Drug Development, Reimbursement, & Regulation
Fuqua Executive Education

This is a four-day executive education course based on courses taught to Duke graduate students. It focuses on biotechnology and pharmaceuticals. It is a non-degree course open to executives.

Links

- Web page for information: https://www.fuqua.duke.edu/programs/executive-education
- Web page for enrolled participants: http://fuqua.instructure.com/
- Professor's email: david.ridley@duke.edu

Professor

David Ridley is 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 has taught health care management to more than 3,000 Duke graduate students since 2001. He received a PhD in economics from Duke University.

Overview

The market for pharmaceuticals and biologics is complex, because of the nature of the science, but also because of reimbursement and regulation. When someone else is paying the bill, such as an insurer or the government, they increasingly want proof of value for the money. Also, because health care is so important to our well-being, governments regulate pharmaceuticals and biologics. People who understand the complexity of the industry can be incredibly valuable for drug makers, payers, providers, investors, consultants, regulators, and patient advocates.

It is insufficient to know part of the pharmaceutical and biologic space because the parts interlink. For example, people involved in drug discovery need to understand reimbursement, regulation, and marketing, because they need to provide products that the market wants.

We will discuss trends for pharmaceuticals and biologics. One trend is increasing pressure on prices. The President wants to tie drug prices to foreign drug prices, and leaders in Congress want the government to negotiate drug prices. Also, drug makers are changing the way they do pricing. One of the leading makers of branded insulin introduced a generic. Another leading drug maker introduced an outcomes-based pricing model in which it doesn't get paid if the drug doesn't work. Yet another drug maker charged a state a flat fee for its Hepatitis C drug, regardless of volume.

We will also discuss the trend toward smaller patient populations as diagnostics become better able to identify which patients respond best to which medicines. Many companies are focusing on rare diseases, moving away from the old blockbuster model.

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 product launches, pricing, and reimbursement. Third, we will discuss competition following patent expiration, including generic and over-the-counter products.

Objectives

At the conclusion of the program participants will understand:

- the process of drug development
- how to estimate the value of a drug in development
- incentives for focusing on rare diseases
- how to estimate the cost effectiveness of a drug
- what price regulations have been proposed and what is likely to be implemented
- how governments and insurers pay for drugs
- new approaches to pricing and outcomes-based pricing
- how to estimate a drug's peak market share
- the role of intermediaries such as pharmacy benefit managers
- strategies used by drug makers to extend sales of a drug approaching patent expiration
- the nature of generic competition

Preparation and Assessment

We flip the classroom. Participants watch video lectures and complete assessments before class. In class, participants have the information from the videos and readings to be active participants in class discussion.

Before each class session participants should do the following:

1. View the videos
2. Read the case
3. Submit a 10-question assessment 30 minutes before class

Pre-class activities take about 3 to 6 hours per session. We ask that these be done before the class session in order to facilitate a richer discussion.

The slides for class will be available 30 minutes before class and the assessment answers will be available a few hours after the class discussion.

Participants who complete each assessment in advance of class will receive a certificate.

Technical Requirements

You will need a computer camera and microphone for Zoom sessions. We will send you an access link to the Canvas web site before the orientation session. You will create a OneLink account in order to access Canvas. The web site is compatible with Google Chrome, Safari and Firefox, but not Internet Explorer.

Schedule

1. Introduction

Topics

- Introduction to class technology
- Introduction to other participants

2. Innovation

Topics

- Pipeline strategy
- Make or buy
- Incentives
- Priority review voucher

Pre-class assignments

- Watch videos: R&D, Make or Buy, and Incentives for Innovation (70 minutes)
- Read "Vertex Pharma: R&D Portfolio Management" (60 minutes)
- Submit session 1 assessment (60 minutes)
- Optional: DiMasi et al., "Innovation in the Pharmaceutical Industry: New Estimates of R&D Costs, Journal of Health Economics

In-class activities

- We'll encourage participation using class discussion, break out rooms, and polls. Questions will include:
- Which 2 molecules should Vertex develop and why?
- What should Vertex do with the candidates that it does not pursue? Hold, license, or other?

Post-class resources

- Class slides
- Video interview of Vertex Founder Joshua Boger

3. Commercialization

Topics

- Flow of funds
- Medicare
- Medicaid

- Patient cost sharing
- Global reimbursement

Pre-class assignments

- Watch videos: U.S Government Drug Reimbursement and Medicare (78 mins.)
- Read "Merck: Pricing Gardasil" (60 minutes)
- Submit session 2 assessment (60 minutes)
- Optional: Frakt, "Low Prices for Vaccines Can Come at a Great Cost," New York Times Blog

In-class activities

- We'll encourage participation using class discussion, break out rooms, and polls. Questions will include:
- At a price of $120 per dose, what is the cost of the vaccine per quality-adjusted life year?
- What factors should the manufacturer consider when setting the price?
- What launch price should the manufacturer choose for the USA? For emerging markets?

Post-class resources

- Class slides
- Video case debrief

4. Competition

Topics

- Drug prices
- Forecasting market
- Life cycle
- Generics and biosimilars

Pre-class assignments

- Watch videos: Drug Prices, Forecasting Market Share, Life Cycle Management, and Biosimliars (58 mins.)
- Read "Teva Pharmaceuticals" (60 minutes)
- Submit session 3 assessment (60 minutes)
- Optional: Grabowski et al., "Entry and Competition in Generic Biologics."

In-class activities

- We'll encourage participation using class discussion, break out rooms, and polls. Questions will include:
- Where should Teva focus: US generics, global generics, biosimilars, or innovative products?

Post-class resources

- Class slides
- Video case debrief