LSMP 121
PROSEMINAR IN MANAGEMENT & THE LIFE SCIENCES

Freshman Year, Fall Semester 2018
Vagelos Life Sciences & Management Program

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Class Meetings: Tuesday/Thursday, 10:30 AM – 11:50 PM
Classroom: Colonial Penn Center 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) and 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 three 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 and personalized medicine with an eye to cancer and cardiovascular disease. 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. 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 22nd by 5 P.M.. The final draft is due on December 3rd at 5 P.M.

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 personalized diagnostics and strategic planning in life sciences firms. Due dates for the two papers are September 13th and October 11th. See the syllabus for those dates for more details.
Readings

Reading assignments for this course will be taken from:


(b) Rea, Pauly, & Burns. *Managing Discovery* (Cambridge University, 2018) which is available for purchase at the bookstore.

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

(d) 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 or use your “My Courses” tab through the SPIKE student portal: http://spike.wharton.upenn.edu/. You will need your Wharton ID and password to log in.

COURSE OUTLINE

**August 28:**

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

Readings

Rea et al., *Managing Discovery*: Chapter 2.


**August 30**

Economic and managerial perspectives on innovation in the life sciences

Readings

Rea et al., *Managing Discovery*: Chapter 15.

September 4: Personalized diagnostics. (Kojo Elintoba-Johnson, MD – Perelman School of Medicine, Director of Center for Personalized Diagnostics)

Readings


September 6: Statins - Part I (Philip A. Rea, D.Phil., University of Pennsylvania Department of Biology)

Readings

Rea et al. *Managing Discovery*: Chapter 4

September 11: Translational research in genomics and personal genome sequencing (Marc S. Williams, M.D., Director, Geisinger Genomics Institute, Danville, PA)

Readings

Rea et al. *Managing Discovery*: Chapter 10

September 13: 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.


**First One-Page Paper Due:**

Without going into great detail (which would be unfair to you at this stage and not possible in ‘one page’), focus your first one-pager on personalized diagnostics by providing a brief account of a recent development in molecular diagnostics, its potential impact, and some of the challenges it has or may have to face if it is to be implemented comprehensively. Either choose a particular molecular diagnostic or a particular disease to which personalized diagnostics might be applied. The type of written piece we have in mind is something along the lines of a *New York Times* (or better still *Financial Times*) OpEd column. In addressing this matter consider some but not necessarily all of the following: what exactly do we mean by personalized and molecular diagnostics; what are the kinds of scientific and technological innovations that have and are continuing to make this possible; who might benefit from these developments, and who might not, and in what way; would you be correct in having concerns about the possibility of widespread disease ‘orphanization’ by stratification; in a perfect world, what types of molecular diagnoses would you like to see come to the fore in the years to come, and why?

No one has readymade answers to these questions but you should back up your conclusions as best you can with either logic, empirical evidence and/or information gleaned from other sources. We encourage you to use any source you see fit such as the primary biomedical literature and/or conversations with investigators, for instance those expert in the field, or others who are able to reinforce and/or shed a new light on the points you wish to make.

The primary objective here is to get you started in your thinking on 21st century biomedical issues; real issues that must somehow be addressed. Writing of a particularly high quality and clarity as if for the educated layperson that catches the attention of the reader without compromising the “truth” or overstating or understating the case is what we’re looking for.

Please keep your text to 1.5 pages, excluding bibliography, using a minimum of a Times 12 pt font, single spacing OK.
September 18  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* 338(6104) (October 12, 2012): 21 and *Supplementary Materials*.


September 20  Statins - Part II (Philip A. Rea, D.Phil., University of Pennsylvania Department of Biology, Philadelphia, PA)

**Readings**

Rea et al. *Managing Discovery*: Chapter 4

Rea et al. *Managing Discovery*: Chapter 5

September 25  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](http://www.insidecancer.org)
September 27
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


October 2
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 4
Fall Break – no class

October 9
Overview of health care system (Lawton R. Burns, Ph.D., Wharton School, University of Pennsylvania)

Readings


**October 11**  
Pricing (Simon-Kucher & Partners)

**Readings**


**Second One-Page Paper Due:**

Readings:

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


**Assignment**: consider the following:

• What is planning like at Amgen?
• Do senior managers and scientists see it the same way?
• Is one of them wrong? Are they both wrong?
• Does planning serve any useful function at Amgen?
• What does the case teach you about strategic planning in general?

There is no one right answer to these questions. You should back up your conclusions as best you can with insights gleaned from class lectures and readings, as well as any other sources you wish to consult. The primary objective here is to get you started in your thinking on how managers in life sciences companies like Amgen plan for the future when the science they are engaged in is so unpredictable.

Please keep your text to 1.5 pages, excluding bibliography, using a minimum of a Times 12 pt font, single spacing OK.

**October 16**  
**October 18**

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

**Readings**

Ng. *Drugs: From Discovery to Approval*. Chapters 7 and 8.
October 23

Beyond CART: CAART technology for autoimmune disease therapy
(Aimee Payne, MD, PhD – Perelman School of Medicine, Associate Professor of Dermatology)

Readings

Rea et al. Managing Discovery: Chapter 14


October 25

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

Readings

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


http://www.youtube.com/watch?v=kIu0gB-day0 (CBS Evening News: “Growing Miracles,” Part 1.

October 30

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. [*]

Christl. Overview of the Regulatory Framework and FDA’s Guidance to the Development and Approval of Biosimilar Products in the US. Skim slide presentation. USFDA.
November 1  Overview of the pharmaceutical sector (David Blumberg, Former Principal, U.S. Pharmaceuticals and Life Sciences Advisory, KPMG LLP)

Readings

November 6  Biotech venture capital and new company creation (Jason Rhodes, M.B.A., Partner, Atlas Venture)

Readings

Generation Bio. “Generation bio announces $100 million series b financing to advance genewavetm platform for re-dosable gene therapy.”


Booth. “If I were a big pharma head of R&D…” *Life Sci VC*. Available at: http://lifescivc.com/2013/08/if-i-were-a-big-pharma-head-of-rd/


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 8  Overview of the medical device sector. Emerging trends and markets. (Mark Turco, M.D.)

Readings

Burns. *The Business of Healthcare Innovation*. Chapter 6. Regenerative medicine (Jon Epstein, MD - Perelman School of Medicine, Executive Vice-Dean and Chief Scientific Officer)

**November 13**

**Readings**


**November 15**

Overview of biotechnology sector. (Eric Schmidt, Ph.D., Chief Financial Officer, Allogene)

**Readings**


**November 20**

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**


**November 22**  
**Happy Thanksgiving – no class**

**November 27**  
Overview of information technology and impact on health care. (William Hanson, M.D., Chief Information Officer, University of Pennsylvania Health System)

**Readings**


**November 29**  
Intellectual property and patent issues in the life sciences. (Marc Segal, M.S., J.D., Ballard Spahr LLP).

**Readings**


**December 4**  
Market Scan Presentations

**December 6**  
Market Scan Presentations