NjP *Journal of International Business Education 14: 221-244.*

A Lecture on the Pharmaceutical Industry in the United States

Yunwei Gai and Lidija Polutnik
Babson College, USA

Abstract. The U.S. accounts for over 40% of the global spending on pharmaceuticals. This lecture provides students an overview of the U.S. pharmaceutical industry, its stakeholders (e.g., drug manufacturers, government, insurers, and pharmacy benefit managers), and their dynamics in the context of regulatory and competitive market realities. We discuss the complexity of its supply chain, stakeholder goals, the R&D process, the relevant analytical framework, the costs and benefits of drugs, as well as outcomes such as drug prices, which have often been perceived as unfair, unethical, and criticized for their lack of transparency. This lecture includes extensive resources, including book chapters, papers, websites, and videos, allowing instructors to adjust the content depending on their courses' learning goals. This lecture was part of an MBA elective course, Health Economics, for students interested in the health industry. It has been used three semesters with highly positive feedback. This lecture can be used alone or in combination with the following case, "Sovaldi: Pricing of New Products and Consequences".

Keywords: pharmaceutical industry, pricing, pharmacy benefit managers, formulary tiers, cost-effectiveness analysis (CEA), cost-benefit analysis (CBA), health technology assessment (HTA).

The U.S. pharmaceutical market accounts for over 40% of the global spending on pharmaceutical products (IQVIA 2019). With six out of the top ten companies based in the U.S. and many small to medium size pharmaceutical companies (Statista), the U.S. pharmaceutical industry is a global leader in drug discovery (Keyhani *et al.* 2010 and Pitts 2017). In this lecture, we provide instructors and students with the necessary background to understand the dynamics and the outcomes in the U.S. pharmaceutical market. Special emphasis is placed on the pricing of prescription drugs, as one of the outcomes which recently captured a lot of regulatory and public attention and has been criticized on account of lack of transparency and fairness. The main goal of this lecture is to provide students with the necessary knowledge of issues in the pharmaceutical prescription markets, such as the power and influence of different stakeholders, the way regulation and level of competition help shape the industry, and ultimately the way companies set prescription drug prices. The teaching objectives of the lecture are:

- To gain knowledge of prescription drug market structure, conduct, and performance.

- To learn about how research and development (R&D), various stakeholders, intermediaries and government regulation shape outcomes in this industry.

- To familiarize students with various pricing methods in prescription drug pricing, cost-effectiveness analysis, and cost-utility analysis.

The first section discusses the demand and supply side in this industry, intermediaries between patients and drug manufacturers, and relevant U.S. government regulation. It covers key drivers and outcomes in the U.S. pharmaceutical market of prescription drugs, including the supply chain, major manufacturers and their performances, total spending and contributing factors, R&D and the FDA, the role of insurance companies, pharmacy benefit managers (PBMs) and government, and their implications for one of the most important market outcomes, the prescription drug prices.

In the second section, we introduce various methods employed by pharmaceutical companies to define the value of prescription drugs. Specifically, we focus on Cost Effectiveness Analysis (CEA) and Cost Utility Analysis (CUA) of drugs. With increasing healthcare costs and pressures from government, insurers, and patients, pharmaceutical companies need to use methods such as CEA and CUA to support the proposed drug prices. Sections one and two contain information for instructors for additional resources, including book chapters, papers, websites, and videos as well as recommendations on how to modify this lecture to the needs of their learning objectives and curricula. We conclude this lecture in section three. In the accompanying teaching note, we provide suggestions for learning objectives, the time frame of the lecture, learning outcomes, suggestions for pedagogy and questions for students.

1. An Overview of Market Structure, Conduct, and Performance

Despite the complexities of the U.S. prescription drug market, basic economic principles are still at work. We can separate the market into the supply side, i.e., drug manufacturers and demand side, i.e., patients. These two sides do not interact directly. Rather, the transactions of goods and finances go through a multitude of intermediaries such as physicians, pharmacists, insurers, PBMs, pharmacies, and wholesalers. All participants in this market are subject to various government regulations.

The price received by the supply side, pharmaceutical companies, varies greatly from the price paid by the demand side, patients. The main source of this