Chapters 14-16

### State mandates

- *Jacobson v. Massachusetts*, 197 U.S. 11 (1905)
- *Zucht v. King*, 260 U.S. 174 (1922)
- *Mont. Med. Ass'n v. Knudsen*, CV 21-108-M-DWM (D. Mont. Dec. 9, 2022)

### Federal mandates

- *NFIB v. OSHA*, Nos. 21A244, 595 U. S. \_\_\_\_ (Jan. 13, 2022)
- *Biden v. Missouri*, No. 21A240, 595 U. S. \_\_\_\_ (Jan. 13, 2022)

### Equal protection

- *Wong Wai v. Williamson*, 103 F. 1/*Jew Ho v. Williamson*, 103 F. 10 (C.C.N.D. Cal. 1900)
  - Watch the 16 1/2-minute segment from 42:00 to 58:32 of the PBS documentary, [Plague at the Golden Gate](#) (Links to an external site)

### Military cases

- *VLP* Chapter 20
- *Doe v. Rumsfeld*, 297 F.Supp.2d 119 (D. D.C. 2003)
- *Rempfer v. Sharfstein*, 583 F.3d 860 (D.C. Cir. 2009)

### Prisoner cases

- *Smith v. Florida*, No: 2:15-cv-183-FtM-29DNF (M.D. Fla. 2015), [https://en.wikisource.org/wiki/Smith v. Florida](https://en.wikisource.org/wiki/Smith_v._Florida) (Links to an external site.) (Links to an external site.)
- *McCoy v. Wooten*, CV 315-047 (S.D. Ga. 2015), [https://en.wikisource.org/wiki/McCoy v. Wooten](https://en.wikisource.org/wiki/McCoy_v._Wooten) (Links to an external site.) (Links to an external site.)
- *VVIL* Chapter IX, section on *Texas*

- Wen S. Shen, *An Overview of State and Federal Authority to Impose Vaccination Requirements*, Congressional Research Service (May 22, 2019), available at <https://fas.org/sgp/crs/misc/LSB10300.pdf> (Links to an external site.) (Links to an external site.)
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Week 7      March 2, 4

### Objectives:

- Learn the historical basis for medical, religious, and philosophical exemptions to public vaccination mandates.
- Examine the various different standards employed by states in allowing exemptions.

### Readings:

- *VVIL Chapter VIII: Vaccination Exemptions, Parts I through III*
- Opinion of Percy V. Long, *Vaccination Necessary Before Pupils Can Attend Public Schools, Unless After Due Diligence Successful Vaccination Is Impossible*, [https://en.wikisource.org/wiki/Vaccination\\_Necessary\\_Before\\_Pupils\\_Can\\_Attend\\_Public\\_Schools\\_Unless\\_After\\_Due\\_Diligence\\_Successful\\_Vaccination\\_Is\\_Impossible](https://en.wikisource.org/wiki/Vaccination_Necessary_Before_Pupils_Can_Attend_Public_Schools_Unless_After_Due_Diligence_Successful_Vaccination_Is_Impossible)(Links to an external site.) (Links to an external site.)

### Medical exemptions

- *Jones v. State, Dept. of Health*, 18 P.3d 1189 (Wyo. 2001)
- *Head v. Adams Farm Living, Inc.*, 775 S.E.2d 904 (N.C. App. 2015) (focus on chiropractic parts)

### Religious exemptions

- *Prince v. Massachusetts*, 321 U.S. 158 (1944), focus on paragraphs 15-16
- *Workman v. Mingo County Board of Education*, 667 F. Supp. 2d 679 (W.D. W. Va. 2009) (skip lengthy section III. A. on “Eleventh Amendment Immunity”)
- *Brown v. Stone*, 378 So. 2d 218 (Miss. 1979)
- *Bosarge v. Edney*, 1:22-cv-00233-HSO-BWR (S.D. Miss., Apr. 18, 2023)
- *Flynn v. Estevez*, 221 So. 3d 1241 (Fla. App. 2017)
- *Caviezel v. Great Neck Public Schools*, 701 F. Supp. 2d 414 (2010)
- *Phillips v. City of New York*, 775 F.3d 538 (2d Cir. 2015)
- *Nikolao v. Lyon*, 875 F.3d 310 (6th Cir. 2017)

## Philosophical exemptions

- *Chenzira v. Cincinnati Children's Hosp. Med. Ctr.*, No. 1:11-CV-00917, 2012 WL 6721098 (S.D. Ohio Dec. 27, 2012) (skip lengthy section III. A. on "Timeliness")
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Weeks 8-9 March 9, 11

### Objectives:

- Discern the legal basis for employer-imposed vaccination mandates.
- Articulate other employer options, such as encouragement, incentivization, and facilitation of employee vaccination, and the legal challenges presented by each.
- Describe the legal regimes requiring employer accommodation of employee medical and religious objections to vaccination.
- Identify the agencies and statutes that make up the employer's "alphabet soup" with respect to vaccine law OSHA, EEOC, ADA, FLSA, NLRA, HIPAA, ERISA, GINA

### Readings:

- *VVIL Chapter VII: Vaccination Mandates, Part IV*
- EEOC, *What You Should Know About COVID-19 and the ADA, the Rehabilitation Act, and Other EEO Laws, Technical Assistance Questions and Answers* (Dec. 16, 2020), Part K. Vaccinations, available at <https://www.eeoc.gov/wysk/what-you-should-know-about-covid-19-and-ada-rehabilitation-act-and-other-eeo-laws> (Links to an external site.) (Links to an external site.)

Note: You are only required to read Part K, but may find the entire document informative to questions raised in this course.

- *Virginia Mason Hospital v. Washington State Nurses Association*, 511 F.3d 908 (9th Cir. 2007)
- *Ruggiero v. Mount Nittany Medical Center*, 736 F. App'x 35 (3rd Cir. 2018)
- *Hustvet v. Allina Health Sys.*, 910 F.3d 399 (8th Cir. 2018)
- *Cunningham v. Univ. of Haw.*, No. 22-cv-00504 (D. Haw., Feb. 14, 2023)
- *Horvath v. City of Leander*, No. 18-51011 (5th Cir. Jan., 2020)
- *Brown v. Children's Hosp. of Phila.*, 794 F. A'ppx 226 (3d Cir. Feb. 2020)
- *EEOC v. Baystate Med.*, No. 3:16-cv-30086 (D. Mass. June 2020)
- *Jenkins v. Mercy Hospital Rogers*, No. 5:19-CV-05221 (W.D. Ark. March 2020)
- Order Granting Motion for Summary Judgment, *Garza v. Houston Methodist Hospital*, No. 4:22-cv-4288 (August 15, 2025)

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Weeks 10-11      March 23, 25, 30, April 1

**Objectives:**

- Discuss whether the National Vaccine Injury Compensation Program is a good torts model. Be able to discuss the following common questions about the program:
  - Is it too generous?
  - Not generous enough?
  - Does alleviating liability from manufacturers impact their incentive to produce a quality product?
- Consider whether injuries should be covered if they are attributed to faulty administration technique, rather than the vaccine itself.
- Discuss whether the Countermeasures Injury Compensation Program is at all adequate to the task of aiding people in times of public emergency
- Explain routes for injury compensation outside of the NVICP and the CICP

**Readings:**

- *VVIL* Chapter XI: *Vaccine Injury Claims*, Parts I through VI and Part VIII (read lightly)
- *VLP* Chapter 5

**Cases**

- *Massing v. Secretary of HHS*, 926 F.2d 1133 (Fed. Cir. 1991)
- *Moss v. Merck & Co.*, 381 F.3d 501, 503 (5th Cir. 2004)
- *Althen v. Secretary of Health & Human Services*, 418 F.3d 1274 (Fed. Cir. 2005)
- *Cloer v. Secretary of Health & Human Services*, 654 F.3d 1322 (Fed. Cir. 2011)
- *Bruesewitz v. Wyeth*, 562 U.S. 223 (2011)
- *DeCostanzo v. Glaxosmithkline PLC*, No. 21-CV-4869 (E.D.N.Y., Nov. 30 2022)
- *Bakeman v. Secretary of HHS*, No. 18-1861V, 2020 BL 178993 (Fed. Cl. Spec. Mstr. Apr. 13, 2020)
- *Parker v. St. Lawrence County Public Health Department*, 102 A.D.3d 140 (N.Y. App. Div. 2012)
- *M.T. v. Walmart Stores, Inc.*, Nos. 125,151, 125,268 (Kan. App. 2023)
- *Monette v. Manatee Mem'l Hosp.*, 579 So.2d 195 (Fla. Dist. Ct. App. 1991)

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Weeks 12-13      April 6, 8, 13, 15

- Articulate the rational limitations on the power that government may exercise in response to a pandemic threat.

- Discuss whether, given the powers at its disposal, governments have done too little or too much in response to the COVID-19 pandemic.
- Identify the legal responses that have been exercised with respect to various forms of antivaccine activism.
- Explain why mandating vaccines requires knowing who has received them, and when, and what the implications of this information are for privacy rights.
- Explain the different levels of responsibility entities have for reporting injuries attributed to vaccination.

### Readings:

- *VVIL* Chapter II: *Vaccine Regulation*, Part II, Section E (re-read)
- *VVIL* Chapter VI: *Vaccination Funding, Payment, and Access Issues*, Part VI
- *VVIL* Chapter IX: *Reporting Requirements*
- *VVIL* Chapter XI: *Vaccine Injury Claims*, Part VII (re-read)
- *VVIL* Chapter XIV: *Responses to Antivaccine Activism*
- VLP Chapters 21-22
- *Rhea v. Board of Education of Devils Lake*, 41 N.D. 449, 171 N.W. 103 (1919)
- *Hammond v. Town of Hyde Park*, 195 Mass. 29, 80 N.E. 650 (Mass. 1907)
- *Millican v. United States*, 744 F. Supp.2d 296 (D.D.C. 2010)
- *Blackwell v. Wyeth*, 971 A.2d 235, 408 Md. 575 (Md. App. 2009)
- HHS, *Declaration Under the Public Readiness and Emergency Preparedness Act for Medical Countermeasures Against COVID-19* (March 17, 2020), available at <https://www.federalregister.gov/documents/2020/03/17/2020-05484/declaration-under-the-public-readiness-and-emergency-preparedness-act-for-medical-countermeasures> (Links to an external site.) (Links to an external site.)
- HHS, *Advisory Opinion 21-01 on the Public Readiness and Emergency Preparedness Act Scope of Preemption Provision* (January 8, 2021), available at <https://www.hhs.gov/guidance/sites/default/files/hhs-guidance-documents/2101081078-jo-advisory-opinion-prep-act-complete-preemption-01-08-2021-final-hhs-web.pdf> (Links to an external site.) (Links to an external site.)

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Week 14    April 20/22

### Objectives:

- Explain international and comparative legal structures for vaccination
- Discuss whether existing international structures are sufficient to provide for global health maintenance, and prevent the spread of infectious disease between countries.

- Identify which structures in the U.S. law are or are not reflected elsewhere in the world.
- Address whether the U.S. has an obligation to take steps to insure availability and deployment of vaccines in the rest of the world; consider whether that changes if the goal is to limit diseases from entering the U.S.

### Readings:

- *VVIL* Chapter XIII: *International and Comparative Vaccine Law*, Parts I through VIII; pick **one country** to read from Part IX
- *VLP* Chapters 18-19

### Assignment:

A list of key countries *not* included in *VVIL* Chapter XIII, Part IX, will be provided.

Claim one country from that list (only one student per country and one country per student!) and write a brief (3-4 page) summary of vaccine law issues in that country.

- How are vaccines approved for use, regulated and distributed?
- Are vaccines mandated by the government, and if so, for whom?
- Is there a vaccine injury compensation system?
- Are there substantial differences from U.S. vaccine law?

Note: the students who write the best summaries may be given the opportunity to have their summary adapted for inclusion in the next annual update of the legal treatise, *Vaccine, Vaccination, and Immunization Law*.

### Objectives:

Review, wrap-up, and writing project summaries

- What have we learned about the place of vaccines in our legal milieu?