California State University, Channel Islands
COURSE SYLLABUS

Faculty: **Zhong John Lu (JL), PhD, Department of Economics, MVS Business School**

Location: California State University Channel Islands (CSUCI)/Smith Center 1908

Time: Weekly Every Monday: 3:00 – 5:50 pm; in-person, and occasionally online

Office Hours : Mazan Hall 1167
Monday 2:00 – 3:00 pm, and by appt (online OK)

Phone : 1-(805)-437-3979(office)
E-mail: john.lu@csuci.edu;

BEC341 Major Deliverables

Deliverable Item	Synopsis of Deliverable	Date Due	Weight for Grade
Mid-term Exam	Closed book, in-class exam, exclusively multiple choice questions (1 hour)	October 7 (first half of lecture)	15%
Group Project #1	TEAM Presentation on a selected, FDA newly approved drug (20 mins)	October 28 (full lecture)	20%
Group Project #2	TEAM Presentation/Debate on a public policy issue affecting the pharmaceutical industry (20 mins)	November 25 (full lecture)	20%
Final Exam	Open book, closed PC/cell, in-class exam, mixture of MC and essay questions (2 hour)	December 9 4-6 pm (Monday)	25%

Required text books: *Pharmaceutical Economics and Policy: Perspectives, Promises, and Problems* 3rd edition, by SO Schweitzer and ZJ Lu. Oxford University Press 2018, New York, NY. ISBN = 978-0-190-62378-4. (new copy ~$60)
Devalued and Distrusted: Can the Pharmaceutical Industry Restore its Broken Image? by JL Lamattina. John Wiley & Sons, Inc 2013, Hoboken, NJ. ISBN = 978-1-118-48747-1. (new copy ~$10)

1. Course Description

The modern pharmaceutical industry has been one of the most innovative and dynamic sectors in the developed world. In the US, this industry has been recognized for the innovation and technology focused culture, the exceptionally talented and well compensated work force, the highly effective and novel medicines against many diseases, and for belonging to a rare group of American industries which has consistently been a dominant net exporter of products and technology. Nevertheless, the industry has no lack of critics, both in the US and globally. It has often been criticized for monopolistic pricing behavior, for engaging in

unethical or illegal promotional activities, and for under-reporting and mis-representing important safety information on its products. The industry is also one of the most regulated in the world.

In this course, we will examine a number of aspects of this fascinating industry, including historical development, research methods and drug innovation processes, regulatory hurdles, intellectual property issues, pricing and competition, marketing and promotion, generics, and health outcomes research.

Further, this course will examine the track record of successes and failures of the newest sector in this industry: the biotechnology firms. We will explore potential factors on why so many biotech firms, in spite of so much early hope, promise, and investor patience and contribution, failed to make to the Big League – an independent, profitable corporation. We want to ask the critical question: can a business of science be run like any other businesses? Are there managerial innovations that must accompany the business of science in order to make it ultimately successful?

It is hoped that the course will provide students with a better understanding of the industry: basic industrial and scientific structures, common business and management strategies, and critical economic, financial, and regulatory issues. It is also hoped that lessons from this industry may be applied to other high tech sectors which rely on continuous innovations for survival. In addition, this course may also be useful for students who are interested in further studying or working in the pharmaceutical industry.

2. Learning Objectives

- Understand the basic health science fundamentals and the industrial organization of pharmaceutical and biotechnology firms;
- Understand the R&D process and regulatory approval process in drug discovery and development, and appreciate the role of innovations in the long term success of pharmaceutical firms including the patent system and R&D funding mechanisms;
- Understand the commercialization of new pharmaceutical products, including the role of health insurance, basic marketing process, pricing and promotional strategy, and the economic evaluation of new medicines;
- Develop ability to learn, collaborate, and interact in a cross-disciplinary learning environment including working in multi-disciplinary teams;

Understand industry best-practices in selected company and drug case studies and "the science of business & the business of science"

3. Major Course Topics (subject to some changes by instructor)

The following broad topics will be covered in this course:

- **Overview of Course and Review of Key Business and Economic Terminologies**
-

- **Introduction to US Healthcare System**
  - The Organization of the US Healthcare Market
  - Health insurance and healthcare financing: Private
  - Health insurance and healthcare financing: Public
  - Healthcare in the US: a Comparison with Other Advanced Economies
  - Are we getting value for money in the US healthcare market

- **Overview of the Global Branded Pharmaceutical Industry**
  - History of the Pharma Industry
  - Emergence of Biotechnology
  - Funding Mechanism: Pros and Cons of each
  - Mergers, acquisitions, and strategic alliances
  - Shifting business models: The Biopharmaceutical Industry

- **The Scientific Landscape: Drug Discovery and Development**
  - Historical sources of drug leads – natural products
  - Drug Targets and Drug Leads
  - New strategies for discovery – genomics and new technologies
  - Methods for drug discovery – from *in silico* to *in vivo*
  - Work processes and decision making in pharmaceutical R&D

- **The Risky Business of Pharmaceutical R&D**
  - Scientific methods in drug research and development
  - Lead optimization – chemical and biological approaches
  - Preclinical studies – efficacy, toxicity, ADME, and other factors
  - Pharmaceutical formulations and drug delivery systems
  - Cost of Pharmaceutical R&D

- **Clinical Trials**
  - The regulatory process
  - Phase I, II, and III clinical trials in Humans
  - The role of the FDA – permissions, review, and oversight
  - Drug Safety and Pharmacovigilance (Phase IV or post-marketing trials)
  - Scientific publications of trial results

- IP, Patent, and Bio-pharmaceutical Innovation
  - The U.S. Patent System – requirements, process, and benefits
  - Patent life and market exclusivity for pharmaceutical products
  - The value and use of IP and patents - products, partnering, licensing
  - Landmark BioPharma patent cases at the US Supreme Court

- **The Regulation of the Pharmaceutical Industry**
  - FDA – its mission, authority and tools
  - How do FDA conduct review of new drug submission?
  - Criticism of the FDA: Can it Do Better?
  - The Political Economy of the Legalization of Recreational Cannabis
  - The Opioid Crisis: Who Should We Assign Blame to?

- Bio-pharmaceutical Promotion: Information or Persuasion?
  - The Marketing Process: What is it?
  - Channels of Pharmaceutical Promotions

- Regulations of Pharmaceutical Promotions

- The Demand for and Pricing of Pharmaceutical Products
  - Basic Principles of Pricing
  - Value-based Pricing of Pharmaceutical Products
  - Price Regulations and Cost-Containment Efforts
  - Economic Evaluation of New Drugs
  - Why Drug Prices Differ so much across Countries

- Generic Drug Global Supply Chain: Market for Lemons?
  - **The Rise of Generics and Biosimilars**
  - Historical development and growth in the U.S. and abroad
  - The Significance of the Hatch-Waxman Act of 1984
  - The regulatory pathway to generic pharmaceutical products
  - The ACA and regulatory policy and pathway for biosimilar products (Biosimilars)

- **A Look Ahead**
  - Future of Pharmaceuticals: Can We Afford Them?
  - Reshoring of the Generic Pharmaceutical Production from China/India
  - AI and Personalized Medicine

4. Required Course Materials

[1] "Pharmaceutical Economics and Policy, 3rd edition" by Stuart Schweitzer and Z. John Lu (Oxford University Press, 2018). The course instructor is a co-author of this policy book. The book provides a good overview of the key economic, scientific, regulatory policy issues facing the pharmaceutical industry, covering topics ranging from R&D, clinical trials, regulatory process, IP, price setting, economic evaluation of new drugs, sales, promotions and controversies, to recent public policies affecting the pharmaceutical marketplace. The book will be referred as PEP in this syllabus.

[2] "Devalued and Distrusted: Can the Pharmaceutical Industry Restore its Broken Image?" by John Lamattina (Wiley & Sons, 2013). Written by a former pharmaceutical executive, this is a very good (and relatively short) book which will clarify common misunderstandings the public often has about this industry. The book will be referred as DD in this syllabus.

5. Recommended Course Materials

[1] Pharmaceutical Industry Profile 2022 (https://phrma.org/en/resource-center/Topics/Research-and-Development/Industry-Profile-2022), by Pharmaceutical Research and Manufacturing Association (PhRMA); Washington, DC. This annual report (and various subsections) contains lots of useful and current statistics and information for the industry.

[2] "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs"; Joseph DiMasi (Tufts Center for the Study of Drug Development, 2014) This briefing provides an

overview of the costs, timelines, and risks involved in developing a new drug product. Posted on Canvas.

[3] "Science Business: The Promise, The Reality, and the Future of Biotech" by Gary P. Pisano (Harvard Business School Press, 2006). If you have a strong interest in strategic management in the business of science, this is a recommended book. It is not as critical that you purchase the book, however.

It is also recommended that you periodocally check on the following sources for up-to-date news and research materials for your book report and the class project: **FierceBiotech** (www.fiercebiotech.com), and **FiercePharma** (http://www.fiercepharma.com), both of which have a free daily subscription newsletter/blog. Also ***The Wall Street Journal***. The Broome Library carries these periodicals in both hardcopy and electronically.

6. Evaluation & Grading

- Participation, QA, Engagement (random roll-call) 20%
- Mid-term Exam (MC questions) 15%
- Group Project 1 - Presentation 20%
- Group Project 2 – Presentation 20%
- Final Exam (in-class) 25%

Failure to take the Final Exam, will result in a score of zero on that item, because there is no make-up final exam.

Grading Rules:

A/A+/A- 90-100%;
B/B+/B- 80-89%;
C/C+/C- 65-79%;

D/D+/D- 55% to 64%;
F <55%

Final course grade cut-offs may change slightly based on grade distributions at the instructors' discretion.

7. Assignments & Projects

7.1 Team/Group Formation:

By week 2, Students will form multi-disciplinary project teams, consisting of 4 students (in rare cases as few as 3 and as many as 5, with instructors' approval). Every team must have at least 1 student, but no more than 3 students, with a STEM/nursing major, and at least 1 student, but no more than 3 students, with a business/econ/social sciences/humanities/health science major.

The same team will work together on the following deliverables:
Group/Team Project 1 – Presentation

Each team will meet outside class and organize (and possibly elect a project manager who serves as the captain of the team), select a topic, decide how to communicate amongst themselves, plan/allocate work, maintain timelines, and jointly present selected case studies.

Project teams should determine their case study topics ASAP, so as to have sufficient time to get organized, conduct research, and prepare the PPT presentations.

All students on each Project Team must make fair and equitable contribution to the research, preparation , presentation, and writing if necessary (in Word).

All students on the same team will receive the same score for this assignment.

7.2 Group Project 1 (20%): In-class Presentation on the Safety and Efficacy of NEW DRUG X (to be selected from Table 1)

This is a team-based project. First come, first serve.

Select a new drug by end of 2nd lecture. First come, first serve. One drug per group.

For each new drug selected, conduct some research and prepare an 8-10 slide PowerPoint presentation including:

- Some information on the manufacturer (history, key products and current pipeline; 2 slides)
- Some information on the disease (2)
  - How many affected patients
  - Current therapies if any
  - If personal/familial experience with the illness, discuss that as well – if willing
- Some information on the efficacy (2; must present data from no less than 2 clinical trials publications)
- Some information on the safety – especially the nasty one(s) (2)
- Price Information (including source), and which type of insurance plans are typically involved in paying (e.g., Medicare for elderly) (1-2)
- Based on the safety/efficacy profile, would you recommend this drug to a family member who is affected by the illness? (1)
- Relevant references (1)

Each group will make a 15-20 minute presentation on their selected drug – every member of the group will cover some slides. The tentative date of the presentations is **October 28** (all groups will present on this day).

Table 1 Notable New Drugs 2020-2023

Drug Name Generic (Trade)	Year of FDA Approval	Indication	Company Name	Link for Start
Aducanumab (Aduhelm)	2021	Treatment of Alzheimer's Diseases	Biogen	https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-drug
Donanemab (Kisunla)	2024	Treatment of Alzheimer's Diseases	Eli Lilly	https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-treatment-adults-alzheimers-disease#
Lecanemab (Leqembi)	2023	Treatment of Alzheimer's Diseases	Eisai/Biogen	https://www.fda.gov/news-events/press-announcements/fda-grants-accelerated-approval-alzheimers-disease-treatment https://www.fda.gov/news-events/press-announcements/fda-converts-novel-alzheimers-disease-treatment-traditional-approval
Semaglutide (Ozempic/ Wegovy)	2021	Chronic Weight Management in adults with obesity	Novo Nordisk	https://www.fda.gov/news-events/press-announcements/fda-approves-new-drug-treatment-chronic-weight-management-first-2014
Tirzepatide (Munjaro/ Zepbound)	2023	Chronic Weight Management in adults with obesity	Eli Lilly	https://www.medicalnewstoday.com/articles/zepbound-explained-glp-1-weight-loss-drug-fda-approval
Tarlatamab (Imdelltra)	2024	Non-small Cell Lung Cancer	Amgen	https://www.usnews.com/news/health-news/articles/2024-05-17/fda-approves-new-drug-for-deadly-lung-cancer
Nirmatrelvir + ritonavir (Paxlovid)	2023	Management of mild and moderate Covid-19 infections in high risk adults	Pfizer	https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-antiviral-treatment-covid-19-adults
Pivmecillianam (Pivya)	2024	Urinary Tract Infections	UTILITY therapeutics Ltd	https://www.fda.gov/news-events/press-announcements/fda-approves-new-treatment-uncomplicated-urinary-tract-infections

7.3 Group Project 2 (20%):

Select a controversial topic (to be selected from Table 2)
Take a position on the topic, and prepare arguments for your position.

Select a topic-presentation by end of 4th lecture. *Each topic may be selected twice, but the position taken must be different from each group*.

First come, first serve.

Please conduct online research on the arguments and empirical evidences supporting the arguments topic. Each team MUST select at least 5 (FIVE) published articles for each topic.

Remember the arguments must be multi-factorial. Do NOT limit the arguments exclusively on one of the following: moral/philosophical, political, technological, or economic/financial.

All references must be properly referenced – including that from ChatGPT. Be sure to use your own rationale and own words in the discussion.

The tentative date of the presentations is **November 25** (all groups present on this day).

Each group will make a 15-20 minute PowerPoint presentation (10-12 slides) on their selected topic. As with Group Project 1, every member of the group will cover some slides in the presentation, and share work fairly and equitably in both the presentation and the paper.

Please note that I am looking to see how each group can work together and comprehensively apply the knowledge learnt in this class. An early start of group projects is very important, as it will require some work, discipline and coordination.

Each group should make an effort to meet with the instructor by October 14 (during office hour or before/after class) to discuss the interim progress and potential issues/difficulty.

Table 2 Let us have a debate on the following controversial topic (each team chooses one topic-position)

	Policy Debate
1	Should the US require that drug firms must not charge drug prices higher than what they charge in Europe? Yes or No? Why?
2	Should the US shorten the length of a typical product patent (currently at 20 years), so that the patent on branded drugs expires more quickly, reducing prices for and improving access to these effective drugs? Yes or No? Why?
3	Should we set an upper limit on blood cannabis level for all drivers, so that drivers caught driving with higher levels will be charged, as we do with alcohol level? Yes or No? Why?
4	Do you agree with the C-19 vaccine mandate that the US adopted during the pandemic? Yes or No? Why?

8 Exams (40%)

Mid-term Exam (15)

Multiple choice questions only. Closed everything. In class. October 7 (first half).

Final Exam (25%)

Final will be in-class, in-person, but open book/notes – though internet access is not allowed. The exam will include some multiple choice questions and some short essay questions. You will have 2 hours to finish. December 9.

Exams are individually scored.

9. Course conduct, rules & attendance (20%)

BUS ECON CHEM 341 meets once a week for a total of 14 times (excluding the Labor Day Monday, and including days of group presentations). The class will be largely held in lecture/discussion/summary mode. Students are expected to a) be prepared for each lecture topic: relevant book chapters or materials will be provided by the instructor; b) be engaged in understanding the fundamentals of each topic; and c) use lecture time for Q/A. Your questions, engagement, participation and contributions will be the difference between a dull class and a fun class. Cell phone use is NOT allowed, and laptop computers are limited to note-taking.

In order to be successful in this course, all students are expected to be in >90% attendance. Attendance will be taken randomly 6 times during the semester, but mandatorily during the 2 group presentations. Each attendance is worth 2% of your grade, except the two lectures where there are group presentations, and those will be worth 4% each.

The attendance will be taken in the 2nd half of class, so let the instructor know if you must leave early so at least you will receive partial credit for the first half.

10. Academic Dishonesty

This course will follow the CSUCI Policy on Academic Dishonesty (SP01-57). Academic dishonesty includes cheating, inventing false information or citations, plagiarism and helping someone else commit an act of academic dishonesty. It usually involves an attempt by a student to show possession of a level of knowledge or skill that he/she does not possess. The course instructors have the initial responsibility for detecting and dealing with academic dishonesty. If the Instructors believe an act of academic dishonesty has occurred, the instructors are obligated to discuss the matter with the student(s) involved. Instructors will ensure that there is reasonable evidence of academic dishonesty. However, if circumstances prevent consultation with student(s), instructors may take whatever action (subject to student appeal) as deemed appropriate.

11. CSUCI Disability Statement

CSU Channel Islands is committed to equal educational opportunities for qualified students with disabilities in compliance with Section 504 of the Federal Rehabilitation Act of 1973 and the Americans with Disabilities Act (ADA) of 1990. The mission of Disability Accommodation Services is to assist students with disabilities to realize their academic and personal potential. Students with physical, learning, or other disabilities are encouraged to contact the Disability Accommodation Services office at (805) 437-8510 for personal assistance and accommodations. Handouts are available in alternative accessible formats on request.

12. SUBJECT-2-CHANGE Disclaimer Statement

All information contained in this syllabus, other than that mandated by the University, may be subject to change with advance notice, as deemed appropriate by the instructor.

Tentative Course Schedule
(subject to change per Instructors' discretion)

Topic	Lecture Time Needed (subject to change)	PEP Book Chapter or DD Book Chapter or other Readings
Overview of this course	1/2	PEP Introduction DD Intro/Chap 1
Review of Useful Business and Economic Terminologies	1/2	
Overview of US Healthcare: The Good, Bad, or Ugly	1	
Overview of the Branded Bio-pharmaceutical Industry	1	PEP Chap 1, 2
The Scientific Landscape: Drug Discovery and Development	1/2	PEP Chap 1, 2; DD Chap 3
The Risky Business of Bio-pharmaceutical R&D	1/2	PEP Chap 1, 2; DD Chap 2
What Are Clinical Trials?	1/2	PEP Chap 1, 2; DD Chap 4
IP, Patent, and Bio-pharmaceutical Innovation	1	Chap 11
Mid-Term	1/2	
The Regulatory Process of Bio-pharmaceutical Products	1	Chap 12
The Political Economy of the Legalization of Recreational Cannabis	1/2	TBD
The Opioid Crisis: Who was to blame?	1/2	TBD
Bio-pharmaceutical Promotion: Information or Persuasion?	1/2	Chap 10
The Demand for Bio-pharmaceuticals	1/2	Chap 5
Team Presentation #1	1	
Pricing of New Drugs	1/2	Chap 7
Economic Evaluation of Bio-pharmaceuticals	1/2	Chap 8
Why Drug Prices Differ so much across Countries	1/2	Chap 9
Generic Drug Global Supply Chain: Market for Lemons?	1	Chap 3
Team Presentation #2		
Summary and Look-Ahead: AI in Drug R&D	1	Chap 14
Final Exam	Monday, Dec 9	