Seminar On Human Rights and Health Law: An Overview of International and U.S. Legal Interventions to Protect and Promote the Public's Health

Erasmus Intensive Course University of Lisbon Law Faculty

October 15-19, 2018 (Revised August 21, 2018)

16:00-18:00

Professor Jennifer S. Bard, J.D., M.P.H., Ph.D. Professor of Law and Medicine, University of Cincinnati

@profbardlaw (twitter)

Jennifer.Bard1@gmail.com

SYLLABUS

Course Description:

The Constitution of the World Health Organization defines the right to health as "[T]he highest attainable standard of health as a fundamental right of every human being." But the challenge of achieving that goal in a world marked by vast economic inequalities, unstable political boundaries, and ever emerging new infectious diseases are immense.

Moreover, when the issue is the health of an entire population, rather than an individual, there are inevitable conflicts between acts taken for the good of the many versus protection of individual human rights. It is in these areas of conflict that the law is particularly important

This course will:

- 1. Offer an introduction to the way that the ways that law is used globally to protect important human rights such as autonomy, right respect for property, and privacy. It will also do so in the context of issues like disease surveillance, drug addiction treatment, development of pharmaceuticals, and measures to counter the spread of disease vectors such as mosquitos. We will consider how nations interact with each-other and how human rights issues are addressed differently by the specific laws of the nations where they arise. It will also provide an introduction into how law is studied and practiced in the USA.
- 2. Using the context of protecting the public's health, the way law is studied in U.S.A. law schools and practiced by U.S.A. lawyers. We will learn the basics of the U.S. Legal System

and how U.S. Law addresses threats to the public's health that arise inside and outside the country. This will include an overview of U.S. Constitutional Law, Commercial Law (Business Law), and Criminal Law.

Why Study Public Health Law?

To law students, studying public health law offers various benefits. It prepares you for working in both government and non-government organizations involving human rights, in the private practice of law representing companies such as food or drug sellers or manufacturers as well as any company which may have an impact on the environment. It also makes you aware of how the law can be used as a tool to promote the health of the general population.

No Prior Knowledge Required:

This Course assumes no prior knowledge of public health or the laws pertaining to it. It is designed for any student currently studying law at the University of Lisbon.

Learning Outcomes

After the completion of this seminar, the students should:

- Have acquired a familiarity with the core human rights concerns that arise in relation to
 measures that governments take in addressing public health issues, the major
 international legal documents governing these conflicts, and the primary principles of
 U.S. Constitutional law that govern addressing these issues in the United States.
- Gain experience in researching, organizing, and presenting a briefing to a government official on legal issues arising from a public health scenario.
- Develop familiarity with finding the sources of legal authority governing public health issues.

Organization of Course:

The class will meet every day from Monday October 15, 2018 through Friday October 19, 2018 from 16:00-1800

There will be a short break in the middle of the class.

Each class will consist of an overview of the material, discussion and in-class group exercises to gain familiarity with the material. This kind of active and experiential learning (learn by doing) is an important part of U.S. Legal Education.

In order to allow for the maximum amount of active learning, students will be required to prepare in advance by reading the assigned material

Course Readings:

Since our time is short, it is important for students to complete reading assignments in advance so that they will be prepared to discuss the information in class.

To make this easier and to save students expense, almost all of the materials in this class will be available without cost, on-line.

We will use multiple sources for class readings in this short, intensive course,. (Do not be frightened by these! We will not read all of these materials; they are provided to you as a resource for subsequent use, in-depth research, or any other purpose you may wish.). We will use many different sources of law as well as information about public health. We will even play some computer games!

Primary Source: The most complete source of information for the topics in this course in *World Health Organization*, 25 Questions and Answers on Health and Human Rights,

https://www.opensocietyfoundations.org/sites/default/files/25_questions.pdf We will refer to it every day. Please read it from start to finish before the first day of class.

Other Sources: We will also use sources on the Internet as we observe current news events relating to our course content. To further assist the students, Prof. Bard's PowerPoint slides used in class will be posted electronically after each class, to insure effective recordation of class instruction, without necessitating numbing note-taking.

Messages and Distribution of Materials: Course related announcements, reading materials, and assignments will be communicated to the students via University of Lisbon Erasmus Office internet communication system.

Class Attendance: Class attendance for the five sessions is required by the policies of the Law Faculty of the University of Lisbon. One absence may be excused by the Erasmus office based on valid reason.

Class participation: is an essential part of student attendance. Students are expected to prepare for class by reading assigned materials, enabling them to understand and contribute to the class analytical discussions. The purpose of classes is not to recite the assigned readings.

Rather, classroom discussion will focus on key principles and give students the opportunity to think, raise questions, and discuss their ideas.

Through active learning exercises, it will give the opportunity to use those tools in class discussions, in simulated briefings, and then in a research memo. Finally, for those interested in producing scholarship, it will introduce the role legal scholars play in addressing human rights issues that arise in public health.

Experiential Learning, I: Real-Time Public Health News: We will regularly track public health legal issues to experience what is really happening contemporaneously with our studies, consulting current trade news, especially online international media reports from credible sources, such as The Economist, The Financial Times, The Guardian, Agence France-Presse, Handelsblatt, etc.

Experiential Learning II: Providing Legal Advice to Clients

In the final class meeting on Friday afternoon, students will participate in a debate on a central issue to public health law.

Office Hours: Prof. Bard will be available to meet with students from 2 p.m. - 3 p.m. before class. Students are encouraged to email or personally arrange a meeting to discuss the course and related topics of interest.

Course Grading & Final Exam: Each student's final grade in the intensive course will be based on a take-home, open book essay and short answer exam that will be distributed at the last class on Friday, and the completed exam must be returned to the Law Faculty Erasmus Office by 4 p.m. on Monday, Only printed out, hard copy exam answers will be accepted.

Arguments supporting both sides will be explored during the previous class meetings. Note, that participation in the debate will contribute to students' class participation grades.

Students' final grades will reflect their score on the exam, as well as the class participation credit described above. Students' grades will be administered according to the traditional numerical system in place at the University of Lisbon Law Faculty. Final grades in the course will be computed on the following basis: class participation 5%, final exam 95%.

OVERVIEW of CONTENT

This seminar begins with a short overview of the kinds of human rights issues that arise when governments address issues of public health. It looks at sources of law and considers jurisdictional issues in the frequent instances where public health interventions of one government affect people in other countries.

The second class will be organized around the activities of governments in preventing outbreaks of disease. We will then consider actions after the outbreak of disease.

The third class will consider the human rights issues raised by the testing of drugs by pharmaceutical companies. In particular, we will look at tests conducted in countries with less rigorous protections of research participants than the countries where the pharmaceutical company hopes to market its products. We will also consider issues of data and genetic privacy that can arise in the course of research studies.

The fourth class will consider issues related to individual rights like organ donation and assisted reproductive technology.

The fifth class will be devoted to an interactive exercise where students will take on the role of briefing government officials on legal responses to various scenarios. Depending on the number of students in the class, students will be assigned to present different viewpoints within the same topic.

At the end of this document is a reference section of general sources of law that may be helpful.

Detailed Schedule and Assignments

Before Start of Class:

Social Media Assignment: Please follow @laurie_Garrett on Twitter. She is an internationally praised expert on global public health. There will be some USA political news, but she is one of the most informed commentators on emerging public health issues.

https://twitter.com/laurie_garrett?lang=

SPECIFIC ASSIGNMENTS FOR EACH CLASS:

NOTE—THIS MATERIAL IS PROVIDED TO GIVE YOU AN IDEA OF THE KIND OF ASSIGNMENTS AND THEIR LENGTH. YOU WILL RECEIVE AN UPDATED LIST OF SYLLABUS TWO WEEKS BEFORE THE START OF CLASS.

Class 1: October 18th

Overview of Public Health Law

Read: World Health Organization, 25 Questions and Answers on Health and Human Rights, https://www.opensocietyfoundations.org/sites/default/files/25_questions.pdf

Questions 1-5

Strengthening health security by implementing the International Health Regulations (2005) http://www.who.int/ihr/en/

Daniel Lins Menucci, International Health Regulations And Aviation
https://www.icao.int/EURNAT/Other%20Meetings%20Seminars%20and%20Workshops/CAPS
CA%20EUR/CAPSCA-EUR01/PPT08%20WHO_IHR%20Aviation_Daniel%20Menucci.pdf

Portugal's Ebola Scare http://portugalresident.com/tags/ebola
https://www.journalofclinicalvirology.com/article/S1386-6532(16)30309-2/fulltext

Formatada: Português (Portugal)

Código de campo alterado

Formatada: Português (Portugal)

Ray Sanchez, Catherine E. Shoichet and Faith Karimi, *Ebola update: Maine judge rejects quarantine for nurse Kaci Hickox (CNN Nov* 1, 2014).¹

http://www.cnn.com/2014/10/31/health/us-ebola/index.html

https://www.nytimes.com/2017/07/27/nyregion/ne
Frequently asked questions about the International Health Re

Frequently asked questions about the International Health Regulations (2005) http://www.who.int/ihr/about/FAQ2009.pdf?ua=1

Lawrence O. Gostin and Allyn Taylor *Global Health Law: A Definition and Grand Challenges* https://academic.oup.com/phe/article/1/1/53/1415563/Global-Health-Law-A-Definition-and-Grand

United Nations General Assembly, "Protecting Humanity from future Health Crises" (http://www.un.org/ga/search/view_doc.asp?symbol=A/7o/723

Overview of USA Legal System

https://www.cdc.gov/immigrantrefugeehealth/laws-regulations.html

Portuguese Public Health Law

http://www.who.int/bulletin/volumes/86/11/08-041108/en/

Class 2: October 19th

Assigned Reading:

World Health Organization, 25 Questions and Answers on Health and Human Rights, https://www.opensocietyfoundations.org/sites/default/files/25_questions.pdf

Questions 6-10

A. Taking Preventative Measures

Erin Walkinshaw, Mandatory Vaccinations: The International Landscape (Canadian Medical Association 2011) http://www.cmaj.ca/content/183/16/E1167

Mandatory Vaccination

¹ If you have trouble getting a video to play, please do not worry. Try to use google to see if you can get a different link, but if it doesn't work just move on to the next reading assignment.

Page **8** of **12**

http://www.eurosurveillance.org/ViewArticle.aspx?ArticleId=20183

http://www.loc.gov/law/foreign-news/article/australia-government-payments-to-be-denied-for-failure-to-vaccinate-for-non-medical-reasons/

The Role of the United States Constitution in Resolving Public Health Human Rights https://constitutioncenter.org/interactive-constitution____

B: Responding to Emergencies: Pandemics and Natural Disasters

Ebola http://www.who.int/news-room/fact-sheets/detail/ebola-virus-disease

Application of SIRACUSA Principles in times of public health crisis, https://www.icj.org/siracusa-principles-on-the-limitation-and-derogation-provisions-in-the-international-covenant-on-civil-and-political-rights/

Jared P. Cole, *Federal and State Quarantine and Isolation Authority*, Congressional Research Service (2014) https://fas.org/sgp/crs/misc/RL33201.pdf

Watch: http://www.pbs.org/wqbh/nova/body/short-history-of-quarantine.html

Health & Safety at Work

http://ec.europa.eu/social/main.jsp?catId=148

Mandatory Testing

Human Rights Watch, *Greece: Repeal Abusive Health Regulation* https://www.hrw.org/news/2013/07/03/greece-repeal-abusive-health-regulation

D. U.S. A Constitutional Law

[Assignments to Come]

Class 3: October 20th

Human Subject Research and Development of Pharmaceuticals

World Health Organization, 25 Questions and Answers on Health and Human Rights, https://www.opensocietyfoundations.org/sites/default/files/25_questions

Bard Seminar on Human Rights and Health Law 2018

Questions 11-15

Declaration of Helsinki, http://www.who.int/bulletin/archives/79%284%29373.pdf

Testing and Developing Drugs Overseas

Watch:-- https://youtu.be/YG2_ekbDa70 (note, this video is accurate but has a strong pharmaceutical company bias).

Vidya Krishnan, *Norms for clinical trials eased*, The Hindu (March 30, 2016). http://www.thehindu.com/sci-tech/health/norms-for-clinical-trials-eased/article8414557.ece

Human Subject Research http://research-compliance.umich.edu/human-subjects/human-research-protection-program-hrpp/resources-international-human-subject-research

https://www.hhs.gov/ohrp/international/compilation-human-research-standards/index.html

Issues of Privacy and Confidentiality

Robert Gellman and Pam Dixon, *Privacy, the Precision Medicine Initiative*, & the All of Us Research Program: Will Any Legal Protections Apply? (2nd Edition, March 2017). http://www.worldprivacyforum.org/wp-content/uploads/2017/03/WPF_PrecisionMedicineInitiative_2nd_ed_March14_2017_fs.pdf

Japan to extend privacy laws to protect genetic data, Global Legal Post (Dec. 30, 2015). http://m.globallegalpost.com/global-view/japan-to-extend-privacy-laws-to-protect-genetic-data-85703603/

Mandatory Treatment Not Effective At Reducing Drug Use, Violates Human Rights, Researchers Say

Science Daily, (June 21, 2016)

Thomas Nicholson, Catherine Admay, Aaron Shakow, and Salmaan Keshavjee, Double Standards in Global Health: Medicine, Human Rights Law, and Multidrug-Resistant TB Treatment Policy, https://www.hhrjournal.org/2016/06/double-standards-in-global-health-medicine-human-rights-law-and-multidrug-resistant-tb-treatment-policy/

E. U.S.A. Business Law

[Assignments to Come]

Class 4 October 21: Bioethics Issues

World Health Organization, 25 Questions and Answers on Health and Human Rights, https://www.opensocietyfoundations.org/sites/default/files/25_questions

Questions 15-20

Bioethics Issues:

Organ Donation

http://www.theportugalnews.com/news/the-truth-behind-organ-donation-in-portugal/24707

Surrogacy

Surrogacy Laws by Country - Where Is It Legal?

https://wearesurrogacy.com/countries/

Dwindling Options for Surrogacy Abroad,

https://www.theatlantic.com/health/archive/2016/05/dwindling-options-for-surrogacy-abroad/484688/

SURROGACY TOURISM TO INDIA COMES TO AN END, 05 October 2016, https://www.imtj.com/news/surrogacy-tourism-india-comes-end/

Vera Lúcia Raposo, *The new Portuguese law on surrogacy - The story of how a promising law does not really regulate surrogacy arrangements*, BRA Assist Reprod. 2017 Sep 1;21(3):230-239. doi: 10.5935/1518-0557.20170044.

https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5574646/

PMID:

28837033

Portugal: New Law Further Regulates Surrogate Pregnancy, (Aug. 14, 2017) On July 31, 2017, the Government of Portugal enacted Regulatory Decree No. 6 to further regulate surrogate pregnancy (*gestação de substituição*), which is governed by Law No. 32 of 2006. (Decreto Regulamentar No. 6/2017, de 31 de Julho (Regulatory Decree No. 6), DIÁRIO DA REPÚBLICA ELETRÓNIO; Lei No. 32/2006, de 26 de Julho (Surrogacy Law), Procuradoria-Geral Distrital de Lisboa website.)

Formatada: Português (Portugal)

Código de campo alterado

Formatada: Português (Portugal)

Formatada: Português (Portugal)

Código de campo alterado

Formatada: Português (Portugal)

http://www.loc.gov/law/foreign-news/article/portugal-new-law-further-regulates-surrogatepregnancy/

Studying Law in the USA

https://www.usa.gov/study-in-US

U.S. Law Practice

[Assignments to Come]

Lawyer Advertising https://www.youtube.com/watch?v=TkDdksghWpo (lawyer advertisement for Medical Malpractice)

Class 5 October 22: In Class Experiential Learning Exercise—Giving Legal Advice

World Health Organization, 25 Questions and Answers on Health and Human Rights,

https://www.opensocietyfoundations.org/sites/default/files/25 questions

Questions 21-25

For our last class, students will take on the task of Advising a public official on the possible human rights violations that might accompany public health measures to address the above conditions. Students should consider the issues raised in 25 Questions and answers on Health and Human Rights.

We will use this class to practice applying the legal principles we have learned.

Students will be assigned one of the following scenarios. Students will get their assignment and get more detailed instructions on the first day of class.

- 1. A research study intended to identify the genetic roots of deafness with the intent to reduce the population of people with hearing loss.
- 2. Mandatory vaccination of all children under 12 to prevent a sexually transmitted disease.
- 3. Drug trial of antibiotic not approved for use in the USA
- 4. Detention of individuals coming from a region with an Ebola outbreak.

Suggested Additional Sources for Reference Material

http://www.doaj.org/doaj?func=subject&cpid=46 for free journals, etc. http://www.who.int/ihr/elibrary/legal/en/

Bard Seminar on Human Rights and Health Law 2018

Código de campo alterado

Formatada: Português (Portugal)

http://www.loc.gov/law/foreign-news/?home

Human Rights Watch, https://www.hrw.org/topic/health Sources of International Law, http://www.humanrights.is/en/human-rights-education-project/human-rights-concepts-ideas-and-fora/part-i-the-concept-of-human-rights/sources-of-international-law https://www.hhrjournal.org/2013/08/bridging-international-law-and-rights-based-litigation-mapping-health-related-rights-through-the-development-of-the-global-health-and-human-rights-database-2/

https://www.hg.org/constitutional-law.html https://www.worldprivacyforum.org/2009/05/resource-page-genetic-privacy/ https://www.sis.nlm.nih.gov/dimrc/ethics.html http://quides.ll.georgetown.edu/c.php?q=364692&p=2463710

....b.//, 3 c. c. c. c. d. c. c. c. c. c. b. c. b. d. 2 - 4 - 2 - c. b. - 4 - 2 / - c

http://www.loc.gov/law/foreign-news/topic/public-health/

Please do not hesitate to contact me by email if you have any questions about this course.

Jennifer.Bard1@gmail.com