HMed 8220: Pharmaceutical Geographies, Pharmaceutical Economies

Fall 2014
Monday 2 – 4 pm
Ford Hall 155

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Course Summary

This seminar examines the emergence and persistence of global disparities in pharmaceuticals by providing historical, political, economic, and cultural analyses of the manufacturing, regulation, and distribution of pharmaceuticals. It covers historical and contemporary issues that underscore the paradoxical nature of the global pharmaceutical enterprise. On the one hand, the pharmaceutical industry's remarkable potential to intervene in major health problems with advances in scientific knowledge and manufacturing capacity has led to an abundance of pharmaceutical resources in Western countries, and has led to what some observers characterize as the over-pharmaceuticalization of American society. On the other hand, global regulatory mechanisms and the prohibitive pricing policies of major pharmaceutical firms have restricted the global circulation of pharmaceuticals and led to pharmaceutical scarcity in many regions of the world, particularly in Africa, Asia, and South America. Disparities in the distribution of pharmaceutical resources also map onto geographic differences in the epidemiology of disease. Numerous chronic diseases with large patient populations in Western industrialized countries, such as hypertension, hypercholesteremia, erectile dysfunction and generalized anxiety disorder, have garnered the attention and significant resources of pharmaceutical firms. This has led pharmaceutical firms to develop scores of new and not-so-new (me-too) drugs to treat these chronic diseases, which in turn has helped generate billions of dollars of profit for the industry. In contrast, however, numerous acute and lethal diseases (such as malaria, diarrhea, and dysentery), which afflict large numbers of people in non-Western and less industrialized (and thus less profitable) regions of the world, suffer from a scarcity of research attention and resources.

In our analysis of these global disparities, we will examine early models of pharmaceutical production in the United States and Europe; the emergence of the politicized patient-consumer and their influence on the development of drugs to treat specific diseases; the development of intellectual property rights under the World Trade Organization in the 1980s, which required global recognition of patents and led to restrictions on the circulation of generic drugs and vaccines; the FDA as a necessary but flawed organization tasked with assuring safety and efficacy of new pharmaceutical therapies; the potential brought by advances in biologics, virology, immunology, and genetics; and finally, the promise and limitations of newly formed public-private partnerships to develop drugs for neglected diseases. In doing so, our seminar will highlight a series of themes that characterize both the history and current state of the

pharmaceutical enterprise: the contested role of the state in the production of essential vaccines and medicines; the historically contingent process by which pharmaceutical firms gained significant political power in the national and global economy; the growing challenge for regulatory agencies such as the FDA of ensuring the safety of new drug products amidst pressing patient demand for faster access to those new drugs; and the shrinking role of governments in assuring equitable access to even essential drugs.

Course Requirements

The focus of this graduate seminar is on detailed and careful reading of the assigned texts, and lively and engaged in-class discussion of the texts. As such, evaluative emphasis will be placed on class participation and short weekly response papers to the reading. There will be no final writing assignment for this course.

Leading Discussion and Participation* (35%):* At each of our meetings, one or two students (depending on final class numbers) will lead discussion of the weekly reading. This will mean formulating a list of discussion questions ahead of time and steering the course of the discussion during the seminar.

***Weekly Response Papers* (35%)**: Students will write weekly response papers to the week's reading assignments (3-4 pages). A good response paper not only consists of a summary of the texts but also includes your critical response to the texts as well as your analysis of the material found in the texts. This means that you will be assessing the information found in the texts and stating your position towards it. It isn't necessary to analyze and respond to every aspect of a text. In fact, it is usually better to select from the text two or three specific things to respond to and analyze—perhaps something that particularly interests you, raises questions for you, or troubles you. Or you may want to contrast and compare the perspective presented by one author to the perspective offered by another. Whatever approach you wish to take is fine, as long as you provide evidence to support your position, and as long as it demonstrates your comprehension of the material and your ability to think critically about it.

Your response paper should have an introduction (just one paragraph)—a mini overview of your paper—that includes your thesis statement. This is a sentence or two in which you state the argument *you* will be making in this paper. Your paper should also include a brief summary of the texts you are responding to that includes a concise statement of the authors' arguments and an overview of how they made their case. In other words, what evidence did the author use? It is very important that you demonstrate that you understand what the author is trying to communicate, but it is equally important that you do this as concisely as possible. The remainder of the paper should be *your* critical response to the reading; it is where *you* evaluate the author's argument, and where you tie this reading into other readings and the themes of the course. Be sure to include why you responded as you did, offering relevant supporting ideas, examples, details, and explanations from the text itself, other readings, and from class.

***Annotated Bibliography* (30%)**: In consultation with the professor, students will prepare an annotated bibliography on a topic within the broad subject of global pharmaceuticals that is of specific interest to them. After identifying a selection of books and articles to be

reviewed, you will prepare one to two paragraphs on each text that summarizes the text's argument, sources, strengths and/or weaknesses, and contribution to the literature. The annotated bibliography will be due at the end of the semester.

Required Books
NB. All required articles and book chapters will be available on the course Moodle site

- Dominique A. Tobbell, *Pills, Power, and Policy: The Struggle for Drug Reform in Cold War American and its Consequences* (University of California Press/ Milbank Books on Health and the Public, 2012).
- Nicolas Rasmussen, *Gene Jockeys: Life Science and the Rise of Biotech Enterprise* (Johns Hopkins University Press, 2014).
- Gabriela Soto Laveaga, *Jungle Laboratories: Mexican Peasants, National Projects, and the Making of the Pill* (Duke University Press, 2009).
- Cori Hayden, *When Nature Goes Public: The Making and Unmaking of Bioprospecting in Mexico* (Princeton University Press, 2003).
- Kristin Peterson, *Speculative Markets: Drug Circuits and Derivative Life in Nigeria* (Duke University Press, 2014).
- Jeremy Greene, *Prescribing by Numbers: Drugs and the Definition of Disease* (Johns Hopkins University Press, 2007).
- Vinh-Kim Nguyen, *The Republic of Therapy: Triage and Sovereignty in West Africa's Time of AIDS* (Duke University Press, 2010).
- Joao Biehl, *Will to Live: AIDS Therapies and the Politics of Survival* (Princeton University Press, 2009).
- Kaushik Sunder Rajan, *Biocapital: The Constitution of Postgenomic Life* (Duke University Press, 2006).
- Adriana Petryna, *When Experiments Travel: Clinical Trials and the Global Search for Human Subjects* (Princeton University Press, 2009).

Recommended Books (not required)

- Adriana Petryna, Andrew Lakoff, and Arthur Kleinman (eds.) *Global Pharmaceuticals: Ethics, Markets, Practices* (Duke University Press, 2006).
- João Biehl and Adriana Petryna (eds.) *When People Come First: Critical Studies in Global Health* (Princeton University Press, 2013).

Syllabus

Mon 9/8 Drugs in the Global Economy
- NB <u>Please read before the first class</u>!

- "Introduction," Joseph Dumit, *Drugs for Life: How Pharmaceutical Companies Define Our Health* (Duke University Press, 2012), pp. 1-25.
- Adriana Petryna and Arthur Kleinman, "The Pharmaceutical Nexus," in Petryna, Lakoff, and Kleinman (eds.) *Global Pharmaceuticals*, pp.1-32.

- Mark Heywood, "Drug access, patents, and global health: 'chaffed and waxed sufficient.'" *Third World Quarterly* (2002) 32 (2): 217-231.
- Donald Light and Rebecca Warburton, "Demythologizing the high costs of pharmaceutical research." *BioSocieties* (2011) 6(1): 34-50.

Mon 9/15 The Science, Culture, and Politics of Pharmaceutical Innovation

- Tobbell, *Pills, Power, and Policy*
- Harry Marks, "Managing chance: statistics and therapeutic experiments, 1950-1960." *Progress of Experiment: Science and Therapeutic Reform in the United States, 1900-1990* (Johns Hopkins University Press, 1997), pp. 129-163.

Mon 9/22 The Science, Culture, and Politics of Bio-Pharmaceutical Innovation

- Rasmussen, *Gene Jockeys*
- Louis Galambos and Jeffrey Sturchio, "Pharmaceutical firms and the transition to biotechnology: a study of strategic innovation." *Business History Review* (1998) 72(2): 250-278.

Mon 9/29 Global Productions

- Soto Laveaga, *Jungle Laboratories*
- Lara Marks, "Human Guinea Pigs? The History of the Early Oral Contraceptive Clinical Trials." *History and Technology* (1999) 15(4): 263-288.

Mon 10/6 Global Circulations Part I

- Hayden, *When Nature Goes Public*

Mon 10/13 Global Circulations Part II

- Peterson, *Speculative Markets*

Mon 10/20 Pharmaceutical Abundance

- Greene, *Prescribing by Numbers*

Mon 10/27 Expanding Abundant Markets

- Jennifer R. Fishman, "Making Viagra: From Impotence to Erectile Dysfunction," in Andrea Tone and Elizabeth S. Watkins (eds.) *Medicating Modern America: Prescription Drugs in History* (New York University Press, 2007), pp. 229-252.
- Joseph Dumit, "Pharmaceutical Witnessing and Direct-to-Consumer Advertising," in *Drugs for Life*, pp. 55-85.
- Andrew Lakoff, "High Contact: Gifts and Surveillance in Argentina," in *Global Pharmaceuticals*, pp. 111-135.
- Stefan Ecks and Ian Harper, "Public-Private Mixes: The Market for Anti-Tuberculosis Drugs in India," in João Biehl and Adriana Petryna (eds.) *When People Come First: Critical Studies in Global Health* (Princeton University Press, 2013), pp. 252-275.

Mon 11/3 On Scarcity: Orphan Drugs and Neglected Diseases

- Dominique Tobbell, "Charitable Innovations" in Viviane Quirke and Judy Slinn (eds.) *Perspectives on 20th Century Pharmaceuticals* (Peter Lang AG, 2010), pp. 301-335.
- David Duffied Rohde, "The Orphan Drug Act: An Engine of Innovation? At What Cost?" *Food and Drug Law Journal* (2000) 55: 125-143.
- Susan Reynolds White, Michael A. Whyte, Lotte Meinert, and Betty Kyaddondo, "Treating AIDS: Dilemmas of Unequal Access in Uganda" in *Global Pharmaceuticals*
- Julie Livingston, "The Next Epidemic: The Pain and the Politics of Relief in Botswana's Cancer Ward," in João Biehl and Adriana Petryna (eds.) *When People Come First: Critical Studies in Global Health* (Princeton University Press, 2013), pp.182-206.
- Susan Craddock, "Drug Partnerships and Global Practices." *Journal of Health and Place* (2012) 18: 481-689.

Mon 11/10 The Lived Realities of Pharmaceutical Scarcity

- Nguyen, *The Republic of Therapy*

Mon 11/17 Pharmaceutical Governance

- Biehl, *Will to Live*

Mon 11/24 Biocapital

- Sunder Rajan, *Biocapital*

Mon 12/1 Globalizing Clinical Trials: An Ethics of Access?

- Petryna, *When Experiments Travel*
- Jill A. Fisher, ""Coming Soon to a Physician Near You: Medical Neoliberalism and Pharmaceutical Clinical Trials." *Harvard Health Policy Review* (2007) 8 (1): 61-70.

Mon 12/8 Constituting Pharmaceutical Citizenship

- Kaushik Sunder Rajan, "Experimental Values: Indian Clinical Trials and Surplus Health." *New Left Review* (2007) 45: 67-88.
- Stefan Ecks, "Global pharmaceutical markets and corporate citizenship: the case of Novartis' anti-cancer drug Gleevec." *BioSocieties* (2008) 3: 165-181.
- Kaushik Sunder Rajan, "Property, Rights, and the Constitution of Contemporary Indian Biomedicine: Notes from the Gleevac Case." *Social Research* (2011) 78(3): 975-998.