1 Product Suppliers in the Healthcare Value Chain

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Innovation Is in the Air

Perhaps as never before, countries around the world are looking at biomedical innovation as a source of (a) knowledge creation by their scientific communities, (b) value creation for their populations, and (c) wealth creation by fostering industries and expansion of employment. In the United States, for example, bipartisan passage of the 21st Century Cures Act of 2016 seeks to accelerate new product development and to ensure patients have faster access to new treatments and therapies. It also elevates the role of biomedical research through an additional $6.3 billion in funding for the National Institutes of Health (NIH) and other agencies. China's Twelfth and Thirteenth Five-Year Plans (FYPs 2011–2015, 2016–2020) emphasize a shift away from manufacturing to higher-end technology sectors such as biotechnology, biomedical and advanced medical equipment, and information technology. China is also on pace to surpass the United States in terms of research funding levels, suggesting biomedical innovation is a national priority.[1]

At the same time, countries around the world are looking at the price tag for these new biomedical innovations. Not only is healthcare a rising percentage of

every country's gross domestic product (GDP), but inflation in the prices of biomedical innovation often outstrips the rate of increase in spending on healthcare services. Newspaper headlines now commonly tout the annual cost of new biotechnology treatments to patients and their insurers. Recently, Novartis announced that its new gene therapy (AVXS-101) to treat spinal muscular atrophy in newborns could be valued as much as $4 million per patient (although it did not say it would charge this price). This follows on the heels of Novartis pricing its drug Kymriah (based on CAR-T technology) to treat acute lymphoblastic leukemia in children at $475,000 and Spark Therapeutics' decision to price its new drug for blindness, Luxturna, at $850,000 for a one-time treatment.

These two observations underlie the tension every country faces – between the benefits of technological innovation and the affordability of such innovation. There are now multiple appeals for "an effective innovation agenda" that calls for, among other things, greater coordination among government agencies responsible for funding this innovation and paying for it.[2] This volume seeks to inform this agenda and the ensuing discussions by focusing on the sources of that innovation and the industrial context in which it occurs.

Innovation in the Healthcare Value Chain

Innovation occurs in the context of industrial value chains. A value chain is defined as the string of firms and industries (sellers) whose outputs serve as the inputs of other firms and industries downstream (buyers). Thus, in a traditional production model, a value chain links together raw material suppliers, manufacturers, distributors, and end customers. Using raw materials from their own suppliers, product manufacturers design and make innovative products and then market them to downstream end-users.

Value chains in healthcare are enormously complex (see Figure 1.1). There are three key sets of actors and two sets of intermediaries between them. The three key sets of actors are the individuals and institutions that purchase healthcare, provide healthcare services, and produce healthcare products (*purchasers*, *providers*, and *producers*). The two sets of intermediaries separate these key actors: those firms who finance healthcare (offer insurance to the purchasers and handle reimbursement to the providers) and those who distribute products (from the producers to the providers).

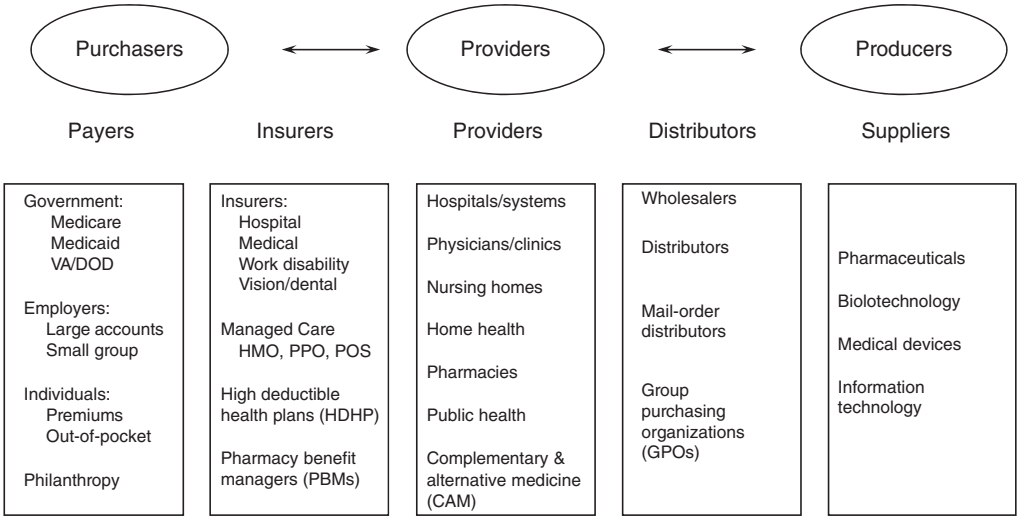


Figure 1.1 The US healthcare value chain

The logic of this chain distinguishes who innovates and who pays for innovation. All of the money that gets pumped into the healthcare system starts on the far left side of Figure 1.1 (the *purchasers*) and flows to all of the boxes to the right. Conversely, much of the innovation in healthcare starts on the far right side (the *producers*) and flows to the adjacent boxes on the left. The two flows collide in the middle among the *providers* of healthcare services – that is, doctors and hospitals – who then have to determine how much of the innovation from the right side they can afford to utilize in patient treatment given the limited supply of funds (with increasing constraints) received from the left side. This is the point at which much of the spending on healthcare and the consumption of healthcare products takes place.

In a prior book, we examined the flow of money, products, and information between producers, providers, and their intermediaries (wholesalers, distributors, group purchasing organizations (GPOs)).[3] This book examines the producers of the innovative products in the healthcare industry in the four sectors found in the right-hand box of Figure 1.1. These sectors include:

- the pharmaceutical sector,
- the biotechnology sector,
- the medical device sector, and
- the information technology sector.

The book analyzes the market structure of each sector, the competitive dynamics among firms within them, and the push for technological innovation

that distinguishes them from other sectors of healthcare. It also analyzes start-up firms in two of these four sectors: biotechnology and medical technology. The following six chapters investigate the four sectors and the two sets of start-ups.

Similarities and Differences across Producer Sectors

Similarities

The producer sectors have several similarities that are important. They are the only truly *global* sectors in the healthcare industry. The adage that "all healthcare is local" clearly applies to insurance companies and providers but not to the suppliers. The pharmaceutical, medical device, and (increasingly) biotechnology sectors clearly sell their products to global markets. The supplier sectors are also the key source of research and development (R&D) spending – at least in the United States – and thus the source of most innovation (hospital innovation centers notwithstanding). Not surprisingly, they earn much higher returns and margins compared to providers of healthcare services (Figure 1.2) and other industrial sectors (Figure 1.3).

This volume emphasizes several themes that cut across these four sectors. One is innovation and the value and benefits conferred by innovative products; such benefits can accrue to both patients and their providers. Another recurring theme is the level of investment in R&D, the mix of public versus private R&D investment, and the productivity of these investments (see shaded insert). R&D investments in the biopharmaceutical sectors greatly exceed those in other technology sectors (see Figure 1.4). A third recurring theme is the importance of market structure and competition among firms in each of these sectors, as well as the growing overlap between the pharmaceutical and biotechnology sectors (now increasingly referred to as "biopharma" or, more generally, life sciences).

Pharma / Biotech	HC Services
High margins	Low margins
Low capital invested	High capital invested
High ROIC	Low ROIC

Figure 1.2 Value creation in healthcare
ROIC: return on invested capital

Figure 1.3 Attractive returns
Source: Datastream

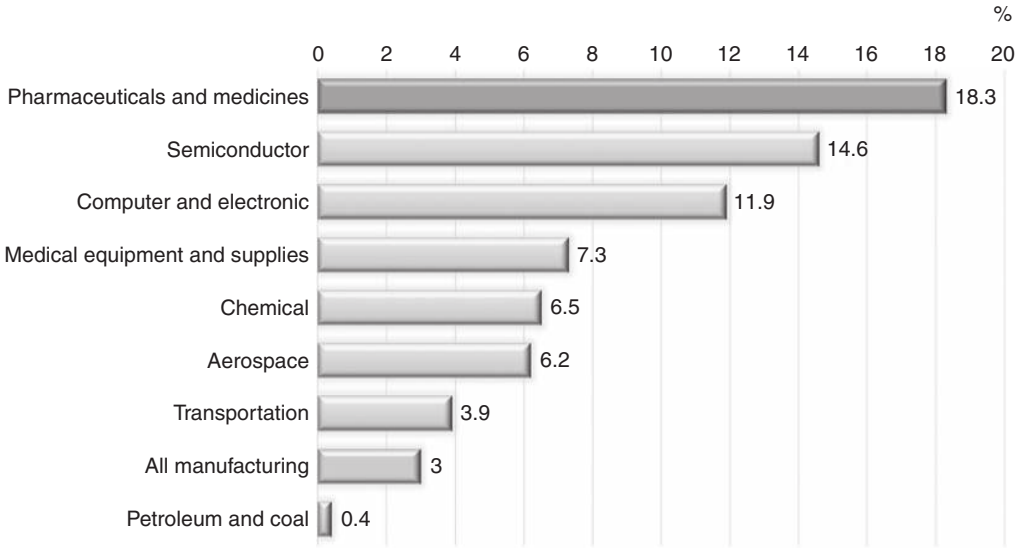
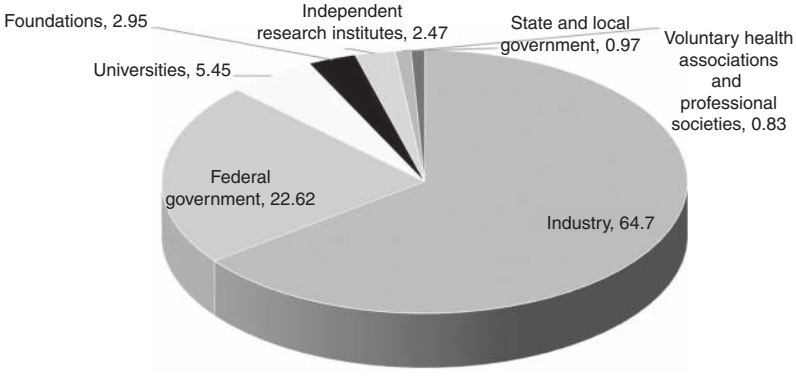


Figure 1.4 The biopharmaceutical sector invests more in R&D relative to sales than other manufacturing industries
Source: NDP Analytics

A fourth recurring theme is the set of strategies that firms in these sectors engage in to manage R&D productivity and deal with competitive pressures. These strategies include mergers and acquisitions (M&A), occupation of niche markets (or "focus"), diversification, and strategic alliances. A fifth recurring theme is the growing demand for the products developed in these sectors by the sectors located downstream from them (see Figure 1.1), a theme also known as "the technological imperative" (described below).

What Is R&D?

R&D is planned, creative work aimed at discovering new knowledge or developing new or significantly improved goods and services. This includes: (1) activities aimed at acquiring new knowledge or understanding without specific immediate commercial applications or uses (*basic research*); (2) activities aimed at solving a specific problem or meeting a specific commercial objective (*applied research*); and (3) systematic use of research and practical experience to produce new or significantly improved goods, services, or processes (*development*). Roughly two-thirds of this effort – $102 billion of the total of $159 billion (2015) – is financed by the private sector in the United States (see Figure 1.5). There is a clear division of labor in the R&D effort: the public sector funds basic research, largely through the NIH, while the private sector funds applied research and development (see Figure 1.6).



Estimated US medical and health research ($ million)

Research segment	2013	2014	2013–2014 change	2015	2014–2015 change
Industry (US operations)	$89,666	$98,097	9.40%	$102,679	4.56%
Federal government	33,634	35,435	5.36%	35,924	1.38%
Other sources	16,807	18,260	8.65%	20,113	10.15%
Total US medical and health R&D spending	$140,107	$151,792	8.34%	$158,716	4.56%

Figure 1.5 US medical and health R&D expenditure (% of total, 2015)
Source: Research America

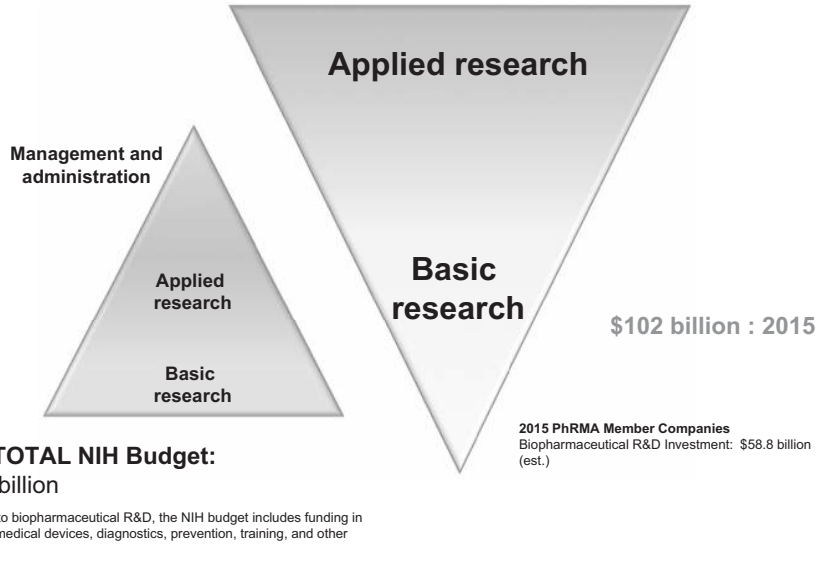


Figure 1.6 Biopharmaceutical companies do the vast majority of research to translate basic science into new medicines
Source: PhrMA

Differences

There are, nevertheless, important differences among the technology sectors – which the subsequent chapters document in great detail. Some of the major differences are summarized here. While they all earn high margins, these margins do differ as well as do their expense components (see Figure 1.7). Pharmaceutical firms earn higher margins and have lower cost of goods sold (COGS) compared to medical device firms; both earn higher returns than makers of medical supplies. Both have high selling, general, and administrative (SG&A) costs due to heavy reliance on sales representatives, and both have outperformed the stock market (Figure 1.8).

In addition, the pharmaceutical, biotechnology, and medical device sectors differ in terms of their product cycles, capital intensity, and entry barriers (see Figure 1.9). There are a host of other differences between these two sectors, as laid out in Figure 1.10.

Commonalities in the Innovation Process

Five commonalities in the innovation process cut across the producer sectors studied here: risk, capital, time, space, and scale. Most of the healthcare

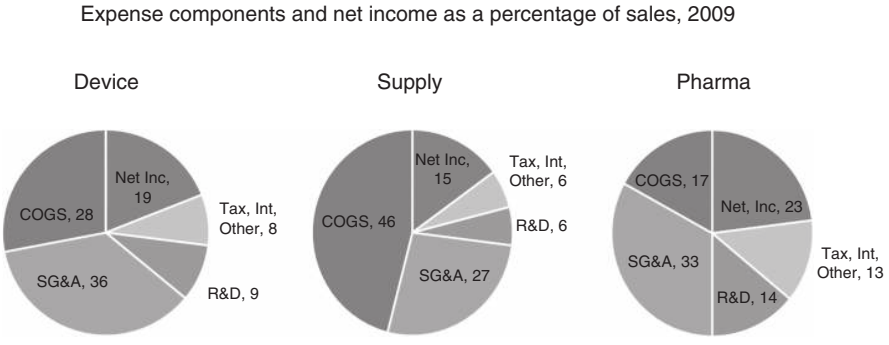
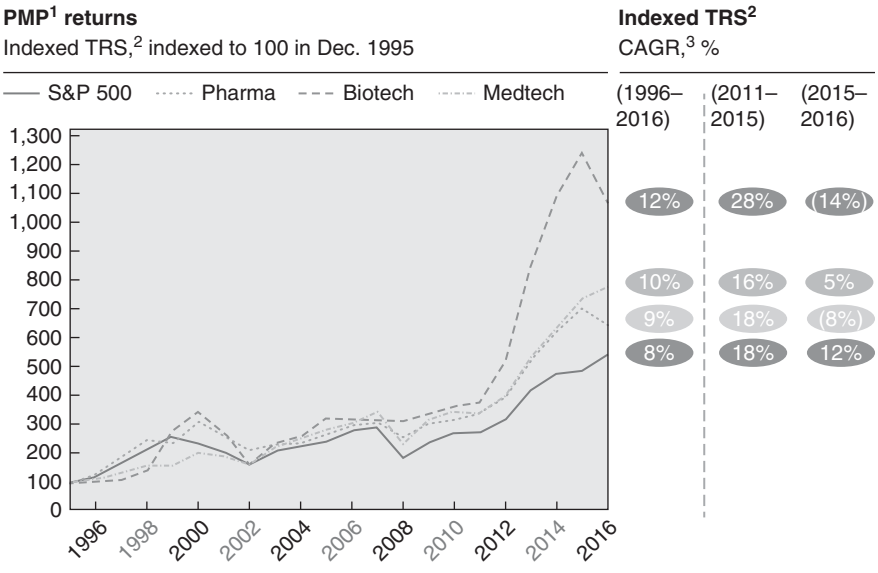


Figure 1.7 Expense components of producer sectors
SG&A: selling, general, and administrative costs
COGS: cost of goods sold
Sources: Compustat; CMS; Kruger and Kruger, 2012



[1]Pharmaceuticals and medical products industry.
[2]Total returns to shareholders.
[3]Compound annual growth rate.

Figure 1.8 Biotech has outperformed the S&P 500, as well as the pharma and medtech sectors, with a significant run-up in value since 2011

sectors examined here are characterized by high risk. Failure rates in the life sciences are especially high, as are the failure rates of new ventures in all of the sectors studied here. Indeed, small firms account for much of the innovation across these sectors, and firm survival rates here are notoriously

	Product cycles	Growth	Capital intensity	Profitability	Self-sufficiency	Barriers
Devices	Short	Moderate to high	Low	High	High	High
Pharma	Long	Moderate	High	Moderate to high	High	High
Biotech	Medium	High	Low	Low to moderate	Moderate	Low

Figure 1.9 Pharma, biotech, and devices: some dissimilarities

Pharma	Devices
$ 1.4T Sales WW (2017)	$ 405B Sales WW (2017)
Prices well understood	Prices not understood
Expenditures easily discerned	Expenditures buried
Heavy policy pressure	Lighter policy pressure
Brands more comparable	Brands less comparable
Products are featureless	Products bristle with features
More consumerism	Less consumerism
Buyers & consumers not separate	Buyers & consumers separate
Un-concentrated customers	Concentrated customers
Channel inefficiencies	Channel efficiencies
Payor formularies & tiers	No payor formularies & tiers
Price elastic demand	Price inelastic demand

Figure 1.10 Pharmaceuticals versus medical devices
Sources: https://www.statista.com/statistics/263102/pharmaceutical-market-worldwide-revenue-since-2001//; https://www.statista.com/statistics/325809/worldwide-medical-technology-revenue/

low. Firms in these sectors require success with the technologies they develop and early success in order to survive. They also require heavy injections of capital from venture capitalists and the public (in the form of initial public offerings or IPOs, secondary offerings, etc.) in order to sustain themselves through the innovation process, especially as this process may take years. Capital and time often interact in the form of "boom and bust" cycles in some of these sectors (e.g., biotechnology), as a sector goes in and out of fashion

with venture capitalists or as the window for IPOs periodically opens and closes.

Time is important in studying these sectors for three other reasons. First, the products developed in these sectors have development cycles that can be either long in duration (e.g., pharmaceuticals and biologicals) or short in duration (e.g., medical devices). Second, the sector itself may be either youthful (e.g., biotechnology) or older (e.g., pharmaceuticals). These time dimensions dictate much of the strategic behavior of firms within these sectors (including entry and exit) as well as their capabilities to innovate. Third, there is a tendency for analysts and observers (as well as investors) to overestimate the impact of new technology on these sectors in the short term and to underestimate the impact of new technology in the long term. Thus, the technological innovations mentioned in this volume may take longer to play out but have a more profound impact than originally anticipated.

Another important commonality is space. As noted above, some sectors (e.g., pharmaceuticals) are truly global businesses, while others, such as biotechnology, are found in many nations with a common aim to become global businesses. Still other sectors, such as medical devices and information technology, are largely domestic (medical devices are heavily based in the United States), although they too are trying to penetrate foreign markets.

Lastly, firm scale and scope are important dimensions. All of the sectors are growing. They all face issues of managing large size and diversity of operations, thus facing the need to coordinate their complex operations. They also all adopt strategies of M&A, while some simultaneously pursue strategies of vertical integration and diversification. Due to the common avenues of growth pursued, these firms are ripe for strategic analysis.

The Technological Imperative in Healthcare

The four technological sectors listed above are responsible for supplying a majority of the innovative products that are utilized by physicians and hospitals and that are increasingly demanded by consumers. This supply and demand logic has exerted both positive and negative effects.

On the one hand, technology is commonly cited as being the major driver of rising healthcare expenditures worldwide. Scholars have characterized this driver as the technological imperative[4] – that is, innovative treatments and equipment are demanded by patients and their (physician) agents on the grounds of quality and are reimbursed by payors and their fiscal