

LSMP 121
PROSEMINAR IN MANAGEMENT & THE LIFE SCIENCES

Freshman Year, Fall Semester 2015
Vagelos Life Sciences & Management Program

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

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 creativity 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 major 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 pertaining 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, 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 drafts, which will be commented on by the faculty and returned to the students for preparation of the final draft, are due on October 27. Final drafts are due on November 19.
- (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 science might match consumer demands/needs, and which outlines a translational strategy. For purposes of background research and presentation, 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 cancer genomics and strategic planning in life sciences firms. Due dates for the two papers are Sept 17th and October 15th. See the syllabus on those dates for more details.

Readings

Reading assignments for this course will be taken from:

- a. Burns, *The Business of Healthcare Innovation* 2nd Edition, (Cambridge University, 2012) which is available for purchase at the bookstore.
- b. 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 [*].
- 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> 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 27: Introduction to the course and general introductions.
The twin towers of innovation.
Data on the scope, size, and rates of growth of life sciences research and products using life sciences research. (Burns)

Readings

Burns, *The Business of Health Care Innovation*: Chapter 8.

September 1: Theories of innovation and creativity. Theories of creativity in the life sciences.
Role of team structures and other supports. Impact of mergers and acquisitions on productivity. (Burns)

Readings

Johnson, “Where Good Ideas Come From”: *The Natural History of Innovation* (2010): “Introduction” and “Conclusion” (two chapters).

Gertner, *The Idea Factory* (Read pp. 101-104, 150-155, 260-263, 343-360). [*]

September 3: The inventor’s challenge: In-class exercise on creativity: when have you been creative? What was needed for you to be creative? What caused it? If you had to, how would you “manage” creativity? (Rea)

Readings

Panel Discussion, “Let your creativity soar,” *Scientific American Mind* (June/July 2008).

Fisher, “Daydream your way to creativity,” *New Scientist* (16 June 2012)

Cain, “The rise of the new Groupthink,” *New York Times* (January 13, 2012)

Gertner, “True innovation,, *New York Times* (February 25, 2012)

Ossola, “Scientists are more creative than you might imagine,” *The Atlantic* (2014), <http://www.theatlantic.com/education/archive/2014/11/the-creative-scientist/382633/>

Tate, “Google couldn’t kill 20 percent time even if it wanted,” *Wired* (2013), <http://www.wired.com/2013/08/20-percent-time-will-never-die/>

D’Onfro, “The truth about Google’s famous ‘20% time’ policy,” *Business Insider UK* (2015), <http://uk.businessinsider.com/google-20-percent-time-policy-2015-4>

Sapienza, “Creativity: influence of structure, size and formal systems,” in *Managing Scientists, Leadership Strategies in Scientific Research* (2004). [*]

September 8: Translational research: The NCI perspective (Sheri Schully, Ph.D., National Cancer Institute)

Readings

Schully et al. “Evidence synthesis and guideline development in genomic medicine: Current status and future prospects,” *Genetics in Medicine* (19 June 2014).

Teutsch et al. “Utility before business,” *Genetics in Medicine* (10 July 2014).

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

Manolio et al. “Implementing genomic medicine in the clinic: The future is here,” *Genetics in Medicine* (10 January 2012).

September 10: Translational research in genomics and personal genome sequencing (Marc S. Williams, M.D., Director, Geisinger Genomics Institute, Danville, PA)

Readings

McCarthy, McLeod, and Ginsburg, “Genomic medicine: A decade of successes, challenges, and opportunities,” *Science Translational Medicine* 5 (12 June 2013): 189sr4.

Jacob et al, “Genomics in clinical practice: Lessons from the front lines,” *Science Translational Medicine* (17 July 2013): 194cm5.

Zerhouni, “Translational research: Moving discovery to practice,” *Clinical Pharmacology & Therapeutics* (January 2007): 126-128.

Khoury, “The continuum of translation research in genomic medicine: How can we accelerate the appropriate integration of human genome discoveries into health care and disease prevention?” *Genetics in Medicine* 9 (October 2007): 665-674.

September 15: The statins - from the obscure to the billion dollar pill. Humble origins and fungal beginnings.
September 17: 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

Endo, “A historical perspective on the discovery of statins,” *Proc. Jpn. Acad. Sci., Ser. B*, 86 (2010): 484-493.

Libby, “Atherosclerosis: the new view,” *Scientific American* (May 2002): 47-55.

Rea, “Statins: from fungus to pharma,” *American Scientist* 96 (2008): 408-415.

Kidd, “Life after statin patent expiries,” *Nature Reviews Drug Discovery* 5 (2006): 813-814.

Articles for first one-pager:

Kolata, “In gene study, a map to fight colon cancer,” *New York Times* (July 19, 2012).

The Cancer Genome Atlas Network, “Comprehensive molecular characterization of human colon and rectal cancer,” *Nature* 487 (19 July 2012): 330-337.

Videos to watch:

<http://cancergenome.nih.gov/newsevents/multimedialibrary/videos/future-of-genomics-research>

<http://cancergenome.nih.gov/newsevents/multimedialibrary/videos/dnasequencing>

http://cancergenome.nih.gov/newsevents/multimedialibrary/videos/Linehan_Kidney

September 22: Cancer genomics applications (John Maris, M.D., Chief, Division of Oncology, Children’s Hospital of Philadelphia)

Readings

Vogelstein et al., “Cancer Genome Landscapes,” *Science* 339 (2013): 1546-1558.

Visit *Inside Cancer* (especially watch “Hallmarks of Cancer”):

<http://www.insidecancer.org>

September 24: Cancer genomics: prospects for science. (John Maris, M.D., Chief, Division of Oncology, Children's Hospital of Philadelphia).

Readings

Pugh et al. "The genetic landscape of high-risk neuroblastoma," *Nature Genetics* 45 (2013): 279-284.

Mosse et al. "Identification of ALK as a major familial neuroblastoma predisposition gene," *Nature* 455 (October 2008): 930-935.

Maris. "Recent advances in neuroblastoma," *NEJM* 362 (June 2010): 2202-2211.

September 29: History of the management of life sciences. The economics of research- intensive products. When to say no to a promising discovery. Profit maximizing research. From laboratory to market: economic choices at each stage. (Prof. Mark Pauly, Wharton Health Care Management Department)

October 1:

Readings

Pauly. "Chapter X: Pharmaceutical Industry Trends."

Pauly, Chen, Myers. "Draft Chapter on the Economic Theory of Investment and Pricing by Profit Maximizing Life Sciences Firms."

October 6: Regenerative medicine. (Prof. Jonathan Epstein, William Wikoff Chair in Cardiovascular Research, and Chair of Department of Cell and Developmental Biology, Penn Medical School)

Readings

Lanza and Rosenthal, "The stem cell challenge," *Scientific American* (June 2004).

Minkel, "Potent alternative," *Scientific American* (February 2008).

Khademhosseini et al., "Progress in tissue engineering," *Scientific American* (May 2009).

<http://stemcells.nih.gov/info/basics/pages/basics1.aspx>

October 8: **Fall Break – no class**

October 13: 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

Koboldt, et al. “The next-generation sequencing revolution and its impact on genomics,” *Leading Edge Review* (September 2013).

Iyer et al. “Genome sequencing identifies a basis for Everolimus sensitivity,” *Science* (October 12, 2012) and *Supplementary Materials*.

October 15: Overview of pharmaceutical development and delivery process. (Robert Willenbucher, M.D., M.B.A., Head of Cell Therapy and Janssen Incubator).

Readings

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

Articles for second one-pager:

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

Gordon Binder, *Science Lessons* (2008): Chapters 3 and 4 (handout)

October 20: Alternative to M&A in Pharma: Franchise swaps (David Gluckman, M.D. Co-Head, Lazard Global Healthcare Group)

Readings

Burns, *The Business of Healthcare Innovation*. Chapter 3.

Novartis Press Release, “Novartis announces portfolio transformation, focusing company on leading businesses with innovation power and global scale: pharmaceuticals, eye care, and generics” (April 22, 2014.)

GSK Press Release, “GSK announces major 3-part transaction with Novartis to drive sustainable sales growth, improve long-term earnings and deliver increasing returns to shareholders” (April 22, 2014)

GSK Circular Summary (November 20, 2014)

October 22: 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

Frechtling et al., *The CTSA National Evaluation Final Report*. (Westat, April 2012).

Booth. “Foundings matter: Thiel’s law applied to biotech,” *Biotech Financing* (June 11, 2013).

Price. “Overhauling translational thinking,” (2013).

October 27: Overview of the pharmaceutical sector – I (David Blumberg, Former Principal, U.S. Pharmaceuticals and Life Sciences Advisory, KPMG LLP)

Readings

Burns, *The Business of Healthcare Innovation*. Chapter 2.

October 29: Overview of the pharmaceutical sector – II (David Blumberg)

Readings

HBS Case: *Shanghai Pharmaceuticals* [*]

November 3: Venture capital and the life sciences. (Jason Rhodes, M.B.A., Executive Vice President and Chief Business Officer, Epizyme, Inc.)

Readings

Goodman, “Epizyme builds a cancer company at Mach speed,” *In Vivo* 30 (May 2012): 1-7.

Kuratko and Brown, “Emerging life sciences ventures: The quest for legitimacy,” *Business Horizons* 53 (2010): 211-220.

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/>

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.”

<http://lifescivc.com/2014/08/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 5: Commercial development of life sciences research (Steven Nichtberger, M.D., M.B.A., Chairman & CEO ControlRad Systems, Adjunct Professor, Wharton Health Care Management Department)

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

Atala, Bauer, Soker, Yoo, and Retik, “Tissue-engineered autologous bladders for patients needing cystoplasty,” *The Lancet* 367: 1241-1246 (2006).

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

November 10: 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

Sorenson. “The Role of HTA in coverage and pricing decisions: A cross-country comparison,” *Euro Observer* 11(1) (2009).

Schoonveld. “The drug pricing challenge,” in *The Price of Global Health: Drug Pricing Strategies to Balance Patient Access and the Funding of Innovation*. Chapter 1.

Longman. “The shrinking value of best-in-class & first-in-class Drugs,” *In Vivo* (July/August 2015).

November 12: Overview of life sciences regulation: FDA and drug approval. (Debbie Cooper, Ph.D., DR Cooper Consulting, LLC)

Readings

Thaul. *How FDA Approves Drugs and Regulates Their Safety and Effectiveness*. Congressional Research Service. (June 25, 2012).

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

November 17: Overview of biotechnology sector. (Eric Schmidt, Ph.D., Managing Director, Cowen).

Readings

Ernst & Young, *Beyond Borders: Reaching New Heights*. Biotechnology Report (2015).

Burns, *The Business of Healthcare Innovation*. Chapter 4.

November 19: Intellectual property and patent issues. (Marc Segal, M.S., J.D., Ballard Spahr LLP).

Readings

Strongin, “Hatch-Waxman, generics, and patents: Balancing prescription drug innovation, competition, and affordability,” *National Health Policy Forum* (June 21, 2002).

Stohr, Decker, and Langreth, “Gene patents limited by court in mixed ruling for Myriad,” (Bloomberg.com) (June 13, 2013)

November 24: Overview of information technology and impact on health care. (William Hanson, M.D., Chief Information Officer, University of Pennsylvania Health System)

Readings

Burns, *The Business of Healthcare Innovation*. Chapter 7.

Mandl and Kohane, “Escaping the EHR trap – The future of health IT,” *New England Journal of Medicine* 366 (June 14, 2012): 2240-2242.

Office of the National Coordinator for Health Information Technology, *Federal Health IT Strategic Plan: A Progress Report* (June 2013).

November 26: **Happy Thanksgiving – no class**

December 1: Health care value chain/Medical Devices (Burns)

Readings

Burns, *The Business of Healthcare Innovation*. Chapters 1 and 6.

Moses et al. “The anatomy of health care in the United States,” *JAMA* 310 (November 13, 2013): 1947-1964.

Moses. “Supplemental online content.”

December 3: Market Scans

December 8: Market Scans