PROBLEMS & CASES IN HEALTH CARE MARKETING

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Preface

By almost any measure, health care is big business. In 2001, spending on health care in the United States totaled $1.4 trillion—almost 15 percent of the nation's gross domestic product. Within a decade, experts estimate that this spending will grow to $3 trillion, or 20 percent of the nation's GDP. Worldwide, these numbers are even more staggering as Latin America, Africa, the Middle East, and Southeast Asia deal with the health ravages of AIDS, malnutrition, and internal conflict.

In the United States, the health care system is at a delicate juncture. Life expectancy, overall quality of care, and likelihood of recovery from disease are all at historic highs. The average American is now expected to live to the age of 76.9 years, up from 62.9 years in 1940. Infant mortality rates have decreased by 75 percent over that same period. And the likelihood of surviving a heart attack has increased by one-third since the 1950s.

Yet, these improvements have come at an ever-increasing cost. Across the board, current health care costs are rising at three to four times the rate of inflation. Annual corporate health insurance premiums now regularly exceed $5,000 per employee, forcing employers and health care providers to shift more of the insurance burden on those being insured. Prescription drug costs exceed $150 billion and are growing at more than 15 percent per year. And the United States General Accounting Office estimates that by 2050 two-thirds of the federal budget will be spent on health care.

Underlying these figures are a host of sometimes conflicting trends. These include an aging U.S. population. In 2000, the 35 million people age 65 or over accounted for 13 percent of the American population and 33 percent of all health care spending. By 2020, this figure is expected to increase to 55 million, or 20 percent of the American population. Another trend is the declining state of health care research productivity. In 2001, U.S. pharmaceutical firms spent in excess of $30 billion on new drug development, more than in any previous year. Yet that same year, the FDA approved only 66 new drugs for sale, the smallest number of drugs approved since 1994. As a consequence, in 2002, the cost of bringing a new drug to market was estimated to be $500 million and 10 years. Finally, this lack of productivity is compounded by the industry's increasing reliance on "blockbuster drugs," leaving it vulnerable to the threat of generics. Between 2002 and 2006, over 40 major drugs with combined sales in excess of $40 billion will come off patent, opening the way for the sale of generic alternatives at a fraction of the branded price. And all of this is happening under unprecedented price pressure from the government, insurers, employers, and consumers.

Worldwide, the trends are no less dramatic, as pharmaceutical firms and health care providers struggle with the added stress of a two-tiered marketplace. Nowhere is this more evident than in the industry's response to the AIDS crisis, where developing countries cannot afford to spend even a small fraction of what more developed countries can for treatment of the disease. This has led, temporarily at least, to a global marketplace in which the very same AIDS drugs are being sold in South Africa, India, and Brazil for a fraction of the price that they are being sold in the United States and Western Europe. But even at these reduced prices, most victims of AIDS in developing countries go untreated, still unable to afford even the cheapest of care. The result? The precedents being set in the pricing of AIDS drugs around the

world are being watched closely by governments, drug companies, insurance companies, health care providers, and the general public.

All of these factors place enormous pressures on the wide range of players in the health care industry. The dozen largest and hundreds of smaller pharmaceutical and biotechnology firms, the 6,000 or more for-profit and nonprofit hospitals, the tens of thousands of device manufacturers, the over 500,000 physicians, and the myriad of distributors, service providers, insurance firms, and other players all face a complex, rapidly changing landscape. Yet, the application of sound business practice to the health care sector only recently has become a focus for management research. The cases collected for this book are an attempt to add to this effort—to shed light on the unique management and marketing challenges faced by firms in the provisioning of health care goods and services in the United States and abroad.

Part 1 of this book, "**Developing a Marketing Strategy,**" takes a look at the development and defense of a corporate strategy when investments are large, development of new products is lengthy, and the cost of errors are potentially fatal (both for the firm doing the developing and the end users doing the consuming). As the cases chosen for this chapter make clear, these characteristics create both challenges and opportunities. For the firms that manage them well, cost, time to market, and quality of product can be the means to establish and defend one's firm in an unforgiving playing field. For the firms that manage them poorly, they can prove to be one's downfall.

In **Part 2, "Developing New Products,"** we take a closer look at the challenges inherent in developing new goods and services for the health care industry. For instance, how should a drug firm think about new product development when 1 in 5,000 new drug candidates reaches market? How should a firm trade off "risk" versus "reward" in an industry where the success of a single product is often measured in the billions of dollars and where failure can lead to bankruptcy? And how should firms think about product development in an industry where customers also can be development partners?

In **Part 3,** we tackle "**Launching New Products**" and highlight the complexities of selling into the typical health care setting. As the cases outline, launching new products in the health care industry requires selling into a multilayered, buying organization—one in which doctors, pharmacists, and administrators, among others, all need to be sold on a new drug, medical device, or procedure based on widely different sets of criteria. In such a setting, how do you change entrenched behavior, as typified by that doctor or that hospital that has been treating a disease or using a particular drug for decades? How do you promote the replacement of a $5 solution with a superior $300 solution? And, if you are a start-up, how do you do all of this with very limited resources?

Part 4 brings us to the challenges of "**Managing Distribution,**" where we explore the dual pressures of minimizing cost, but fostering strong channel partners. For instance, what roles do channel partners have in the distribution of medical products and what incentives are provided for them to play these roles? How should firms think about forward and backward integration in markets where price and quality are increasingly critical to a firm's success? And how does modern technology, such as the Internet, change the way firms think about satisfying demand for medical goods and services? Across the board, as cost pressures increase, as new markets are being opened up and

as distribution technology advances, the channel structure for firms in the health care industry are being redefined. How should firms leverage these changes?

In **Part 5,** we address the increasingly complex question of "**Managing Communications.**" With the advent of direct-to-consumer advertising in the pharmaceutical market and the increased visibility of everything from hospitals to device manufacturers, a growing focus on marketing communications is clearly evident. Whether it involves the promotion of new drugs, the transition of a prescription drug to an OTC drug, the position of a community hospital among other treatment facilities, or the adoption of new forms of birth control, the goals are often the same—to effectively and efficiently reach the critical decision makers. How best to do this are explored in the cases selected for this part of the text.

Part 6, "Managing the Brand," investigates the concept of branding in the health care domain. Long a favorite topic in the marketing of consumer packaged goods, consumer durables, and the service industry, the concept of "managing the brand" is no less important for drug companies, device manufacturers, health care providers, and hospitals. Here we take a look at the challenges of developing and managing a brand in the health care arena. For instance, what types of consumers is a firm looking to attract and not attract? What image is the firm looking to convey to those consumers? How does a firm differentiate itself when it is first to market? What if it is later to market? These and other questions go a long way toward determining the salience of the brand in the minds of consumers, a critical factor in a market where a 5 percent shift in share can translate into several hundred million dollars in revenue.

Finally, in **Part 7,** we take a look at the challenges of "**International Marketing,**" where we compare and contrast the provisioning of health care in the United States and Western Europe with that of the developing world. In particular, what roles and responsibilities does the health care industry have in places like South Africa and India? And how can the industry balance the basic needs of developing nations with the increasingly customized demands of the well-to-do? Few industries possess the moral dilemmas inherent in the rationing of health care services between those who can pay and those who cannot.

As is the nature of case writing, asking and answering these questions has proven to be a collaborative effort. First, we are deeply indebted to all of the companies and executives who provided us access to their practices, insights, and efforts. Without them, these cases would never exist. Second, we are grateful to our many colleagues who have given their permission for the use of their cases in this text. These include Ernst Berndt, Frank Cespedes, John Deighton, Robert Dolan, Charles King, Lisa Klein, Melvyn Menezes, Michael Roberts, Al Silk, Debora Spar, and Stefan Thomke. Next, we recognize the invaluable contributions of our research assistants, without whom these cases would be much the poorer. Finally, we thank the support of our employer, the Harvard Business School, which has allowed us the freedom and resources to pursue the type of research that motivates us greatly.

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Chapter 1

Millennium Pharmaceuticals, Inc. (A)

Stefan Thomke and Ashok Nimgade

"Great meeting" were the words echoing in the halls of Millennium's new headquarters in Cambridge, Massachusetts, as a dozen people in business suits swarmed out of the meeting room, shaking hands and slapping backs. Their dark suits contrasted sharply with the daily informal wear at the fast-moving biotechnology firm where even the CEO often appeared in loud Hawaiian shirts. Six of the meeting participants representing the European agribusiness conglomerate Lundberg had flown in by private plane. Their eagerness to access Millennium's genetic technology for agricultural applications showed throughout the meeting. The proposed alliance enjoyed support from the very highest levels at Lundberg; in fact, C. Marie Lundberg, heiress to the closely held family business and a senior vice president herself, had attended this August 1999 meeting.

The real question, however, that CEO Mark Levin pondered was the amount of middle-level support from Lundberg for the deal. Although no specific amount of money had been discussed, both sides remained aware that since 1993, Millennium had graduated to multi-hundred-million-dollar technology and drug discovery deals. The firm was currently involved with a half-dozen technology and pharmaceutical deals worth over a billion dollars. In fact, even without a single drug even close to clinical development, just on the basis of its technology and drug discovery deals alone, Millennium had broken into the ranks of the top biotechnology firms. Just one year ago, it had created history by signing a half-billion-dollar alliance with the German multinational company Bayer AG—the largest deal ever between a biotechnology and a pharmaceutical firm.

Professor Stefan Thomke and Research Associate Ashok Nimgade prepared this case. HBS cases are developed solely as the basis for class discussion. Cases are not intended to serve as endorsements, sources of primary data, or illustrations of effective or ineffective management.

Over the past year, Millennium's stock had skyrocketed, creating unexpected fortunes for its staff, which received part of its compensation as stock options. But continued performance on Wall Street meant pleasing both investors and analysts who wanted to see the company continue its highly successful alliance stream (see Exhibit 1.1 for financials). Already many biotech firms were starving for money and a clear sense of strategic direction.

Although the firm attracted some of the world's leading human genetics experts, it viewed itself as operating in a much larger context; in the words of its CEO and founder Mark Levin, "I never thought of Millennium as just a technology company." Millennium, in fact, sought to break into the ranks of the giant pharmaceutical firms. And it planned to do so by revolutionizing drug development—a process as notoriously lengthy as it was unpredictable. As Chief Technology Officer Michael Pavia, Ph.D., outlined his vision, "Developing drugs ought to be managed like any other complex development process; some day, we will make it as predictable as developing and making automobiles." To accomplish this vision would require time and a lot of cash.

The Biotechnology Revolution(s)

In the mid-1970s, stunning biological breakthroughs set the stage for the modern biotechnology industry. Scientists could now cut and paste snippets of deoxyribonucleic acid (DNA), the blueprint of life and the longest known molecule in the universe. In fact, if all the DNA in any given human cell were laid end to end, it would span over a meter across. Since there are trillions of cells in the human body, all of the DNA in a given adult would easily stretch from earth to the sun and back, *several times over.* This provides just one index of the complexity of the human body. Each second in the body, millions of basic compounds are being synthesized and thousands of interrelated biochemical reactions occur. These all rely ultimately on the accuracy with which DNA in each cell is being deciphered to create proteins, vital building blocks of the body. A small misstep virtually anywhere in these processes can potentially result in morbidity and mortality.

By gaining the power to revise DNA and create new protein products, biologists in the laboratory could more precisely manipulate the primary biological molecules of life. In the 1970s and 1980s, commercial possibilities for the new technologies were seen well in advance of the ability to deliver on them. In these decades, Wall Street and individual speculators poured millions of dollars into new biotech firms, often even without the faintest idea of what differentiated a gene from its homonym.

Part of the excitement stemmed from the fact that the traditional way of finding cures for diseases was extremely effort-intensive and expensive. Large pharmaceutical companies spent up to 15–20 percent of sales in R&D. In the United States, as part of an extensive, highly regulated safety approval process, each drug had to pass three phases of clinical trials under the scrutiny of the U.S. Food and Drug Administration (FDA): Phase I, which tested clinical safety; Phase II, which assessed drug efficacy; and Phase III, which tested adverse effects from long-term use. For each successful product the sponsoring drug firm typically spent more than $230 million, with the average time to market being 14.8 years—over twice as long as it took the U.S. space program to get a man on the moon. (See Exhibit 1.2 for a description of drug development.)

Metaphorically, drugs were molecular-sized "keys" that had to fit "locks" or targets; chemists were the locksmiths. Indeed, they were effectively semi-blind locksmiths, for they had to make up thousands of different keys to find the one that matched. Newly synthesized molecular keys were then tested by biologists, typically using ani-

mals that served as models for a disease (for example, a mouse with a neurological problem similar to Parkinsonism). Most compounds would show no activity or be too toxic for further evaluation. A few, however, might show promise, and chemists would modify these "lead compounds" until a good clinical candidate emerged. Typically, for each successful drug that made it to market, a firm began with roughly 10,000 starting compounds. Of these, only 1,000 would make it to more extensive *in vitro* trials (i.e., outside living organisms in settings such as a test tube), of which 20 would be tested even more extensively *in vivo* (i.e., in the body of a living organism such as a mouse) before ten compounds made it to human clinical trials. The entire process represented a long and costly commitment, with the human trials closely monitored by the U.S. government.

Biotechnology, by promising a shortcut through the cumbersome and risky drug development process, promised investors wealth. It attracted entrepreneurs and maverick scientists. The hub of biotech activity was near academic centers like San Francisco and Cambridge (some observers even transformed the old Boston-Cambridge moniker "beantown" into "genetown"). In the 1980s the guiding principle behind quicker drug discovery was "rational drug design." By finding out about the disease-causing receptor in the body on which a potential drug compound acts, scientists hoped to make better compounds. The analogy would be to find out about key features of a lock before designing a properly fitting key rather than a brute force strategy of making keys at random with the hope that one might eventually fit.

But rational drug design often turned out difficult to implement because of the subtle complexities of biological systems and the difficulties of finding the right receptors. In fact, the biotech industry generally disappointed investors in the 1980s partly because of the hype, and partly because biotechnology firms were not large enough to absorb the high rate of failures in drug development. A crushing blow to a biotech firm might be absorbed like a gnat's sting by a pharmaceutical firm. The crushing blows, unfortunately, came usually late in the drug development process during human clinical trials, after considerable investments of time and money had been made. Following announcements of negative human clinical trial outcomes, stock prices for biotech firms dipped by an average of a third—quite often they remained depressed for the following half-year.[1] Thus, even with the newest technologies up their sleeves, small biotech firms often played David to the pharmaceutical Goliaths, with a few exceptions such as the California firm Amgen.

Here, however, biblical parallels end, for most biotech upstarts wanted nothing more than to become fully integrated pharmaceutical giants themselves. But after more than a decade of inflated promises made by biotech firms, investors became increasingly wary. Biotech firms established primarily for product discovery often disappointed investors. As a result, many biotech firms were forced to form partnerships with pharmaceutical firms or even merged with one another.

In the 1990s, the nascent fields of "combinatorial chemistry" and "high throughput screening" breathed new life into the industry by allowing scientists to create and screen prodigious numbers of novel compounds. Returning to the lock-and-key metaphor, scientists could now churn out keys by the thousands and test them almost equally rapidly. Drug companies, however, would still need to muster as many biochemical tricks as they could to identify worthwhile pharmaceutical "targets" (the industry parlance for the "locks" in the lock-and-key metaphor).

While technologies evolved, so did industry dynamics. Biotech firms in the late 1990s wove more intricate alliances with their pharmaceutical partners, often leveraging these

[1] G. S. Burrill, *Biotech 98: Tools, Techniques, and Transition* (San Francisco: Burrill & Co., 1998).

relationships to gain access to Wall Street money and gaining downstream synergies for manufacturing and marketing infrastructures. The giant firms, in return, gained access to emerging technologies that could often be protected; furthermore, they could add to their product pipelines. For a pharmaceutical giant with $10 billion annual revenues to continue growing at 10 percent a year would require three to four new products a year (a typical product generating $300–$400 million annually). Even more would be needed to cover drugs going off patent. With internal pipelines producing less than one significant product a year, big firms increasingly needed to partner with smaller firms.

Many newer generation biotech firms began emphasizing sales of drug development technologies more than pharmaceutical products. These firms, sometimes termed "tool companies," hoped to generate revenue faster by providing services to drug discovery companies, thus avoiding the high cash "burn-rates" involved in searching for drugs. Many of these firms developed multiple relationships with different drug firms, thus blurring the line between sales and strategic partnerships. By the late 1990s, two decades into the biotech revolution, about 300 biotech-based drugs were on the market, and nearly 450 were in clinical trials.[2] These seemingly impressive numbers paled in comparison to the over 1,300 biotech firms actually in existence. The year 1997 saw 228 new biotech-pharmaceutical collaborations, valued at $4.5 billion.[3] Those biotech firms unable to create products or merge with other companies often foundered, leaving their investors holding worthless stock. In such an environment, pharmaceutical firms could often "cherry-pick" drug candidates from financially troubled smaller companies. Only a half-dozen U.S. biotech firms had marketed major drugs without selling majority stakes to pharmaceutical firms. Of these, only Amgen, a California firm with a market valuation of over $30 billion, had emerged as a major drug company with very successful drugs. Onto this sea of broken dreams and treacherous regulatory currents Millennium set sail in 1993.

Birth of a New Millennium

When Mark Levin interviewed early in his career at the pharmaceutical giant Eli Lilly without socks, his staid recruiters thought him "a little weird." Even as CEO, he continued raising eyebrows, taking family outings to the local horse racetrack, and appearing annually at Millennium Halloween parties in drag—in a recent year he appeared, wife and daughter in tow, dressed as a French maid in a low-cut dress. Photographs of Levin in any of his large collection of colorful shoes, including zebra-patterned, adorned investor publications.

A one-time Midwestern shoe salesman and former donut shop owner, Levin leveraged his training in chemical engineering to climb his way out of small-town obscurity. After helping start up a beer-brewing plant and getting exposure to the pharmaceutical world through Lilly (he did get the job), Levin quickly found his niche in the emerging biotech industry of the early 1980s. While working for Genentech, the pioneering California-based biotech firm, Levin's brilliance in managing complex projects won him a job at Mayfield Fund, a San Francisco venture capital firm. Here Levin founded some 10 biotech firms—serving as interim CEO of five. His crown jewel, however, proved to be Millennium Pharmaceuticals (see Exhibit 1.3 for historical milestones).

[2] D. Stipp, "Hatching a DNA Giant," *Fortune,* May 24, 1999.

[3] Burrill, *Biotech 98.*

Levin's concept for Millennium proved so new and strange that an extensive executive search concluded that only Levin could head up the proposed company. According to Grant Heidrich, general partner at Mayfield, Levin "has tremendous vision for what is looming out there. For most people, there are those elements that are hidden in the fog bank. But Mark finds these disconnected pieces and just pulls them together."[4] The plan was to build a drug development company around findings emerging from the Human Genome Project, an ambitious international effort to identify and map every bit of human DNA (which in its entirety is termed the "genome").

Genes causing disease could prove potential targets for drug development. These targets could then be used to develop families of new drugs the world has never seen before. Mapping the human genome "may be the most important step we've taken in science," according to Nobel laureate James Watson, co-discoverer of the DNA structure.[5] Since every disease has a genetic component, deciphering the "Book of Life," as some scientists refer to the genome, promised to revolutionize medical research over decades to come. Even if only 5–10 percent of all estimated 30,000 to 100,000 human genes would yield viable drug targets, it could still open up a rich lode of pharmaceutical drug leads. For the past 100 years, after all, the painstaking efforts involved in drug research had limited medicines developed to less than 500 targets. Even several decades after Watson and Crick discovered the structure of DNA, scientists of the 1980s took years to find and sequence just a single gene or a stretch of DNA of particular interest. For drug companies in 1999, the new revolution could not have been better timed because patents on some 30 major drugs were to expire in the next three years, placing pressure to add to the product pipeline.

With this vision in mind, starting in 1993 with $8.5 million in venture capital funding, Levin set up the company in Cambridge, Massachusetts, in order to court the nation's leading genome scientists. Even without a written business plan or formal organizational charts, Levin sold his vision for a new Millennium well. "The reason spectacular scientists want to come to Millennium is that spectacular scientists work at Millennium," according to Professor Eric Lander, a scientific founder of Millennium and himself one of the leading genome experts in the world, "Mark saw that from the beginning."[6] Levin and his team leveraged off the star scientist reputations to raise large amounts of funding with which to create far better research facilities than even the finest universities.

The firm's roster of brilliant technologists included its Chief Technology Officer, Michael Pavia, a pioneer in the combinatorial chemistry revolution. Pavia wanted to leverage the lessons he learned as former head of research at Sphinx Pharmaceuticals, another Cambridge-based biotech firm that was acquired by Eli Lilly, and also wanted to take part in the next revolution: that of transforming the drug development process itself. Millennium also recruited top businesspeople and legal counsel, some of whom were high-performing mavericks in larger pharmaceutical firms and many of whom had nontraditional backgrounds. The company's Chief Business Officer, Steven Holtzman, for instance, is an Oxford-trained Rhodes Scholar whose philosophy training in making fine distinctions helped craft partnership deals that left Millennium with sizable shares of finely cut pies.

Senior management strategically highlighted technology development from the very start. Levin and Holtzman wanted to avoid the mistakes of other biotech firms,

[4] K. Blanton, "Millennium's Chief Found His Calling Starting up New Biotechnology Firms," *Boston Business Journal,* December 5–11, 1997.

[5] A. Zitner, A. Saltus, and R. Saltus, *The Boston Globe,* September 26, 1999, p. 1+.

[6] Blanton, "Millennium's Chief Found His Calling."

which often found themselves stranded in the vise of big pharmaceutical firms because of not having resources to market drug compounds or not having a broad enough technology platform to avoid becoming research boutiques. If risk diversification for a biotech firm proved difficult on the basis of different products, then at least it should occur on the basis of leading-edge technologies.

The initial vision of Millennium was to marry molecular biology with automation and informatics. This would allow for discovering and processing huge amounts of information about genes, making thousands of new targets possible. A dramatic increase in targets would also require quicker screening technologies in order to test many more compounds. Proprietary lab technology included software for analyzing gene function, and machines that decode DNA sequences. Harking on Levin's background as a chemical engineer with work experience in process control, the *Economist* noted:

> Whereas biologists tend to see biotech as the search for a compound, Mr. Levin thinks of it as a complex production process. While they concentrate on the bio, he also thinks hard about the technology. Mr. Levin focuses on trying to make each link in the discovery chain as efficient as possible. . . . He has assembled an impressive array of technologies—including robotics and information systems as well as molecular biology. He then enhances them and links them together in novel ways to create what the engineer in him likes to call "technology platforms," [which] should help drug searchers to travel rapidly on their long and tortuous journey from gene to treatment. And Mr. Levin is prepared—keen, even—to use or buy other people's technology to help in the struggle to keep up to date. One observer has called him the "Mao Zedong" of biotech, a believer in continuous revolution in both technology and organization.[7]

By creating a technology platform considered the finest available, the firm generated capital for updating the platform to keep ahead of the competition. Biotechnology promised a shortcut for finding cures for human genetic diseases. It allowed for skirting the traditional time-consuming study of family trees of diseased individuals in order to track down the responsible genes. Since these genes could be anywhere along the vast expanse of human DNA, some firms tried to take advantage of rulings that allowed for filing patents on naturally occurring gene sequences as fast as they could find them. "The important thing is to get California instead of Appalachia" in this pharmaceutical land grab, according to Millennium executive John Maraganore.[8] To find these prime pieces of genetic real estate, researchers analyzed hundreds of gene sequences simultaneously using miniature "DNA probes" that could ferret out promising stretches of DNA. These probes were derived through research on DNA samples from people suffering from diseases of particular interest.

Not only could a gene sequence be patented, but also the specific protein produced by that gene as well as the engineered drug produced by splicing the gene into a microbe for production could be. In addition, patents could be filed for the use of the gene in diagnostics tests as well as in drugs targeted at the gene. By 1999, although every large drug company had incorporated combinatorial chemistry into its R&D arsenal, such was not the case with genomics. In April 1999, several large drug companies including the two giant firms Glaxo Wellcome and Bayer AG started a collaboration to locate tens of thousands of areas on the genome that may be implicated with disease and put these in the public domain.[9] Skeptics view this as an effort of the Goliaths to thwart growth of the biotech Davids.

[7] "Millennium's Bugs," *Economist,* September 26, 1998, p. 70.

[8] Stipp, "Hatching a DNA Giant."

[9] I. Amato, "Industrializing the Search for New Drugs," *Fortune,* May 10, 1999.