LSMP 121
PROSEMINAR IN MANAGEMENT & THE LIFE SCIENCES

Freshman Year, Fall Semester 2021
Vagelos Life Sciences & Management Program

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Class Meetings: **Time – Tuesday/Thursday, 10:15 am – 11:45 am**
Room – Colonial Penn Center Auditorium (3641 Locust Walk)

Office Hours: **Fridays by Zoom appointment (contact Tina Horowitz to schedule)**

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:

- allocation of resources, public and private, to the discovery and development process
- organization and management of the 'twin towers' of innovation – research and discovery

(R&D) and commercialization – the translation of discoveries into products/services
- 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 and four minor assignments. These are:

1. Term paper on research translation: drug repurposing.

For this paper we are asking you to critically analyze the translation process for a recently repurposed drug or one that is being considered for repurposing. Also known as drug repositioning or indication expansion, drug repurposing involves the establishment of new uses for drugs that area already known, including approved, discontinued, shelved or experimental drugs. Although this strategy is not a new one, it has attracted a lot of attention in the last decade. Indeed, about one-third of recent approvals have come from repurposed drugs which collectively account for roughly 25% of the pharmaceutical industry's annual revenue.

One of the most famous examples of drug repurposing is Viagra™ (sildenafil, Pfizer). Originally discovered and developed as an antihypertensive in the mid-1990s, Viagra was serendipitously shown in its Phase I clinical trials to have beneficial effects on erectile dysfunction (ED). On the basis of this finding and in the light of its limited efficacy in treating the very thing it was targeted to treat, hypertension and angina, it was studied and approved for the treatment of ED in 1998. Since then, Viagra™ has generated over $35 billion globally with peak sales in the order of $2 billion in 2012.

What we are asking you to do is select a particular repurposed drug or one that is being explored

with an eye to repurposing and consider the pros and cons of this approach *versus* the discovery and development of a drug *de novo*. Among the issues we would like you to address are:

- Development costs and timelines
- De-risking
- Barriers to repurposing
- Patent and market exclusivity considerations
- Regulatory matters
- Measures of technical and commercial success

In engaging in this analysis be sure to define the consumer need, balance the benefits and drawbacks of the potential product, and consider the impact the product might have on the stakeholders, for instance payers and physicians. Be careful to strike a good balance between scientific/clinical and business commercialization considerations, while at the same time incorporating some of the principles learned from course as a whole.

Your paper should be 10-15 double-spaced pages (12 pt font). The first draft is due on November 1st by 11:59 pm when we will give you comments on it and a preliminary assessment/grade. The final draft is due by December 3rd at 11:59 pm.

2. Market Scan

Students will present an oral briefing at the end of the semester together with written background material (i.e. a PowerPoint deck) 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 self-select and form six teams of four people each. Student teams need to identify their topic and inform the instructors of both the topic and team composition by October 29th. The teaching assistants – second-year MBA students in Wharton's healthcare management program who have science backgrounds – will serve as team advisors. Market scans will be presented in the last two class sessions (December 7th and 9th).

3. Short Essays

There will also be four short ('one-two pagers') 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 strategic planning in life sciences firms (due September 9th at 11:59 pm), the development of COVID-19 vaccines (due October 4th at 11:59 pm), an explanation of the rising price for Epi-Pens (due October 19th at 11:59 pm), and a discussion of the inequities in the prevalence and treatment of COVID-19 patients (due November 8th at 11:59 pm).

Readings

Reading assignments for this course will be taken from:

1. Burns. *The U.S. Healthcare Ecosystem* (McGraw-Hill, 2021), available at bookstore.
2. Rea, Pauly, and Burns. *Managing Discovery* (Cambridge University, 2018), available at

bookstore.

3. Burns. *The Business of Healthcare Innovation* 3rd Edition, (Cambridge University, 2020), available at bookstore – This text, which provides more in-depth coverage of the technology sectors, is optional.

   The remainder of your readings can be found in three different places on *Canvas*: under "Files" in the "Reading" folder, "Course Materials @Penn Libraries" or "Study.Net Materials". You can access *Canvas* directly through the following link: https://canvas.upenn.edu using your PennKey and password.

Files – is a folder in which the course Syllabus ("Syllabus"), most of the readings ("Readings"), the slide decks for the classes ("Slides"), notes, assignment instructions, and other resources provided by the instructors are posted.

Course Materials @ Penn Libraries – is a collection of newspaper and journal articles, book chapters, ad videos placed on electronic course reserves and provided through Penn Libraries. The provision of materials through electronic course reserves helps reduce costs for students.

Study.Net materials – is a collection of copyright-protected case studies, book chapters, and simulations. Study.Net materials are marked with an [*] on the syllabus.

COURSE OUTLINE

August 31

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

Readings

Rea et al. *Managing Discovery* (2018): Chapter 2.

Burns. *The U.S. Healthcare Ecosystem* (2021): Chapter 20.

USFDA. *New Drug Therapy Approvals 2020* (January 2021). Available at: https://www.fda.gov/drugs/new-drugs-fda-cders-new-molecular-entities-and-new-therapeutic-biological-products/new-drug-therapy-approvals-2020

September 2

Economic and managerial perspectives on innovation in the life sciences (Burns)

Readings

Rea et al. *Managing Discovery* (2018): Chapter 15.

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

September 7

The statins: cholesterol's 'penicillins' – Part I (Rea)

Readings

Rea et al. *Managing Discovery* (2018): Chapter 4.

September 9 The statins: cholesterol's 'penicillins' – Part II (Rea)

Readings

Rea et al. *Managing Discovery* (2018): Chapter 5.

First One-Page Paper Due: September 9th

Role of Strategic Planning in Amgen's Early Success

Readings:

HBS Case: "Amgen, Inc: Planning the unplannable." [*]

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

For this assignment consider the following questions based on the two readings listed above:

- 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, but 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 1-2 pages, excluding bibliography, using a minimum of a Times 12 pt font, single spacing.

September 14 Translational research in genomics in the age of personalized medicine (Sheri Schully, Ph.D., National Institutes of Health, Deputy Chief Medical and Scientific Officer of the *All of Us* Research Program)

Readings

Khoury et al. "A collaborative translational research framework for evaluating and implementing the appropriate use of human genome sequencing to improve health," *PLoS Medicine*. (August 2, 2018).

Khoury and Evans. "A public health perspective on a national precision medicine cohort: Balancing long-term knowledge generation with early

health benefit," *JAMA* 313(21) (2015): 2117-2118.

Stark et al. "Integrating genomics into healthcare: A global responsibility," *American Journal of Human Genetics* (January 3, 2019).

Birney et al. "Genomics in healthcare: GA4GH looks to 2022," *GA4GH Connect* (October 2017).

Burns. *The U.S. Healthcare Ecosystem* (2021): Chapter 4.

September 16 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)

VIA ZOOM (from Rome)

Readings

Melamud et al. "The promise and reality of therapeutic discovery from large cohorts," *Journal of Clinical Investigation* 130(2) (2020): 575-581.

FitzGerald et al. "The future of humans as model organisms" *Science* 361 (2018): 552-553.

Fitzgerald. "Anecdotes from ITMAT: Building capacity for translational science," *Clinical Pharmacology & Therapeutics* 94(3) (2013): 291-296.

Fitzgerald. "Evolution in translational science: Whither the CTSAs?" *Science Translational Medicine* 7(284) (2015): 1-3.

Cappola and Fitzgerald. "Confluence, not conflict of interest: Name change necessary," *JAMA* 314(17) (2015): 1791-1792.

Fitzgerald. "Measure for measure: Biomarker standards and transparency," *Science Translational Medicine* 8(343) (2016): 1-2.

September 21 Overview of health care system (Burns)

Readings

Burns. *The U.S. Healthcare Ecosystem* (2021): Chapters 1-3.

September 23 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

Chakravarty and Solit. "Clinical Cancer Genomic Profiling," *Nature Reviews* (March 2021).

Hyman et al. "Precision medicine at Memorial Sloan Kettering Cancer Center: Clinical next-generation sequencing enabling next-generation

targeted therapy trials," *Drug Discovery Today* 20(12) (2015): 1422-1428.

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* 338(6104) (October 12, 2012): 21 and *Supplementary Materials*.

Zehir et al. "Mutational landscape of metastatic cancer revealed from prospective clinical sequencing of 10,000 patients," *Nature Medicine* 23(6) (2017): 703-713.

September 28 Translational research in genomics and personal genome sequencing (Marc S. Williams, M.D., Director, Geisinger Genomics Institute, Danville, PA)

Readings

Williams. "Early Lessons from the implementation of genomic medicine programs." In *Annual Review of Genomics and Human Genetics* (2019).

Williams et al. "Patient-centered precision health in a learning health care system: Geisinger's genomic medicine experience," *Health Affairs* (May 2018).

Dewey et al. "Distribution and clinical impact of functional variants in 50,726 whole-exome sequences from the DiscovEHR study," *Science* (December 23, 2016).

Rea et al. *Managing Discovery* (2018): Chapters 1 and 10.

September 30 Life sciences venture investing: Oncoceutics, a case study (Lee Schalop, M.D., formerly with Oncoceutics, Inc., Philadelphia)

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).

Second One-Page Paper Due: October 4th

How were COVID-19 vaccines developed so quickly?

Reading: Ball. "What the lightning-fast quest for COVID vaccines means for other diseases," *Nature* (2021).

Under normal circumstances, making a vaccine can take 10-15 years (and even longer for some). Until COVID-19 vaccines came on the scene, the fastest vaccine – the one for mumps – took four years to develop. So, how were the COVID-19 vaccines developed at 'warp speed' in under a year? Does this set a new precedent for other vaccines and, if so, for what indications might these vaccines be purposed?

The type of written piece we have in mind is something along the lines of a *New York Times* OpEd-type column. Of course, no one has a ready-made answer to this question, but you should back up your conclusions/ opinions as best you can with 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 make.

The primary objective here is to get you started in your thinking about current (very current!) biomedical issues. 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 1-2 pages, excluding bibliography, using a minimum of a Times 12 pt font, single spacing.

October 5 Genetic testing for cancer susceptibility: an evolving landscape (Payal Shah, M.D., Assistant Professor of Medicine, Perelman Center for Advanced Medicine, and Danielle McKenna, M.S., LCGC, Genetic Counselor, Perelman Center for Advanced Medicine)

VIA ZOOM

Readings

Domchek et al. "Multiplex genetic testing for cancer susceptibility: Out on the hire wire without a net?," *Journal of Clinical Oncology* 31(10) (2013): 1267-1270.

Tandy-Connor et al. "False-positive results released by direct-to-consumer genetic tests highlight the importance of clinical confirmation testing for appropriate patient care," *Genetics in Medicine* 20(12) (2018): 1515-1521.

Ford. "Totally unexpected: Nonsyndromic *CDH1* mutations and hereditary diffuse gastric cancer syndrome," *Precision Oncology* (2017).

October 7 Promises and challenges for utilizing cancer genomics to improve patient outcomes: Focus on childhood cancers (John Maris, M.D., Giulio D'Angio

Chair in Neuroblastoma Research, Professor of Pediatrics Division of Oncology, Children's Hospital of Philadelphia)

Readings

Bosse, Raman, Zhu et al. "Identification of GPC2 as an Oncoprotein and Candidate Immunotherapeutic Target in High-Risk Neuroblastoma," *Cancer Cell* (2017).

Brady, Liu, Ma et al. "Pan-neuroblastoma Analysis Reveals Age- and Signature-Associated Driver Alterations," *Nature Communications* (2020).

October 12 Cancer genomics applications (Brian Keith, Ph.D., Dean, Biomedical Studies, Wistar Institute)

Readings

Vogelstein et al. "Cancer genome landscapes," *Science* 339 (2013): 1546-1551. [Please read the entire article, but don't worry about the gene names/acronyms and details in the section "Signaling pathways"]

Rozenblatt-Rosen et al. "The human tumor atlas network: Charting tumor transitions across space and time at single-cell resolution," *Cell* 181 (April 16, 2020): 236-249. [Please read only the first few sections of the article up to "How to build a tumor atlas" on p. 240]

October 19
October 21 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.

Burns. *The U.S. Healthcare Ecosystem* (2021): Chapter 21.

Third One-Page Paper Due: October 21st

What explains the rising price of Epi-Pens?

Reading: *EpiPen ERISA Litigation*

This complaint suggests that pharmacy benefit managers (PBMs) are largely responsible for the dramatic hike in prices for EpiPens by virtue of inducing (or colluding with) the pharmaceutical manufacturer of EpiPen to raise prices. Your analysis, in attempting to explain the rising price of Epi-Pens, should:

- Sketch out the causal logic of the complaint
- Critically evaluate this causal logic

- Examine what other factors might explain EpiPen price hikes and what types of insurance coverage lead patients to be exposed to these price hikes

Some background reading that will also help you is:
Burns. *The U.S. Healthcare Ecosystem* (2021): Chapter 16.

Please keep your text to 1-2 pages, excluding bibliography, using a minimum of a Times 12 pt font, single spacing.

October 26 Beyond CART: CAART technology for autoimmune disease therapy (Mike Milone, M.D., Ph.D., Associate Professor of Pathology and Laboratory Medicine, Perelman School of Medicine, and Aimee Payne, M.D., Ph.D., Professor of Dermatology, Perelman School of Medicine)

Readings

Rea et al. *Managing Discovery* (2018): Chapter 14.

June et al. "CAR T cell immunotherapy for human cancer," *Science* 359 (23 March 2018): 1361-1365.

Ellebrecht et al. "Reengineering chimeric antigen receptor T cells for targeted therapy of autoimmune disease," *Science*, 08 Jul 2016: Vol. 353, Issue 6295, pp. 179-184. doi: 10.1126/science.aaf6756

Ellebrecht et al. "On the mark: genetically engineered immunotherapies for autoimmunity," *Current Opinion in Immunology*, 2019 Dec;61:69-73. doi: 10.1016/j.coi.2019.08.005.

October 28 Regenerative medicine (Saar Gill, M.D., Ph.D. Associate Professor of Medicine, Perelman School of Medicine)

Readings

Marks and Gottlieb. "Balancing Safety and Innovation for Cell-based Regenerative Medicine," *NEJM* (March 2018).

Charo and Sipp. "Rejuvenating Regenerative Medicine Regulation," *NEJM* (2018).

Blau & Daley. "Stem Cells in the Treatment of Disease," *NEJM* (2019).

November 2 Overview of information technology and impact on health care (William Hanson, M.D., Chief Information Officer, University of Pennsylvania Health System)

Readings

Burns. *The U.S. Healthcare Ecosystem* (2021): Chapter 24.

Dorsey and Topol. "State of telehealth," *NEJM* 375 (2016): 154-161.

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 2015-2020* (Washington, DC: ONC).

Schulte and Fry. "Death by 1,000 clicks: Where electronic health records went wrong," *Fortune* (March 8, 2019). https://khn.org/news/death-by-a-thousand-clicks/.

November 4 Overview of the pharmaceutical sector (David Blumberg, VP Global Commercial Compliance, Teva Pharmaceuticals)

Readings

Burns. *The Business of Healthcare Innovation* (2020): Chapter 2.

Fourth One-Page Paper Due: November 8th

COVID-19 pandemic and inequities in the U.S. healthcare system

The COVID pandemic has made apparent certain inequities in the U.S. healthcare system. Explain what these inequities are, how they manifest themselves, and how they might be addressed.

As was the case for the first one-pager, the type of written piece we have in mind is something along the lines of a *New York Times* OpEd-type column. Of course, no one has a ready-made answer to this question, but you should back up your conclusions/opinions 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 make.

Please keep your text to 1-2 pages, excluding bibliography, using a minimum of a Times 12 pt font, single spacing.

November 9 COVID-19 and its impact on minority populations (Natasha Chida, M.D., Assistant Professor Infectious Diseases, Johns Hopkins University)

Readings

CDC. COVID Data Tracker Weekly Review. Available online at: https://www.cdc.gov/coronavirus/2019-ncov/covid-data/covidview/index.html.

Chowkwanyun & Reed. "Racial health disparities and Covid-19 : Caution and context," *NEJM* (July 16, 2020).

November 11 Overview of biotechnology sector (Eric Schmidt, Ph.D., Chief Financial Officer, Allogene)

Readings

Burns. *The U.S. Healthcare Ecosystem* (2021): Chapter 22.

Burns. *The Business of Healthcare Innovation* (2020): Chapter 4.

November 16 FDA regulation of regenerative medicine: Stem cell-based therapies (Donald Fink, Ph.D., Master Practice Expert – Regulatory. Dark Horse Consulting, Cell and Gene Therapies)

Readings

PEW Charitable Trusts. "FDA's Framework for Regulating Regenerative Medicine Will Improve Oversight", (October 2019)

Fink. "FDA regulation of stem cell-based products." *Science*, 324: 1662-1663, (2009). doi: 10.1126/science.1173712

Halme and Kessler. "FDA regulation of stem-cell based therapies," *NEJM* (October 19, 2006). doi: 10.1056/NEJMhpr063086

November 18 Pricing and market access 101 (Volker Janssen, Ph.D., Senior Partner, Simon-Kucher & Partners)

VIA ZOOM

Readings

Schoonveld. "Market access and pricing strategy implementation." In *The Price of Global Health*, 2nd edition: 277-341.[*]

Burns. *The U.S. Healthcare Ecosystem* (2021): Chapters 15, 17-19.

November 23 Biotech venture capital and new company creation (Jason Rhodes, M.B.A., Partner, Atlas Venture)

Readings

Burns. *The Business of Healthcare Innovation* (2020): Chapter 4.
Generation Bio. "Atlas venture launches generation bio." https://generationbio.com/atlas-venture-launches-generation-bio/
Generation Bio. "Generation bio announces $100 million series B financing to advance GeneWave™ platform for re-dosable gene therapy. " https://generationbio.com/generation-bio-announces-100-million-series-b-financing-to-advance-genewavetm-platform-for-re-dosable-gene-therapy/
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.* 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 25 **Happy Thanksgiving – no class**

November 30 Overview of medical device sector: Emerging trends and markets (Mark Turco, M.D., Chief Innovation Officer, Penn Center for Innovation)

Readings

Burns. *The U.S. Healthcare Ecosystem* (2021): Chapter 23.

Burns. *The Business of Health Care Innovation* (2020): Chapters 5 and 6.

Ernst & Young. *As Change Accelerates, How can Medtechs Move Ahead and Stay There? Pulse of the Industry 2017* (2017).

Gottlieb. "Advancing policies to promote safe, effective MedTech innovation," *FDA Voice* (2017).
https://www.fda.gov/news-events/fda-voices-perspectives-fda-leadership-and-experts/advancing-policies-promote-safe-effective-medtech-innovation

December 2 Intellectual property and patent issues in the life sciences (Marc Segal, M.S., J.D., Ballard Spahr LLP).

Readings

Holman. "AbbVie hopes to maintain Humira exclusivity through secondary patents and regulatory barriers to entry." *Biotechnology Law Report* 36(1) (2017), 9-16.

Gene Patents: A Brief Overview of Intellectual Property Rules. Congressional Research Service. (January 2014).

December 7 Market Scan Presentations

December 9 Market Scan Presentations