California State University, Channel Islands
COURSE SYLLABUS

Faculty: **Maria Silva Elipe (MSE), PhD, Department of Chemistry;**
Zhong John Lu (JL), PhD, Department of Economics

Location: California State University Channel Islands (CSUCI)/Del Norte 1500

Time: Tuesdays: 6:00 – 8:50 pm

Office Hours : [Lu] Sage Hall 2151 or Del Norte 1500
Tuesday 5:30 – 6:00 pm, and 8:50 - 9:20 pm, plus times by appointment
[Silva Elipe] Solano Hall 1123 or Del Norte 1500
Tuesday 4 :50-5 :50 pm (Days of MSE lectures only, but available upon request other Tuesdays)

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Exams: **MID-TERM EXAM:**
Tuesday, October 16 (week 8), 2018 (1st half of class)

FINAL EXAM:
Tuesday, December 11, 2018 (7:00 - 9:00PM)

Term Paper: **Tuesday, November 6 (week 11), 2018, in class**

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 praised by many for the science focused culture, the highly effective medicines against many previously untreatable diseases and conditions, the substantial and well compensated employment opportunities, and for being a global leader in net exports. On the other hand, the industry has no lack of critics, both in the US and globally. It has often been criticized for monopolist like pricing behavior, for engaging in unethical or illegal promotional activities for off-label usage of its products, and for under-reporting and misreprensenting important safety information. 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 reimbursement, marketing, business ethics, generic and biosimilar drugs, and health outcomes research. Selected topics from these areas will be analyzed in depth.

It is hoped that the course will provide students with a better understanding of the industry: basic structures, common business strategies, and critical issues. It is also hoped that lessons from this industry may be applied to other sectors which rely on continuous innovations for survival. In addition, this course may also be useful for students who are interested in employment opportunities 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 its significance;
- 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 (chemistry, biology, basic pharmacology), business, 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 biotherapeutics/biologics (biology) will be instructed, including high-level content, overall process, key milestones & decision points, best-practices and selected case studies.

4. Course Credit

Credit in BUS ECON CHEM 341 could be applied either as an elective course within the BS Business program (as BUS 341) or as an elective outside of the business program (as ECON 341 or CHEM 341). This course provides credit towards the Chemistry minor. Class target audience : Junior and Senior-level students, including, but not limited to, BUS ECON CHEM and STEM students. Underclassmen students with strong, college level academic records may be considered on a case-by-case basis.

5. Course Topics

The following broad topics will be covered in this course:

- **Overview of the Global Pharmaceutical Industry**
  - The BioPharma Industry (Big Pharma and Biotech)
  - Stages and phases of drug research and development (R&D)
  - Cost, risk, and timelines in BioPharma R&D
  - Mergers, acquisitions, and strategic alliances
  - Firm size and shifting business models

- **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

- **Discovery of Drug Targets and Drug Leads**
  - Historical sources of drug leads – natural products
  - 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
  - Biologics drug discovery

- **Pharmaceutical Research and Development (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
  - Biologics drug development

- **Clinical Trials**
  - The regulatory process – what is done in Phase I, II, and III trials
  - The role of the FDA – permissions, review, and oversight
  - Drug Safety and Pharmacovigilance (Phase IV or post-marketing trials)

- **Pharmaceutical Manufacturing and Production**
  - Scale-up from lab to pilot plant to full-scale manufacturing
  - The FDA and Good Manufacturing Practices (GMP) production
  - Work processes and decision making in scale-up and commercialization
  - The role of outsourcing in pharmaceutical development and manufacturing
  - Biologics manufacturing and production
  - Medical devices

- **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

- **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 regulatory pathway to generic pharmaceutical products
  - Regulatory policy and pathway for biosimilar products (Biosimilars)

- **Business Ethics**
  - Importance of Doing the Right Thing in Drug Development and Commercialization: what is legal vs. what is right
  - Company Vision, Mission, and Business Reality
  - Case studies in the pharmaceutical industry

- **A Look Ahead**
  - Affordable Care Act (Obamacare) and Future of Pharmaceuticals
  - Rise of Chinese and Indian Pharmaceutical Industries
  - Personalized Medicine (Pharmacogenomics): science and economics

6. Required Course Materials

[1] "Genentech: The Beginnings of Biotech" by Sally Smith Hughes (The University of Chicago Press, 2011). This book can be purchased online**.**

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

7. Recommended Course Materials

[1] "Devalued and Distrusted: Can the Pharmaceutical Industry Restore its Broken Image?" by John LaMattina (John Wiley & Sons 2012). This recommended book discusses a number of issues facing the pharmaceutical industry from the perspective of a former industry executive. It will be quite useful to consult with when you write the term paper. Short in length and inexpensive in price.

[2] "Pharmaceutical Economics and Policy, 3rd edition" by Stuart Schweitzer and Z. John Lu (Oxford University Press, 2018). This new book is written for upper division undergraduate and master level students in health economics, health management, pharmaceutical administration and public policy. Provides a good overview of key economic, scientific, regulatory, and policy issues facing the biopharmaceutical industry. If you have a serious interest in this industry, either for career or for graduate or professional school, this book is highly recommended. The book will be referred as S-LU 2018 in this syllabus.

[3] "2015 Profile of the Biopharmaceutical Research Industry"; Pharmaceutical Research and Manufacturing Association; Washington, DC. This annual report contains lots of useful and current statistics and information for the industry. Posted on Canvas.

[4] "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 Economist, Business Week, Forbes***, and ***The Wall Street Journal***. The Broome Library carries these periodicals in both hardcopy and electronically.

8. Assignments & Projects

8.1 TEAM PRESENTATION (20%):

This team-based project is a key deliverable for this course, as it reflects the key modus operandi of most pharmaceutical companies.

Students will form multi-disciplinary projects teams, consisting of 4 persons (range 3-5 with instructors' approval) from different disciplines. Every team must have at least 1 student, but no more than 2 students, with a biology/chemistry/STEM/nursing major, and at least 1 student, but no more than 2 students, with a business/econ/social science/health science major. Project Teams will 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, and jointly present selected case studies as posted on Canvas. The last three lectures of the semester will be reserved solely for student project teams to make PowerPoint presentations (20 minute presentation, 5 minute QA, ~15-20 slides) to the entire class.

Project teams should determine their case study topic ASAP, so as to have sufficient time to get organized, conduct research, and prepare the PPT presentations and executive summary reports. More detailed instructions and the project list for you to select from will be provided later in this document.

All students on each Project Team must make contribution to the research, the preparation of presentation, the PPT slides, and the (~250 words) Executive Summary Report (in Word).

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

8.2. TEAM BOOK REPORT (20%):

This is the 2nd team-based project in this course: the same team for the presentation will be for the book report as well.

"Genentech: The Beginnings of Biotech" is written by a noted science historian, Sally Smith Hughes, PhD, at the University of California, Berkley. It chronicles major events leading up to the Initial Public Offerring (IPO) of Genentech, considered by many as the most innovative company in the history of biotechnology industry (it was purchased by and merged with a pharmaceutical giant, Roche, in 2009). The early history of Genentech evolves around two critical figures, both of whom were born in a humble background: Herbert Boyer, the scientist who co-invented the DNA splicing techniques that laid the scientific foundation for the commercialization of molecular biology, and Robert Swanson, the businessman whose vision, passion, and tenacity led to the establishment of Genentech against incredible odds. Although not a lengthy book by any measure (about 170 pages), it covers a number of important topics relevant to the understanding of the business of science, and the science of busines. These include:

1) Success achieved thru hardwork and preseverance, despite a humble beginning
2) Business culture vs. Science culture
3) Importance of intellectual property
4) Innovation and competition
5) Industry – academia collaboration (advantages and conflict of interest)
6) Time management
7) Risk management (in science, entrepreneurship, business collaboration)
8) Personnel management
9) Funding of a start-up company: own funds, ventura capital, and IPO

Your book report will summarize your reflections on this book. You should focus on a few (3-4) key aspects that strike you the most, and explain the lessons learnt in depth. Recommended length is 2,500 words excluding word count in the reference section – less than 2,250 or more than 3,000 words will incur penalty. Be sure to properly reference 8-10 articles you come across in your research, or your paper grade will be penalized. Plageriasm (including audio/video sources) will NOT be acceptable (and your grade will be severely impacted). We want to see what you have learned from reading the book AND taking this course, not repeating what others have learned. We can tell a book report written by a student vs. a business professor or business journalist.

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

9. Course conduct, rules & attendance

BUS ECON CHEM 341 meets once a week for a total of 15 times (including midterm and student team 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 (posted on Canvas); 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 phones and laptop computers are limited to lecture recording and 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. You can miss one lecture without excuse without any penalty, after that each unexcused absence will cost you 1% of the course grade during regular lectures, and each unexcused absence during *guest lectures* (if any) and *student presentations* (last three lectures) will cost you 2%.

10. Evaluation & Grading

- Participation, QA, Engagement 10%
- Book Report 20%
- Midterm Exam 20%
- Team Case Study (content, presentation, teamwork) 20%
- Final Exam 30%

Failure to take the Mid-Term exam, or Final Exam, will result in a score of zero on that item. Makeup exams will be given in rare instances, and on a case-by-case basis, including clearly documented evidence (medical and family emergencies) provided by the student.

Grading Rules:

A/A+/A-	90-100%;
B/B+/B-	80-89%;
C/C+/C-	70-79%;
D/D+/D-	55% to 69%;
F	<55%

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

11. 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.

12. 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.

13. 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 both Instructors.

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

Date	Lecture Topic	Items Due	Instructor (JL, MSE)	Required/Recommened Course Materials
8/28 Week 1	Class introduction and syllabus; Introduction to the global biopharmaceutical industry	Purchase required book (for book report); Forming groups for class project	MSE	Slides + S-LU 2018 (Chap 1)
9/4 Week 2	Discovery of Drug Targets and Drug Leads	Read books for book report	MSE	Slides + A + B + C
9/11 Week 3	Pharmaceutical Research and Development	Read books for book report	MSE	Slides + D
9/18 Week 4	Introduction to Healthcare System and its relationship to Drug Industry	Forming groups for class project	JL	Slides
9/25 Week 5	Intellectual Property: Patent, Innovation, and Affordability	Read books for book report	JL	Slides + S-LU 2018 (Chap 11)
10/2 Week 6	Clinical Trials + FDA	Read books for book report	MSE	Slides + E + S-LU 2018 (Chap 12)
10/9 Week 7	Value and Pricing of Pharmaceutical Products	Read books for book report	JL	Slides + S-LU 2018 (Chap 7 + 8)
10/16 Week 8	Midterm (60 minutes); Importance of Generics and Biosimilars (2nd half of lecture)	Finalization of groups for class project; Selection of Project Topic	JL	Slides + S-Lu 2018 (Chap 3)
10/23 Week 9	Pharmaceutical Manufacturing and Production	Read books for book report	MSE	Slides + F
10/30 Week 10	The Opioid Crisis; Business Ethics and the Drug Industry (I)	Read books for book report	JL	Slides + video
11/6 Week 11	Case Study: Development of Lipitor at Pfizer	**Book Report Due**	MSE	Slides + JLL
11/13 Week 12	Business Ethics and the Drug Industry (II); Future of Biopharma Industry		JL	Slides + S-LU 2018 (Chap 14)
11/20 Week 13	Team project presentations I (all groups) First day presenters extra credit	Final project PPT slides; Word executive summary report	JL, MSE	
11/27 Week 14	Team project presentations II (all groups)	Final project PPT slides; Word executive summary report	JL, MSE	
12/4 Week 15	Team project presentations III (all groups); Wrap up and Final Exam Prep	Final project PPT slides; Word executive summary report	JL, MSE	
12/11 Week 16	Final Exam 7-9 pm		JL, MSE	

S-LU = "Pharmaceutical Economics and Policy, 3rd edition" by Stuart Schweitzer and Z. John Lu (Oxford University Press, 2018).
JLL = "Devalued and Distrusted : Can the Pharmaceutical Industry Restore its Broken Image?" by John LaMattina (John Wiley & Sons 2012).
A-F Handouts from "Drugs : From Discovery to Approval" by Rick Ng (Wiley Blackwell, 2015) :
A = Drug Discovery Target Receptors
B = Drug Discovery Small Molecule Drugs
C = Drug Discovery Large Molecule Drugs
D = Drug Development & Preclinical
E = Clinical Trials
F = Manufacturing & Production

14. Topics for Team Project (Each Team Picks One)

Development of a Launch Strategy for Name of Drug

Required readings (on Canvas):

1) "Forecasting Denosumab"; T. Calkins; Kellogg School of Management, 2011 (Case No: KEL 531)
2) "Why Are Prescription Drugs so Expensive ?" by Amy Nordrum (International Business Times ; May 19, 2015).
3) "A Tale of Two Drugs" by Barry Werth (MIT Technology Review; October 22, 2013)

In the article by Tim Calkins: "Forecasting Denosumab", he describes how Amgen is anticipating, planning, and forecasting the launch of Denosumab, considered by many industry experts as the next blockbuster innovative drug therapy for patients with osteoporosis (a bone disorder) and for patients with bone metastasis (experienced in many late stage cancers).

You (your group) are now asked to create a launch plan for one of the following newly approved drugs (select ONE per group – at most 2 groups per drug) in the US, using a similar approach to the one taken Calkins:

- **Venclexta (venetoclax):** by AbbVie; for the treatment of chronic lymphocytic leukemia; approved in April 2016.
- **Spinraza (nusinersen):** by Biogen/Ionis; for the treatment of spinal muscular atrophy; approved in December 2016.
- **Cinqair (reslizumab):** by Teva Pharmaceuticals; for the treatment of asthma; approved in March 2016.
- **Zepatier (elbasvir & andgrazoprevir):** by Merck & Co.; for the treatment of HCV genotypes 1 &4; approved in January 2016.
- **Ozempic (semaglutide):** by Novo Nordisk; for the treatment of diabetes 2; approved in December 5, 2017.
- **Besponsa (inotuzumab ozogamicin):** by Pfizer; for the treatment of acute lymphoblastic leukemia; approved in August 17, 2017.

- **Kisqali (ribociclib):** by Novartis; for the treatment of HR-positive/HER2-negative advance or metastatic breast cancer; approved in March 13, 2017.

- **Kevzara (sarilumab):** by Sanofi/Regeneron Pharmaceuticals; for the treatment of reumathoid arthritis; FDA approved on May 22 2017.

In this plan, you are expected to analyze/discuss:

- A description of the company launching the drug
- The disease the drug is indicated for and the existing treatment options prior to the new drug approval.
- Summary of key clinical trial results, efficacy, side effects on the new drug. How the new drug may be better than the existing treatment options?
- How the price for the new drug compares to the existing treatment options. Does the price reflect its value?
- Briefly discuss the promotional plan for the new drug (which channels of promotion to focus on)
- Potential challenges facing the new drug in the near future (using the SWOT framework)

You are encouraged to research company annual reports, published literatures on the disease and treatment options, FDA website and announcements, and press coverages on these new drugs. Be sure to properly reference all sources.

The deliverable for this project is 1) a 250 word executive summary in Microsoft WORD (excluding title or references; 2) a 18-20 slide deck in PowerPoint; and 3) group presentation to the whole class at end of the semester (~20-25 minutes + 5 minutes Q&A).

Please note that we are not looking for a perfect launch plan with this exercise. We are looking to see how you can comprehensively apply the knowledge learnt in this class to a real world scenario. An early start of this project is very important, as it will require a significant amount of work. Feel free to check with us along the way.