

Course Syllabus

Course Objectives

This course will acquaint students with policy issues pertaining to the pharmaceutical sector, together with tools of economic analysis that may be used to design and evaluate policies. Though the share of national health expenditures allocated to pharmaceuticals is smaller than that allocated to either hospitals or physician services, there are several reasons why this particular sector deserves independent, serious study. The first reason is that the relatively small share of expenditures belies the significant effect that drugs have in improving the efficiency of other health system inputs, especially hospitals, physician services, nursing homes, and home care. The second is the important role that the pharmaceutical industry plays in development of America's high-tech industrial base. It derives from and contributes to the enormous increase in the nation's stock of intellectual and human capital. The pharmaceutical sector also contributes favorably to the nation's financial and commodity trade balance. Lastly, the sector illustrates many conflicts inherent in allocating new technology in a health system that utilizes government intervention as well as free markets.

Parts of this course will be held jointly, by videoconference, with a similar course taught at the Ecole Supérieure de Science Economique et de Commerce (ESSEC) in Paris, one of the leading business schools in France.

Course Readings

The text for the course will be S.O. Schweitzer and J.Z. Lu (2018), Pharmaceutical Economics and Policy 3rd ed (New York: Oxford University Press). The text is noted as **PEP** in the schedule of readings. Additional readings will be available on the web. UCLA students can access the readings through the website at <http://ccle.ucla.edu/course/view/18W-HLTPOL205>.

Course Organization and Requirements

Student performance in the course will be evaluated through class discussion (50 percent) and a series of 1-2 page discussions of particular pharmaceutical policies (50 percent). The pharmaceutical policy papers will be due Monday 4 March 2019 at 8am. The course will be in a seminar format, with students reporting on required readings. Classes will be held Mondays and Wednesdays from 8-9:50 am in room 41-235 CHS, with the videoconference sessions held in the FSPH Square Conference Room (off of the Foyer of the FSPH).

Office Hours

The instructor is available to meet with students during office hours Tuesday from 10-11am in 31-293. He is also available through email at sschweit@ucla.edu.

Course Learning Objectives and Competencies for FSPH Core and HPM Masters and PhD Students

Learning Objectives and Competencies for HPM 205

Course Learning Objectives	FSPH Core Competencies	Department of HPM Competencies	
		Policy Track	Management Track
1. Given either numerical data or a graph, students shall be able to apply graphical analysis to accurately describe a microeconomic situation	E1. Apply epidemiologic and statistical reasoning and methods to address, analyze, and solve problems in public health	L.1.3 Describes and understands the main characteristics, components and issues of the organization, financing, and delivery of health services and public health systems in the U.S.	K1.8 Analyzes economic decisions related to health care organizations and the health care system. K1.13 Describes and understands the main characteristics, components and issues of the organization, financing, and delivery of health services and public health systems in the U.S. K3.1 Comprehends financial and economic analyses and their application
	E.4 Discuss the policy process for improving the health status of populations	L1.9 Analyzes economic decisions related to health care organizations and the health care system.	K1.10 Analyzes the effects of political, social and economic policies on health systems, community health, and access to care
	E.7 Apply quality and performance improvement concepts to address organizational performance issues	L3.7 Achieves familiarity with use of data to conduct needs analysis, market assessment, outcome and process evaluation, forecasting, and quality improvement activities	K3.1 Comprehends financial and economic analyses and their application
	F.4 Collaborate with communication and informatics specialists in the process of design, implementation, and evaluation of public health programs.		
	F.5 Demonstrate effective written and oral skills for communicating with different audiences in the context of professional public health activities.		

2. Given a case example, students shall be able to work independently and in groups to summarize, explain, and predict consumer and producer behavior using the relevant microeconomic concepts such as supply, demand, elasticity, and utility.

3. Given an article from the popular press, students shall be able to understand the performance of present and proposed health insurance markets.

4. Given raw numerical data pertaining to consumer demand and production, students shall be able to calculate prices, elasticity, quantities produced and purchased, and surplus and shortage.

5. Given an example

E.7 Apply quality and performance improvement concepts to address organizational performance issues.

F.7 Identify public health programs and strategies that are responsive to the diverse cultural values and traditions of the communities being served.

E.1 Apply epidemiologic and statistical reasoning and methods to address, analyze, and solve problems in public health

E.6 Apply principles of strategic planning and marketing to public health

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F.8 Engage in dialogue and learning from others to advance public health goals.

E.1 Apply epidemiologic

L1.6 Differentiates and understands private and government roles in health care delivery.

L1.7 Comprehends public and private payment methods used to finance health care.

L 3.9 Interprets substantive results of statistical analyses in public health, management, and health policy studies.
L1.11 Analyzes the effects of political, social and economic policies on health systems, community health, and access to care.

L3.1 Evaluate the efficiency of public policies using economic concepts.

L3.5 Identifies and

K1.6 Comprehends public and private payment methods used to finance health care

K3.11 Utilizes creative and innovative thinking to arrive at solutions to critical issues, or to adopt previous solutions in new ways.

K1.8 Analyzes economic decisions related to health care organizations and the health care system

K3.9 Assesses economic decisions of health care consumers, providers, organizations, and the health care system

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L1.9 Analyzes economic decisions related to health care organizations and the health care system

K1.12 Understands quality

of health resource allocation, such as over-use and under-use of various health services, students shall be able to explain how markets achieve or fail to achieve efficiencies with respect to production and allocation.

6. Given a summary of a current problem in health care policy, such as the use of hospital emergency departments, students shall be able to describe policy options and be able to argue the merits and demerits of each.

and statistical reasoning and methods to address, analyze, and solve problems in public health

E.6 Apply principles of strategic planning and marketing to public health

F.7 Identify public health programs and strategies that are responsive to the diverse cultural values and traditions of the communities being served.

F.14 Apply evidence-based principles and the scientific knowledge base to critical evaluation and decision-making in public health.

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E.6 Apply principles of strategic planning and marketing to public health

F.7 Identify public health programs and strategies that are responsive to the diverse cultural values and traditions of the communities being served.

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analyzes problems, potential solutions and best practices in order to determine appropriate courses of action.

L.311 Analyzes interest group and stakeholder concerns.

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of care, patient safety, and other performance indicators in the context of the U.S. and international health systems

K3.12 Seeks to understand more deeply by searching for the root of issues, asking penetrating questions, uncovering complexity and going beyond routine questions.

K1.12 Understands quality of care, patient safety, and other performance indicators in the context of the U.S. and international health systems

K3.12 Seeks to understand more deeply by searching for the root of issues, asking penetrating questions, uncovering complexity and going beyond routine questions.

The Course Schedule

Introduction

Monday 7 Jan

Readings: PEP Introduction

Dooren J, "Drug Approvals Slipped in 2010" WSJ 31 December 2010.

Harris G, "FDA Officials, Hoping to Stave off Critics, Point to Increased Drug Approvals," New York Times, November 3, 2011
<http://www.nytimes.com/2011/11/04/health/policy/drug-approvals-rise-for-fda.html>

Jonathan Rockoff and Ron Winslow, "More Drugs Emerge, But Few Blockbusters," WSJ 16 December 2013.

Novel New Drugs Approved by the FDA 2017,
<http://www.fda.gov/Drugs/DevelopmentApprovalProcess/DrugInnovation/ucm537040.htm>

The Industry

Wednesday 9 Jan

Pharmaceutical Industry Research and Development

Readings: PEP Chapter 1, 2, and 3

Kesselheim AS, "Using Market-Exclusivity Incentives to Promote Pharmaceutical Innovation," NEJM 363:19, November 4, 2010.

The Consumer and the Market

Monday 21 Jan - Martin Luther King Day: NO CLASS

Wednesday 23 Jan

Marketing Pharmaceuticals to the World

Readings: PEP

Chapter 4, 5, and 7 Including drug pricing

Monday 28 Jan

The Demand for Pharmaceuticals

Readings: PEP Chapter 6, 8

Zhang U, Baicker K, and Newhouse JP, "Geographic Variation in the Quality of Prescribing," NEJM, November 3, 2010.
Pollack A, "Genentech Offers Secret Rebates for Eye Drug," The New York Times, November 4, 2010.

Public and Private Intervention in the Pharmaceutical Market

- Wednesday 30 Jan Drug Approvals in the US and Abroad
Readings: PEP Chapter 9
Gottlieb S, "The FDA Is Evading the Law," WSJ December 23, 2010.
- Monday 4 Feb Drug Approvals in the US and Abroad:
Readings
Intriligator, M "The Conundrum of Type One and Type Two errors in drug approval", UCLA Economics Department, unpublished manuscript.
- Wednesday 6 Feb Evaluating and Regulating Drugs
Readings: PEP Chapters 14 and 15
Pollack A, "F.D.A. Plans to Revoke Approval for Breast Cancer Drug," The New York Times, December 16, 2010.
Pollack A, "FDA Revokes Approval of Avastin for Use as Breast Cancer Drug," New York Times. November 18, 2011.
http://www.nytimes.com/2011/11/19/business/fda-revokes-approval-of-avastin-as-breast-cancer-drug.html?_r=1&scp=1&sq=avastin%20breast%20cancer&st=cse
Wilson D, "Novartis Pays \$422.5 Million in Settlement," The New York Times, September 30, 2010.
- Monday 11 Feb The Role of Patent Protection in Maintaining Innovation
Readings: PEP Chapter 13
Wilson D, "Senators Question Deals to Block Generic Lipitor," New York Times. December 1, 2011.
<http://www.nytimes.com/2011/12/01/health/senators-question-plan-to-stall-generic-lipitor.html?scp=2&sq=atorvastatin%20generic%202011&st=Search>
- Wednesday 13 Feb The Role of Patent Protection in Maintaining Innovation: Two important court decisions about the roles of patents and firms: marketing:
Readings: PEP Chapter 16

	<p>Court Decision on Off-label marketing Robertson C, and Kesselheim AS (2016), “Regulating Off-Label Promotion — A Critical Test” <u>NEJM</u> p1611755 DOI:10.1056/November 2016</p>
	<p>Court Decision on Pay-to-Delay “The Pay for Delay’ Rap, <u>Wall Street Journal</u>, October 5, 2010.</p>
Monday	Balancing Interests in the Pharmaceutical Sector: Consumers, Regulators, Industry, and Insurers
Wednesday	<p>What’s so “special” about “specialty drugs”? Readings: Conti RM, Fein AJ, and Bhatta SS (2014), “National Trends in Spending On And Use Of Oral Oncologics, First Quarter 2006 Through Third Quarter 2011, <u>Health Affairs</u>, (33)10:1721-1727,(October). Lotvin AM, Shrank WH, Singh SC, Falit BP, and Brennan TA (2014) <u>Health Affairs</u> 33:10:1737-1744 (October).</p>
Monday 18 Feb	President’s Day Holiday: No class
Wednesday 20 Feb	Resolving Conflicts in Pharmaceutical Policy: A Look Ahead, Consider conflicts between R&D incentives, financial access, quality of existing drugs, safety and efficacy of new drugs, and lowering cost of care while assuring appropriate use of medication.
Monday 25 Feb* (Paris)	<p>The French Health Care System and Pharmaceutical Policy: Gerard de Pouvourville, ESSEC, Paris Readings: PEP Chapter 12 and Steffen M (2015), “Universalism, Responsiveness, Sustainability – Regulating the French Health Care System,” <u>NEJM</u>, <u>374(5):401-405</u>, February 4, 2016 Sandier S, Paris V, Polton D (2004), <i>Health care systems in transition: France</i>. Copenhagen, WHO Regional Office for Europe on behalf of the European Observatory on Health Systems and Policies. dePouvourville G (2007), “Economic evaluations of drugs and medical devices in France: Part 1 – The Context”. Unpublished manuscript (gdepouvo@kb.insrm.fr) Grandfils N and Sermet C, “Pharmaceutical policy in France: Evaluating and Regulating Drugs</p>

- Monday 4 March Presentations of term papers
- Wednesday 6 Mar* (Paris) The U.S. Health System and Pharmaceutical Policy: A Blend of Private and Government Activity in Regulation and Cost-containment, S O Schweitzer
Readings: PEP Chapters 10-11 (pp 209-237).
 Schweitzer SO and Comanor WS (2014), "Controlling Pharmaceutical Prices and Expenditures," in Kominski GF (ed.) Changing the U.S. Health Care System, 4th ed. (San Francisco: Jossey-Bass).
- Wednesday 13 Mar Last day of class. New issues in pharmaceutical policy
 Supply issues, such as biotechnology and patents
 Demand factors, such as demographics, cost, and value.
 Third-party payers: Balancing coverage and cost
 Government dilemmas, such as drug approvals vs maintenance of quality

*Note that two class sessions are at an irregular place. On March 1 and 8 we will have our class meetings together with students at the ESSEC Business School in Paris! These sessions take place in the "square" conference room in the main lobby of the FSPH (first floor) at 8am SHARP. The time that each class begins is *critical*, so please allow enough extra time to find the venue and take your seat.