LSMP 121
PROSEMINAR IN MANAGEMENT & THE LIFE SCIENCES

Freshman Year, Fall Semester 2017
Vagelos Life Sciences & Management Program

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Class Meetings: Tuesday/Thursday, 10:30 AM – 12:00 PM
Classroom: CPC Auditorium

Introduction and Course Objective

This is the introductory course for the joint Wharton-College Life Sciences & Management (LSM) Program. Enrollment is limited to students admitted to that program; no other Wharton or College students are permitted to enroll. The objective of this seminar-type course is to introduce students to the multiple dimensions in which the life sciences, society, markets, and firms interact in market-based economic systems. The course deals with three fundamental issues in the management of science:

1. allocation of resources, public and private, to the discovery and development process
2. organization and management of the ‘twin towers’ of innovation – research and discovery (R&D) commercialization – the translation of discoveries into products/services
3. prioritization and marketing of useful products and services
All three questions will be considered from a descriptive/behavioral viewpoint—how do they actually occur—and from a normative/social viewpoint—how should they ideally occur? The course will be led by Robert Burns from Wharton and Philip A. Rea from the Department of Biology, and will rely on both outside speakers and lectures/discussions with the course faculty. Written papers, participation in class discussion, and student presentations will form the basis for grading.

Course Sequencing
The course has four major sections. The first section discusses the changing rates of discovery in the life sciences, the sources of creativity that lead to discovery, and whether the creative process can be managed. We then illustrate some of these themes in a case study of the discovery of statins. This section also sketches the history of the management of science. The second section of the course discusses the prospects and problems for the development and implementation of new discoveries in genomics. Genomics applications are considered in cancer therapy and cardiac therapy (regenerative medicine). The third section of the course provides an overview of the life sciences sectors (pharmaceuticals, biotechnology, information technology, and medical devices), the major trends occurring within each, and the central issues that need to be confronted. The final section of the course discusses start-up companies and the requirements for commercialization. Please note that the classes corresponding to each section may not be contiguous because many of the speakers who were so kind as to contribute to the course have very tight schedules that necessitated their speaking on days other than those that would have been ideal for the course sequence.

Assignments
Students will have two major assignments:

(1) A paper critically examining the translation process for new beneficial life sciences products and what government, firms, investigators, investors, and universities have done or are doing well or ought to do differently in the context of some aspect of genomics and consumer need. The first draft, which will be commented on by the faculty and returned to the students for preparation of the final draft, is due on October 17th. The final draft is due on November 30th.

(2) An oral briefing to be presented at the end of the semester together with written background material on a “market scan” that identifies a product or area in which scientific discoveries might match consumer demands/needs, and which outlines a translational strategy. For the background research and presentations, students will be grouped into six teams. The teaching assistants—second-year MBA students in Wharton’s healthcare management program who have science backgrounds—will serve as team advisors.

There will also be two very short (‘one-pager’) writing assignments which will form the basis for formulating ideas, researching small sections of the literature and/or enlarging on some of the ideas discussed in class. The topics will cover ‘superbugs’ and strategic planning in life sciences firms. Due dates for the two papers are September 14th and November 9th. See the syllabus for those dates for more details.
Readings

Reading assignments for this course will be taken from:


(b) Book chapters compiled into a coursepack which is available for purchase through [www.study.net](http://www.study.net); the coursepack materials are marked in the syllabus with an asterisk [*].

(c) Readings that will be posted to the course e-room on Canvas. You can access Canvas directly through the following link: [https://canvas.upenn.edu](http://https://canvas.upenn.edu) or use your “My Courses” tab through the SPIKE student portal: [http://spike.wharton.upenn.edu/](http://http://spike.wharton.upenn.edu/). You will need your Wharton ID and password to log in.

COURSE OUTLINE

August 29: Introduction to the course and general introductions
The twin towers of innovation & R&D trends in the pharmaceutical discovery.
(Burns)

**Readings**


USFDA. *Novel Drugs 2015 Summary* (2016).

August 31 Economic and managerial perspectives on innovation in the life sciences

**Readings**


September 5: Theories of innovation and creativity (Dr. John Kounios, Drexel University)

**Readings**

John Kounios. *The Eureka Factor*, Chapters 1 & 2. [*]

September 7: Translational research in genomics and personal genome sequencing (Marc S. Williams, M.D., Director, Geisinger Genomics Institute, Danville, PA)

**Readings**


September 12: September 14: The statins - from the obscure to the billion dollar pill. Humble origins and fungal beginnings. Lipitor and the power of plan B – an advantage of a disadvantage made. Collateral benefits – from the basic to the practical and back. “Evergreened” blockbusters. (Rea)

Readings


Articles for first one-pager (due 9/14):

Sun and Dennis, “The superbug that doctors have been dreading just reached the U.S.,” Washington Post (May 27, 2016). For instructive videos associated with this publication go to https://www.washingtonpost.com/news/to-your-health/wp/2016/05/26/the-superbug-that-doctors-have-been-dreading-just-reached-the-u-s/

Yong, “The plan to avert our post-antibiotic apocalypse,” The Atlantic (May 19 2016).


September 19  Translational research in genomics: going beyond the clinic to make a population-level impact (Sheri Schully, Ph.D., National Institutes of Health, Office of Disease Prevention)

Readings


Evans and Khoury. “The arrival of genomic medicine to the clinic is only the beginning of the journey,” *Genetics in Medicine* 15 (10 July 2013): 268-269.


September 21  Cancer genomics applications (Brian Keith, Ph.D., Director of Education, Abramson Family Cancer Research Institute, Perlman School of Medicine)

Readings

Visit *Inside Cancer* (especially watch “Hallmarks of Cancer”):
http://www.insidecancer.org

September 26  Promises and challenges for utilizing cancer genomics to improve patient outcomes: Focus on childhood cancers (John Maris, M.D., Division of Oncology, Children’s Hospital of Philadelphia).

Readings


**September 28**

The investor’s challenge: Moving discoveries to practice. Colon cancer genomics from an investor’s perspective, followed by in-class exercise to discuss translation. Groups will discuss and develop examples in their experience of both promising ideas that were carried forward to success and promising ideas that failed to be translated – either appropriately or inappropriately. What made the difference? (Lee Schalop, M.D. and Wolfgang Oster, M.D., Ph.D., PolyTechnos Venture-Partners, Munich, Dublin, New York, San Francisco)

**Readings**


**October 3**

Overview of life sciences regulation: FDA and drug approval. (Debbie Cooper, Ph.D., DR Cooper Consulting, LLC)

**Readings**


HBS Case. *Note on the U.S. Food and Drug Administration*. Case # 9-807-050. [*]


**October 5**

Fall Break – no class

LDI Symposium
October 10

Issues in translational medicine. (Garret FitzGerald, M.D., McNeil Professor in Translational Medicine and Therapeutics, Associate Dean for Translational Research. University of Pennsylvania, Perelman School of Medicine)

Readings


October 12

Overview of medical device sector. Conflicts of interest in research, sales, and marketing. (Mark Turco, M.D.)

Readings


October 17

Defining the actionable cancer genome (David B. Solit, M.D., Geoffrey Beene Chair in Cancer Research; Director, Marie-Josée and Henry R. Kravis Center for Molecular Oncology, Memorial Sloan Kettering Cancer Center)

Readings


Iyer et al. “Genome sequencing identifies a basis for Everolimus sensitivity,” Science

**October 19**

Commercial development of life sciences research (Steven Nichtberger, M.D., M.B.A., Serial Entrepreneur and Investor, Adjunct Professor, Wharton Health Care Management Department)

HBS Case: *Tengion: Bringing regenerative medicine to life*. Case # 9-510-031. [*]


[http://www.youtube.com/watch?v=klu0gB-day0](http://www.youtube.com/watch?v=klu0gB-day0) (CBS Evening News: “Growing Miracles,” Part 1).

**October 24**

Overview of pharmaceutical development and delivery process. (Robert Willenbucher, M.D., M.B.A., Head of Cell Therapy and Janssen Incubator).

**October 26**

Readings
Ng. *Drugs: From Discovery to Approval*. Chapters 7 and 8.

**October 31**

Overview of the pharmaceutical sector (David Blumberg, Former Principal, U.S. Pharmaceuticals and Life Sciences Advisory, KPMG LLP)

Readings

**November 2**

Cost-effectiveness, comparative effectiveness: Achieving market access for pharmaceuticals. (Robert DeMarinis, Ph.D., Principal, AccessPharmaCon; former Vice President, Global Health Outcomes Assessment at *Wyeth*).

Readings


**November 7**

Regenerative medicine. (Prof. Jonathan Epstein, M.D., Executive Vice-Dean and Chief Scientific Officer, William Wikoff Smith Professor of Medicine, School of Medicine, University of Pennsylvania)
Readings


November 9

The health care value chain. Part I: Ecosystem of payers, providers, producers (Burns)

Readings


Moses. “Supplemental Online Content.”

Articles for second one-pager:

HBS Case: “Amgen Inc.: Planning the Unplannable.”[*]


November 14

Venture capital and the life sciences. (Jason Rhodes, M.B.A., Partner, Atlas Venture)

Readings


Booth, “If I were a big pharma head of R&D…” *Life Sci VC*. Available at: http://lifescive.com/2013/08/if-i-were-a-big-pharma-head-of-rd/
Booth, “Lessons learned: Reflections on early-stage biotech venture investing,”
http://lifescivc.com/2013/02/lessons-learned-reflections-on-early-stage-biotech-venture-investing/

Life Sci VC. “VC-backed biotech IPOs: Valuations and virtuous cycles.”

Fleming, “The decline of venture capital investment in early-stage life sciences poses a challenge to continued innovation,” Health Affairs (February 2015)

November 16
Overview of biotechnology sector. (Eric Schmidt, Ph.D., Managing Director, Cowen).

Readings


November 21
The health care value chain. Part II: Financing & delivery (Burns)

Readings

November 23
Happy Thanksgiving – no class

November 28
Overview of information technology and impact on health care. (William Hanson, M.D., Chief Information Officer, University of Pennsylvania Health System)

Readings


November 30  Intellectual property and patent issues. (Marc Segal, M.S., J.D., Ballard Spahr LLP).

Readings


December 5  Market Scans

December 7  Market Scans