RCW MIRUS

WHITE PAPER

The Health Industry

From drug discovery to care delivery to enabling technology, companies in the health industry are facing an ever more daunting list of market and financial forces. Which companies should partner, merge, license, or divest - and why?

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Study Overview

RCW Mirus has prepared this white paper to provide insights into the rapidly changing industry involved in enabling, at all stages, the delivery of healthcare to patients. The scope of our discussion includes companies involved in drug discovery, development, clinical trials, and distribution; the providers and financiers of healthcare to patients; and the companies that provide enabling technologies and services to the above entities. Because of the expansive, yet interconnected, nature of the industry, we use the phrase "health industry" to describe the aggregation of these industry segments.

Section I of this document provides an overview of the health industry, and **Section II** details the different categories of forces that influence industry participants. In **Section III**, we present a framework for identifying the various objectives that industry participants may have, as well as a list of the tools and vehicles that companies can use to achieve these objectives.

Section 1: Industry Overview

The health industry "business chain" starts with the research and discovery of new ways to diagnose and treat patients, and ends with the delivery of care (including the application of these diagnostic and therapeutic products) to diagnose and treat patients. The core of this business chain, which is depicted on the right side of **Figure 1**, encompasses two distinct market segments within healthcare: life sciences companies and healthcare providers. At the bottom of the diagram are the payers, which finance the delivery of healthcare to patients. Enhancing and accelerating both the delivery and the financing of healthcare is the enabling technology and services ("ETS") market, which provides products and services to life sciences companies, healthcare providers, and payers. We address each of these industry segments in subsequent white papers.

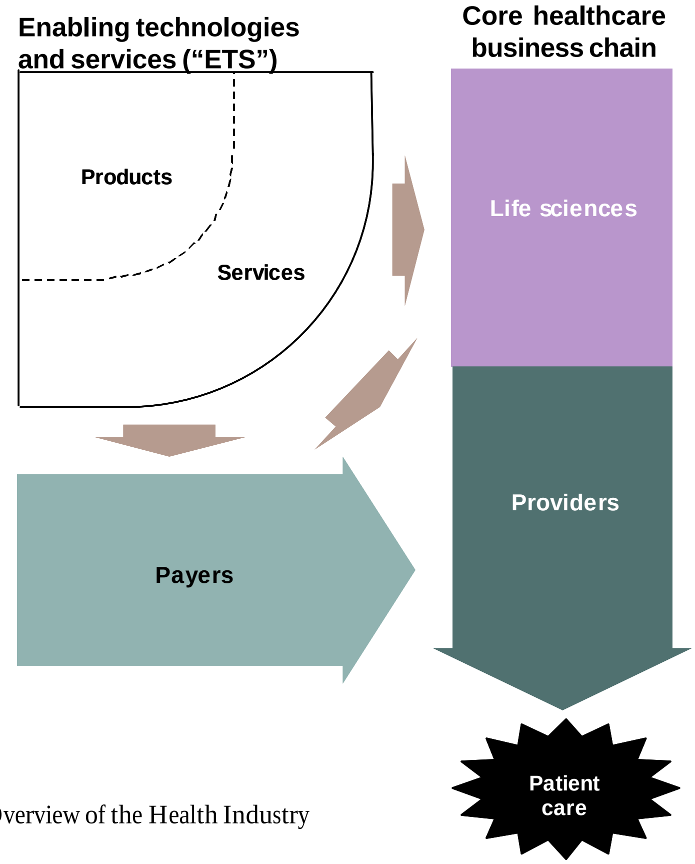

Figure 1: Overview of the Health Industry

The life sciences industry deals with the earlier part of this business chain, which is focused principally on the discovery and development of pharmaceutical and biotechnology products. Participants in the life sciences industry include pharmaceutical companies, biotechnology companies, academic medical centers and other research organizations.

Typically, pharmaceutical companies are involved both in early drug discovery and preclinical and clinical trials, as well as in manufacturing, marketing and distribution. Biotechnology companies tend to focus more on the early stages of drug discovery and validation, although some of the larger biotechnology companies are involved in all stages of addressing the market. Academic medical centers and other groups support the development process with basic research as well as by providing a venue for clinical trials. These organizations will also directly interact with industry participants through licensing arrangements and partnerships.

Healthcare providers are ultimately responsible for the delivery of care (including preventative and diagnostic services, as well as the provision of pharmaceutical and biotechnology products and other therapies). This segment includes integrated delivery systems; inpatient and outpatient facilities, such as hospitals; general practitioners, specialists and pharmacies.

The financing side of the healthcare industry is populated by both public and private payers, which include self-insured employers, insurers, healthcare plans, uninsured individuals, and government agencies (Medicare and Medicaid). The institutional payers have direct influence over the types of drugs and treatments that are covered, and in this "gatekeeper" role they can significantly impact the activities of all participants in the healthcare industry because they set the reimbursement rates for products and services. (See **Figure 2**).

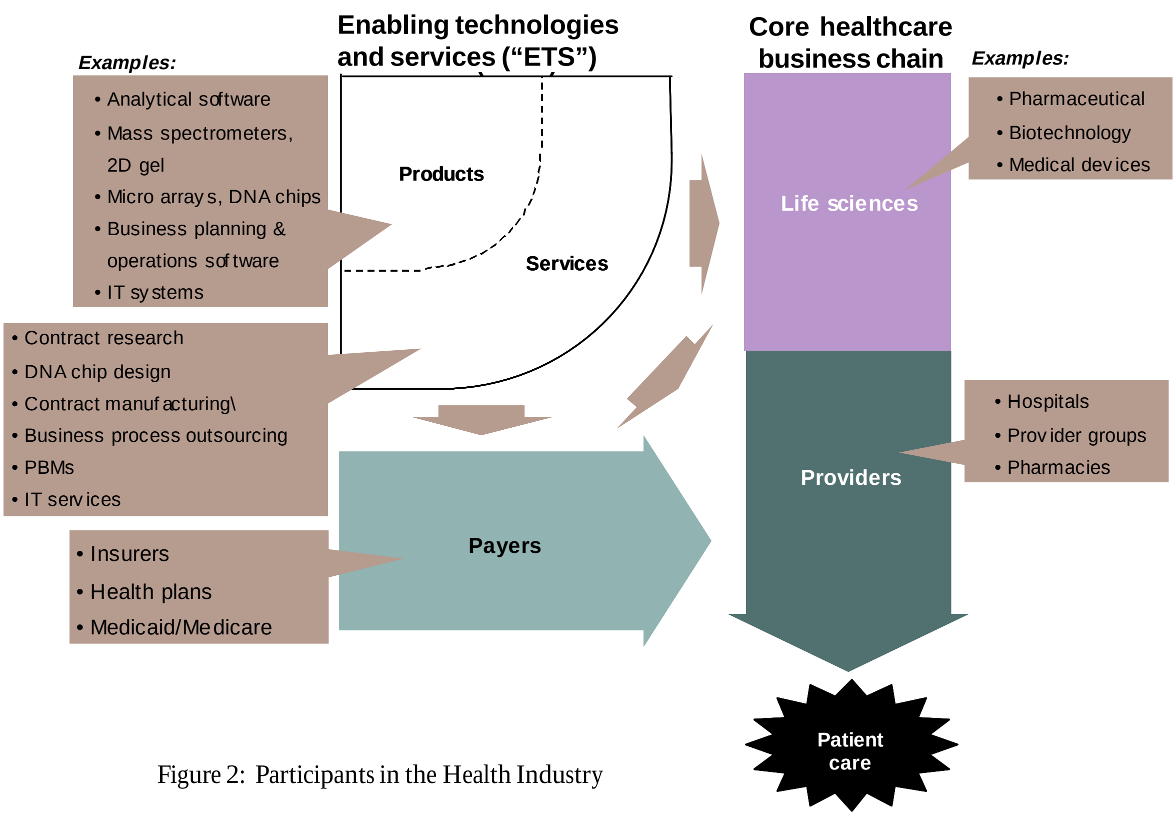

Figure 2: Participants in the Health Industry

Although the life sciences companies, providers and payers form the backbone of the "health industry" business chain, they are increasingly dependent on a wide range of enabling technologies and services provided by a complex underlying web of technology and services companies and non-profit organizations. Life sciences organizations require ever more sophisticated technology and tools to support research and successfully navigate the clinical trials and FDA approval processes. Healthcare providers use increasingly sophisticated information systems and medical devices to manage and treat their patients, capture medical and financial information and to interface with payers. Managed care plans are outsourcing claims processing, membership management, and marketing to specialized service providers. Accordingly, industry participants are using strategic deployment of enabling technologies and services as competitive differentiators in an increasingly competitive market.

Section II: Forces Influencing Industry Participants

Regardless of size, stage of development, or location, all companies in the life sciences, provider, payer and ETS markets are influenced by many different forces. These industry-specific forces, in addition to those generic market forces that affect all companies (such as Wall Street's demand that companies generate predictable growth and profits), influence key decisions that management faces. These forces fundamentally alter the range of strategic options available to companies in the health industry, and how management teams respond to them can often spell the difference between success and failure.

The forces influencing industry participants can be classified into four categories, based on the genesis of each force:

A. *market forces* – driven by customers and end users of the industry's products and services

B. *regulatory forces* – driven by the Food & Drug Administration (FDA), Patent & Trademark Office (PTO) in the United States (and their counterparts in other countries), as well as other governmental and quasi-governmental bodies with authority to impose restrictions and guidelines on market participants

C. *industry forces* – driven by the participants in the health industry

D. *financial forces* – driven by the capital markets

A compilation of some of these key forces is listed below.

A. Market Forces

- Pharmaceutical usage in the managed care industry is the fastest growing segment of healthcare services and is driving national premium increases because medications are being utilized more often.[1]

- Increasing sophistication and quality concerns from consumers and consumer "watchdog" groups are putting pressure on industry participants to put more focus on quality and safety initiatives. As many as 98,000 Americans die from patient safety related errors per year.[2]

- The "graying" of the population is shifting the demand for healthcare products and services toward higher-cost care and a demand for care management, particularly for retirees.

- Healthcare payers and pharmacy benefit managers (PBMs) play an increasingly significant role in supervising the selection of therapies, leading to changes in how drugs are developed, tested, and marketed.

B. Regulatory Forces

- The regulation of drugs and medical devices by the FDA is constantly evolving, sometimes in unpredictable ways. The intensity of FDA scrutiny has increased on the whole, in part due to the proliferation of investigative new drug (IND) applications, new drug applications (NDAs), and the number and complexity of clinical trials.

- The shifting landscape of patent protection, including new requirements proposed for the submission of patent applications and the inconsistency between patent laws across borders, obligates companies to take increasingly significant (and costly) steps to protect their intellectual property.

- The United States offers the highest quality and cost of care in the world - 12% of GDP and rising beyond $1.3 trillion per year. Governmental agencies are facing increasing pressure to regulate the price of healthcare services and drugs, as part of a broader initiative (to date unsuccessful) to reform the health insurance industry.

- The Health Insurance Portability and Accountability Act (HIPAA) sets standards for the interaction between providers, health plans and employers, and for the privacy of patient information. These standards aim to eventually simplify administration, but require initial investments in information systems and business processes.

C. Industry Forces

- High development costs drive strong competition for "blockbuster" products. Pharmaceutical R&D is rising, but fewer than one in 5,000 new chemical entities (NCEs) come to market – despite significant investments in both the successes and the failures.[3]

- Competition among healthcare providers and payers is increasing, which intensifies the price pressure on suppliers.

- Manufacturers of generic pharmaceuticals continue to put pressure on manufacturers of proprietary drugs as the latter come off patent.

- With the industry's heightened investment in genomics and proteomics, pharmaceutical companies are under competitive pressure to rethink their drug discovery process to accommodate many more drugs at any given time, as well as to dramatically reduce the development cost per drug.

- Hardware, software and telecommunications technology costs are dropping 35-50% per annum with no sign of a diminution, while computer processing power is doubling every 18 months.

D. Financial Forces

- An increasingly large amount of capital has been deployed in the industry, leading to intensifying competition for healthcare dollars as well as management expertise and resources. The biopharmaceutical segment alone raised $4 billion in 2000, $3.1 billion in 2001 and $1.6 billion in the first half of 2002.[4]

- Capital requirements for drug and device development are growing. On average today, a new drug costs $800 million and takes 15 years to bring from conception to market. Half of this figure is attributable to allocated losses from discovery or product failures.

- Threats and opportunities from mergers and acquisitions are increasing, as consolidation in the industry accelerates. Financial market expectations about product "pipelines" and revenue growth drive acquisitions of companies with promising or proven products.

Section III: Strategic Options Available to Industry Participants

Faced with the need to grow in the midst of a daunting list of market, regulatory, industry, and financial forces, industry participants have a number of strategic objectives that they may choose to pursue, as well as a range of vehicles available to effect those objectives. However, typically only a handful of key decisions that set the overall direction for a company determine its success or failure. In the health industry, most of these key decisions are linked to movements along two dimensions (see **Figure 3**):

1. *Vertical position along the core health industry business chain.* Companies in the targeted industry segments can be classified based on whether they are focused on the earlier stages in the health enabling business chain, (e.g. drug discovery), the later stages in the chain (e.g. delivery of care), or somewhere in the middle. These activities can be represented by a company's vertical position in the diagram. For example, biotechnology companies and their suppliers would be found near the top of the diagram, while hospitals and their suppliers (as well as the payers that finance the delivery of care) would be found near the bottom. Of course, some companies span multiple segments in this framework.

2. *Horizontal position relative to the core health industry business chain.* Companies can be further classified based on whether they are in the core business chain itself (appearing at the right of the diagram) or providing products or services to companies in

the core business chain (appearing at the left). Frequently, service providers interact more directly with the companies in the core business chain than do suppliers of products, which places the product suppliers furthest to the left in the framework – though this is not always the case. Payers can be viewed as providing a service (financing) to the provider market, while themselves also benefiting from certain products and services in the ETS industry segment.

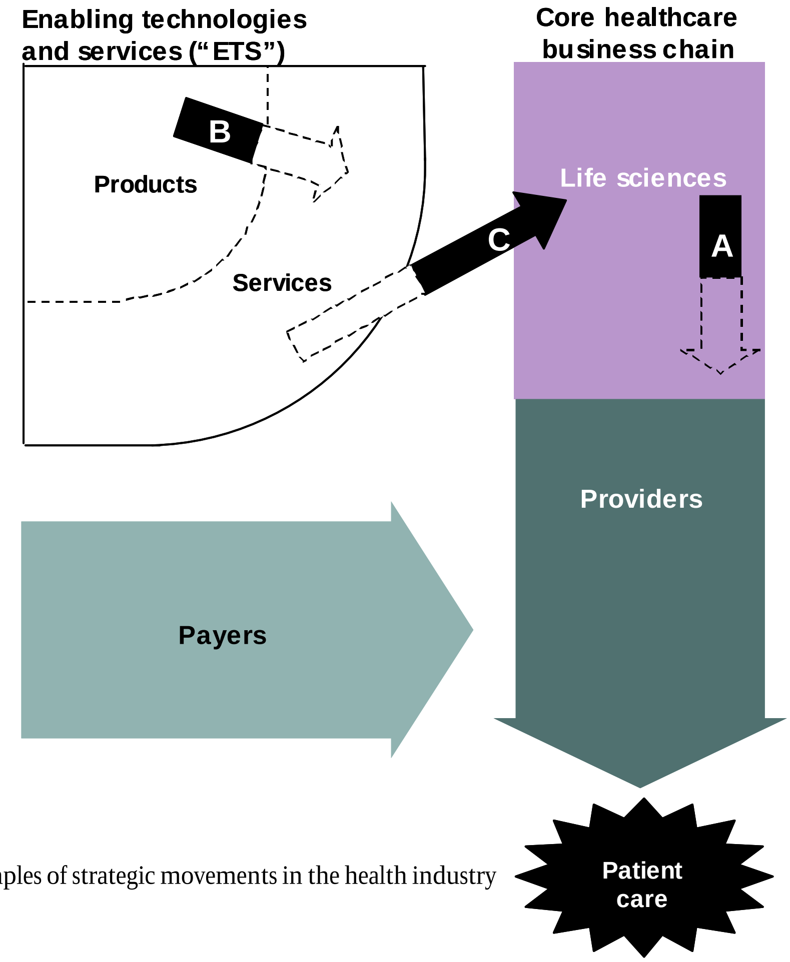

Figure 3: Examples of strategic movements in the health industry

Using this framework, each potential strategic option can be seen as a migration, contraction, or expansion along one or both dimensions in the diagram. For example, a biotechnology company focused on early stage drug discovery could decide to develop its manufacturing or sales and distribution skills, thereby expanding in a downward direction in the framework (see **Figure 3, arrow A**). Alternatively, a company that develops DNA chips could start offering chip design services directly to the discovery companies, thereby expanding into the service segment toward the right of its current position in the framework (see **Figure 3, arrow B**). Companies can also decide to move out of specific segments, as when a fully integrated pharmaceutical company spins out its pharmacy benefit management units (an enabling service for healthcare providers), focusing its activities on the life sciences segment (see **Figure 3, arrow C**).

To execute movements, contractions and expansions in the industry, companies have a wide range of strategic and tactical options available to them. Some of these options help a company to expand its business, either by strengthening current activities or by moving into new market segments. Other options help the company to refocus its activities and move out of businesses that are no longer attractive or which do not leverage the company's core competencies. Some examples of the different "vehicles" used to pursue or exit strategic initiatives are listed below.

Pursue growth:

- *Organic growth* – grow a new or existing product, service or market segment without the aid of mergers, alliances and acquisitions, perhaps using revenues from an existing business line to subsidize a new one

- *Partnership / joint venture* – grow in a particular segment through close cooperation with another industry participant

- *In-licensing* – strengthen or expand capabilities or product offerings by obtaining a license to use or sell products and services

- *Acquisition* – move into a new segment or strengthen an established position by acquiring another entity

- *Merger* – combine forces with another entity to capture synergies and consolidate market positions.

Focus strategy:

- *Wind down* – cease producing particular products or abort specific service activities

- *Out-licensing* – effectively move risk and returns of specific products to another company.

- *Outsourcing* – contracting out specific business functions to third parties

- *Divestiture* – sell a business unit or specific product line to another entity

- *Spin-off or carve-out* – separate a business unit and give it greater independence from its parent through a stock offering, usually with the parent retaining a significant stake in the business.

- *Sell company* – sell the entire company to another entity

None of these strategic or tactical options is necessarily optimal in all situations; rather, a company must weigh the totality of facts and circumstances in deciding which options will best enable it to achieve its objectives. This process can be complex and time-consuming, and management teams can better use their time by executing on a focused business plan rather than engaging in a distracting process to consider and explore other options.

Because of the need for management to focus on execution, companies often turn to outside advisors for both objectivity and support in making such decisions because some of these decisions can involve "bet the company" considerations. An investment bank can aid a management team in identifying key objectives, weighing strategic options for achieving those objectives, and implementing a tailored process to achieve a timely and favorable result, whether in a merger, acquisition, divestiture, restructuring, or joint venture.

ABOUT RCW MIRUS

Founded in 1987, RCW Mirus is a middle-market investment bank headquartered in Boston, Massachusetts. With a track record of over 100 completed transactions, the firm works exclusively with companies and business units in the middle market (ranging from $5 million to $150 million) across a wide variety of industry sectors, including healthcare, IT services, software, manufacturing, consumer products, and others. By leveraging a time-honored set of processes, a proprietary database of acquirers, investors, and targets, and an unwavering commitment to client satisfaction, Mirus can assist companies in the life sciences, healthcare provider and payer, and enabling technology and services industries. Interested parties are invited to explore Mirus's web site at www.merger.com or to contact David Hoffer at hoffer@merger.com.

Mirus is a registered broker-dealer and NASD member.

Footnotes:

[1] Drug Costs are Up Because We are Medicating More, National Center for Policy Analysis, http://www.ncpa.org/pi/_health/pd112700d.html

[2] Institute of Medicine, "To Err is Human: Building a Safer Health System", November 1999, http://www.iom.edu/iom/iomhome.nsf/

[3] Simon Hughes, "Increasing Productivity Through eR&D", Pharma R&D Directions, Barcelona, Spain, 2001, http://www.pwcglobal.com/gx/eng/about/ind/pharma/index.html

[4] Source: VentureOne (http://www.ventureone.com/ii/Financing2Q02.xls)