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 occasionall online but until further notice

Office Hours : Sage Hall 2151
Monday 2:00 – 3:00 pm, and by appointment

Phone : 1-(805)-437-2058 (office)
E-mail: john.lu@csuci.edu;

Exam:

FINAL EXAM:
Monday, December 4, 2023 (4:00 - 6:00PM) – IN CLASS

Group Projects:

Project 1 Group Presentation: Sept 25, 2023 – IN CLASS
15 minutes per group, covering the entire lecture time

Project 2 Group Presentation: November 6, 2023 – IN CLASS
25 minutes per group, covering the entire lecture time

Group Term Paper:

Monday, November 20 (turn in a hardcopy only)
≥ 3,000 word paper based off results in Project 2

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 misreprensenting 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 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, including the use of student led case studies, on why so many biotech firms, inspite of so much 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 longterm 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. Value Proposition

Key value proposition of BUS ECON CHEM 341 is to demonstrate the value of the science-based, strongly R&D-driven pharmaceutical industry, and how deeply science and technology (including biochemistry, engineering, genomics, pharmacology), finance (capital market), economics, and management are interconnected & integrated in this sector. The entire pharmaceutical value chain from basic research to product commercialization of both small molecules (chemistry) and large molecule biologics will be discussed, including high-level content, overall process, key milestones & decision points, best-practices and selected case studies.

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

The following broad topics will be covered in this course:

- **Overview of the Global 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**
  - 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

- **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?

- **Intellectual Property (IP) and Patent Protection**
  - 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

- **Introduction to US Healthcare System**
  - The organization of the US healthcare market
  - Health insurance and healthcare financing: Private
  - Health insurance and healthcare financing: Public
  - Health insurance and demand for pharmaceuticals

- **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

- **Sales and Marketing of Pharmaceutical Products**
  - The Marketing Process: What is it?
  - Channels of Pharmaceutical Promotions
  - Regulations of Pharmaceutical Promotions

- **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)

- **The Success and Failures of Biotechnology Firms**
  - Why did so many biotech startups fail?
  - Why has the Capital Market been so patient with biotech firms?
  - Student led case studies

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

5. Required/High Recommended Course Materials

[1] "Pharmaceutical Economics and Policy, 3rd edition" by Stuart Schweitzer and Z. John Lu (Oxford University Press, 2018). 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. The book will be referred as S-LU 2018 in this syllabus.

[2] "Science Business: The Promise, The Reality, and the Future of Biotech" by Gary P. Pisano (Harvard Business School Press, 2006). This book can be purchased at the CI book store**.** The book will be referred as GPP 2006 in this syllabus.

[3] Cases (to be provided by instructors, posted on Canvas) : All class materials including PowerPoint Presentations (PPTs), additional reading assignments, group projects, instructions for cases and projects etc., will be posted on Canvas https://cilearn.csuci.edu/ in due time.

6. 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 Centerfor 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.

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.

7. Evaluation & Grading

- Participation, QA, Engagement 20%
- Group Project 1 - Presentation 15%
- Group Project 2 – Presentation 25%
- Group Project 2 – Paper 15%
- Final Exam (in-class and open book) 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.

8. Assignments & Projects

8.1 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
Group/Team Project 2 – Presentation and Paper

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 (both projects) and the paper (Project 2 only).

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.

8.2 Group Project 1 (15%): In-class Presentation on the Safety and Efficacy of NEW DRUG X (to be selected from Table 1)

This is a team-based project.

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; no less than 2 clinical trials publications)
- Some information on the safety – especially the nasty one(s) (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 minute presentation on their selected drug – every member of the group will cover some slides. The tentative date of the presentations is **September 25** (during Lecture 6).

Table 1 Notable New Drugs 2020-2023

Drug Name	Year of FDA Approval	Indication	Manufacturer	Link for Start
Semaglutide (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
Remdesivir (Veklury)	2020 (Emergency Use)	Treatment of Covid-19 requiring hospitalization	Gilead Sciences	https://www.fda.gov/news-events/press-announcements/fda-approves-first-treatment-covid-19
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
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
Zuranolone (Zurzuvae)	2023	Treatment of postpartum depression	Biogen/Sage Therapeutics	https://www.fda.gov/news-events/press-announcements/fda-approves-first-oral-treatment-postpartum-depression
Lenacapavir (Sunlence)	2022	Treatment of adults with HIV-1 infections who have failed other treatments	Gilead Sciences	https://www.fda.gov/news-events/press-announcements/fda-approves-new-hiv-drug-adults-limited-treatment-options
Tezepelumab (Tezspire)	2021	Add-on maintenance therapy to improve severe asthma symptoms	Amgen	https://www.fda.gov/drugs/news-events-human-drugs/fda-approves-maintenance-treatment-severe-asthma

8.3 Group Project 2 (40%):

A. In-class Presentation on a Failed Biotech Firm (select from Table 2) -25%
B. A jointly written summary paper -15%

Select a firm by end of 4th lecture. First come, first serve. One firm per group.

Please conduct online research on the history of this failed firm. Also review the firm's Annual Reports (10K), especially in the last few years before it failed – you may need to ask CSUCI Library to help you get the documents.

Each case study should include answers to the following questions about the firm:

- How was the firm formed?
- When was the first IPO? Was it a successful one?
- When was the first product? Was it a successful launch? What was the peak annual sales?
- How many products did the firm launch in its entire history?
- How did the firm conduct drug R&D? Internally or through an alliance with an external partner? How did it work out?
- Did the firm market its own product(s), or work with an external partner? How did it work out?
- Did the firm every earn positive profit in any year of its history? If yes, how far was the year of profit from the year it was first established?
- Was the firm profitable in any of the last three years of its life? If yes, what was the profit margin in % term (in the year or years of profitability)? If no, what was the Cost of Goods Sold (COGS) to Revenue (Sales) ratio in the last three years?
- How did it fail? Through merger, acquisition, or just chapter 11 bankruptcy?
- If M&A, a hostile takeover or friendly merger? By whom? What was the premium on the share price at M&A?

List and discuss a few factors/reasons for the failure (internal as well as external ones): Poor Management, Pipeline woes, Competitive Pressures, Economic Scales, Running out of Funds?

Any important lessons learned your group can share with the rest of class?

Be sure to cite any references you use for the paper.

For A: Please prepare a 12-15 slide PowerPoint presentation (25 minutes) for A. The tentative date for the presentation is **Nov. 6** – covering entire Lecture 11.

For B: Please write a 3,000 word paper (8 pages double sized) summarizing the above findings. This paper is due **Nov. 20**, in-class.

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 not looking for a perfect paper on management – that would be beyond the scope of this course. I am looking to see how each group can work together and comprehensively apply the knowledge learnt in this class to understand what happened to a

real world firm. An early start of this project 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 16 (during office hour or before/after class) to discuss the interim progress and potential issues/difficulty.

Table 2 Prominent Biotech Startups That Ultimately Failed

Manufacturer	Year Established	Year of IPO	Last Year of Independence	Link
Alexion Pharmaceuticals	1992	1996	2021	https://www.zippia.com/alexion-pharmaceuticals-careers-381/history/
Celgene	1986	1987	2019	https://www.zippia.com/bristol-myers-squibb-careers-1752/history/
Cubist Pharmaceuticals	1992	2002	2014	https://www.crunchbase.com/organization/cubist-pharmaceuticals
ICOS	1990	1991	2007	https://www.zippia.com/icos-inc-careers-26975/history/
ImCLone	1984	1991	2008	https://www.zippia.com/imclone-systems-llc-careers-27072/history/
La Jolla Pharmaceuticals	1989	2014	2022	La Jolla Pharmaceutical History: Founding, Timeline, and Milestones - Zippia
MedImmune	1988	2001	2007	https://www.zippia.com/med-immune-careers-62885/history/
NPS Pharmaceuticals	1986	1994	2015	https://www.crunchbase.com/organization/nps-pharmaceuticals

8.4 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.

Final exam is 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 in every lecture. Each attendance is worth 1% 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)

Date	Broad Lecture Topic	Specific Topics	Required/Recommened Course Materials
8/21 Week 1	Class introduction and syllabus; The Culture of Technological Innovation – Can It Co-exist with the Culture of Business? The Random Nature of Drug D&D	Movie: BlackBerry – Science and Business: Can They Co-Exist? Youtube: The Shadow of the Thalidomide Tragedy	https://www.youtube.com/watch?v=41n3mDoVbvk
8/28 Week 2	Introduction to the global biopharmaceutical industry	Overview of the Industry (I) – History, Industrial Organization, Basic Performance	S-LU 2018 (Introduction, Chap 1, Chap 2); GPP 2006 Chap 1
9/4 Week 3	No Class; Labor Day		
9/11 Week 4	Introduction to the global biopharmaceutical industry (II) **Guest Speaker: Dr. Thomas Schulze**	Biotech Firms: Are They Really Different? New Landscape for Pharmaceutical RD	GPP 2006 Chap 2, 3, 4; https://www.youtube.com/watch?v=DRmHFa_CODc
9/18 Week 5	Business of Pharmaceutical R&D; Stages of Drug R&D	Comparison of Pharmaceutical R&D over time and across sectors; Stages of Preclinical and Clinical Trials	GPP 2006 Chap 5, 6; S-LU 2018 Chap 12
9/25 Week 6	Students Led Presentation and Discussion: Safety and Efficacy of Drug X	Recent Blockbuster Drugs (Weight Loss, AZ, Covid-19, etc.) – Should one take them?	Group Presentation #1
10/2 Week 7	Regulatory Approval Process	How are drugs approved in the US & EU? Cross country comparisons on drug approval; Major Drug Legislations	S-LU 2018 Chap 12, Chap 13
10/9 Week 8	Intellectual Property: Patent, Innovation, and Affordability **ONLINE Session.** **Guest: Dr. Maria Elipe (Amgen)**	Rationale for a Patent System; Economics of Patent; Criticism of Patent	S-LU 2018 Chap 11.
10/16 Week 9	Introduction to Healthcare System, Health Insurance and relationship to Pharma	Different types of Health Insurance in the US; Adverse Selection and Moral Hazard; Demand for Pharmaceuticals w. Insurance	S-LU 2018 Chap 5
10/23 Week 10	Value and Pricing of Pharmaceutical Products	How Do Firms Set Prices? How Do Insurers Counter-Offer? Are Pharmaceuticals Cost-Effective	S-LU 2018 (Chap 7 + 8)
10/30 Week 11	Sales and Promotion of Pharmaceutical Products	What is Market Research? Channels of Rx Promotions; Ethical Considerations	S-LU 2018 Chap 10
11/6 Week 12	The Success and Failure of Biotech Startups – Student Led Discussions	Case Studies	Group Presentation #2
11/13 Week 13	Business Ethics in the Healthcare and Pharmaceutical Industry	The Tuskegee Syphilis Study; The Opioid Crisis; The Amgen-JNJ Epo History	(https://www.youtube.com/watch?v=ZV7RzS8QRXE) (https://www.youtube.com/watch?v=WvCld2vKug8); (https://www.c-span.org/video/?404343-1/blood-medicine)
11/20 Week 14	Generics and Biosimilars	The economic benefits of generics; The offshoring of generic API productions; The reshoring of API production?	S-Lu 2018 (Chap 3); Group Project Paper due.
11/27 Week 15	AI and The Pharmaceutical Industry: The Good, The Bad, and The Ugly	https://www.google.com/search?q=youtube%3A+AI+and+pharamceuticals&rlz; (1 hr) https://www.google.com/search?q=youtube%3A+AI+and+pharamceuticals&rlz#fpstate=ive&vld=cid:c09c13a6,vid:sdt0sl6LkSg	S-Lu 2018 (Chap 14); https://www.youtube.com/watch?v=5dZ_lvDgevk

12/4 Week 16	**Final Exam 4-6 pm (in-class; open books/open notes)**	