

The Future of Pharmaceuticals

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EXECUTIVE SUMMARY

Introduction

In the next five to ten years, the pharmaceutical industry will begin to experience major changes. Advances in biological and genetic sciences and the increasing power of the consumer in the health care marketplace will be the primary drivers of these changes. The revolution in science will transform the pharmaceutical marketplace; there will be changes in what companies can offer and what consumers—patients, doctors, and payers—can expect to receive. Advances in science, coupled with increased consumer demand for pharmaceuticals and passage of legislation allowing companies to market products directly to consumers, already have begun to transform the landscape for pharmaceuticals.

Two broad themes emerge in the pharmaceutical marketplace of the future: an increase in the segmentation of products and markets, and the importance of relationships. Advances in science will allow innovative new drugs to treat specific populations based on their genetic makeup. Industry will deliver these drugs to people based on their preferences and will tailor specific treatment regimens supporting their lifestyles and behaviors. Consumers will receive highly targeted and specific marketing messages based on their use of technology, health status, ethnic and racial background, gender, age, and interests and activities.

As a result of this segmentation, the relationships maintained by players up and down the supply and demand chains—among pharmaceutical companies and their suppliers, their customers (both patients and providers), and public regulatory agencies, as well as between patients and their providers and health plans, to name just a few of the permutations—will become more important to the success of all parties, both

individually and collectively. Partnering with consumers and providers will allow the industry to advance to its next phase of providing more targeted and appropriate health care by helping pharmaceutical companies learn more about their customers. If consumers see that their personal information is going to be misused—for example, to deny them health insurance because they are predisposed to certain diseases, or to be sold to the highest bidder—they are unlikely to cooperate and all the science in the world won't convince them otherwise.

These two themes—the segmentation of the market and the importance of relationships up and down the supply and demand chains—weave their way through five specific forecasts.

Science: Advances in Science Will Transform the Pharmaceutical Marketplace

Science marches to the beat of its own drum, constrained somewhat by discussions of ethics and application, but driven by the desire for discovery and new knowledge. Science will continue to push the envelope of pharmaceutical knowledge by applying discoveries in information technology, biotechnology, and genomics to create new, more efficient ways to discover, develop, deliver, and monitor drugs. As more and more varied drugs are discovered, however, approval bottlenecks are likely to develop, slowing, but not halting, the miracles of science.

The mapping of the human genome is the significant initial step into this new era of drug discovery and development. The deeper understanding of proteomics (the study of how proteins are coded for and expressed and how they interact with other molecules) and functional genomics (the study of how genes and their products interact with each other and the environment) resulting from this mapping will promote revolutionary research and development in the pharmaceutical industry. Proteomics and functional genomics will define new proteins and their functions, and identify interactions with other genes and gene products.¹ A decade from now, structural and functional understanding of new and existing chemical entities, such as proteins, will inform the development of highly targeted—even individualized—pharmaceutical treatments, with fewer adverse effects. No longer will one drug fit all.

These developments will erode the markets of traditional pharmaceutical companies, and those companies that don't adapt to the new market conditions must reinvent themselves or they will likely suffer over time.

Industry: Competitive Pressures Will Force the Pharmaceutical Industry to Strengthen Relationships

Due to advances in science and escalating demands from consumers, the pharmaceutical industry is growing increasingly competitive, and the old ways of doing business are becoming less effective. Strengthening relationships up and down the supply chain will be a critical strategy for pharmaceutical companies to succeed in the market of the future.

Competition to make the most of advances in science and technology and to bring new products to market already is causing big pharmaceutical companies to focus on their relationships with both suppliers and consumers. Between 2000 and 2010, nearly \$53 billion in sales will be vulnerable to generic competition.² Even now, pharmaceutical companies are beginning to worry about how they will fund the research and development necessary to incorporate advances in science and technology as many blockbuster drugs go off patent. No longer can they succeed by being the self-contained monoliths of the 1980s and the 1990s, conducting everything from research to marketing internally. The traditional pharmaceutical markets will grow more and more segmented as science allows companies to tailor product offerings to individuals based on their genetics, preferences, and lifestyles. Furthermore, pharmaceutical company product offerings will diversify to include complementary and alternative medicine products, food products, information, and services that help people maximize the benefits of new drugs. In short, pharmaceutical companies will be required to do more than simply develop and sell pharmaceuticals to a receptive mass market.

To compete in this new world, pharmaceutical companies will do less of their research in-house and instead will pursue strategic partnerships by means of mergers, acquisitions, contracts, and licensing

agreements. In addition to their traditional physician marketing channels, they will also continue to reach out to consumers more directly. Information technology is expanding opportunities for the pharmaceutical industry to distribute targeted messages to a broad public and to engage consumers and patients more directly with information about health, wellness, and new products. They will deliver this information through a mixture of broadcasting and “narrowcasting” techniques, and will include traditional media such as TV and printed publications. In ten years’ time, the pharmaceutical industry and its products will look very different, concentrating more on bringing drugs to market as part of a complete health package and leaving more of the bench research to smaller laboratories that are capable of the focus required of that discipline.

Regulation: The Food and Drug Administration and Other Agencies Will Have New Regulatory Responsibilities

The Food and Drug Administration will continue to be the primary regulator of pharmaceuticals in the United States, but as the influx of nutraceuticals, functional foods (foods for which a health benefit claim can be made), and complementary and alternative medicine products makes the market more complex, and pharmaceutical companies conduct more extensive direct-to-consumer marketing, the Food and Drug Administration will come to share monitoring responsibilities with nonhealth agencies such as the Federal Trade Commission. New products arising from advances in science and the trend toward direct-to-consumer marketing will drive the Food and Drug Administration to expand its scope to regulate products after they have entered the market. These new regulatory responsibilities for monitoring drugs and medicinal products will require increased capacity, including more people and more extensive training, all of which will require greater funding from the government.

Consumer Demand: What Consumers Want, Consumers Will Get

The aging of the U.S. population, sophisticated consumers' increasing awareness of treatment options, and expanded expectations about the efficacy of drugs will all lead to increases in the demand for new pharmaceutical products. Other factors influencing demand will include a moderate Medicare drug benefit that will provide some, but not all, necessary drug coverage for seniors, and patients' larger out-of-pocket payments for drugs through multitiered benefits packages. The consumer market for drugs will be segmented by personal characteristics, including ability to pay, health status, health literacy, and, eventually, genetic profile. This segmentation of the population will guide treatment decisions and shape the demand for new and existing pharmaceutical products through 2010.

Payment: With Higher Pharmaceutical Costs Will Come Increased Tiering of Consumers

Drug prices and overall expenditures for drugs are increasing, and this trend will persist through 2010. By 2010, the availability of targeted drugs, consumer demands for access to these new treatments, and the increasing costs of drugs will lead to more complex insurance benefits and greater consumer involvement in treatment decisions about the choice of drugs.

As expenses for drugs mount, payers will shift costs onto consumers, creating tiered benefits that cover the drugs differently by price. Insurers will design multitiered benefits packages that segment consumers based on their ability and willingness to pay for access to different drugs. A simple two-tiered drug benefit will have a smaller copayment for the payer-preferred drug (preferred either because of a lower cost or a greater efficacy) and a larger copayment for more expensive or nonformulary drugs. Wherever possible, lower-cost generics will be substituted for more expensive brand-name drugs, and consumers will be asked to pay the difference if they want the

brand-name products. As the market for pharmaceuticals separates consumers by their ability and willingness to pay for drugs, issues of ethics and equal access to necessary health treatments will be discussed in public policy debates.

Conclusion

The story for the future of pharmaceuticals lies in how the trends forecasted in this report—revolutionary innovation in science, business models changing to leverage scientific advances, regulatory shifts to adapt to the new products, increasing costs and tiering of benefits, direct-to-consumer promotion we can only begin to fathom, and consumer demand for drugs—converge to shape the market for pharmaceuticals in the future.

Endnotes

¹ Agnew, B. When pharma merges, R&D is the dowry. *Science* (March 17) 2000; 287. Herrera, S. Functional genomics makes drug discovery cheaper and faster, reinvigorating all of biotech. *Red Herring* (December 4) 2000. Voss, D. Upstream: Protein chips. *Technology Review* (May) 2001.

² Food and Drug Administration *Orange Book*; Banc of America Securities.

INTRODUCTION

Where Pharmaceuticals Meet the Market

In the next five to ten years, the pharmaceutical industry will begin to experience major changes. Advances in biological and genetic sciences and the increasing power of the consumer in the health care marketplace will be the primary drivers of these changes. These two powerful drivers will trigger other transformations throughout the supply and demand chains for pharmaceuticals: a reorganization of corporate structures and strategies, a shift in responsibilities for regulating drugs, and a rethinking of how drugs will be marketed and paid for.

Advances in science—including decoding the human genome and introducing new technologies for faster, much more specific, large-scale investigation, processing, and analysis—are enabling the biotechnology and pharmaceutical industries to create new ways to discover, develop, and deliver drugs. In the future, computer-based drug discovery and clinical trials conducted almost entirely via computer models will be the norm, not the exception. Pharmacogenomics (the science of increasing the effectiveness of drugs and minimizing their side effects by matching drugs to people according to their genetic makeup) and such advances in computerized modeling will mean that scientists will be able to create drugs that are not only more effective and have fewer side effects but also are personalized for an individual at the genetic level.

This revolution in science is promulgating tremendous changes throughout the pharmaceutical marketplace, changes in what companies can offer and what consumers—patients, doctors, and payers—can expect to receive. The fundamental advances in science, in conjunction with the increased consumer demand for pharmaceuticals and the passage of legislation allowing companies to market products directly to consumers, already have begun to transform the landscape for pharmaceuticals.

These changes offer many opportunities for patients and pharmaceutical companies: patients are likely to receive more effective treatments, with fewer side effects, for previously debilitating diseases such as cancer and Alzheimer's; and pharmaceutical companies will be able to sell more effective products with more spectacular outcomes. However, these transformations also pose some challenges: patients will face the prospect of wading through the rivers of health (and, specifically, drug) information now available through both traditional media and new media like the Internet; and they'll also have to figure out how to pay for these increasingly expensive drugs.

As patients learn about new drugs through direct-to-consumer (DTC) advertising and begin to demand them from their doctors, institutional payers, such as health insurance companies and employers, will resist rising drug costs and annual double-digit spending increases.

Because the new drugs won't have the broad applicability of today's blockbusters, pharmaceutical companies will have to balance their pipelines, selling these more customized drugs even as they continue to sell blockbusters and hoping for enough return on investment to continue their long tradition of groundbreaking research and development (R&D), either internally or by partnering with smaller research labs.

Throw into this mix the fact that complementary and alternative medicine (CAM) products such as glucosamine and ginkgo biloba are becoming more and more popular, and the current marketplace becomes a tangle of new trends and competing interests.

How will these trends play out in the future? What will the pharmaceutical marketplace look like in 2010?

Two broad themes emerge. Though more drugs will be sold in general, some will be sold to narrowly defined groups. As a result, the markets for these drugs will become more segmented, and it will take greater marketing efforts and better communication with customers for pharmaceutical companies to find and reach these markets. Pharmaceutical companies will have to balance their narrowed focus with a continual effort to find drugs with the broad applicability of blockbusters.

Furthermore, because of this segmentation, the relationships maintained by players up and down the supply and demand chains—among pharmaceutical companies and their suppliers, their customers (both patients and providers), and public regulatory agencies, as well as between patients and their providers and health plans—will become more important to the success of all parties, both individually and collectively. At the core of these relationships is the patient and consumer, who will become ever more empowered by information, especially personal information, which by the end of the decade will include genetic profiles. If these consumers come to trust that their personal information will be used to their benefit, allowing them to live healthier lives, they may be motivated to bypass the middlemen (providers) and to partner with pharmaceutical companies. Such partnering will allow the industry to advance to its next phase of providing more targeted and appropriate health care by helping pharmaceutical companies learn more about their customers. If consumers see that their information is going to be misused—for example, to deny them health insurance because they are predisposed to certain diseases, or to be sold to the highest bidder—they are unlikely to cooperate and all the science in the world won't convince them otherwise.

These two themes—the segmentation of the market and the importance of relationships up and down the supply and demand chains—weave their way through five specific forecasts.

Segmentation plays out as a theme throughout our pharmaceuticals forecast in a variety of ways. Science will allow innovative new drugs to treat specific populations based on their genetic makeup. Industry will deliver these drugs to people based on their preferences, and clinicians will tailor specific treatment regimens that support their patients' lifestyles and behaviors. Consumers will also receive highly targeted and specific marketing messages based on their use of technology, health status, ethnic and racial background, gender, age, and interests and activities, among other things. The combination of drugs people receive as part of an overall health treatment regimen will depend on their lifestyle, insurance status, willingness to pay, and genetic makeup.

Drugs no longer will be treatments with broad applicability for the whole population; what treatment a person receives, and how, will be highly individualized and based on a multitude of attributes.

Relationships are the second major theme for our pharmaceuticals forecast. Relationships among all players involved in developing, prescribing, and consuming pharmaceutical products will be of greater importance in the future. This shift will come because as markets and functions become more segmented, the strength of the relationship will color the value of the exchange. Pharmaceutical companies will outsource innovation and clinical trials processing. Companies with the greatest skills and capacity to manage their working relationships with outsourced entities will be best equipped to leverage advances in science and to protect and differentiate their new products. Industry will be collecting and analyzing intimate information about consumers and their preferences to provide valuable product and health-related information. This will require consumers to trust pharmaceutical providers to protect their information and to use it appropriately. In the highly segmented, individually targeted environment we forecast, trust will be a critical component for facilitating a segmented approach to studying patients, battling disease, and delivering drugs.

Methodology

The themes of segmentation and new relationships among the pharmaceutical industry and its customers are the guiding principles for our forecasts. In order to determine how these themes will play out, we first divided the market into supply-side and demand-side players, because both will drive any market transformations. On the supply side are science and industry; on the demand side are the consumers, who include patients, health care providers, and institutional payers. In general, regulatory agencies and government policy mediate the relationship between the supply and demand players. We then created specific forecasts for science, industry, regulation, consumer demand, and payment.

More of the Past in the Future

We created our forecasts by mapping the supply and demand sides of the pharmaceutical industry between 1900 and 2000. We created a map, entitled “History Map 1900–2000: Mapping the Supply and Demand of Pharmaceuticals,” by tracing trends in three major areas: science and industry (supply), regulation and policy, and consumers and society (demand). (See Appendix A at the back of this book or reference Special Report SR–761, Institute for the Future (IFTF), June 2001). After linking events and developments over time, we presented our Pharmaceuticals History Map to a panel of experts, who vetted it and helped us to identify its strengths and weaknesses. This enabled us to get a full perspective on social and health care trends. Using the history map and aggregated expert opinion, we created a forecast map, “The Future of Pharmaceuticals.” (See Appendix B at the back of this book or reference Special Report SR–756, IFTF, December 2001). The forecast map pulls the threads of history through the present and into the future, and integrates them to create the individual forecasts presented in this report.

The Forecasts

The pharmaceutical forecasts for 2010 are as follows:

- Science: Advances in Science Will Transform the Pharmaceutical Marketplace
- Industry: Competitive Pressures Will Force the Pharmaceutical Industry to Strengthen Relationships
- Regulation: The Food and Drug Administration and Other Agencies Will Have New Regulatory Responsibilities
- Consumer Demand: What Consumers Want, Consumers Will Get
- Payment: With Higher Costs for Pharmaceuticals Will Come Increased Tiering of Consumers

We elaborate on these forecasts in the following chapters, presenting specific forecast summaries, analyzing each in depth, and exploring the possible drivers and barriers. We follow the forecasts with a chapter on wild cards—low-probability events that would have a significant effect if they occur—before closing the report.

Chapter 1

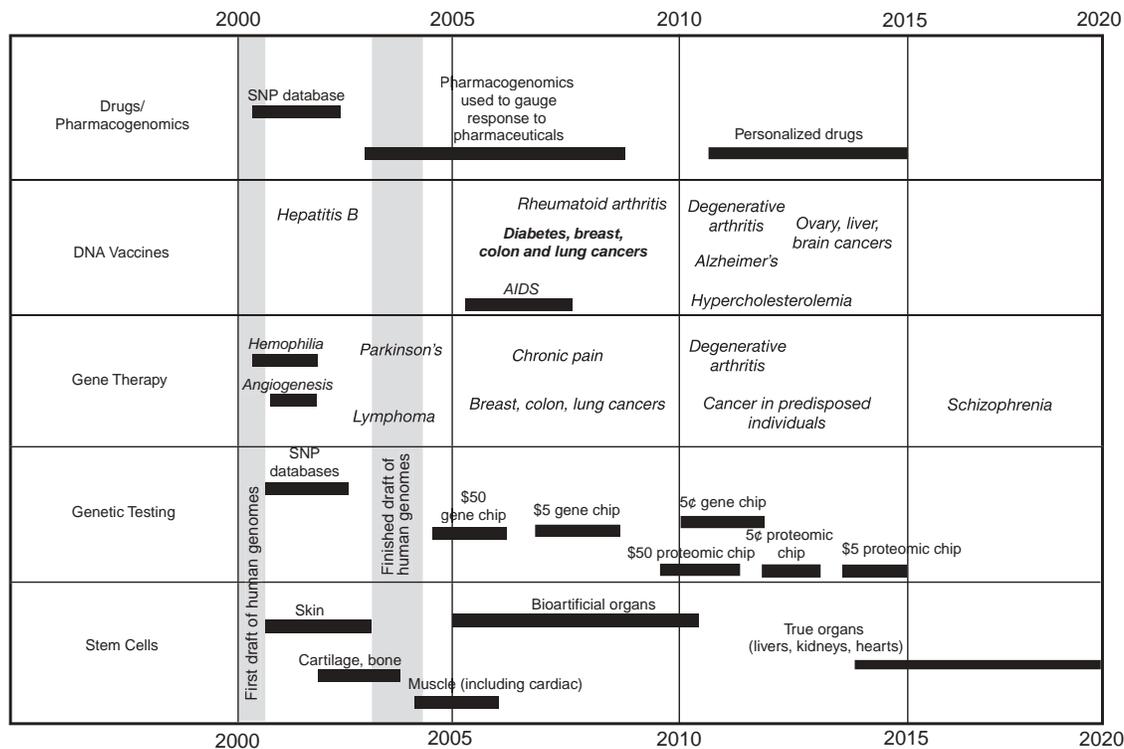
SCIENCE: ADVANCES IN SCIENCE WILL TRANSFORM THE PHARMACEUTICAL MARKETPLACE

Science marches to the beat of its own drum, constrained somewhat by discussions of ethics and application, but driven by the desire for discovery and new knowledge. Science will continue to push the envelope of pharmaceutical knowledge by applying discoveries in information technology, biotechnology, and genomics to create new, more efficient ways to discover, develop, deliver, and monitor drugs. As more and more varied drugs are discovered, however, approval bottlenecks are likely to develop, slowing, but not halting, the miracles of science.

The mapping of the human genome is the significant initial step into this new era of drug discovery and development. The deeper understanding of proteomics (the study of how proteins are coded for and expressed, and how they interact with other molecules) and functional genomics (the study of how genes and their products interact with each other and the environment) resulting from this mapping will promote revolutionary R&D in the pharmaceutical industry. Proteomics and functional genomics will define new proteins and their functions, and identify interactions with other genes and gene products.³ A decade from now, structural and functional understanding of new and existing chemical entities, such as proteins, will inform the development of highly targeted—even individualized—pharmaceutical treatments, with fewer adverse effects. No longer will one drug fit all. Indeed, beyond our forecast horizon of 2010, gene therapy will come to replace some of what we now know as traditional drug therapy, and further developments in genetic testing and nutrigenomics (the customization of diet based on genetic profile) will put more power in the hands of individuals (see Figure 1–1 on page 16).

These developments will erode the markets of traditional pharmaceutical companies, and those companies that don't adapt to the new market conditions must reinvent themselves or they will likely suffer over time. The implications of science for the transformation of the pharmaceutical marketplace are so fundamental that our science forecast provides the foundation for the rest of the forecasts in this report.

Figure 1-1
Genetics Timeline: The Pace of Change



Source: Institute for the Future.

Science Forecast Summaries

- Drug development will be increasingly sophisticated as the functions of genes and proteins are discovered and families of genes sharing pathways and functions are identified, which will enable the creation of highly specialized drugs.
- Information technologies and other tools will continue to transform drug discovery and development, though not immediately.
- Diseases will be reclassified based on their genetic and molecular profiles.
- New bottlenecks will obstruct the drug development pipeline.
- Genetic testing will affect the use and selection of drugs at the time of treatment.
- Reducing adverse events from drugs will be the first application of pharmacogenomics.
- Lack of provider preparation will slow the diffusion of genetic testing.
- Gene therapy could capture many drug markets from pharmaceutical companies by making a pharmaceutical patient a gene therapy patient.
- Newly developed and developing vaccines will change our present concept of immunization.

Drivers and Barriers

Drivers

- *New technologies and advances in genetics and genomics will drive researchers and scientists to discover new ways to treat widely prevalent diseases.* The rapid scientific advances in genetics and genomics have had two effects. For the scientific community, they mean new tools and research capabilities previously only imagined; but for the public, they mean vast amounts of new information, often offered up by the popular press, which has a tendency to promote unrealistic expectations for disease-conquering and life-extending

drugs. For example, most common chronic diseases, such as heart disease, most cancers, and Alzheimer's, have a complicated and variable genetic component plus superimposed environmental and behavioral contributing factors. The sheer complexity of these diseases will make accurate prediction impossible from genetic information alone. Still, public interest and the resulting demand for new solutions will drive science to try and solve many health problems such as these.

- *Drug safety concerns will encourage further research into developing drugs and dosages that can target a subpopulation and reduce adverse drug events.* Regulators and consumers will continue to advocate for research that focuses on safety. This movement was prompted by the seminal Institute of Medicine report, *To Err Is Human: Building a Safer Health System*, which identified adverse reactions to medications (but also emphasized medication errors) as a serious safety issue.⁴
- *Customized drugs promise to change medicine, eventually. Mapping the human genome will spur excitement about, interest in, and demand for customized drugs.* Consumer expectations will drive science to develop drugs appropriate for an individual's genetic profile near the end of the forecast period as consumers learn how genetically appropriate drugs can improve their quality of life and recovery from disease.

Barriers

- *Privacy and ethical concerns will be obstacles to applying genetic knowledge in health care. In this age of data collection on all consumer behavior, the proper and ethical handling of personal data will be the key to ensuring protection of privacy.* However, legislative measures to protect privacy could have the unintended consequence of preventing the acquisition of critical information for research in medical science and public health. A particularly sensitive issue is information that results from genetic testing. Aside from the ethical concerns about genetic testing in general, such as the ability to discriminate based on genetics, there will be

questions about who should be tested, how informed consent should be managed, and how the information obtained by the tests can be used.

The Forecasts

Drug development will be increasingly sophisticated as the functions of genes and proteins are discovered and families of genes sharing pathways and functions are identified, which will enable the creation of highly specialized drugs.

The development of drugs tailored to an individual or a subpopulation is evolving rapidly, driven by the integration of proteomics, functional genomics, new information technologies, and bioinformatics (an approach that allows researchers to study biological processes using computers and other information technologies). The speed at which researchers are discovering information about drug targets, how targets interact with their environment, and drug efficacy is unprecedented. Given a strong boost and influx of information by the mapping of the human genome, the current pace of change in drug development is increasing, and the end result will be a new generation of drugs that will transform our concepts of preventable, treatable, and even curable diseases. Drugs will be individualized to the extent possible to avoid adverse drug responses and to assure efficacy. (This concept is further developed in our discussion of “nichebusters” in the industry forecast in Chapter 2.)

Information technologies and other tools will continue to transform drug discovery and development, though not immediately.

One way information technology contributes to the narrowing focus in drug development is by integrating massive amounts of data about specific targets. The identification of critical drug targets and the application of high-speed, powerful computer processing capabilities to drug discovery and early research will accelerate the preclinical phase of drug development. One consequence will be the development of many new classes of small and large molecule drugs. In addition, animal models of disease, genetically modified animals, *in silico* (computer-modeled) drug discovery, and modeling that uses bioinformatics will be increasingly important tools for drug R&D.

The rate at which base technologies are developed will determine the pace of change in drug discovery and development. Target validation technologies are expected to become robust only after 2005. Between now and then, financial analysts are banking on more downstream technologies such as new toxicology modeling, better chemistries, and patient stratification in clinical development.⁵

Diseases will be reclassified based on their genetic and molecular profiles.

The development of increasingly tailored drugs will change the concept of disease in medicine. Diseases and the drugs used to treat them will be classified by their genetic, structural, and molecular characteristics rather than by the organ systems they affect. An example of this shift in classification already exists in the use of Herceptin to treat breast cancer. Herceptin targets the specific tissue type involved in HER-2 breast cancer, not breast cancer in general. This reclassification could turn the medical community on its head as a new method of classifying diseases could also mean a reorganization of education, training, and reimbursement. This reorganization could mean practicing clinicians will have to learn a new way of conceptualizing disease. Medical schools and facilities organized to train and treat patients based on an organ-based disease model would need to reorganize around a molecular- and function-based definition of disease.

New bottlenecks will obstruct the drug development pipeline.

Thanks to new information technologies and other tools, drug discovery time frames will shrink and the categories of molecular entities (according to the Food and Drug Administration [FDA], new molecular entities are active ingredients that have never been marketed in the United States) will expand far beyond those represented by the classes of drugs available today. Drugs currently in use target approximately 500 proteins. Proteomics will yield 10,000 new disease targets. Many more drug candidates will be investigated, but with a much smaller chance of making it through clinical trials.

With all this activity, two bottlenecks are likely to occur: during biological validation and in phase II clinical trials, because both the industry and the FDA will be assessing new drugs for which there is no

chemical precedent.³ Even with an expansion of FDA personnel, the transition of a drug from preclinical to clinical development is likely to be slow.

Genetic testing will affect the use and selection of drugs at the time of treatment.

With more information about drug targets and new tools for discovery, genetic testing will grow more important. There are three major ways genetic testing will affect the use and selection of drugs in the future:

- *Determining individual susceptibility to common adult-onset conditions.* Genetic testing will shift the emphasis of intervention upstream to preventing disease (or illness) before it happens. This is already taking place today; for example, statins are being prescribed for asymptomatic patients with a genetic predisposition to coronary artery disease.
- *Classifying disease states by genetic fingerprinting rather than the present method of diagnostic separation by organ and histopathology.* In the future, a disease will be classified by its molecular uniqueness and a specific treatment will be designed to exploit it. One present-day example is identifying breast cancer's HER-2 overexpression and initiating treatment with Herceptin. This method will become a dominant theme in the future of rational drug design (the development of specific nontoxic drugs based on the molecular and structural information of a target molecule).
- *Changing the way drugs are prescribed by using genetic tests to select a drug that is free of adverse effects and will be efficacious based on the specific molecular characteristics of the disease target.*

The potential effect of genetic testing on pharmacotherapy is enormous—in short, scientific precision will replace trial and error in prescribing drugs. Historically, genetic testing has been conducted primarily in conjunction with family planning to estimate the probability of potential parents passing on an inheritable disease. In the next ten years, computer chip technology and the identification of critical genes will provide information on individual genetic information, which in turn will lead to safer and more effective use of prescription drugs, and

potentially the prevention of disease for people of all ages. Though less expensive than invasive treatments, genetic testing will not come without cost. Indeed, genetic testing materials and counseling will be expensive. Charges for a test range from \$200 to more than \$3,000, depending on the lab, the gene being tested, and the analysis being done.⁶ This expense, combined with uncertainties based on confounding and non-genetic factors, will put up barriers to widespread adoption of genetic testing through 2005.

Currently, health insurance companies pay for some genetic tests, such as those related to reproduction, but often individuals opt to pay out of pocket so they can control the dissemination of the results. However, as the benefits of genetic testing are realized and the costs decrease, broader application of these techniques will occur. Appropriate public policy that protects individuals from genetic discrimination will be important to expanding the opportunities for state-of-the-art genetic testing and could speed more general access to that approach.

Reducing adverse events from drugs will be the first application of pharmacogenomics.

The primary focus of pharmacogenomics (the study of variability of patient responses to drugs, and a form of genetic testing) in the next five years will be the reduction of drugs with adverse effects in the pre-clinical development phase. This will be followed by the limited use of individual genetic profiles to determine drug safety and efficacy prior to initiating treatment, especially in situations where the underlying condition is life-threatening—for example, cancer—or where an adverse reaction to the drug may be serious.

For example, Cytochrome P450 2D6 is an enzyme critical for metabolizing a number of commonly prescribed drugs, including tricyclic antidepressants, such as Elavil. The 5 percent of patients lacking this enzyme may have a toxic, severe, or even fatal reaction if the non-metabolized drug builds up in the body.⁷ Genetic testing for this enzyme can go a long way toward eliminating these negative episodes. Similarly, genetic testing for the gene controlling the metabolism of mercaptopurine, a drug used to treat childhood leukemia, can identify the one out of every 300 patients who lacks the enzyme and for whom customary doses of the drug may be fatal.⁸

Individual genetic profiles will be contained on a “simple” chip that will be in limited clinical use in five years. We anticipate that a more robust and complex pharmacogenomic chip will be in widespread use in ten years. Early testing will be restricted to specific single genes that determine the activity of key metabolizing enzymes, but at the end of this decade genetic testing for drug responses will evolve into looking at multiple genetic interactions, including a complete pharmacogenomic work-up (see Figure 1–1).

The pharmaceutical industry is eager to use pharmacogenomics to optimize drug discovery and development and patient treatment in every phase of drug development, including marketing and post-release surveillance. Limited knowledge generated from genetic information is a barrier to realizing this potential today, but with the availability of annotated single nucleotide polymorphism (SNP)⁹ databases, progress in pharmacogenomics over the next five years will accelerate.

Lack of provider preparation will slow the diffusion of genetic testing.

Once the science of genetic testing is well established, diffusion of these techniques will be limited by the lack of adequate training for physicians, nurses, and other providers. Even Dr. Francis Collins, director of the National Human Genome Research Institute, has expressed concerns about the ability of primary care and other providers to become genetically literate in response to increased demand for genetic testing.

Before genetic testing can take hold, more genetic counselors, genetic specialists, and clinical geneticists will be needed to help patients understand genetic testing. As of February 2000, there were approximately 1,800 master’s trained genetic counselors, and only 24 training programs throughout the United States, which graduate between 120 and 130 counselors per year. Genetic counselors are not a very diverse group: 95 percent are women and 93 percent are white. They also are not very well distributed throughout the United States, with nine states having three or fewer counselors and 25 states having 14 or fewer counselors. It is estimated that other specialists who counsel patients, such as clinical geneticists and nurse specialists, are also few in number; they were estimated to number 2,500 in 1996.

Gene therapy could capture many drug markets from pharmaceutical companies by making a pharmaceutical patient a gene therapy patient.

Gene therapy involves the use of gene products, namely proteins, as drugs for treatment of disease, whereas most pharmaceuticals today consist of chemicals. Gene therapy has the potential to permanently change tissues in addition to providing long-term delivery of a drug, which is a clear advantage to the intermittent administration of the same molecules, characteristic of standard drug therapy. The best example of a condition for which gene therapy is already replacing drug therapy is hemophilia. Hemophilia can be treated with a protein, factor VIII. Many experts believe this success is the only proof of this principle since research began a decade ago. The feasibility of gene therapy has been shown in the case of subacute combined immunodeficiency disease and ischemia of cardiac and skeletal muscle, and other uses will follow throughout this decade.

Gene therapy will not have an easy path, however. As of June 2001, fatalities had resulted from gene therapy clinical trials, and the intense scrutiny under which such research must proceed will challenge its rapid development. But the lure of gene therapy persists despite its failures and adverse publicity, and in time it will have a secure place in health care's armamentarium. When it does, companies invested primarily in biotechnology products will see their markets eroded. Though the majority of the change will happen beyond our forecast horizon, gene therapy could threaten the existence of the pharmaceutical industry, unless companies are able to reinvent themselves to provide gene-based therapies rather than traditional, chemical-based pharmaceuticals.

Newly developed and developing vaccines will change our concept of immunization.

New methods of vaccination will be introduced, along with both preventive and therapeutic vaccines. Vaccine therapy got a huge boost from the mapping of the genetic and molecular information of disease-causing organisms (e.g., researchers have completed or nearly completed mapping genomes for the organisms that cause malaria, tuberculosis, and AIDS). Knowledge of critical pathways and

pathogen-specific genes will allow the identification of new vaccines, both in the form of genes and gene products. These new DNA-based vaccines will be delivered by means of inhalation, ingestion, skin patches, and gene guns (devices that use highly pressurized air to inject DNA through the skin into the bloodstream). Within ten years, vaccines to prevent chronic diseases such as diabetes, Alzheimer's, and atherosclerosis may be available, completely changing the epidemiology of chronic disease.

Clinical trials of vaccines are intentionally lengthy, with post-vaccination observation of three to five years to ensure product safety, and this process will slow the introduction of the new vaccines. In addition—despite education promoting the public value of vaccines and herd immunity—limited public understanding and a continued but limited distrust of vaccines will slow widespread adoption of vaccines brought to market through 2010. However, by 2010 at least half a dozen new preventive and unique therapeutic DNA-based vaccines, including a therapeutic vaccine for HIV, will be in general use¹⁰ (see Figure 1-1 on page 16).

Endnotes

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- ⁹ An SNP is a single nucleotide variation in a sequence of genes. Studies of populations and their gene sequences allow researchers to determine predisposition to disease and potential reaction to a drug.
- ¹⁰ Wilson, C., and Nilsen, G. *Genetics and genomics: Transforming health and health care*. Menlo Park, CA: Institute for the Future, 2000, p. 28.

Chapter 2

INDUSTRY: COMPETITIVE PRESSURES WILL FORCE THE PHARMACEUTICAL INDUSTRY TO STRENGTHEN RELATIONSHIPS

Due to advances in science and escalating demands from consumers, the pharmaceutical industry is growing increasingly competitive, and the old ways of doing business are becoming less effective. Strengthening relationships up and down the supply chain will be a critical strategy for pharmaceutical companies to succeed in the market of the future.

Competition to make the most of advances in science and technology and to bring new products to market already is causing big pharmaceutical companies to focus on their relationships with both suppliers and consumers. Between 2000 and 2010, nearly \$53 billion in sales will be vulnerable to generic competition.¹¹ Even now, pharmaceutical companies are beginning to worry about how they will fund the R&D necessary to incorporate advances in science and technology as many blockbuster drugs go off patent. No longer can they succeed by being the self-contained monoliths of the 1980s and the 1990s, conducting everything from research to marketing internally. The traditional pharmaceutical markets will grow more and more segmented as science allows companies to tailor product offerings to individuals based on their genetics, preferences, and lifestyles. Furthermore, pharmaceutical company product offerings will diversify to include CAM products, food products, information, and services that help people maximize the benefits of new drugs. In short, pharmaceutical companies will be required to do more than simply develop and sell pharmaceuticals to a receptive mass market.

To compete in this new world, pharmaceutical companies will do less of their research in-house and instead will pursue strategic partnerships by means of mergers, acquisitions, contracts, and licensing agreements. In addition to their traditional physician marketing channels, they will continue to reach out to consumers more directly. Information technology is expanding opportunities for the pharmaceutical industry to distribute

targeted messages to a broad public and to engage consumers and patients more directly with information about health, wellness, and new products. Pharmaceutical companies will deliver this information through a mixture of broadcasting and “narrowcasting” techniques, and will include traditional media such as TV and printed publications. In ten years’ time, the pharmaceutical industry and its products will look very different, concentrating more on bringing drugs to market as part of a complete health package and leaving more of the bench research to smaller laboratories that are capable of the focus required of that discipline.

Industry Forecast Summaries

- Pharmaceutical companies will outsource innovation and look to smaller biotechnology companies as sources of new products and ideas.
- R&D expenditures will grow at a compound annual growth rate of between 8 and 10 percent through 2005. Between 2006 and 2010, the compound annual growth rate will increase to 13 percent.
- “Nichebusters” will be a new focus.
- Consumer marketing will increase to \$11 billion annually by 2010.
- Spending on marketing to physicians will remain higher than spending on marketing to consumers.
- The pharmaceutical industry will increase its understanding of consumer market segmentation.
- The pharmaceutical industry will use information technologies to develop, market, and distribute new drugs and to build and maintain stronger relationships with customers.
- Pharmaceutical companies will build brands and diversify products.
- Competition will drive pharmaceutical companies to develop a strong post-approval marketing strategy.
- Some CAM products and foods will be tested and accepted.
- Pharmacogenomics will inspire more upstream disease management.

Drivers and Barriers

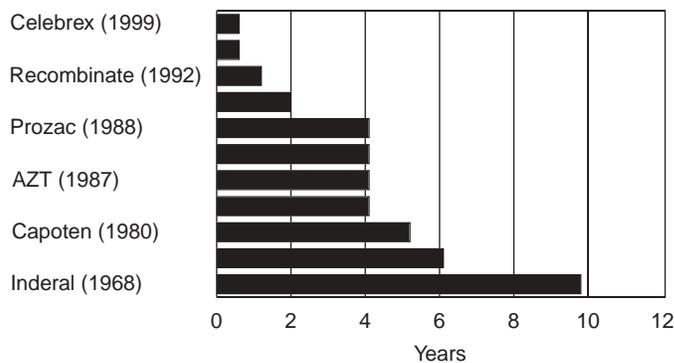
Drivers

- *Competition for dominance among pharmaceutical companies will drive them to find new ways to maintain profitability and integrate scientific advances, leading to significant industry reorganization.* Large pharmaceutical companies began another wave of mergers in the late 1990s to achieve economies of scale in marketing, R&D, and distribution. This trend will continue, driven by the fact that today an average of only three of ten approved drugs recover R&D costs (despite more than 10 percent annual increases in R&D expenditures in most years since 1980¹² and steady increases in marketing to both providers and consumers in the late 1990s).
- *Cultural differences among pharmaceutical companies will drive companies to turn to licensing and outsourcing to innovate.* Mergers among companies with different corporate cultures can be extremely difficult and time-consuming, especially between large, established pharmaceuticals and younger, typically more flexible and innovative biotechs. Companies will prefer to outsource and create new partnerships to expand their product offerings and bring their product to market rather than pursue a strategy of mergers and acquisitions.
- *Patent expirations will drive pharmaceutical companies to extend the reach of their markets and the value of their products.* (See Figure 2–1 on page 30). A pharmaceutical company can extend the effective patent life of a drug in a number of ways. For example, a company can reformulate the product (e.g., make changes in drug delivery or dosing), provide wraparound services (e.g., information about the drug or disease-related support groups), or pursue drug rescue efforts (e.g., repatenting medication for use with children).
- *Segmentation of the consumer market will increase the demand for product customization.* As pharmaceutical companies learn more about the consumer market and further segment that market

by health status, demographic characteristics, and, eventually, genetic profiles, they will have to learn to balance their product offerings between those with general applicability and those that are tailored to the individual, to maintain a diverse product portfolio. This means that pharmaceutical companies will need to develop new competencies in market research and customer relationship management to identify and appropriately market to a segmented population.

- *DTC has shown remarkable early success.* Shortly after the introduction of DTC advertising, patient requests for brand-name drugs increased 59 percent and product sales increased by 15 to 100 percent for some drugs.¹³ Patients reported that advertisements were the primary source of information that led them to request specific drugs. Twenty-eight percent of people surveyed by *Prevention* magazine in 1998 said that they had specifically asked for a drug they had seen marketed, and that 80 percent of the time they received those drugs (see Figures 2–2 through 2–4 on pages 31 and 32).

Figure 2–1
Market Exclusivity Period Is Shrinking



Source: Pharmaceutical Research and Manufacturers of America, 2000; The Wilkerson Group, 1995.

- “New consumers” (defined as more educated, affluent, and informed than traditional consumers) are information hungry, and this need will drive pharmaceutical companies’ marketing departments to provide the information that consumers crave. New, more sophisticated consumers want to be involved in their health care decisions. They have the analytical skills necessary to search many sources of information and to determine how to use and how much to trust each source. Consumer marketing efforts will focus on providing valuable information and fostering consumer trust to build relationships with consumers.

Figure 2–2
 More Than One-Fourth of Consumers Have Asked for a DTC-Advertised Prescription Medicine

Proportion of consumers who asked their doctor to prescribe advertised medicines vs. asked for information:		Proportion of consumers whose doctor honored their request for a prescription medicine:	
Asked For	%	Asked For	%
Prescription	28	Yes	80
More information	70	No	18
Don't know	2	Don't know	2

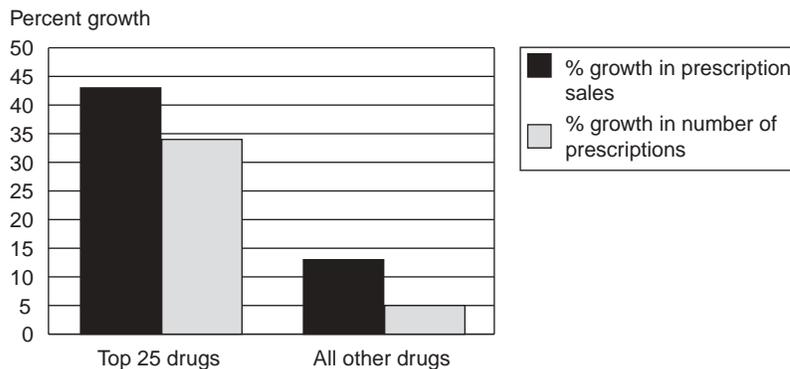
Source: *Prevention* Magazine Survey, July 1998, www.ecrm-epps.com.

Figure 2-3
Advertising Is Correlated with Increased Revenues

Drug	Promotional Spending, 1999 (millions)	1999 Sales (millions)	Percent Change, 1998-1999
Claritin	136.8	2,591	+21%
Propecia	71.1	63	+56.7%
Zyrtec	57.1	551.5	+31.5%
Flonase	53.5	489.5	+37.9%

Source: National Institute for Health Care Management, from Scott-Levin Prescription Audit Data.

Figure 2-4
Top-Selling DTC-Promoted Drugs Contributed Most to Growth in Prescription Drug Use and Sales, 1999



Source: American Institute for Research Analysis, from Scott Levin Prescription Audit Data, published in *Research Brief*, September 2000, National Institute for Health Care Management.

Barriers

- *Consumers' concern for the privacy of their personal information could be a barrier to developing genetically based targeted drugs and conducting consumer marketing efforts.* Consumers are already concerned about the privacy of their health information and will be hesitant to share genetic or genomic information with pharmaceutical companies if they fear the information may wind up in the wrong hands—even if sharing would mean receiving more effective drugs. If consumers are not willing to share personal information, the ability to match disease profiles with a product and thereby deliver personalized medicine will be difficult, if not impossible.

The success of DTC marketing is based on the assumption that the target audience wants the marketing information, and that it is useful to them. In order to receive this valuable information, consumers will need to share personal information about their health status with pharmaceutical companies. Consumers need to believe that the information they share with all health care providers—including pharmaceutical companies—is secure and will be used appropriately.

- *An incomplete understanding of genetics and genomics will concern and confuse the public.* The public already is confused about what is early hype and what has true promise in the fields of genetics and genomics research. This confusion will cause conflicts between consumers' expectations and the actual capabilities of medical science—a disconnect that could undermine public support for the application of genetics and genomics research to drug development.
- *Physicians and payers will pose a challenge to the expansion of DTC.* Both physicians and payers may lobby against DTC advertising, but for very different reasons. Physicians will lobby against DTC marketing if they find that it excessively undermines their prescribing authority when patients request brand-name products rather than allow their physicians to prescribe an appropriate treatment. The American Medical Association has not taken this on as a major issue at the moment, but that could change in the future if physicians begin to feel their role as prescribers is being significantly eroded due to DTC advertising.

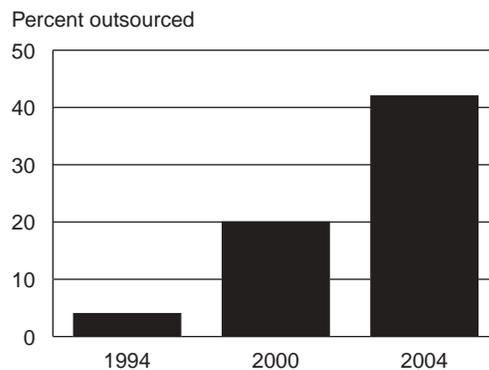
Payers will lobby against increased DTC marketing when it increases their pharmaceutical costs without a measurable benefit. Payers are generally willing to pay for new drugs if using them will lower overall health care costs. However, they will push back against DTC marketing by lobbying to reclassify some prescribed drugs to over-the-counter drug status if they believe the advertising generates an artificial need for expensive drugs that they must purchase at significant cost.

The Forecasts

Pharmaceutical companies will outsource innovation and look to smaller biotechnology companies as sources of new products and ideas.

The consolidation of pharmaceutical companies will take new forms. Instead of growing by means of the more traditional path of large mergers and acquisitions, pharmaceutical companies will continue to pursue new partnerships and licensing agreements to integrate external sources of innovation, grow their R&D efforts, and promote new products (see Figure 2–5). By partnering with, or licensing from, small, flexible organizations, pharmaceutical com-

*Figure 2–5
Pharmaceutical Companies Are Outsourcing a Greater
Proportion of Their R&D*



Source: Advantech Monitor, Frost & Sullivan; *The Pink Sheet*, April 3, 2000.

panies will avoid the difficulty of merging vast and different corporate structures and cultures, while enabling complementary companies to work together.

As a result, big pharmaceutical companies will form an increasing number of partnerships with contract research organizations and biotechnology companies. Contract research organizations provide assistance to pharmaceutical companies conducting clinical trials in study protocol and case report design, clinical trial recruitment, medical services and study monitoring, and data collection, among other important activities. Revenues to contract research organizations grew quickly at a compounded rate of 17 percent between 1997 and 1999. The global nature of the pharmaceutical industry and cost-containment pressures will continue to drive the pharmaceutical industry to outsource operational functions provided by contract research organizations.¹⁴

Similarly, biotechnology companies will continue to provide new ideas and develop innovative products for the industry as a whole. Biotechnology companies' emphasis on basic discovery—roughly two-thirds of biotech's R&D expenditures in 1999 were dedicated to basic discovery, compared to approximately one-quarter of research in large pharmaceutical companies—is one strong reason pharmaceutical companies are outsourcing innovation to them. Though the biotechnology industry is much smaller than the traditional pharmaceutical industry, the dollar amounts allocated to R&D by each are nearly equal and have resulted in the dramatic increase in disease-related patents from firms other than large pharmaceutical companies since 1994.¹⁵ (See Figure 2–6.)

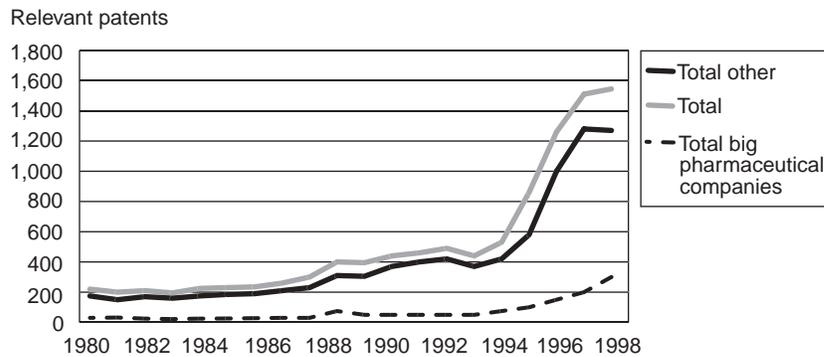
As large pharmaceutical companies outsource their innovation, some are shifting their role from that of a major R&D center to marketing specialist, focusing less on pure research and more on bringing new products to market. A major driver enabling the transformation of big pharmaceutical companies to marketing specialists has been the success these companies have had with DTC marketing. Companies that have invested in developing infrastructure to manage drugs through the approval process are leveraging this experience to bring new biotechnology products to market as well.

One potential drawback of heavily outsourcing innovation is that there will be less individual corporate ownership of new technologies and ideas, since, with more partners involved, it will be easier to reverse-engineer processes leading to the innovation. This could erode the competitive advantage of big pharmaceutical companies.

Research and development expenditures will grow at a compound annual growth rate of between 8 and 10 percent through 2005. Between 2006 and 2010, the compound annual growth rate will increase to 13 percent.

In the early portion of our forecast, between 2001 and 2005, the compound annual growth rate for R&D will be between 8 and 10 percent, resulting in total R&D spending between \$41 and \$45 billion in 2005. The more aggressive spending on R&D in the past ten years was possible because gross profit margins grew faster than annual sales revenue (first due to drug prices increasing faster than the consumer price index and then because supply chains were reengineered), creating an opportunity for pharmaceutical companies to invest heavily in R&D. Between now and 2005, the cost of goods will grow at the same rate as the pace of sales, which means that the annual increase for both R&D investment and sales will be 8 percent.¹⁵ Between 2006 and 2010,

Figure 2-6
Biotechnology Patents Dominate



Source: U.S. Patent and Trademark Office; Sanford Bernstein & Company analysis, 2000.

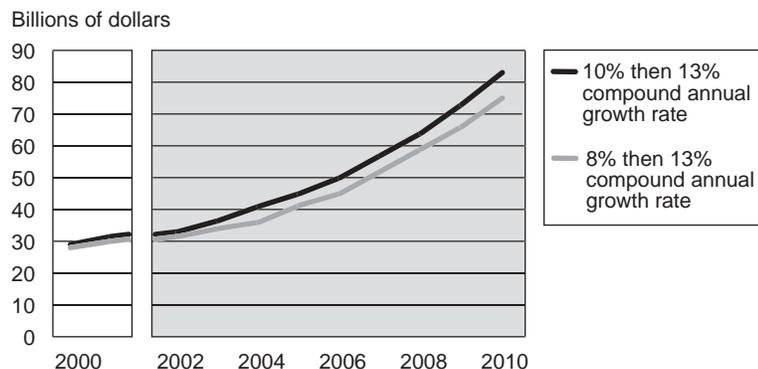
R&D spending will increase by approximately 13 percent annually, with up to \$83 billion dedicated to R&D in 2010 (see Figure 2–7). This growth will be fueled by the enormous opportunity to apply genetic technologies to the creation of new pharmaceutical products, and the need to invest in R&D to determine and validate the best application of the new tools available through science (see Figure 2–7).

Pharmaceutical companies will rely more on partnerships with biotechnology companies to introduce genetic advances into product development. Building strong relationships with biotechnology companies will ensure that the R&D investments in biotech are aligned with the research and product goals of large pharmaceutical companies.

“Nichebusters” will be a new focus.

New drug markets will include not only blockbuster drugs but also a new category of drugs we call “nichebusters.” Nichebusters are drug products designed for a more narrowly defined population and characterized by higher unit pricing, fewer treatment failures, and longer duration of effectiveness.

Figure 2–7
R&D Spending Will Continue to Grow Through 2010



Source: Institute for the Future; Sanford Bernstein & Company, 2001; Pharmaceutical Research and Manufacturers Association, 2001.

Blockbuster drugs are those with annual sales of more than \$1 billion. Nineteen drugs achieved blockbuster status in 2000 (see Figure 2–8). Nichebusters target a smaller segment of the population, and it is likely that at first they will be produced by the smaller pharmaceutical companies eager to capture a market segment but too small to compete with the big pharmaceutical companies for market share in a broad disease class. Large pharmaceutical companies will initially explore nichebusters by means of licensing agreements and eventually are likely to pursue them on their own as smaller companies demonstrate their marketability and success.

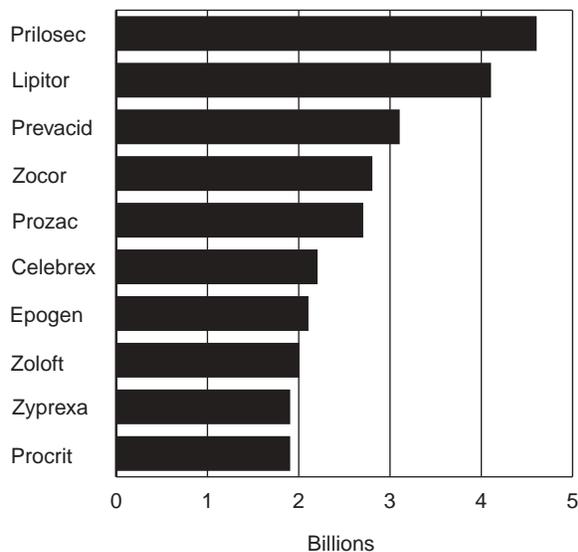
Both blockbusters and nichebusters will contribute to pharmaceutical industry revenues, and, in fact, some drugs will be classified as both—nichebusters based on their target markets and blockbusters based on their profitability. Changes in demand (e.g., the diminishing rate of clinical returns for each new round of blockbuster drugs) and changes in supply (e.g., the emergence of a process that combines genetic data with lab testing) are driving this trend. The first incarnation of this trend will be drugs that can be applied to a narrowly defined patient population for afflictions for which there is no treatment precedent or alternative. Gleevec, used for chronic myelogenous leukemia, is a perfect example of a revolutionary drug treating a previously untreatable disease. The next incarnation—the more mature nichebusters—will be drugs targeted to small segments of patient populations based on genetic profiles or personal preferences—that is, customized or personalized drugs. Thirteen percent of clinical trial sponsors already use genotyping to recruit and stratify patients in clinical trials; by 2005, 70 percent of sponsors are expected to be doing so.¹⁶ The result will be more people taking more appropriate medicines.

One key reason for the predicted growth in nichebusters is that the number of large clinical targets not addressed by major new drug breakthroughs is shrinking (e.g., treatment of high cholesterol and depression), while a large number of smaller clinical targets are only crudely treatable (e.g., stroke and hepatitis). This balkanization of disease targets, combined with the emergence of pharmacogenomics, which matches patients by phenotype with the most appropriate drug in a class, will result in market segmentation of drug products. Each individual new drug will be uniquely applicable to a small number of

patients for whom any other drug would be inadequate. This will, in effect, give each drug—even those for large disease populations—an effective monopoly for its phenotyped population. New drugs developed in this way will be nichebusters, with expanded pricing power. This focus will cause pharmaceutical companies to organize around groups of disease targets with similar disease characteristics.

The development of such nichebusters with the ability to command high prices will face some resistance, however. Third-party payers and purchasers will resist paying for the customization of drugs as an additional service until the new products are proven cost-effective. In the next decade, as technology improves, cost-effectiveness is demonstrated, and drug company pipelines generate new products, the trend toward nichebusters will accelerate. We will begin to see fewer drug-related adverse events and more personalized treatments.

Figure 2–8
Blockbusters Are a Major Source of Revenues for Pharmaceutical Companies:
Top Ten Blockbusters and Sales for 2000
(Billions of dollars, U.S. wholesale prices)



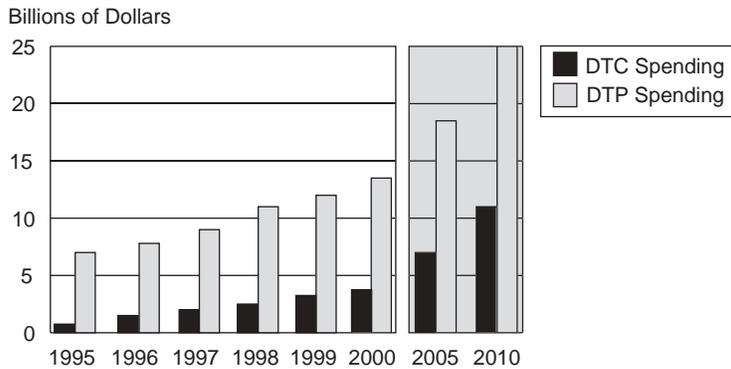
Source: Brian O'Reilly, "There's Still Gold in Them Thar Pills," *Fortune*, July 23, 2001.

Consumer marketing will increase to \$11 billion annually by 2010.

When the FDA Modernization Act in 1997 opened the gates to DTC, the first wave of advertising was relatively untargeted, delivered through the mass media of print and television. Given early successes with DTC, pharmaceutical companies will broaden the scope of their consumer marketing campaigns.

As a result, pharmaceutical companies will increase their DTC promotion efforts from an expected \$2.3 billion in 2001 to nearly \$7 billion in 2005, and \$11 billion in 2010. The total spent on marketing to consumers and physicians together will top \$36 billion by 2010 (see Figure 2–9). Data mining that analyzes transaction data to generate summaries of consumer behaviors or preferences will grow increasingly sophisticated, and some consumers will be willing to trade a degree of control over private information for specific services they perceive as valuable.

Figure 2–9
DTC and Direct-to-Physician Spending Will Increase Through 2010

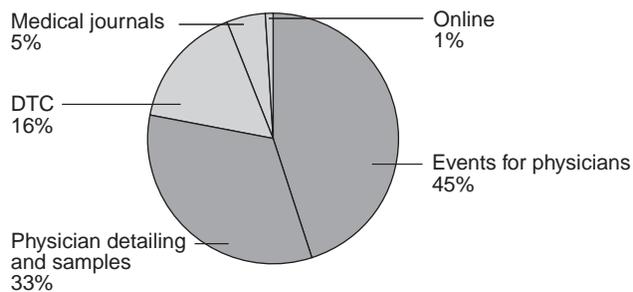


Source: IMS Health; Raymond James Associates; Institute for the Future, 2000.

Spending on marketing to physicians will remain higher than spending on marketing to consumers.

Annual pharmaceutical spending on marketing to physicians will remain significantly higher than that for consumers (see Figures 2–9 and 2–10). Expenditures for marketing to physicians will remain higher because the return on investment is greater than the return on investment for DTC advertising; physicians control a patient’s access to prescription drugs, pharmaceutical companies can provide information that fits well with a physician’s practice profile or specialization, and physicians share information and product samples with many of their patients.

*Figure 2–10
Physicians Are Still the Target:
Most Pharmaceutical Promotion Efforts Are Directed at Physicians*



Source: WR Hambrecht & Co., February 2001.

The pharmaceutical industry will increase its understanding of consumer market segmentation.

Pharmaceutical companies, learning as they go, will apply a greater understanding of consumer market segmentation to develop their targeted marketing messages to both patients and providers. Pharmaceutical companies will slowly learn how to reach the consumers they want to target. A higher return on their marketing investment will reflect their progress in this area, and spending on marketing will become more thoughtful regarding which medium to use and which message to deliver to a specific population. To reflect preferences across the consumer market, sophisticated marketing messages will differ in content, language, frequency, and choice of media channel. Marketing messages will be part of an integrated strategy that uses many different media—online and offline, broadcast and narrowcast—together in a cohesive, comprehensive campaign. The goal will be the right mix of messages, and this will depend on individual preferences (determined by analyzing the data collected about each patient and provider) and the nature of the message being shared.

Efforts to segment both the physician and the patient markets will share many characteristics. The pharmaceutical industry will use data it has tracked or acquired regarding both parties' responsiveness to advertising and promotional techniques to customize messages to each segment and to build relationships with each.

The Internet will play a critical role in targeting messages to both physicians and patients, but perhaps more so for patients. Empowered consumers are seeking specific health information on the Internet—a big opportunity many pharmaceutical companies have yet to maximize. Though many pharmaceutical companies have made initial forays online, most have not moved beyond the stage of trying to gain the trust of patients. In 2001, IMS Health found that only 5 percent of the pharmaceutical industry's marketing budget was spent on online marketing. This outlay will increase as companies recognize the relatively low cost of generating a single request for a drug on the Internet as compared to more traditional marketing techniques. Cyberdialogue reports the cost of a single drug request driven by advertisements in print and television to be \$728 and \$474, respectively, whereas it is just \$171 online.¹⁷

Consumers' concerns about privacy will cause only small, incremental increases in online requests for drugs at first. Pharmaceutical Web sites will offer even more online health and disease management, personalized product messages, support information, and patient education, and will introduce new monitoring tools that enable computer-based communication between patients and physicians.

For physicians, pharmaceutical companies will supplement and expand their expertise in marketing and use new media to generate clinician interest in their products through “e-detailing” (the practice of providing drug information and marketing materials to physicians directly via the Internet or other electronic media). Online communication with physicians by means of product education and practice support is one way of doing so. Practice support involves providing goods or services that assist physicians in their work—such as a system that automatically sends a prescription entered onto a handheld device to a pharmacy. Some physicians will be particularly receptive to more traditional one-on-one product detailing, and others will be more willing to receive marketing information online. Many different forms and mixes of provider education will be used: e-detailing for physicians who are too busy for face-to-face meetings with drug representatives, face-to-face meetings to explain the more complex drugs, or, as is most likely, some combination of the two. Wireless devices capable of tracking contraindications and providing better drug reference information will reduce the physician’s “hassle factor” and potential patient adverse drug events at the point of patient care. Finally, the pharmaceutical industry will keep and even expand its sales force and target physician extenders (providers who collaborate with physicians on a team and assume some of the physician’s responsibilities) in addition to physicians.

The pharmaceutical industry will use information technologies to develop, market, and distribute new drugs and to build and maintain stronger relationships with customers.

Patient demand for a more responsive health care delivery system began to change health care in the late 1990s. The direction of change was toward a more consumer-friendly and customer-oriented system in which informed patients became more involved in determining the

services they received. The Internet was one of the key drivers of this change. The highly distributed nature of the Internet, coupled with the vast amounts of information that can be communicated, allows consumers to explore information about health and health care that previously has not been available to the general public. The Internet also facilitates communication among people and organizations in separate locations. Payers, providers, and patients have all made significant investments in developing information technology infrastructures to communicate with players up and down the supply chain, and to provide support and services to patients and providers.

Pharmaceutical companies will become more sophisticated users of the Internet and other mass-communication tools to exchange research, collect and measure outcomes data, and market products to consumers and providers. Among researchers, the Internet is an effective way to investigate and communicate findings. Industry use of new media technologies to communicate with regulatory agencies will increase as the federal government develops systems to manage and automate new drug-approval processes within the next ten years.

Furthermore, the industry will increase its use of the Internet and communications media to conduct targeted marketing to consumers and providers. WR Hambrecht and Company forecasts that the pharmaceutical industry will spend \$600 million in online marketing promotions in 2004,¹⁸ up from \$47 million in 2000.¹⁹ By sponsoring disease-specific chat rooms and providing Web sites with rich information about diseases and drugs, pharmaceutical companies will use the Internet to gather personal information about people who use their products and those who might in the future. Pharmaceutical companies will also provide physicians with handheld devices that allow electronic prescribing—a practice physicians are warming to slowly. Approximately 15 percent of the physician population uses handheld devices in their work, in many cases as part of a demonstration project. Pharmaceutical companies are marketing products directly to physicians and collecting data on prescribing practices. This information can be mined to target future e-detailing efforts. Pharmaceutical companies are just now beginning to learn how they can market products directly to physicians by means of information technologies.

Information technologies can also be valuable tools for interacting with patients. If companies heed patients' privacy concerns by allowing interested consumers to choose to develop these types of relationships—to “opt in” to the relationship in return for more customized services, for example—pharmaceutical companies will receive valuable feedback from patients as an extension of wraparound support services. In this way, they will be more directly involved in fulfilling the needs of individual consumers, and they are more likely to earn their trust.

Pharmaceutical companies will build brands and diversify products.

As pharmaceutical companies move from research to marketing in the future, they will focus on building product and company brand recognition and strengthening and expanding their distribution channels. They will seek to become the trusted providers of a total health experience for consumers, an effort critical to developing new, closer (and thus more lucrative) relationships with consumers. To this end, pharmaceutical companies will focus on building brand loyalty to individual products and, in some cases, to the company as a whole. One way they will build brands is by providing wraparound products and services to support product sales, such as computer-based consulting and educational services for physicians that are an extension of drug e-detailing. Driving this trend are a pharmaceutical company's desire to maintain product profitability as patents expire and their exclusivity decreases, along with the desire to meet consumer demand for disease education and to satisfy FDA pressure on companies to assume accountability for greater product effectiveness. To make wraparound services successful, new distribution channels in the retail and social service areas will emerge.

Competition will drive pharmaceutical companies to develop a strong post-approval marketing strategy.

Competition for market share and the importance of generating immediate revenue from sales of new products will cause pharmaceutical companies to devise new product-release strategies. Historically, the primary focus for pharmaceutical companies has been on bringing new products through the approval process—the product launch that followed was secondary and more or less took care of itself. The current, highly com-

petitive pharmaceutical marketplace requires a long-term strategy for bringing products to market and then maximizing profits before a patent expires or a “me-too” competitor drug is launched. Presently, pharmaceutical companies prepare a market for the launch of a new product by providing relevant patient education and disease awareness programs well before the product is introduced, thereby creating interest. Consumer and provider education and marketing efforts during the time preceding a product launch can make or break the success of a new drug during its period of market exclusivity.

Some complementary and alternative medicine products and food will be tested and accepted.

Research funded by the National Center for Complementary and Alternative Medicine is beginning to test the safety and efficacy of the most frequently used CAM products. Saw palmetto, St. John’s wort, ginkgo biloba, glucosamine, and chondroitin sulfate are among the first compounds being tested. CAM products that are scientifically validated will gain public acceptance. As they are validated, these products will become more mainstream and will no longer be considered alternative.

Validation of such products will cause the pharmaceutical industry to consider the CAM industry competition seriously. The CAM industry is already well versed at selling directly to the consumer, and has a large network of distributors through local grocers and health food stores. Some pharmaceutical companies will try to move into the production and distribution of CAM products.

Pharmacogenomics will inspire more upstream disease management.

Pharmacogenomics will inspire the next generation of disease management, where at-risk individuals are identified earlier than they are now via genetic testing and patient profiling, and are offered an opportunity to enroll in prevention programs. In addition, more conditions previously considered “natural,” such as baldness and premenstrual syndrome, will be considered diseases and will become “medicalized.” As a result, the range of treatment targets will be expanded and the sales of drugs will increase significantly, while the markets will be more segmented. The next generation of disease management will depend on a renewed focus on prevention throughout medical training and service delivery.

Endnotes

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Chapter 3

REGULATION: THE FOOD AND DRUG ADMINISTRATION AND OTHER AGENCIES WILL HAVE NEW REGULATORY RESPONSIBILITIES

The FDA will continue to be the primary regulator of pharmaceuticals in the United States, but as the influx of nutraceuticals, functional foods (foods for which a health benefit claim can be made), and CAM products makes the market more complex, and pharmaceutical companies conduct more extensive DTC marketing, the FDA will come to share monitoring responsibilities with nonhealth agencies such as the Federal Trade Commission (FTC). New products arising from advances in science and the trend toward DTC marketing will drive the FDA to expand its scope to regulate products after they have entered the market. These new regulatory responsibilities for monitoring drugs and medicinal products will require increased capacity, including more people and more extensive training, all of which will require greater funding from the government.

Regulation Forecast Summaries

- The FDA will need greater resources as it moves into risk management.
- Regulators will subtly redraw the lines between pharmaceuticals and dietary supplements, focusing on safety and quality.
- Generics will be on the regulatory and consumer balance beam.
- Privacy will continue to be a contentious regulatory issue through 2010.
- The FTC will allow the pharmaceutical industry to continue to consolidate.
- Medical error and drug effectiveness will be monitored and regulated by requiring adherence to new processes.

Drivers and Barriers

Drivers

- *Consumers' demand for a fast-track approval process for certain drugs will motivate regulators to improve the fast-track approval process and facilitate more consumer education for new drugs.*
- *Consumers will simultaneously push regulators to ensure the safety of drugs overall throughout the approval process and on into the marketplace.* Media exposure of some failures of recently approved drugs such as Fen-Phen has increased consumer awareness of the risks associated with a faster approval process. This may drive regulators to consider new and more stringent policies, even though the rate at which drugs have been recalled has remained the same during the faster approval process. What is different now is that the recalls generate more publicity than in the past and thus increase consumer awareness of such failures.
- *Information technologies could enable regulators to better monitor adverse drug events.* Use of technologies to collect adverse event information, either during clinical trial or once the drug is released, will enable data to be aggregated and analyzed electronically. If used well, information technologies could support regulators in monitoring the safety and ongoing efficacy of drugs by means of such improved tracking.

- *Pharmaceutical companies will create new products in addition to their traditional chemical entities, including wraparound services.* Wraparound services primarily will be in the area of information for patients and consumers, though some companies will provide more extensive services to assist patients in taking their drugs. This expansion of pharmaceutical activities will drive the FDA to develop new competencies as its regulating responsibilities expand to cover these new services. Specifically, the FDA will have to oversee the generation and dissemination of information, analyze new biologic products, and review nutritional foods and nutraceuticals.
- *Payers will push for cost-effectiveness studies of both existing and new drugs.* In addition, they will lobby the FDA to move some drugs to over-the-counter status—those drugs that are broadly prescribed, that require minimal clinical supervision, and that are expensive.

Barriers

- *Industry lobbyists will attempt to maintain the status quo.* Lobbying by large pharmaceutical companies, the generics industry, and the dietary supplement industry will continue to attempt to limit the scope of pharmaceutical and dietary supplement policy. During the 2000 presidential election campaign, the pharmaceutical manufacturing and product industries contributed more than \$80 million²⁰ to promote and ensure that each industry's needs are met through regulation. Lobbyists for the pharmaceutical industry will continue to push against price controls or other measures that may limit their activity and will concern themselves with the specifics of any Medicare prescription drug benefit. Despite the enormous lobbying effort by the pharmaceutical industry, real changes in policy toward the pharmaceutical industry are a function of who controls Congress and the executive branch and mass-media coverage—not just political action spending.
- *Without increased funding, a finite regulatory capacity will limit the FDA's scope.* The administration's personnel is finite, although their responsibilities are increasing. For example, to meet the increased responsibilities brought about by DTC advertising, the FDA hired

only one additional person between 1996 and 1999, bringing the total number of advertising reviewers in the agency to 13. In contrast, during the same period pharmaceutical spending on DTC advertisements increased 133 percent. Budget cuts and the current lack of a leader in the FDA do not bode well for an overextended agency whose responsibilities are expanding. A greater proportion of money for regulation will come from private industry itself, similar to the way the Prescription Drug User Fee Act (PDUFA) of 1992 implemented an agency user fee to generate new revenue for the FDA and increase its capacity to approve drugs. The fee for a full drug application (with clinical data) is slightly more than \$300,000 and is anticipated to generate \$135 million in 2001.²¹ Since the PDUFA's passage, user fees have allowed the FDA to hire 600 new employees and decrease the approval time for many new drugs.

The Forecasts

The Food and Drug Administration will need greater resources as it moves into risk management.

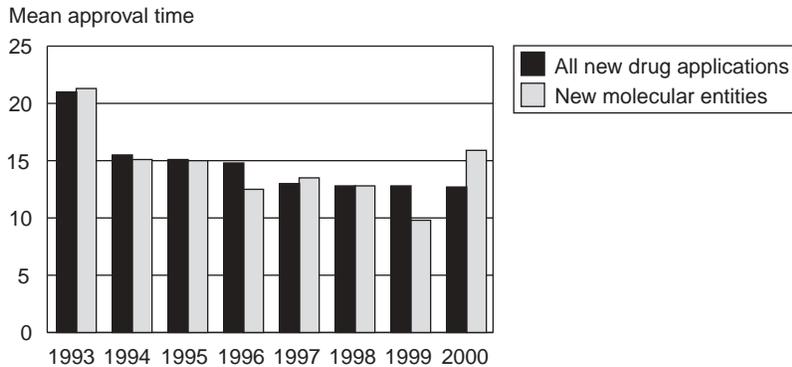
Regulatory changes prompted by the PDUFA of 1992 and the FDA Modernization Act of 1997 achieved the objective of speeding up the new drug-approval process. Since 1993, the average time to bring a new product through the approval process decreased from 24 to 12 months. During that same time the number of new drug approvals increased from just under 60 per year to a peak of over 130 in 1996, before decreasing steadily every year since then.²² Many legislators and consumer advocates fear the process may be moving too fast, placing patients at risk of adverse events and, potentially, death. Perhaps as a result, the FDA approved only nine drugs in the first half of 2001, compared to 16 approved during the first half of 2000; both numbers are far fewer than in years since the passage of the PDUFA and the FDA Modernization Act (see Figure 3-1).

Spurred on by consumer and regulatory concerns that the faster approval process will harm people, the FDA has expanded its role into post-marketing risk management and surveillance. The administration is stepping up its efforts to monitor the effects of new drugs once they are available to consumers in the marketplace.

In this role, the FDA will collaborate with providers, consumers, and other federal agencies to ensure that marketing messages are appropriate and consistent with clinical findings and that patients are using the products safely. The FDA will need greater resources to function as a post-market risk management and surveillance engine. The FDA is currently responsible for ensuring the safety and efficacy of drugs, foods, medical devices, cosmetics, animal feed and drugs, and biologics such as vaccines. The staffing shortage at the FDA is slowing down the post-market monitoring process and hindering the agency’s ability to warn clinicians about new side effects, contraindications, and complications as they are revealed in the marketplace.

Since the PDUFA requires authorization every five years, PDUFA III is currently in development for 2002. As a result of this reauthorization process, it is likely that pharmaceutical companies can expect new fees levied by the FDA to subsidize this post-market surveillance.

*Figure 3-1
Mean Approval Time for New Drugs Has Decreased,
1993-2000*



Source: Data for 1993-1999, Food and Drug Administration; data for 2000, Food and Drug Administration data from TheStreet.com, June 27, 2001.

***Regulators will subtly redraw the lines between
pharmaceuticals and dietary supplements,
focusing on safety and quality.***

The legislative boundaries between pharmaceuticals and functional foods are blurring as Americans add botanicals, nutraceuticals, functional foods, and other dietary supplements to their daily health regimens. A published survey shows that the number of Americans using alternative therapies rose from about 33 percent in 1990 to more than 42 percent in 1997.²³ People in this study reported using the following therapies most often: herbal medicine, massage, megavitamins, self-help groups, folk remedies, energy healing, and homeopathy. Now the market is expanding into supplemental nutritional food and drink. In 1997, the market for herb-laden food and beverages totaled no more than \$20 million in annual sales. Then large companies like Pepsi and Cadbury introduced herbal-enhanced drinks, moving herbal remedies into the mainstream, and in 2000 the figure jumped to \$700 million.²⁴

The vast array of available complementary and alternative remedies is inspiring consumers to demand evidence of their effectiveness. In response, in 1994, Congress passed the Dietary Supplement Health and Education Act (DSHEA). The DSHEA was based on the premise that “legislative action that protects the right of access of consumers to safe dietary supplements is necessary to promote wellness.”

The DSHEA classifies dietary supplements as a category of food, granting authority to the FDA to increase its activities in regulating them. Public funding will increase to study and eventually regulate widely used dietary supplements on the basis of safety and efficacy. A plethora of data is expected to come out of trials being conducted at medical centers across the country under the direction of the National Center for Complementary and Alternative Medicine. In 1999, the center funded five new Specialty Research Centers, each with a budget of approximately \$7.5 million over five years, bringing the total number of such centers to nine. In these early days the center is emphasizing safety and the overall regulatory framework for gathering and reporting adverse events resulting from the use of these medicinals. As a result, throughout the forecast period, we will learn much more about various dietary supplements and their efficacy, and they will come under the purview of federal regulatory agencies.

Because empowered consumers are demanding high-quality products, they are, indirectly, the main driver for this change in regulatory policy. The increase in demand for supplements has been slowing since 1999, and the supplements industry recognizes that the lack of quality standards, the mass media's coverage of horror stories, and consumer scams have given the industry a black eye. Increasingly, large pharmaceutical companies and packaged food and beverage companies are competing in the nutritional supplement market. To stay competitive when larger companies enter their markets, nutritional product manufacturers will place more emphasis on research and increasing consumer awareness of quality and safety.

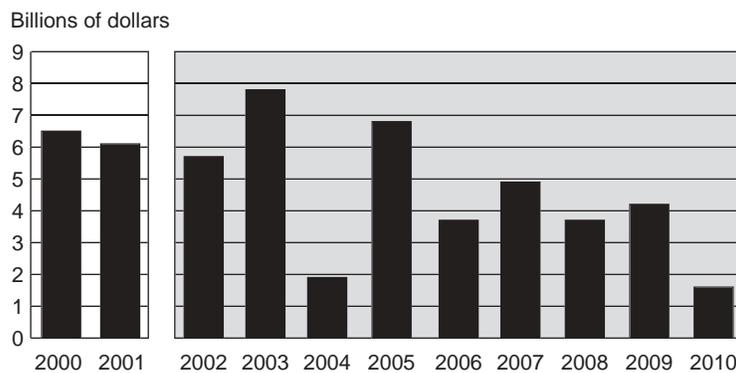
Generic drugs will be on the regulatory and consumer balance beam.

The tension between patented and generic products will increase due to consumer awareness of brands, industry lobbying, and cost-control pressures. The tension among these product spheres will be manifest in the reevaluation of the Hatch-Waxman Act, also known as the 1984 Drug Price Competition and Patent Term Restoration Act. The Hatch-Waxman Act provided opportunities for patent expiration extensions and an abbreviated new drug approval procedure. An abbreviated new drug approval allows the first company demonstrating its ability to produce a safe and effective generic substitute to receive approval for 180 days as the sole generic producer. It also exposes branded drugs to generic competition, which the pharmaceutical industry finds frustrating. Entry of generics into the market can reduce a product's prescriptions by up to 75 percent almost immediately—an enormous blow to patented drug producers and the key reason they are trying to limit the entry of generics into the market (see Figure 3–2 on page 56).

The players in this debate are payers (including the government and consumers), the pharmaceutical industry lobbyists, and the generics industry. Payers are concerned about growing expenditures for drugs. Pharmaceutical companies would prefer no change in policy regulating generics and patented drugs, as they are currently well protected. And the generics industry would like to see opportunities for generic substitution increased.

The pharmaceutical lobby is much stronger than the generic drug manufacturers' collective force, as evidenced by its presidential campaign contributions in 2000. However, the countervailing power of purchasers and payers, the mass media, and health plans' desire to reduce drug costs will help the generic industry in its push against the large pharmaceutical companies. As out-of-pocket payments for prescription drugs increase, consumers will demand generic substitutes if—and only if—they are roughly equivalent in performance and have minimal side effects. (Generic products as a lower-cost alternative are discussed in Chapter 5.) For the pharmaceutical industry to maintain its market share, it must communicate the benefits of higher-cost prescription drugs as part of its DTC promotional strategies. Although the patented drug industry has enormous power to influence policy, the realities of cost-control demands from consumers, purchasers, and policymakers means that there will be an equal balance between the goals of large pharmaceutical companies and producers of generics.

Figure 3-2
Sales of Brand-Name Drugs Will Be Vulnerable to Generics Competition, 2000–2010



Source: Food and Drug Administration *Orange Book*; Banc of America Securities.

Privacy will continue to be a contentious regulatory issue through 2010.

Pharmaceutical companies' increasing use of technology to collect information and to communicate directly with patients about their conditions will present opportunities and challenges for both pharmaceutical companies and consumers. Worried by media stories of identity theft and other privacy violations, some consumers are likely to be cautious about the information they share with drug companies. Other consumers, particularly those who are actively managing chronic conditions, will be more willing to trade some privacy for valuable information that is beneficial to their health.

Pharmaceutical companies will struggle to understand and implement effective communication strategies with consumers. As a result, one-to-one communication will grow slowly between pharmaceutical companies and individual patients who choose to have such a relationship. This relationship, however, will be tenuous and will depend on pharmaceutical companies' ability to maintain their customers' trust. Scandals highlighting the industry's public release of private information will drive consumers away from the Web. These relationships will not be regulated as long as consumers consent to the privacy policies and companies successfully adhere to them. If unsolicited, mass-customized DTC promotions become the norm, however, regulators will likely step in to monitor these messages and to protect consumers from unwanted intrusions into their personal health information.

The Federal Trade Commission will allow the pharmaceutical industry to continue to consolidate.

Large pharmaceutical companies will continue to consolidate and to acquire smaller companies. The FTC will allow big companies to grow bigger, as long as market share is distributed among pharmaceutical companies. Regulators will allow large pharmaceutical companies to continue to consolidate because no single company has a large enough market share to behave in an anticompetitive manner in the current market.

Medical error and drug effectiveness will be monitored and regulated by requiring adherence to new processes.

New medical error regulations will not directly proscribe what doctors do in their offices or hospitals regarding the way they prescribe drugs, but new processes and policies will be developed to reduce medication errors. This will be an era of increasing accountability with respect to medical errors. We will see a more consistent use of clinical pathways and guidelines that incorporate new medical findings and a greater utilization of information systems that provide optimum access to both in-house and external data. Continuous performance improvement should provide the resources and support to help physicians adopt best practices. As we mentioned in Chapter 1, this trend toward greater accountability and safety is being driven largely by the widely disseminated report *To Err Is Human: Building a Safer Health System*. This document reported that 10 percent of adverse events in the hospital are caused by mistakes in using drugs.²⁵ The Institute of Medicine committee recommended applying information systems to both eliminate and track errors through standardized processes. On Capitol Hill and among regulators and consumers, *To Err Is Human* is a call to action.

International Pharmaceutical Issues

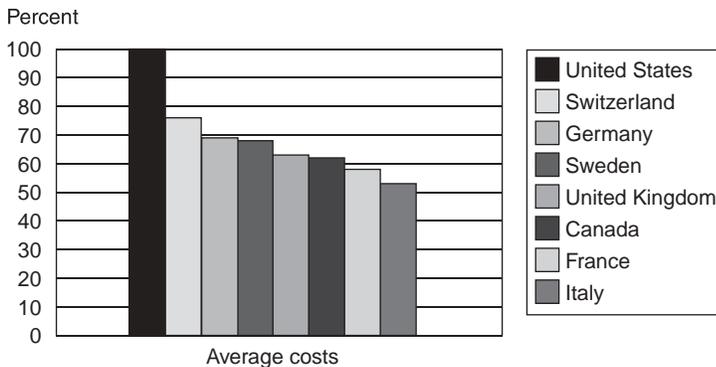
Our core forecasts for the international market for pharmaceuticals highlight the critical issues policymakers, manufacturers, and consumers will face in the future: intellectual property rights and patent piracy, drug reimportation, and Internet drug sales.

The Forecasts

Variation in global pharmaceutical practices and pricing will drive international collaboration on regulatory policy. Trade policies and intellectual property protections are crucial factors in pharmaceutical regulation. Although methodological

approaches and estimations can differ, many studies indicate that the United States remains the highest-priced market for pharmaceutical products.²⁶ Prices for HIV/AIDS drugs are being cut by 90 percent in some countries and busloads of U.S. citizens are crossing into Canada to purchase their prescriptions to save money (see Figure 3–3). Payers and consumers alike will pressure the industry for access to drugs at the lower prices charged in other parts of the world. However, the growing generics industries of emerging economies (especially India and, toward the latter part of the forecast period, China) that don't neces-

Figure 3–3
International Prescription Drug Prices Are Lower Compared to the United States
(Average cost of prescription drugs as a percent of average costs in the United States)



Source: Patented Medicine Prices Review Board, *Trends in Patented Drug Prices*, 1999.

International Pharmaceutical Issues (cont.)

sarily heed global intellectual property and patent laws will exacerbate the pharmaceutical industry's problem of maintaining its prices in the United States.

Worldwide access to medical products will push regulators to assume a more collaborative, global perspective on drug regulation. Global trade will open up access to U.S. consumers for pharmaceuticals that are currently unavailable in the United States. This will drive regulators and policymakers to collaborate with other nations to regulate pharmaceuticals in terms of supply flows and intellectual property protections.

International public health authorities will push for increased access to necessary drugs. The migration of people and goods around the globe will drive the migration of new diseases across geographic boundaries, particularly from the developing to the developed world. Twenty-nine new infectious diseases have been identified since 1973, along with 20 that are reemerging. This phenomenon will increase attention on the global public health community and, as a result, create a stronger emphasis on worldwide access to necessary drugs.

The Issues

Patents and Piracy

Patent piracy is one of the most important intellectual property-related issues for pharmaceutical companies to consider in the future. Patent piracy in the pharmaceutical industry occurs when a rogue drug company produces drugs that are still protected by patents and sells them for less than what the patented company charges. It is estimated that the U.S. pharmaceutical industry loses \$500 million annually to India alone, due to poor patent protection laws in India.²⁷

Pharmaceutical producers state that intellectual property protection is the lifeblood of innovation and new drug development, and has become one of the most contentious issues in international development. In North America, the promise of 20 years of patent protections to recoup costs spent on development provides individuals and companies with an incentive to innovate and patent new ideas. Full entry into the World Trade Organization (WTO) is predicated on participating nations' adherence to or plans for adhering to international patent laws, as put forward by the Trade-Related Imports Property Rights (TRIPS)

agreement, which provides strict guidelines for enforcing patent protections. The United States is pushing to expand TRIPS adherence to all WTO-participating countries.

Intellectual property protections have, and will continue to have, serious implications for developing nations. If mandatory adherence to the TRIPS agreement is necessary for all WTO-participating countries, patent piracy will be a barrier to entry into the WTO. Many countries for which patent and trade protections are important but not critical national issues will not be able to dedicate the resources required for intellectual property law enforcement. The estimated cost per country to build a bare-bones infrastructure to implement the TRIPS requirements is \$1.5 to \$2 million.² Both developing and developed countries will struggle with how to protect intellectual property rights, encourage sustainable development, and ensure access to necessary drugs.

Drug Reimportation

The issue of drug reimportation has gained visibility as consumers go to great lengths to access drugs in an international market. Between 1995 and 1999, for example, U.S.

citizens reimported \$13 billion in prescription drugs, and drug reimporting is on the rise.²⁸

Drug companies are concerned about drug reimportation because products sold on the international market are the same products sold within the United States—but sold for less. Lower drug prices drive groups of U.S. citizens across borders, into Canada and Mexico, to fill their regular and usually long-term prescriptions to treat ongoing conditions. The FTC's primary concern is that reimported drugs are not regulated and could put consumers at risk of receiving impure or bogus drugs. Pharmaceutical companies oppose drug reimportation because it introduces price competition.

Federal and State Drug Reimportation Policy

Both state and federal policymakers are attempting to resolve the issues of consumers in border states traversing national boundaries to purchase lower-cost drugs. Border states such as Maine, New Hampshire, and Vermont have led the way for national policy by directing attention at this issue and by experimenting with a number of different approaches. Issues of jurisdiction between state- and federal-level regulation will require

International Pharmaceutical Issues (cont.)

the federal government to step in and establish rules of conduct for individuals and companies wishing to engage in drug reimportation. Drug prices, made visible by the success of purchasing consortia, which are able to negotiate lower prices, and the media, will drive a policy resolution in the near future. Congress is beginning to shape federal policy to allow individuals to purchase FDA-approved drugs internationally, on a limited basis. It is unlikely that the government will pass legislation liberalizing drug sales cross-nationally, unless regulation enables the government to assume oversight and ensure patient safety.

Internet Sales

Protecting patients and consumers from bogus or unsafe drugs available online will continue to drive regulators worldwide to track and penalize offenders who advertise or distribute “bad” drugs via the Internet.

One example of an effort to reduce health-related fraud on the Internet is Operation Cure.All. This effort, spearheaded by the FTC, was launched in 1998 to identify distributors who provided unsafe drugs or made unfounded claims about products they were selling. The main goal is to ensure quality rather than to eliminate “quackery,” although both are

important issues. In June 2001, the FTC issued its fourth series of complaints and targeted six vendors who had made fraudulent claims about the effectiveness of products they were selling on the Internet. Many of the unfounded claims regard use of herbal remedies as substitutes for prescribed health care treatments. Most of the identified vendors settled with the FTC directly.²⁹

Consumers will continue to use the Internet to purchase lower-cost or otherwise unavailable drugs, requiring the government to devote time and attention to this issue. The future of Internet regulation for pharmaceutical products will depend on how a number of interrelated issues play out. These issues include online privacy, the Safe Harbor agreements between the United States and the European Union regarding online privacy and commerce, the frequency and publicity of experiences where consumers receive “bad” drugs sold online or are otherwise harmed by drugs purchased online, and the political climate and approach toward Internet regulation.

Endnotes

- ² Food and Drug Administration *Orange Book*; Banc of America Securities.
- ²⁰ Drug industry: Spent \$80 million in successful campaign. *Wall Street Journal*. November 9, 2000.
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- ²⁷ The right to good ideas. *The Economist* (June 23) 2001.
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- ²⁹ “Operation Cure.All wages new battle in ongoing war against Internet health fraud.” Federal Trade Commission press release, June 14, 2001.

Chapter 4

CONSUMER DEMAND: WHAT CONSUMERS WANT, CONSUMERS WILL GET

The aging of the U.S. population, sophisticated consumers' increasing awareness of treatment options, and expanded expectations about the efficacy of drugs will all lead to increases in the demand for new pharmaceutical products. Other factors influencing demand will include a moderate Medicare drug benefit that will provide some, but not all, necessary drug coverage for seniors, and patients' larger out-of-pocket payments for drugs through multitiered benefits packages. The consumer market for drugs will be segmented by personal characteristics, including ability to pay, health status, health literacy, and, eventually, genetic profile. This segmentation of the population will guide treatment decisions and shape the demand for new and existing pharmaceutical products through 2010.

Consumer Demand Forecast Summaries

- The demand for medicines will continue to expand at rates greater than those of the past ten years.
- Consumers will be more sensitive to drug prices and will use information to help them select the most cost-effective treatments.
- Consumers will be progressively more segmented into specific markets based on education, income, personal preferences, and ability to pay, among other characteristics.
- The “medicalization” of natural life processes will increase the overall demand for drugs, because previously untreated and untreatable conditions will have pharmaceutical solutions.
- Information will empower some consumers to apply genetic information to better manage their health.
- Genetic modification of food holds enormous promise for “healthy” eaters.

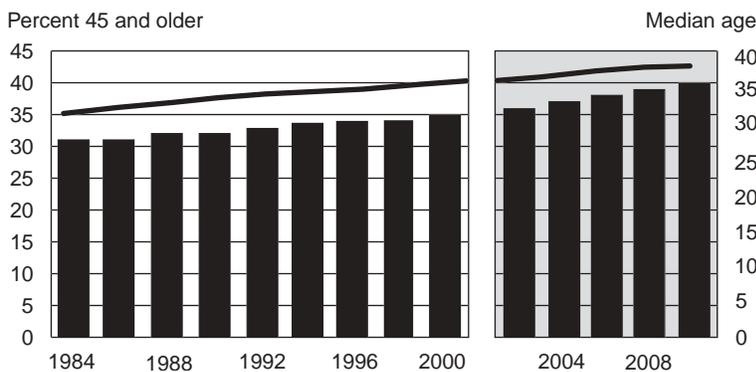
Drivers and Barriers

Drivers

- *Some illnesses that are now acute and fatal will become chronic illnesses (e.g., AIDS, prostate cancer, and colon cancer), and their long-term treatment will increase demand for drugs.* Science and industry will produce expensive new medicines that significantly delay mortality for some diseases. These medicines include immune system modulation drugs for AIDS and severe infections; vascular endothelial growth factor drugs for severe cardiovascular disease; and epidermal growth factor and monoclonal antibody drugs for cancer. These medicines will dramatically increase the life expectancy of patients with these diseases, thereby compounding demand for these and other drug therapies. According to the Pharmaceutical Research and Manufacturers of America’s interpretation of the Centers for Disease Control and Prevention statistics, from 1995 to 1997 the mortality rate for AIDS dropped more than threefold, due to increasing use of combination antiretroviral therapy.³⁰

- *The average age of the population is increasing, which will result in an increase in the demand for drugs.* (See Figure 4–1.) The people in the well-elderly and frail-elderly demographic categories—the two age groups that consume the largest number of medicines per capita—make up the two fastest growing age groups in the industrialized world (see Figure 4–2).³¹ This trend constitutes a total drug utilization increase of 1.5 percent per year, but may accelerate less rapidly than commonly assumed as recent studies call into question whether the age-related disability increase that has been projected is an overestimate, given advances in medical technology.³²
- *Demographic changes in income and wealth also suggest the likelihood of more spending on health in the future.* The per capita income and net worth of the U.S. population has been increasing, especially among the elderly and the baby boom generation, which is approaching retirement.³³ As income and net worth increase, individuals spend a larger absolute amount of discretionary funds—though not a larger proportion—on medical products and services,

Figure 4–1
Average Age of the Population Is Increasing



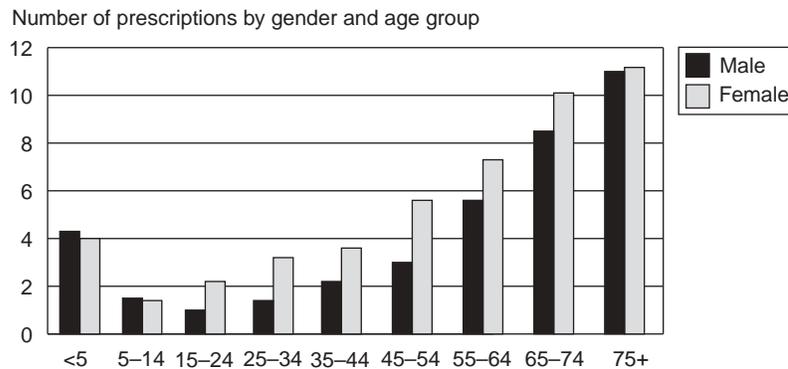
Source: U.S. Census Bureau; Institute for the Future.

especially on those not covered by traditional insurance. This trend is especially pronounced if the increase in compensation in the form of expanded health benefits (e.g., insurance coverage for more, newer, and better medicines) is considered along with traditional cash income.

Barriers

- *Purchasers and payers will experiment with cost-containment and cost-shifting strategies.* Growth in the demand for pharmaceuticals and medicinals will be constrained by purchasers' and third-party payers' efforts to control costs. Most cost-containment strategies will involve shifting an increasing percentage of drug costs to patients. This will be done directly, through copayments, and indirectly, through continued administrative mechanisms, such as use of formularies (see Figure 4-3).
- *A token minimal Medicare drug benefit will be created.* The minimal Medicare prescription drug benefit will constrain growth in overall demand for pharmaceuticals.

Figure 4-2
Average Number of Prescriptions Increases with Age



Source: Kaiser Family Foundation, *Prescription Drug Trends: A Chartbook*, July 2000, Figure 3.6.

The Forecasts

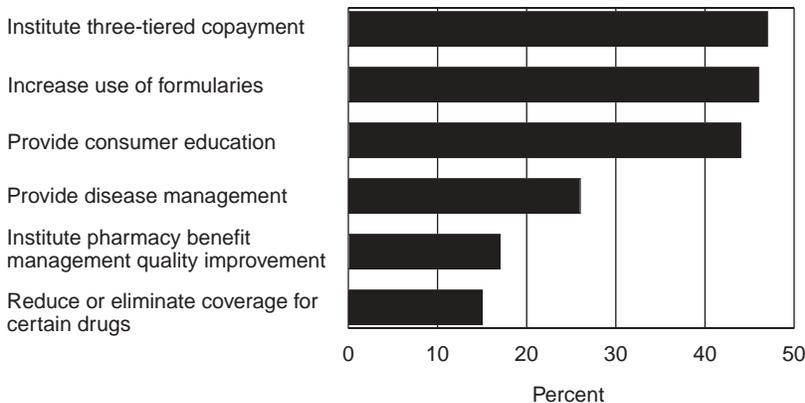
The demand for medicines will continue to expand at rates greater than those of the past ten years.

The health care industry will see a continued movement away from hospital-based, palliative care toward ambulatory-based, chronic care. As a result, the proportion of all health expenditures that goes to hospitals will decline, the proportion that goes to outpatient care and pharmaceuticals will increase, and the share of physician services will remain constant.

Pharmaceutical companies will work to ensure that a larger number of new medicines is discovered, approved, marketed, and prescribed each year, and a larger number of current medicines is approved and marketed for expanded indications, thereby keeping demand for both existing and new drugs high.

The effects of cost-containment strategies used by third-party payers and purchasers will be tempered by consumers' greater direct access to drugs through their benefits plans. The end result will be more people on more medications, for more conditions, and for longer periods of time.

*Figure 4-3
To Manage Increases in Pharmaceutical Costs, Employers Will ...
(Percent of employers surveyed)*



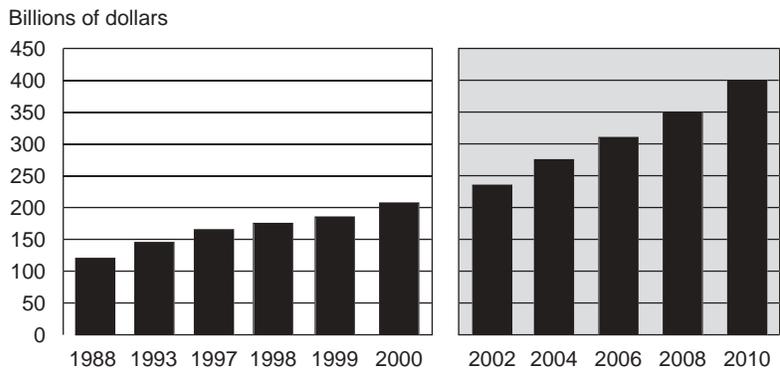
Source: Watson Wyatt/HFMA, 2001.

Patient self-care will also increase and the physician’s role as sole decision maker will decline. We forecast that over-the-counter retail sales, a proxy for self-care, will continue to increase at a compound annual growth rate of 6.8 percent, from just under \$20 billion in 1999 to nearly \$40 billion in 2010.

Consumers will be more sensitive to drug prices and will use information to help them select the most cost-effective treatments.

Consumers will become more savvy and sensitive about the price of prescription drugs as their out-of-pocket burdens increase and payers educate them about those cost increases (see Figure 4–4). This price sensitivity will vary directly with the percentage of commercial prescription benefits plans that adopt copayment and coverage tiering. Price sensitivity, as it does with other consumer products, will lead to greater selectivity of pharmaceutical products. Consumers will use information gleaned from marketing efforts and social networks to help them make decisions about how they want to spend their health care dollars. The overall effect of increased price sensitivity will not dampen the demand for pharmaceuticals, but it will mediate it, making pharmaceutical companies work harder to find their best customers.

Figure 4–4
Consumers’ Out-of-Pocket Payments Are Rising



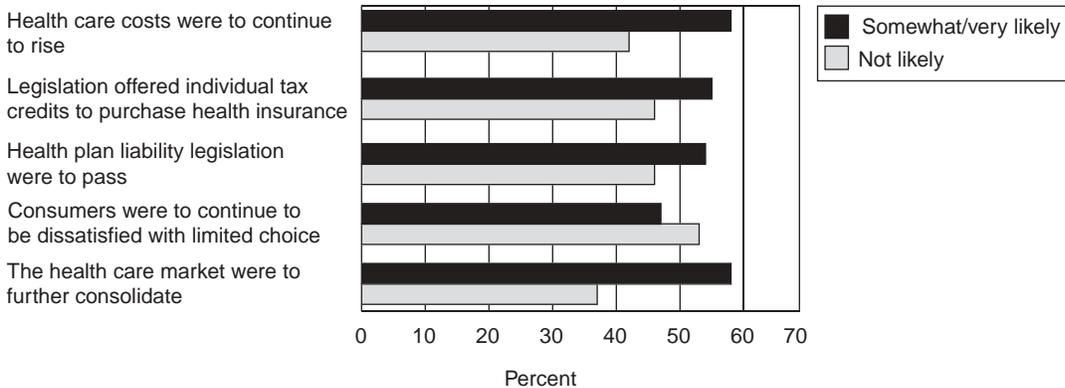
Source: Health Care Financing Administration, Office of the Actuary, National Health Statistics Group.

Consumers will be progressively more segmented into specific markets based on education, income, personal preferences, and ability to pay, among other characteristics.

A number of movements will contribute to this shift. First, third-party payers and purchasers have said they will use more aggressive cost-containment strategies (especially cost sharing) in response to rising medical costs. Seventy percent of employers and 99 percent of health plans have said they are passing on costs, and the majority said they would shift purchasing decisions to employees if health care costs keep rising (see Figure 4–5).³⁴ Future cost-containment strategies will focus on creating tiered benefits plans that separate consumers’ purchasing capabilities and preferences based on their willingness to pay.

The consumer market is also becoming increasingly stratified as the disparity in income levels grows in the United States.³⁵ The impact of this disparity on socioeconomic classes is accelerated by the aging of the population (as the rich—and their children and grandchildren—get richer). Similarly, a “digital divide” separates the tech-savvy educated from less educated people without computers, galvanizing the dispari-

Figure 4–5
Employers Would Shift Purchasing Decisions to Employees If ...
(Percent of employers surveyed)

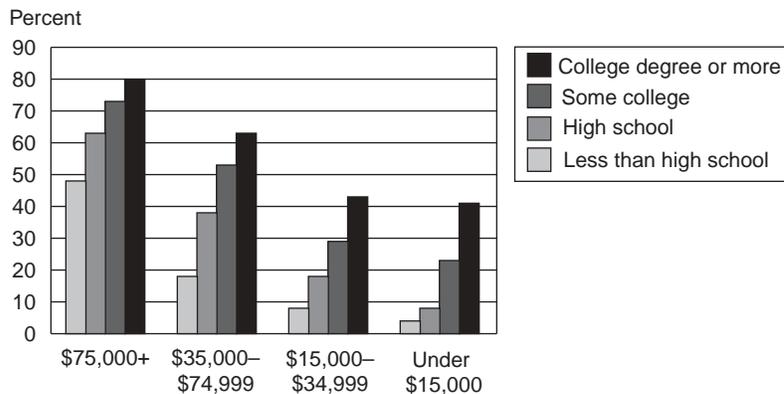


Source: Watson Wyatt/HFMA, 2001.

ty in access to information as technologies are increasingly used as tools of consumer activism in health care (see Figure 4–6 on page 72). Public policy attempting to maintain parity by expanding health care entitlement programs for the poor, the disabled, and the elderly has been ineffective in combating these trends. As a result, the pace of change in socioeconomic disparity will continue to be incremental.

The culmination of these trends will be more marketing of more medications in more thoughtful ways to more people, segmented by insurance coverage, gender, and access to information technology (primary factors); and by income, education level, and health status (secondary factors). Pharmaceutical companies will identify specific consumer segments based on consumer profiles and plan their marketing messages accordingly, ranging from heavily DTC-oriented promotions that target affluent segments to heavily institution-oriented promotions for economically poorer segments. This will mean more work for the pharmaceutical companies, but those that do it well will stay competitive in the long run.

Figure 4–6
Home Access to the Internet Increases with Education and Income
 (Percent of U.S. households with home Internet access by annual income and education, 2000)



Source: NTIA and ESA, U.S. Department of Commerce, using U.S. Bureau of the Census Current Population Survey supplements.

The “medicalization” of natural life processes will increase the overall demand for drugs, because previously untreated and untreatable conditions will have pharmaceutical solutions.

The medicalization of natural life processes will continue and will induce demand for new and existing medications such as the recent lifestyle products Rogaine and Sarafem. For example, baldness, a natural part of aging for some people, and premenstrual dysphoric disorder, are now both treatable with drugs. Increased utilization of such lifestyle drugs will generate greater demand for pharmaceutical products.

Information will empower some consumers to apply genetic information to manage their health.

The public will have access to more sophisticated information about advances in medicine, science, and health care, thereby empowering a major segment of the population to use genetic profile information to manage their own health. Patients empowered with such information can be facilitators of their own health; but they can also demand an increased amount of attention and time from providers. The sheer amount and sophistication of the information could overwhelm some, however, unless public education designed to help individuals interpret and understand what these advances mean becomes widely available and easily accessible. Public education about personal genetic information will be provided by a mixture of industry, government, and non-profit groups.

Genetic modification of food holds enormous promise for “healthy” eaters.

Many ingredients found in common foods are now known to have specific and important health benefits. Called phytochemicals, these substances, found in plants, number in the thousands. So far, only a small number of them has been identified and their mechanisms of action studied. Some familiar protective phytochemicals include allicin in garlic, isoflavones in soybeans, lycopene in tomatoes, flavanoids in green and black teas, sulforaphane glucosinolate in broccoli and broccoli sprouts, carotenoids in carrots, and lignans in flaxseed.

Nutritional science will promote phytochemical micronutrients, vitamins, and antioxidants through genetic manipulation. As a result, many foods will be marketed as scientifically proven supplements or even as alternatives to traditional drugs. By 2010, nutrigenomics—the matching of an individual’s genomic profile with the most appropriate diet—will be available to a limited population of early adopters and health-focused consumers. Nutritional genomics is in its infancy, but in the future, some physicians will help their patients select specific foods to promote health and to avoid disease (such as prostate cancer) with the certainty they prescribe a drug for the same purpose.

Unlike prescription pharmaceuticals, food is a consumer product that is easily integrated into a self-care program, and the emergence of nutrigenomics has critical implications for pharmaceutical companies in particular and the field of health care in general. Food companies that pursue nutrigenomics could compete with pharmaceutical companies to incorporate advances in science. Already, nutritional scientists are studying the physical reaction to food in the same way pharmaceutical researchers attempt to study the human response to a drug. Public education about nutrition will make it possible for interested individuals to tailor their food selections to enhance health without the intervention of physicians. Food manufacturers are slowly moving in this direction, but are currently focusing most of their efforts on enhancing the taste and affordability of functional and fortified foods. While U.S. consumers who are interested in healthful eating will increasingly accept the power of functional and fortified foods, the threat of public resistance to genetically modified foods is significant. A backlash in Europe has already flared up, and this may, at least temporarily, place a moratorium on further development of genetically modified foods with direct health benefits.

Endnotes

- ³⁰ Pharmaceutical Research and Manufacturers of America. Backgrounder: AIDS and the Pharmaceutical Industry. November 24, 1998. <http://www.phrma.org/publications/backgrounders/development/aids98.phtml>
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- ³³ Kennickell, A. et al. Recent changes in U.S. family finances: Results from the 1998 survey of consumer finances. *Federal Reserve Bulletin* (January) 2000.
- ³⁴ Watson Wyatt Worldwide, Washington Business Group on Health and the Healthcare Financial Management Association. *Putting employees in charge: A survey of employers, health care providers and health plans*. March 2001.
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Chapter 5

PAYMENT: WITH HIGHER PHARMACEUTICAL COSTS WILL COME INCREASED TIERING OF CONSUMERS

Drug prices and overall expenditures for drugs are increasing, and this trend will persist through 2010. By 2010, the availability of targeted drugs, consumer demands for access to these new treatments, and the increasing costs of drugs will lead to more complex insurance benefits and greater consumer involvement in treatment decisions about the choice of drugs.

As expenses for drugs mount, payers will shift costs onto consumers, creating tiered benefits that cover the drugs differently by price. Insurers will design multitiered benefits packages that segment consumers based on their ability and willingness to pay for access to different drugs. A simple two-tiered drug benefit will have a smaller copayment for the payer-preferred drug (preferred either because of a lower cost or a greater efficacy) and a larger copayment for more expensive or nonformulary drugs. Wherever possible, lower-cost generics will be substituted for more expensive brand-name drugs, and consumers will be asked to pay the difference if they want the brand-name products. As the market for pharmaceuticals separates consumers by their ability and willingness to pay for drugs, issues of ethics and equal access to necessary health treatments will be discussed in public policy debates.

Payment Forecast Summaries

- Expenditures for pharmaceuticals will continue to grow faster than the overall rate of health spending.
- Employers and payers will manage increases in drug costs and utilization by instituting tiered copayments, formularies, and prescriber and consumer education programs.
- Increasing drug benefits tiering will raise questions of access to affordable drugs and their cost.
- Generics will provide lower-cost alternatives to brand-name drugs as the brand-name patents expire.
- There will be a moderate Medicare prescription drug benefit passed by Congress in the next ten years.
- Genetic profiling will help providers prescribe appropriate, cost-effective medications.

Drivers and Barriers

Drivers

- *Drug companies will continue to develop and promote new products and stimulate demand for expensive, brand-name drugs.*
- *Payers are interested in understanding drug-related cost increases and their respective benefits, and in controlling costs where appropriate. As a result, payers promote the use of generic drugs and will continue to support moving prescription drugs to over-the-counter status.*
- *Cost shifting to consumers by health plans and employers will grow in the form of increased premium share, larger deductibles, and bigger copayments.*

Barriers

- *As multitiered drug benefits become the norm in the United States, cash and out-of-pocket spending will ultimately determine who gets what new, expensive drugs in the commercial market, which is politically unpalatable. Activists and policymakers concerned with the*

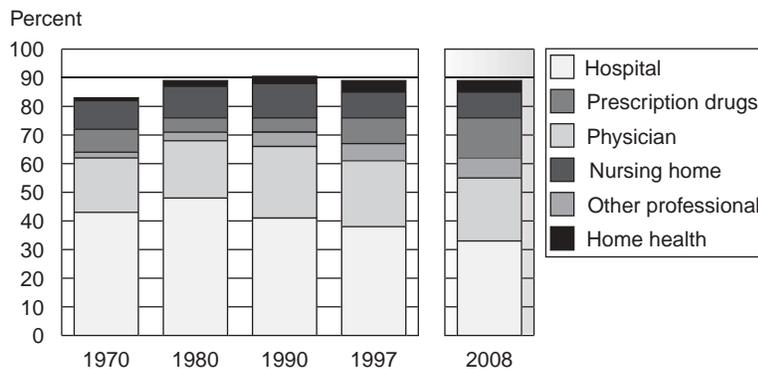
social justice of pharmaceutical costs and access will protest the development of benefits plans that determine access to drugs based on a person's ability to pay for them. Their efforts will keep these issues a topic of policy debate with pharmaceutical companies struggling to manage their public image via public relations efforts and their political position via lobbying.

The Forecasts

Expenditures for pharmaceuticals will continue to grow faster than the overall rate of health spending.

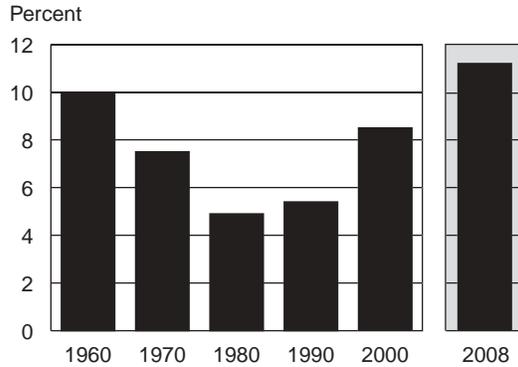
Expenditures for prescription drugs, currently 9 percent of total health spending, will continue to increase at a faster rate than other health costs and will represent a growing proportion of the total health spending at 11.2 percent in 2008.³⁶ (See Figures 5–1 through 5–3.) There is no perfect ratio that describes how much should be spent on drugs as compared to other health care products and services. Advances in medicine have created drugs with the potential to substitute for more expensive and traumatic procedures. As health care services move to outpatient settings, and drugs take the place of physical interventions, drug

Figure 5–1
Hospital Spending Will Decrease While Pharmaceutical Spending Will Increase
(Composition of health spending, by type of service: selected years 1970–2008)



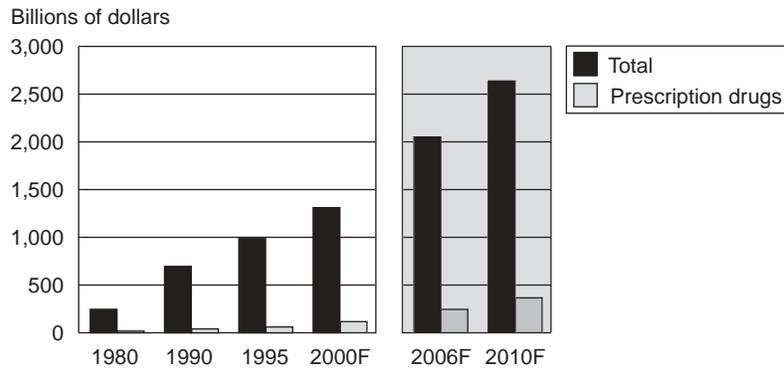
Source: Health Care Financing Administration, Office of the Actuary, National Health Statistics Group.

Figure 5-2
Spending on Prescription Drugs Is on the Rise
 (Spending on pharmaceuticals as a percent of total health spending)



Source: Health Care Financing Administration, *Health Affairs*, Summer 1999.

Figure 5-3
All Health Care Expenditures Will Increase
 (National health care and prescription drug expenditures, 1990-2010F)



Source: Health Care Financing Administration, Office of the Actuary, National Health Statistics Group.

spending as a proportion of the health care dollar will continue to increase. Pharmaceutical companies would benefit from understanding this substitution effect and could justify receiving this increased proportion of the health care dollar if they could calculate the cost savings to the system as a whole.

There are three major barriers to reconciling the costs of pharmaceuticals to any savings elsewhere. The first of these barriers is the accounting system used by health plans. Pharmacy budgets are typically segregated in their systems, and providers are reimbursed differently for pharmaceuticals. This “siloed” budgeting makes it very difficult to connect pharmaceutical use with other data on health costs. But even if that problem could be overcome, there are two further complicating factors. Because people change health plans from time to time, any future savings resulting from current investment is very difficult. Finally, most new technologies become additive rather than substitutional; for example, many consumers who take a new lifestyle drug would never have gone to their doctor in the past to seek medication for their condition. For these people, the quality of life may be improved, but their health costs are now higher.

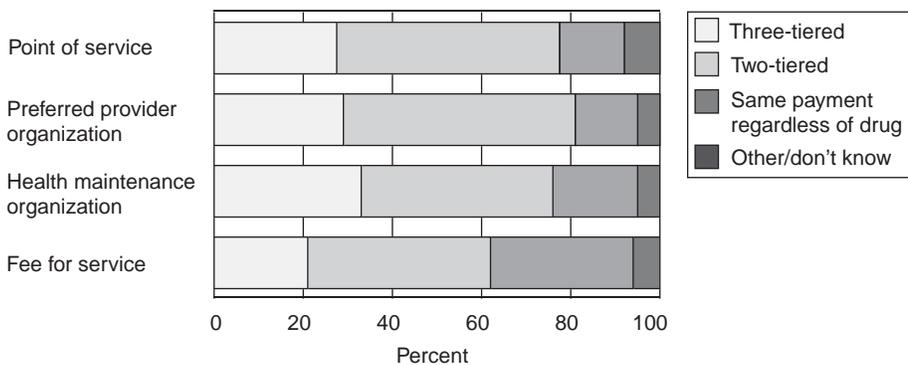
Employers and payers will manage increases in drug costs and utilization by instituting tiered copayments, formularies, and prescriber and consumer education programs.

Employers will manage increases in pharmaceutical costs and utilization by instituting multitiered copayment plans that make patients pay more out of pocket for more expensive drugs, the use of formularies to stratify comparable drugs by cost, and consumer education that makes the differences in drug prices explicit. A recent Watson Wyatt report found that most health insurers already have begun to diversify their benefits packages to offer two- or three-tiered drug benefits (see Figure 5–4 on page 82). Payers and consumers will decide which benefits best suit their health care budgets and needs. This will generate purchaser and consumer interest in the trade-off between purchasing a richer drug benefit with greater coverage and paying for more drugs on an out-of-pocket basis. Prescriber profiling is another form of education. Prescriber profiling, or tracking physicians’ prescribing patterns and

giving them feedback about their choices from the purchaser’s perspective, is one way health insurers will try to influence doctors to choose less-expensive and higher-quality drugs.

In response to the rising drug costs they identify as a factor in rising premiums, employers and other payers are leading an effort to fund cost-benefit evaluation initiatives, such as RxHealthValue and Rx Intelligence (see Figure 5–5). RxHealthValue’s mission is to conduct research comparing the pharmacoeconomic value of new drugs with existing ones. RxHealthValue released a study in July 2000 that examined national prescription drug utilization and expenditure increases among continuously insured populations and reported increases close to 25 percent between 1995 and 1999, which is significantly higher than the 15 to 20 percent increases that have been reported among the general population.³⁷ Rx Intelligence is an independent, nonprofit Blue Cross Blue Shield company that has as its ultimate goal “to put in the hands of consumers, doctors, and hospitals credible and objective information so that they can make wise choices about the pharmaceuticals they take and prescribe.”

Figure 5–4
 Insurers Implement Tiered Benefits Plans for Pharmaceuticals
 (Percent of covered workers facing different cost-sharing
 formulas for prescription drugs, by plan type, 2000)



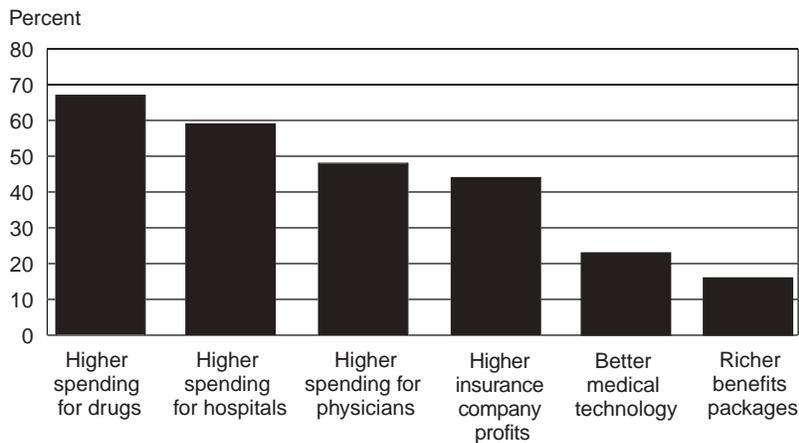
Source: Kaiser Family Foundation/Health Research and Educational Trust, Employer Benefits Survey, 2000.

Increasing drug benefits tiering will raise questions of access to affordable drugs and their cost.

Cost, quality, and access are the three criteria used by health care payers and consumers to evaluate new health products and programs. As pharmaceutical companies introduce new, more expensive drugs and their wraparound services, payers will limit their exposure to rising costs by segmenting access to products and by implementing multitiered drug benefits plans that shift costs to consumers. Segmentation of the consumer market by health plan benefits package will lead to greater disparity of access to new drugs and drug-related health products based on ability to pay. This segmentation will raise questions of equity and medical necessity. The question of “Who pays?” also raises the question of “Who decides what gets covered?” as purchasers become more selective about the benefits they provide for their employees.

With consumer pressure on health plans to be more inclusive than exclusive, decisions about what is on a health plan’s formulary are driven somewhat by consumer demand and are not necessarily based on clinical or cost-effectiveness. The result will be less-standardized formularies created with less-clinical rationale and, subsequently, imbalanced benefits structures.

*Figure 5-5
Firms Identify Higher Pharmaceutical Spending as a Reason for Higher Premiums
(Factors firms say contribute “a lot” to health insurance premium increases)*

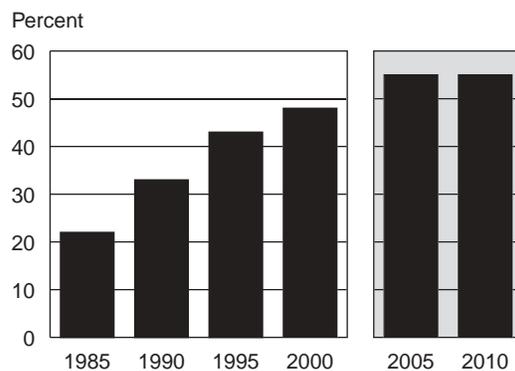


Source: Kaiser Family Foundation/Health Research and Educational Trust, Employer Benefits Survey, 2000.

Generics will provide lower-cost alternatives to brand-name drugs as the brand-name patents expire.

The market for generic drugs will grow slightly as these drugs continue to provide a lower-cost alternative to more expensive brand-name drugs (see Figure 5–6). The balance of power among regulators, the pharmaceutical industry, and payers in relation to generics and patents for brand-name drugs will not tip significantly in our forecast period. Pharmaceutical companies will work hard to extend patent protections and to slow the market entry of generic drugs, while payers (including the government), will push regulators to open the market for generic products. The overall effect will be the increased availability of both new and generic drugs as \$52 billion in branded drugs becomes vulnerable to the competition of generics during the next ten years. The large number of brand-name drugs going off patent and the influx of generics will be welcomed by more informed consumers and frustrated payers looking for cheaper alternatives. In a countervailing move, pharmaceutical companies will try to keep their pipelines strong and do what they can to leverage existing brands before they go off patent.

Figure 5–6
Generics Will Be Half of Total Prescription Units



Source: IMS Health, 2000; Institute for the Future, 2001.

There will be a moderate Medicare prescription drug benefit passed by Congress in the next ten years.

Any Medicare prescription drug benefit that is created in the next few years will be a token effort, limited in scope and reach. The two options for providing a benefit that nonetheless limits seniors' access to drug benefits are means testing and caps on consumer expenditure. A means testing approach will likely be an incremental expansion of the existing Medicaid program. This approach is less popular with the public and clearly would not expand coverage to all seniors. The consumer expenditure approach would track total annual spending for all seniors and cover costs paid by consumers above a certain dollar amount.

Even with a Medicare prescription drug benefit, there will be little real change in the amount of drug spending covered, despite significant expectations. There is a great deal of political pressure from the senior lobby, and episodic opportunism by politicians seeking to exploit that pressure. Fundamental political disagreement between liberal and conservative factions over how health care entitlements should be funded, administered, and utilized are holding back the resolution of this issue. Anything short of a comprehensive drug benefits plan for seniors will leave many seniors without access to new medications in the future. Though the topic may lose public attention if some type of prescription drug benefit is created, access to prescription drugs for seniors will not disappear from the policy radar screen during our forecast period.

Genetic profiling will help providers prescribe appropriate, cost-effective medications.

Beyond 2005, the inclusion of genetic information in cost-effectiveness analysis will reframe outcomes research. In a market segmented along many lines (e.g., ability to pay, preferences, and genetic composition), information will be the key to helping providers and consumers make wise health decisions. Cost-effectiveness analysis is an attempt to quantify and compare treatment options in hopes of helping consumers, payers, and providers make rational treatment choices. The premises upon which cost-effectiveness analyses are based can vary significantly, depending on how criteria are included and the assumptions that an analyst makes. Information profiling a person's genetic predisposition toward a specific treatment will add valuable insight into future cost-

effectiveness analysis, and help providers prescribe appropriate treatments for their patients. Such treatments may be more cost-effective in the long run because they will represent the best, most efficient way to solve the health problem. By the end of the decade, we forecast that genetic information will guide cost-effective treatment decisions and reduce adverse events due to medication.

The Ethics of Pharmaceuticals

Ethical issues arise in most health care discussions, and the future of pharmaceuticals is no exception. In this section we focus on a select few issues among the many we could have chosen: DTC advertising and health information, market segmentation, and the potential for conflict of interest in research and prescribing.

DTC Advertising and Health Information

Pharmaceutical companies are joining hospitals and clinicians as information providers, and the public expects them to provide information that is reliable, unbiased, and trustworthy, because consumers will use this information to make health care decisions. Pharmaceutical promotional information directed toward consumers is, and will continue to be, under intense scrutiny from the FDA and the FTC to ensure that marketing messages provide a balanced and realistic view of what a pharmaceutical product can offer.

Because advertising is a mechanism to drive sales, pharmaceutical companies have invested large sums of money in understanding the

diseases their drugs target. They have even funded education programs to raise public awareness about the diseases in which they are invested. A pharmaceutical company that sells a diabetes drug is motivated to raise awareness about the disease and to make sure all individuals with diabetes get diagnosed and begin treatment, hopefully with its drug. However, the methods by which pharmaceutical companies provide information to consumers are sometimes circumspect.

In the past, the only way pharmaceutical companies communicated with their consumers was through patient-packet inserts that accompanied prescriptions. These inserts are still heavily regulated by the FDA, however, the information often is printed in very small type, is too technical for the average consumer to understand, and is directed toward regulators, not patients. For these reasons, complete information about a drug, such as its potential side effects and contraindications, is considered to be inaccessible to the average patient, even though it may be of high quality and trustworthy.

The Ethics of Pharmaceuticals (cont.)

The passage of the FDA Modernization Act in 1997 paved the way for DTC advertising and expanded the ways in which pharmaceutical companies provided information. When the first DTC ads were created for consumer magazines, billboards, and television, they often contained most of the same side-effect and contraindication information found in the patient-packet insert, though in very small type in print ads and in quick-talking voiceovers at the end of television ads for drugs.

The Ethics of Market Segmentation

Segmentation is a major theme in our forecast and will shape many of the elements in the future pharmaceutical market. Though there are many positive aspects to market segmentation—providing the right products and information to people in the best way possible—the less optimistic view of segmentation is that it can unnecessarily and unfairly create disparities based on uncontrollable factors, such as a person's ability to pay for drugs.

The spread of HIV/AIDS throughout the developing world has prompted governments and people to respond to help those in

need. HIV/AIDS drugs have transformed the course of disease for some patients from a devastating to a chronic (although still terminal) illness. Efforts have been directed toward getting these high-cost treatments to people who otherwise would not be able to afford them, sometimes by negotiating with pharmaceutical companies to get lower prices for drug-based HIV/AIDS treatments. The success of these efforts highlights the fact that pharmaceutical companies are supporting a market price that is higher than necessary. The marginal cost of producing one more pill (or thousands more) once a drug is through development and the approval process is well below the market price pharmaceutical companies are charging. The low cost of manufacturing the pills has been discussed openly, and patent pirates (rogue drug companies that produce patented drugs and sell them at reduced prices), as well as some governments of developing countries hit hard by AIDS, claim that sick people should have access to these potentially life-saving drugs for a lower price. Large pharmaceutical firms that hold the patents claim

that the price of producing a drug encompasses their investment in many years of R&D, clinical trials expenses, and the costs of all the failures along the way.

A by-product of this public debate has been increased price transparency of prescription drugs, regarding the real manufacturing costs of most drugs. This increased transparency has added fuel to the debate around disparity in access to drugs based on ability to pay. When a new brand-name drug enters the market, pharmaceutical producers test the market to determine the price that the market will bear to recoup its initial investment costs. If the drug is a significant improvement on the current treatment and is considered “medically necessary,” health insurers may have no choice but to cover the drug fully except for a small copayment. Health insurers cover most clinically proven new drugs and place them on their formulary. Should a health insurer decide a drug is not a significant improvement, it may still cover the drug but charge a larger copayment.

This tiering of drug benefits is segmenting people in the insured population by their ability to pay more out of pocket for more expensive drugs. Most health insurers have instituted three-tiered drug benefits and are moving to five-tiered benefits. In such cases, individuals make decisions about how much health insurance they want and can afford. Consumers are also starting to make decisions about how much they are able and willing to pay out of pocket to get brand-name drugs. Ability to pay is the largest factor determining a person’s access to pharmaceutical products. Because access to health care is often considered a right rather than a benefit, greater segmentation in the market for pharmaceuticals will create enormous opportunities for real and perceived inequality among U.S. consumers. This will continue to be a major issue for policymakers to grapple with as drug expenditures rise, as companies innovate and develop more effective but costlier treatments, and as consumers are required to pay more directly for their health care.

The Ethics of Pharmaceuticals (cont.)

The Potential for Conflict of Interest in Research and Prescribing

There is a current debate as to whether researchers can maintain an “unbiased perspective” when they report research findings or if physicians can prescribe the most appropriate drug for a patient if the researchers or the physicians receive funding or “gifts” from an “interested third-party,” such as a pharmaceutical company whose product is in clinical trial or being sold on the market. Researchers and physicians often find themselves in a position where there is a potential for a conflict of interest between pharmaceutical companies’ goals (i.e., getting a drug through the approval process and generating profits on products) and patients’ needs (i.e., the best treatment for their condition).

Research indicates that the conflict of interest researchers and physicians experience may be real; though gifts and funding are usually not given with explicit assumptions or directions, scientists with financial ties to the companies whose products they study are “more likely to write favorably” about those prod-

ucts and physicians courted by drug companies are more likely to engage in “nonrational” prescribing. In other words, they are more likely to order a drug that is more expensive, or less effective, than what the patient actually needs.³⁸

There are a number of ways pharmaceutical companies can influence clinical trials research and prescribing. They can pay the salaries of scientists, fund academic research centers, pay physicians honoraria to attend educational seminars about a particular drug, and give small gifts with a drug’s logo as part of the detailing process.

In submitting an article for publication, academic researchers are always expected to reveal their “financial ties” to companies or entities that might “influence their work.” Studies have shown that as many as half of all academic researchers “consult with industry,” and about 8 percent have “stakes in biomedical companies related to their research.” But most researchers don’t report these ties and most journals assume that no conflicts reported means no conflicts exist.³⁹

In response to concern about drug company-sponsored research, especially in cases when companies tried to withhold results or present them to favor certain drugs, a group of editors from leading medical journals, including the *New England Journal of Medicine* and the *Journal of American Medical Association*, signed a policy that will give the editors the right to reject studies unless researchers are granted adequate independence.⁴⁰ We anticipate that more of these types of solutions will be used to ensure that the highest-quality information about new health treatments is available.

Endnotes

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Chapter 6

WILD CARDS

Wild cards are events of low probability, but if they do occur, their impacts can resonate on a global scale. The following wild cards, if they come to pass, could have major impacts on the forecasts in this report.

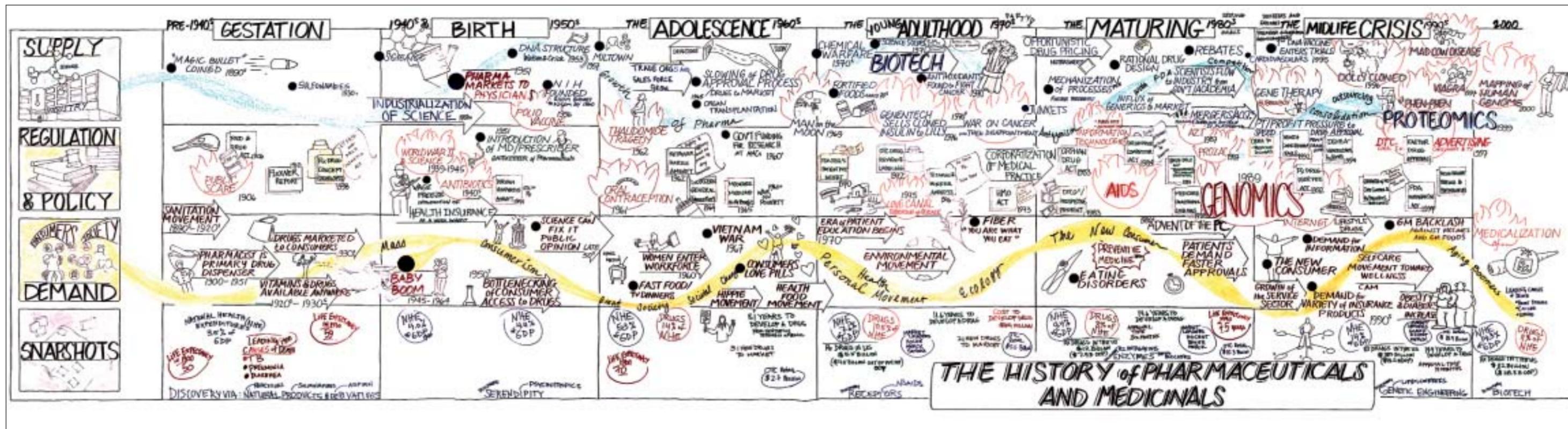
- The public debate around the application of genetic technologies in health care heats up, creating intense scrutiny and very onerous regulations for companies conducting clinical trials involving genetic sciences.
- Passage of price-control regulation in the United States diminishes the funds available for R&D. Policymakers implement measures that effectively control market prices for pharmaceuticals, eroding product profitability and subsequently threatening funding for new product R&D. Reduced funding forces pharmaceutical companies to increase scrutiny in allocating funds for R&D.
- A new financing mechanism for pharmaceutical R&D emerges, modeled somewhat after the biotechnology industry. Pharmaceutical companies auction all of their patents in a public market prior to product development, and use this funding to support future R&D. Pharmaceutical companies' core business focus shifts away from approvals and marketing and toward internal innovation.
- The patent model erodes as international generic pharmaceutical companies ignore patent law, develop, and sell "me-too" drugs into U.S. markets at drastically reduced prices. The largest 15 pharmaceutical companies merge into five that acquire the largest generic manufacturers, thereby controlling the influx of higher-priced generics into the market.

Conclusion

The overarching themes in this forecast are segmentation and relationships. Both of these themes appear again and again, and weave through the components of our forecast. Relationships and segmentation parallel one another because as markets, trends, and functions become more disaggregated, relationships provide the glue that facilitates valuable transactions.

Segmentation and the importance of relationships in business are not big news. Pharmaceutical companies, scientists, and marketers have all been focusing on segmenting their research and markets to better understand separate trends before integrating them into a multi-dimensional context. Companies have always been concerned about the business relationships they form with their suppliers and their consumers. Technology is allowing customization and targeted research on a broad scale. Industry is integrating increasingly specific information about consumers to narrowcast messages and information, whereas in the past they were constrained to broadcasting techniques. Science and industry are developing a portfolio of highly targeted drugs that better suit the needs of a diverse patient population. The story lies in how the trends forecasted in this report—revolutionary innovation in science, business models changing to leverage scientific advances, regulatory shifts to adapt to the new products, increasing costs and tiering of benefits, DTC promotion we can only begin to fathom, and consumer demand for drugs—converge to shape the market for pharmaceuticals in the future.

HISTORY MAP 1900–2000: MAPPING THE SUPPLY AND DEMAND OF PHARMACEUTICALS



In an effort to understand today’s pharmaceutical market and how it came to be, we have created a history map that tracks the trends in production and consumption of pharmaceuticals and medicals during the 20th century. Our supply and demand framework highlights the intersections of these two trend lines in the form of events such as pharmaceutical regulation, epidemics or new products.

Supply Side

On the supply side are science and industry. Scientific advances in academic and corporate laboratories have brought new understandings of chemistry and biology, resulting in improved medicines. Industry brings those advances to the market in the form of pharmaceuticals.

Science

We tracked advances in science and identified occasions when an invention or discovery changed the way medicines are created or how scientists and clinicians think about illness. Penicillin and Prozac are examples of scientific advances that resulted in new products, and shifted the way people and physicians view illness or disease.

Industry

The amazing growth of the pharmaceutical industry in the last half of the 20th century can be attributed to many factors, including the following:

- Regulation created the physician prescriber/gatekeeper role and shifted dispensing away from the local pharmacist.
- Advances in pharmacology created drugs that were safer and more effective.
- Changes in social norms resulted in a consumer market that embraced drugs.

Demand Side

The demand side describes consumers’ use of medicines within the context of social change. In the United States, consumer desire for miracle cures and life-saving medicines continues to be intertwined with our fascination with science and technology. Since the early 1950s, consumer access to prescription drugs has been tempered by the physician/gatekeeper. The pharmaceutical industry quickly recognized the importance of the physician’s role in distributing pharmaceutical products. In recent years, the pharmaceutical industry has made note of the consumer/patient’s power and has been investing heavily in direct-to-consumer advertising to directly engage this market.

Regulation

Policy and regulation mediate the relationship between supply and demand by ensuring the safety and efficacy of drug products as they enter the market. The regulation of the pharmaceutical industry began in earnest in 1906 with the Pure Food and Drug Act. Health regulation was often the result of public concern following a series of events, or activism toward consumer protection.

Eras of Growth and Development

Beginning with World War II, every decade of the 20th century represents an era in the growth of the pharmaceutical industry. The Baby Boom generation’s lifecycle is the metaphor we’ve chosen to describe the emergence of the pharmaceutical industry.

Pre-1940s: Gestation

The beginning of pharmaceutical regulation followed decades of effort by the sanita-

tion movement to protect people from illness through improvements in public health. Upton Sinclair’s exposé of meatpacking industry practices described in *The Jungle* prompted the inception of the Pure Food and Drug Act in 1906. There was minimal product regulation at that time; drugs and medicals of all kinds were marketed as consumer goods. The pharmacist was the primary drug dispenser and patients paid for drugs out-of-pocket.

1940s and 1950s: Birth

World War II tremendously affected the pharmaceutical industry. The country’s significant investment of financial and human resources into science translated into advances in chemistry and medicine (e.g. antibiotics and a polio vaccine). The organization and industrialization of science that occurred during and after the war created the foundation for today’s pharmaceutical research community and industry.

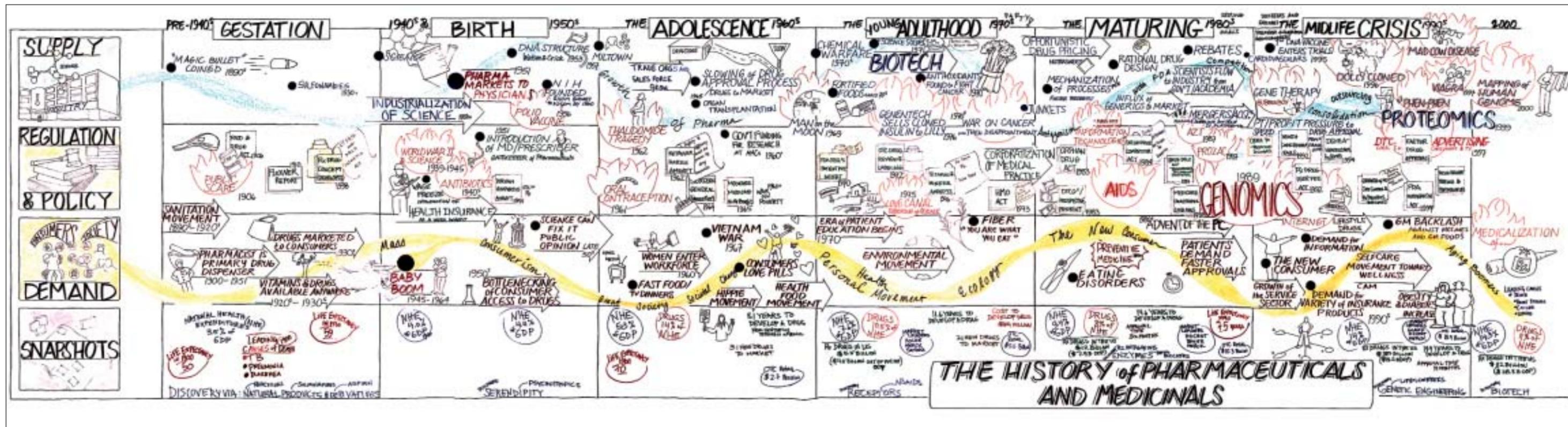
During the war, wages were frozen and health insurance benefits were introduced as a way to increase employees’ compensation without raising their pay. The third-party payment system has persisted to this day and is one of the most important political issues for the future pharmaceutical industry.

1960s: Adolescence

In every way, the 1960s was a time of expansion and growth for the pharmaceutical industry. Advances in science and technology allowed people to alter their world with a simple pill—and they loved it.

Young and old alike were trying new prescriptions with very little consideration of their long-term effects. The introduction of the oral contraceptive pill in 1960 gave women unprecedented control over their reproductive health and therefore their lives.

HISTORY MAP 1900–2000: MAPPING THE SUPPLY AND DEMAND OF PHARMACEUTICALS



They entered the workforce in record numbers. The achievements of American science and its potential to overcome enormous barriers was well illustrated when the United States sent a man to the moon in 1969.

Policies and regulations passed in the 1960s significantly slowed the process of bringing drugs to market by requiring extensive safety and efficacy review. The creation of trade organizations and the growth of pharmacies and the pharmaceutical sales force greatly expanded the distribution of pharmaceutical products.

1970s: Young Adulthood

The new responsibilities of young adulthood characterized the 1970s. A less optimistic view of the capabilities of science and greater government presence became the norm. Attitudes toward America's involvement in the Vietnam War divided the country.

Nixon's proclaimed "War on Cancer" increased funding for research. When scientists were unable to develop a cure for such a complex disease, many were disappointed. The birth of the biotechnology industry was a highlight of science. In the early 1970s, the eras of patient education and self-care began with new FDA reviews of prescription drugs that were moving to over-the-counter (OTC) status and patient packet insert requirements.

The Health Maintenance Organization (HMO) Act of 1973 was a major step toward organizing physicians and other health care providers. It led to the corporatization of medical practice that characterizes the current health care environment.

1980s: Maturation

The 1980s are characterized by new pharmaceutical product development. In 1989,

the U.S. government launched a seminal study to decode the human genome. Industrialization of processes, coupled with advances in information technology, allowed standardization and a more rational approach to developing drugs. Pharmaceutical company consolidation created a largely research-based industry that drew scientists away from government and academia.

New policies enabled the development of a generics industry that could compete on price and quality as pharmaceutical product patents expired. Patients demanded faster approvals for drugs to treat the emerging infectious disease, HIV/AIDS. The research and medical communities voiced their observations that lifestyle and environment are strong determinants of health status, and developed health risk assessments to examine a person's predisposition toward health, illness and disease.

1990s: A Midlife Crisis

A midlife crisis hit the pharmaceutical industry in the 1990s. Advances in science were promising, but slow moving. Competition forced industry consolidation in order to maintain strong research and development pipelines and opportunities for profitability. The industry also pushed on the regulatory structure and sped up the FDA approval process. Backlash against genetically modified foods and bans on cloning and human tissue-based research created a darker image of science than had previously existed.

The use of new media, especially the Internet, allowed dissemination of health information to a wide audience. Consumers used this information to demand greater participation in their health care decisions, creating a strong shift toward self-care.

THE FUTURE OF PHARMACEUTICALS

