Biotech and Pharmaceutical Strategy (HLTHMGMT 717)

Duke MBA Program

Spring 1 (February-March) 2021

Mondays and Thursdays from 8:30 am to 10:45 am on Zoom and in Geneen Auditorium

Faculty

David Ridley is the Faculty Director for Health Sector Management at Duke University's business school. In his research, he examines innovation and pricing in health care. David was the lead author of the paper proposing the priority review voucher program which became law in 2007 and created a market of more than a billion dollars for drug development for neglected diseases. He was the principal investigator on a grant from the Bill & Melinda Gates Foundation for 2018 to 2020. He received a PhD in economics from Duke University.

George Abercrombie served as President and Chief Executive Officer of Hoffmann-La Roche Incorporated from 2001 to 2009 where he was responsible for leading North American Pharmaceuticals Operations. Before joining Roche he held leadership positions at Glaxo Wellcome and Merck. He currently serves as a Duke University adjunct professor, as well as on government and commercial boards of directors. George began his career as a pharmacist and later earned an MBA.

Paige Bolander and Tommy Schram are the teaching assistants. Paige worked for Elil Lilly before business school and worked as a summer intern at Titleist. Tommy worked for Deloitte before business school and worked as a summer intern at Amgen.

Outside of class

- David enjoys talking after class. Please stick around after class or Email him to reserve a slot.
- George enjoys mentoring students, especially about careers, and is available by appointment.

Links

- Course web: http://fuqua.instructure.com/
- David's web: https://sites.duke.edu/ridley/
- David's email: david.ridley@duke.edu

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Overview

We will examine the life of a drug from innovation to generic competition. First, we will discuss research and development, including managing scientists, financing clinical trials, and selecting molecules. Second, we will discuss emerging markets, including intellectual property, incentives for innovation, and access to medicines. Third, we will discuss pricing and reimbursement. Fourth, we will discuss leadership and regulatory compliance. Fifth, we will discuss product launches. Sixth, we will discuss competition following patent expiration, including generic and over-the-counter products.

We will begin each class by discussing a case. We will use "cold calling," to draw on the expertise and preparation of all those in the room. We will integrate current events throughout class discussion. Both business strategy and public policy will be important components. We will conclude each class with additional insights from economics, management, marketing, and strategy.

The class faculty have experience with biotech and pharmaceutical companies which could make them too supportive of some companies. Nevertheless, we genuinely hope to encourage a vigorous discussion about the industry and we welcome diverse views.

Objectives

Participants will learn

- How researchers estimated the average industry cost of research and development for an approved drug. Many people misunderstand the calculations which can lead to flawed business decisions and bad public policy.
- How to estimate the value of a drug in development in order to make better decisions about which drugs to advance and which drugs to stop.
- What incentives governments create to reward developers of drugs for rare and neglected diseases.
- How governments regulate drug makers and the important steps drug makers must take to avoid penalties, fines, lost revenue, and embarrassment.
- How to estimate the cost effectiveness of a drug in order to secure reimbursement.
- What price regulations have been proposed and which are likely to be implemented.
- What are the new approaches to pricing, including the "Netflix Model" and outcomes-based pricing, and under what conditions drug makers and payers should adopt them.

- How to estimate a drug's peak market share in order to forecast sales.
- What role intermediaries such as pharmacy benefit managers play in drug access and reimbursement.
- What ten strategies drug makers use to extend sales of a drug approaching patent expiration.
- How generic drug makers compete with brand name drug makers.

Materials

We will read cases from the course pack and use supplemental articles and videos from the course web page. For those with less background in biotech and pharmaceuticals, the following resources might be useful: https://sites.duke.edu/ridley/teaching/resources-pharma/

Grading

MBA students, especially in their second year, generally focus on learning rather than grades, but it is nevertheless important to outline the grading criteria.

- 30% participation
- 30% daily assignments; we will drop the lowest
- 15% midterm exam
- 25% final exam

The Fuqua School of Business Honor Code applies to the course.

Participation

Please attend class and participate. We grade on the quality, not the quantity, of class participation. Feel free to change seats each day.

It is not necessary to E-mail us about absences, unless you expect to have five or more absences. Other obligations arise, including health, family, and career. These are all important. Fortunately, you can still submit your answers even if you cannot attend class. We do not record lectures, but we share the slides.

Class recordings

We neither record nor share videos of class discussion, unless Fuqua policy requires it. Class discussions cover controversial topics in health care and we want to have an open discussion. Instead of class discussion recordings, we provide recordings of many lectures as well as class slides. Also, the exams do not include questions from class discussion.

Assessments

For each class, including the first, there will be an assessment on the class web page. You may ignore the questions in the case. Past students reported working an average of 4 hours per assessment. We will drop the lowest assessment score for each person. The assessments are formatted as quizzes, but have no time limit, other than a deadline.

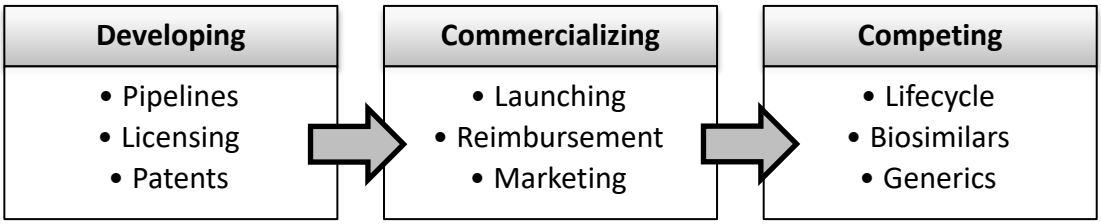
The assessments are "open" meaning that you can use class readings and readings from outside class to answer the questions. You may discuss the assessments with other current students in the class, but each student should submit a unique copy in her own words, and you should not rely on others to do your work.

Assessments are due 30 minutes before the start of class. Assessments are not accepted after class, because i) the primary objective of the homework is to encourage preparation for class, ii) answers are included in the slides posted on the web page after class, and iii) it is generally better to work on future homework rather than past homework.

Exams

The exams are online and consist primarily of multiple-choice questions. The time limit is 45 minutes (adjusted for those with disabilities), and most students finish within about 30 minutes. Exams are "closed", meaning that you may not consult materials or other people. The midterm covers content from the first half of the class and the final exam is comprehensive. Exams are based on material in the video lectures, class slides, and readings. Exams are *not* based on content marked "optional" or minutiae in the readings.

Schedule



	Date	Topic	Case	
1	11-Feb	Outsourcing	Dr. William Carson - Intrapreneurial Innovation in the Pharmaceutical Industry	
2	15-Feb	Pipeline Strategy	Vertex Pharmaceuticals: R&D Portfolio Management	
3	18-Feb	Neglected Diseases	Genzyme's CSR Dilemma: How to Play Its HAND	
4	22-Feb	Diagnostics	GenomicHealth: Launching a Paradigm Shift	
5	25-Feb	Reimbursement in the US	See course web site	
6	1-Mar	Reimbursement in Established Markets	Novartis' Gilenya	
	1-Mar – 6-Mar	Online midterm available		
7	4-Mar	Vaccine Launch	Merck: Pricing Gardasil	*The coursepack order is wrong for classes 7 & 8.*
8	8-Mar	Regulatory Compliance	Merck: Managing Vioxx (A-C)	
9	11-Mar	Intellectual Property & Emerging Markets	Viagra in China: A Prolonged Battle over Intellectual Property Rights	*Also, classes 8 and 9 will be only on Zoom.*
10	15-Mar	Pharmaceutical Financial Model	See course web site. Team assignment	
11	18-Mar	Lifecycle Management	Pharmaceutical Switching	
12	22-Mar	Generics & Biosimilars	Teva Pharmaceuticals	
	22-Mar – 27-Mar	Online final exam available		

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