Life Science Strategy (HM 718E)
Executive MBA Program

The course is open to students in the executive MBA programs at Duke University.
Course web: http://fuqua.instructure.com/
David's web: https://sites.duke.edu/ridley/
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The instructor is David Ridley

David has enjoyed teaching this class for more than a decade. In addition to teaching, David serves as the Faculty Director for the Center for Health Sector Management. In his research, he aims to develop innovative policy and business tools that address pressing healthcare problems. He is especially interested in incentives to spur innovation and improve quality. David was the lead author of two papers that became law. In 2006, he and his colleagues proposed the Food and Drug Administration's priority review voucher program. In 2017, he and his colleagues proposed the Environmental Protection Agency's vector expedited review voucher program. David has a doctorate in economics from Duke University.

The course examines business strategy in the life sciences

The course is appropriate for anyone interested in the life sciences, both health sector experts and people new to the health sector. Those who are new can excel if they do the work. For those with less background in biotech and pharmaceuticals, the following resources might be useful: https://sites.duke.edu/ridley/teaching/resources-pharma/

The course examines business strategy and public policy for biotech, device, diagnostic, and pharmaceutical products. We will examine case studies and real-world examples to understand industry dynamics. First, we will discuss research and development, including managing scientists, financing clinical trials, and selecting products. Second, we will discuss rare and neglected diseases, intellectual property, innovation incentives, and access to health care. Third, we will discuss pricing and reimbursement. Fourth, we will discuss product launches. Fifth, we will discuss competition following patent expiration, including generic drugs and biosimilars.

Materials include a course pack, on-line readings, and videos

Materials include cases in the course pack, supplemental readings on the class website, and videos. Three sets of slides are available: (1) slides posted before class, (2) slides posted after class, and (3) slides from the videos (the latter are not especially useful).

Grades don’t matter much, but here is how they are determined

The Fuqua School of Business Honor Code applies to the course. MBA students generally focus on learning rather than grades, especially for electives, but it is nevertheless important to outline the grading criteria.

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

Assessments are due before each class

Each session will have an assessment on the class web page, including the first. Ignore the questions in this case. Past students reported working three hours per assessment. We will drop the lowest assessment score for each person. The assessments (unlike the exams) have no time limit other than a deadline.

Please read the case and watch the videos to answer the assessment questions. Students may also use other readings and discuss the assessments with other current students. Each student should submit a unique copy in her own voice. We will penalize assignments copied from another publication, person, or outputted from a large language model. Scores will typically be higher on the short-answer questions if the answer is wrong but in the author's voice. The assessment aims to motivate students to think about a topic to facilitate class discussion.

Assessments are not accepted after class

Assessments are due 30 minutes before the start of class. Before the deadline, students may resubmit an assessment, but reentering an assessment will require all answers to be resubmitted. Before submitting the assessment, consider copying the free entry (not multiple-choice) answers to a separate document to reference during class discussion.

Assessments are not accepted after class for any reason because i) the objective of the assignment is to encourage preparation for class, ii) answers are included in the slides posted on the web page after class, iii) it is generally better to work on future assignments rather than past assignments, and iv) grades rarely matter (if the scores are high enough to pass the course).

The midterm exam is in-person, and the final exam is online

The midterm exam will take place in person during Friday's class. Please bring a tablet or another computer. The time limit is 45 minutes (with extended time for approved accommodations), though most students finish in less than 30 minutes. Students may leave after completing the exam.

The final exam is online and also 45 minutes, with some flexibility about which day it is taken. It is comprehensive but emphasizes material from the second half of the course.

Both exams are multiple-choice and based mainly on the video lectures. The exams are closed-book and closed-note; you may not consult any materials or other people.

Class discussions are not recorded

Class discussions are not recorded for four reasons. First, exams cover material from the pre-class videos, not the in-class discussions. Second, discussions often involve sensitive healthcare topics. Third, the class slides summarize the key points. Finally, the value of the discussions comes from participation, not from watching them later. There are higher production quality videos available on the Internet.

A typical day of class

For each class, please remember to do the following:

- Submit the assignment as described above.
- Bring a tablet computer or print a hard copy. We will not distribute handouts.
- Put away your laptop.
- Participate in the discussion. We grade on the quality, not the quantity, of class participation. On a given day, a student receives no more credit for speaking four times than speaking once, unless the comments substantially move the discussion.

In the first hour of class, we will discuss a case. We will use "cold calling," to draw on the expertise and preparation of all those in the room. In the second hour of class, we will lecture about the topic using tools from economics, business strategy, and public policy. When time permits, we will end class by discussing recent news that matters for the industry.

The schedule includes 10 class discussions and 2 exams

Format	Date	Topic	Case
Online	20-Sep	Outsourcing	Dr. William Carson - Intrapreneurial Innovation in the Pharma Industry
Residency	28-Sep	Pipeline Strategy	Vertex Pharmaceuticals: R&D Portfolio Management
	29-Sep	Neglected Diseases	Genzyme's CSR Dilemma: How to Play Its HAND
	30-Sep	Diagnostics	GenomicHealth: Launching a Paradigm Shift
	1-Oct	Product Launch in China & Intellectual Property	Viagra in China: A Prolonged Battle over Intellectual Property Rights
	2-Oct	Vaccine Launch	Merck: Pricing Gardasil
	3-Oct	In-class midterm exam	
Online	18-Oct	Medical Devices	Medtronic: Navigating a Shifting Healthcare Landscape
	25-Oct	Pharmacy Benefit Managers	CVS Health: Redefining the Value Proposition
	1-Nov	Government Reimbursement	Novartis' Gilenya
	8-Nov	Generics & Biosimilars	Teva Pharmaceuticals
		Online final exam	

We will discuss the following lessons from life science economics

1. A firm with an inferior product in its pipeline might choose to out-license it. This is the adverse selection problem. A prospective buyer can mitigate adverse selection by conducting due diligence on the product and the company and using milestone payments.
2. A product with a low net present value might have a high option value if, for example, one of the concerns is that the product could be highly toxic, but this will mostly be revealed in early testing.
3. Some economic estimates of product development costs already consider both the failure rate and the opportunity cost of capital. The Tufts study already accounts for both, so it is incorrect to say, "development costs are around $3 billion and there is a high failure rate," because that is double counting.
4. Prices depend on supply and demand. For example, priority review voucher prices have decreased due to increased supply as Congress expanded eligibility.
5. Clinical trials provide information for regulators, payers, and providers. Therefore, regulatory shortcuts in clinical trials might mean less evidence available for providers and insurers.
6. Baumol's cost disease can partly explain the rising costs of healthcare. While other industries replace costly labor with capital, healthcare remains labor-intensive. For example, one provider still sees one patient at a time. As skilled labor in other sectors becomes more productive, wages rise. To attract skilled labor, healthcare must pay more. One approach to control the rise in healthcare spending would be to increase the ratio of capital to labor, such as using more artificial intelligence.
7. Governments incentivize firms to invest in costly clinical trials by limiting competition through patents, data exclusivity, and market exclusivity.
8. Firms do not price products based on past clinical trial costs, because those are sunk costs. However, they consider potential prices before investing in trials.
9. To address moral hazard, insurers charge patients copayments. However, drugmakers sometimes offer coupons to cover these copayments, thus increasing the quantity demanded. Given that copays have become less effective, insurers rely less on high copays and more on exclusions.
10. If providers purchase a product and are reimbursed by insurers based on the average price, they may overuse the high-priced product. Also, the drug maker might launch the drug at a higher price. Insurers could instead pay a flat amount based on value instead of price.
11. A firm must have market power, prevent arbitrage, and identify differences in willingness to pay to engage in differential pricing.
12. The U.S. pays high prices for drugs and devices for various reasons, but one is noblesse oblige. U.S. policymakers know that the U.S. market is a major driver of innovation, given that it accounts for about half of global drug profits. In contrast, policy makers in

Canada, which accounts for only 2% of the worldwide drug market, know that they have little or no effect on innovation, so they can pay low prices.

13. Many governments and insurers use cost-effectiveness analysis to evaluate products. They compare the incremental cost to the incremental effectiveness and then evaluate the product against a threshold.
14. Market definition matters. For example, a biologic might lose market share to competition at the product level, but succeed at the class level if it has a follow-on product.
15. Makers of small-molecule drugs often raise prices when facing generic competition. This strategy segments the market into two groups: (1) price-sensitive customers who switch to generics and (2) loyal customers with generous insurance or strong brand preferences.
16. Generic drugs are not inherently cheap. They offer low prices when demand is high and barriers to entry are low, allowing many competitors to enter the market.

The following terms might be useful

Term	Abbrev.	Definition
340B		Requires drug discounts for hospitals serving low-income people.
510(k)	510(k)	FDA clearance for devices similar to existing devices.
Abbreviated New Drug Application	ANDA	Application for a generic drug approval.
Accelerated Approval		Conditional approval based on a surrogate endpoint.
Accountable Care Organization	ACO	Network of providers paid per head rather than fee for service.
Active Pharmaceutical Ingredient	API	Substance used in a finished pharmaceutical product.
Affordable Care Act	ACA	Law passed under President Obama expanding health insurance.
Average Sales Price	ASP	The average price of a drug net of most rebates.
Biologic		A medical product derived from living organisms.
Biologics License Application	BLA	Application to FDA for marketing a biologic product.
Biosimilar		Generic biologic.
Black box warning		Warning of serious or life-threatening risks.
Breakthrough status		A program that gives the developer special access to FDA staff.
Buy-and-bill reimbursement		Providers purchase products and are reimbursed by insurers.
Center for Biologics Evaluation and Research	CBER	FDA center overseeing tissues and vaccines.
Center for Devices and Radiological Health	CDRH	FDA center overseeing medical devices.
Center for Drug Evaluation and Research	CDER	FDA center overseeing drugs.
Centers for Disease Control and Prevention	CDC	US agency focused on public health.
Children's Health Insurance Program	CHIP	The government program for children in low-income families.
Class I device		Low-risk medical device.
Class II device		Moderate-risk medical device.
Class III device		High-risk medical device requiring premarket approval.

Contract Manufacturing Organization	CMO	Company that manufactures products for other companies.
Contract Research Organization	CRO	Company providing clinical trials for other companies.
Copayment		Amount paid by a patient with the remainder paid by insurance.
Corporate Integrity Agreement	CIA	Agreement as part of a civil settlement with the Inspector General.
De novo		New but low or moderate-risk device.
European Medicines Agency	EMA	European agency responsible for drug evaluation and supervision.
Fast Track		FDA process to expedite drug development.
Food and Drug Administration	FDA	US agency regulating cosmetics, devices, drugs, food, and tobacco.
Generic		A product intended to be equivalent to a branded product.
Good Manufacturing Practices	GMP	Standards for manufacturing processes.
Health Care Provider	HCP	A person providing medical services.
Health Technology Assessment	HTA	Evaluation of the cost effectiveness of a product or service.
Incremental Cost Effectiveness Ratio	ICER	Added cost per additional health outcome achieved.
Inflation Reduction Act	IRA	US law that created new Medicare price controls.
Institute for Clinical and Economic Review	ICER	Non-profit organization evaluating clinical and economic value.
Intellectual Property	IP	Legal rights protecting inventions.
ISO 13485		International standard for quality management systems.
Medicaid		US health insurance program for low-income people.
Medicare		US health insurance program for seniors and disabled people.
Monoclonal Antibody	mAb	Antibody from cloned cells which is used to neutralize antigens
National Institute for Health and Care Excellence	NICE	Agency that evaluates health technologies for the United Kingdom.
National Institutes of Health	NIH	US agency that funds medical research.
New Chemical Entity	NCE	Newly developed active ingredient in a drug.
New Drug Application	NDA	Application for approval to market a new drug.
New Molecular Entity	NME	Newly approved drug with no prior equivalents.
Orphan drug		Drug for a rare disease.
Over the Counter	OTC	Drugs available without a prescription.

Paragraph IV challenge		Legal challenge stating that a patent is infringed by a generic.
Patent		Exclusive right granted for an invention.
Pharmacy Benefit Manager	PBM	Manages which drugs are covered and negotiates prices.
Phase I trial		Initial clinical trials assessing safety.
Phase II trial		Clinical trials assessing efficacy and side effects.
Phase III trial		Large-scale trials confirming effectiveness.
Phase IV trial		Post-marketing studies on long-term effects.
Premarket Approval	PMA	FDA clearance for devices different from existing devices.
Prescription	Rx	A doctor's authorization for medication.
Prescription Drug User Fee Act	PDUFA	Law allowing FDA to collect fees from drug manufacturers.
Priority Review		Expedited review for drugs addressing unmet needs.
Priority Review Voucher	PRV	Reward for treatments for neglected and rare diseases.
Risk Evaluation and Mitigation Strategy	REMS	Strategy to manage a drug's risks.
Substantial Equivalence	SE	FDA criterion based on similarity to an existing device.
Vaccines for Children Program	VFC	US program providing vaccines to children.
Warning Letter		FDA notice of regulatory non-compliance.
Wholesale Acquisition Cost	WAC	Manufacturer's list price for a drug.

Please feel free to suggest edits to the glossary with a 60-character limit.