Pharmaceutical Marketing and the Industry Environment

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LEARNING OBJECTIVES

1. Describe how the advent of the prescription altered the dynamics of the pharmaceutical industry.
2. Identify pharmaceutical manufacturers’ customers, describe their needs, and assess how those needs are met.
3. Describe the social, ethical, political, and legal issues unique to the pharmaceutical market and how these issues affect the marketing and choice of pharmaceuticals.
4. Describe the issues unique to pharmaceutical marketing, including differentiating the marketing focuses between prescription and over-the-counter medications and brand and generic medications.
5. Assess the pharmaceutical industry’s future and evaluate the role of marketing and possible changes necessary.

While watching television one Saturday afternoon, a 58-year-old seemingly healthy man sees an advertisement for Livalo (pitavastatin). The advertisement depicts the diet and lifestyle choices that lead to high cholesterol and the subsequent cardiovascular and heart problems that can result. After seeing the ad, the man realizes his cholesterol is probably too high and that he should check into
getting Livalo or something similar. In a different scenario, an 8-year-old child has been having difficulties with bedwetting. His parents have tried limiting his fluid intake late in the evenings and are sure to take him to the bathroom right before bed, without success. In both of these scenarios, the consumer has a problem that can likely be solved through the use of a pharmaceutical. Why can’t they go to a community pharmacy and simply purchase the medication that would help them solve their problem, as people routinely do for most other consumer goods?

In health care, the issues and solutions for supply and demand are different from those of other consumer goods and vary depending on cultural norms, societal values, and even government regulation. In other cultures, the solution to a health issue might be a visit to a medicine man or ingesting an herb or natural substance. In the United States, the primary answer to most health problems is a trip to the physician. Physicians then use their education, training, and experience and data they collect from the patient (e.g., physical exam or blood analysis) to determine the cause of symptoms (i.e., they make a diagnosis). More often than not, a physician visit usually concludes with the physician prescribing some type of medication for the patient to purchase to help alleviate symptoms or prevent future negative health outcomes.

THE PRESCRIPTION

Sickness can take many forms, including bacterial infection, elevated blood pressure, pain, erectile dysfunction, depression, and even extreme cognitive issues, such as schizophrenia or Alzheimer’s disease. Thus, in the mind of the consumer, the factor sparking the need for help can be physical or cognitive. To ensure proper diagnosis and treatment of health issues, laws and regulations have been passed to ensure the safety and well-being of consumers in the healthcare environment. For example, the authority of the Food and Drug Administration (FDA) has been augmented over time, requiring pharmaceutical manufacturers to conduct rigorous research and work through an extensive application process to have a medication approved for use in patients and available for sale in pharmacies.

Of the many laws and regulations related to pharmaceuticals, none has altered the pharmaceutical industry like the advent of the prescription. In 1951, when the Durham-Humphrey Amendment to the original Food, Drug, and Cosmetic Act of 1938 was passed, the requirement for a written prescription from an authorized prescriber was legislated, creating a distinction between prescription medications and all other types, such as nonprescription or over-the-counter (OTC) medications. Whereas the prescription requirement is rigid, the
generation of a prescription is quite flexible. Currently, a prescription can be written by an authorized prescriber, phoned in to a dispensing pharmacy by an agent of the prescriber, faxed in, or, increasingly popular, submitted electronically with an e-prescribing software system (Surescripts, 2011). The requirement for a prescription to purchase certain medications has created a distinct environment in which pharmaceutical manufacturers market and sell their products, one much different from the market for traditional consumer goods.

From the pharmaceutical manufacturers' and marketers' perspectives, the Durham-Humphrey Amendment created opportunities for healthcare businesses. Although most people cannot recall a time when they did not have to obtain a physician's written prescription, a world did exist prior to the prescription requirement, a virtual “wild, wild west of health care.” The use of prescriptions creates barriers to entry that help manufacturers remain competitive. It prevents “snake oil” salesmen from putting together a concoction, claiming it has therapeutic benefits, and selling it. Second, the amendment creates a unique business environment that operates on the idea of directed demand. Directed demand in the pharmaceutical industry means the prescriber, the learned intermediary, usually a physician, determines which medication(s) or treatment the consumer needs.

Continuing the situations posed at the beginning of the chapter, the man with high cholesterol and the boy who wets his bed must confirm they indeed have a medical condition and determine the best corrective action or treatment. The man who saw the Livalo advertisement might, for example, do extensive research on the subject of cholesterol, purchase a home cholesterol test, and determine that his cholesterol level is well outside the normal limits and should be treated. He might then research the literature and decide, based on his cholesterol numbers and personal medical history, that Lipitor (atorvastatin) is his best treatment option. However, to purchase Lipitor, he must see his primary physician, obtain a written prescription for that medication, take the prescription to a pharmacy, and purchase the medication when the prescription is filled by the pharmacy. The caveat with directed demand is that, although the patient might request a specific drug, the prescriber might deem another medication the best choice based on the patient’s clinical case.

This situation presents a unique challenge for the pharmaceutical industry and its marketers. Whereas marketing is a process that creates value for customers through exchange, in pharmaceutical marketing the value medicines bring to patients and society are actualized. Given the nature of the pharmaceutical market and the fact that medicines might be necessary to sustain life, pharmaceutical marketers play a vital role in health care. In being responsive to this
role, pharmaceutical marketers recognize the unique nature of their operating environment (e.g., legal, social, political, technologic, regulatory, or economic issues), especially the fact that often the customer is not the patient but rather a third party, such as a physician or pharmacy, that is, in turn, reimbursed by insurance companies or government payers. From a societal marketing perspective, the challenge for the pharmaceutical marketer is to meet customer needs across each potential target market, while keeping patient welfare in mind.

CUSTOMERS OF PHARMACEUTICAL MANUFACTURERS

From a marketing perspective, the key to success and long-term survival in any industry is continually understanding the organization’s customers and working to meet their needs in the most efficient manner possible. In the pharmaceutical industry, the customer takes many forms, depending on the perspective taken. This is especially true when examining a pharmaceutical manufacturer’s customer base. Given the desired end result of continual new prescriptions filled and purchased, the product ultimately dispensed is primarily a function of three entities: the prescriber, consumer/patient, and third-party payer. Figure 2-1 graphically depicts this interaction in which the dispensed product is represented by the point of intersection among the three and shows the point at which each customer’s needs have been met. Physicians desire the best product to treat the patient therapeutically, while consumers and third-party payers want the best value, or the highest therapeutic benefit at the lowest cost.

The use of the term *dispensed* as opposed to *prescribed* is significant. Whereas the physician can prescribe a medication based on available knowledge and patient characteristics, the consumer must take the prescription to the pharmacy and determine whether it is covered by his or her prescription insurance at a desired co-payment or coinsurance and, if not, whether it is a reasonable cost. Third-party prescription insurance has grown from only a small percentage (5–10%) in the 1970s to 80% or more of the typical pharmacy’s prescription business (Kaiser Family Foundation, 2010).

Even though prescribers, patients, and payers do not all work together, each contributes to the decision about which product
is dispensed, especially for generic medications. Each of these three entities is a customer of the pharmaceutical manufacturer. If Figure 2-1 is expanded to include those logistically involved, the pharmacy and wholesaler are included in the model as well (see Figure 2-2).

The following subsections examine the various customers of pharmaceutical manufacturers, discuss the needs of those customers, and illustrate how manufacturers work to meet those needs.

**Physicians**

In the United States, when someone gets sick, he or she typically goes to the doctor. The doctor, using specialized knowledge and experience and through the use of prescriptions, has long been pharmaceutical manufacturers’ primary customer.

For physicians as customers of the pharmaceutical industry, the primary “need” or solution to a problem is information. Physicians must constantly stay up-to-date on the drugs they prescribe and the associated medical information on diseases and treatments. By staying abreast of the most current medical and drug information, usually through published research, physicians can make the most appropriate (in terms of cost and quality) treatment decisions. Additionally, pharmaceutical manufacturers that want physicians to prescribe their products must work to provide as much information about the products as possible so this information can lead to prescription trials and adoption.
The sheer number of practicing physicians makes them important pharmaceutical industry customers. According to the Association of American Medical Colleges (AAMC), there are currently about 680,000 actively practicing physicians (AAMC, 2011). Further, there are approximately 97,000 enrolled medical school (MD) and osteopathic medical college (DO) students. Finally, each of the 680,000 physicians sees multiple patients daily, with many visits resulting in a prescription. According to the Centers for Disease Control and Prevention (CDC) national health statistics, there were nearly 1 billion physician office visits in 2010 (Schiller, Lucas, Ward, & Peregoy, 2012), which generated approximately 4 billion prescriptions. This number includes both new prescription orders by physicians as well as refill prescriptions. Generally, new prescriptions are about 40% of the prescriptions filled (Kaiser Family Foundation, 2010).

**CASE IN POINT 2-1**
Are There Enough Physicians?

One debate in U.S. health care is whether there are enough physicians to meet the nation’s healthcare needs (Sataline & Wang, 2012). Currently, those arguing there are enough physicians cite comparisons to global health indicators, where the United States falls in about the middle of the range of physicians per capita when compared to other industrialized countries (CodeBlueNow!, 2008). However, those on the other side of the issue cite the large numbers of specialist physicians compared to primary care physicians (only about 35% of all physicians) as evidence that the U.S. per capita ratio is overestimated (AAMC, 2011).

An argument also exists as to the adequacy of the future physician supply. Those who believe enough physicians are being trained point to the increase in the amount of nursing and home care in addition to the increasing role of other providers, such as physician assistants, nurse practitioners, and pharmacists, which all serve to extend the supply of physicians. Those who argue the nation will not have enough physicians in the coming years point to the increasing age of the population and the increase in the number of insured lives resulting from the Patient Protection and Affordable Care Act of 2010.
How pharmaceutical manufacturers provide the necessary drug and medical information needed by physicians has evolved over the last 50 years as physicians’ time and pharmaceutical industry access to physicians have decreased. Even though pharmaceutical manufacturers are still the primary providers and sponsors of continuing medical education (CME), gone are the days when pharmaceutical manufacturers could shower physicians with gifts and trips that provided information while trying to entice written prescriptions. Further, based on the voluntary yet universally followed Pharmaceutical Research and Manufacturers of America (PhRMA) Code on Interactions with Healthcare Professionals (PhRMA, n.d.), the popular “reminder items” such as pens and coffee mugs with a product’s name on it have disappeared. The code describes guidelines that manufacturers should follow in their interactions with healthcare providers, including rules on educational items, consultant arrangements, meals, and support of educational events, such as CME, speaker programs and speaker training meetings, scholarships and educational funds, interactions with healthcare providers on formulary committees or developers of clinical practice guidelines, and use of prescriber data. This code is meant to help member companies comply with the Office of Inspector General (OIG) guidelines and relevant laws and regulations. Even given these restrictions, pharmaceutical manufacturers spend approximately $12 billion to $16 billion annually on marketing to physicians (Blumenthal, 2004; Deloitte, n.d.).

The staple and still primary route of information delivery is through pharmaceutical manufacturer sales representatives and medical science liaisons (MSLs). The roles of these two professionals differ with respect to compliance with industry regulations and the topics they are allowed to discuss: The sales representative focuses on product promotion, while the MSL cannot promote product sales and functions instead as the drug and medical information expert. MSLs, in particular, work to identify and develop various experts, or key opinion leaders (KOLs), within their field or disease specialty. KOLs often serve as speakers or information experts who perform a variety of functions depending on need, such as consulting for clinical trial design or presenting clinical trial data at a national conference. KOLs, usually leading physicians, expand the pharmaceutical manufacturer’s reach and information delivery network.

Pharmaceutical manufacturers have also begun to harness the power of the Internet for information delivery. Product-specific websites now exist for most all branded medications and include a separate section for prescribers and other healthcare professionals. In addition, many manufacturers now operate disease-specific educational websites and online communities. Perhaps most important in today’s society, manufacturers are now communicating through mobile technologies, including tablet and smartphone messaging and applications. Pharmaceutical
marketers can deliver product messages to physicians’ personal devices without incurring the expense of a sales representative. The messages can be changed as needed in real time, are customized according to the recipient, and even provide the ability to receive physician feedback. Obviously, as technology evolves, pharmaceutical manufacturers must continue to adapt their information delivery methods to ensure that they meet the information needs of their physician customers in the most cost-effective and efficient manner.

**Pharmacies**

One of the pharmaceutical manufacturers’ largest direct customers is the community pharmacy. Pharmacies across the country that dispense medications have to keep in stock the manufacturers’ products in order to provide these medications to consumers. As mentioned earlier, prescription volume has continued to grow over the past few decades, with almost 4 billion prescriptions (including both new and refill prescriptions) filled in the community pharmacy setting in 2010, approximately 40% more than a decade earlier (Kaiser Family Foundation, n.d.).

The primary business needs of pharmacies are the best possible pricing and consistency of supply. Even though community pharmacies offer a variety of services to patients, much of the community pharmacy business model is tied to dispensing prescription products. Inability to stock their shelves with adequate inventory to meet consumers’ needs hurts the bottom line and can also drastically reduce patient care and customer service levels. In addition to a consistent supply of medications, pharmacy buyers need manufacturers to ensure their medications can be reimbursed by third-party payers (e.g., insurance companies, pharmacy benefits managers, and the government through Medicare or Medicaid). Typically, the first question a practicing community pharmacist asks a pharmaceutical manufacturer’s sales representative is whether the medication is included and preferred on the Medicaid formulary. The answer to this question has a significant impact on the numbers of prescriptions generated for that product.

To meet the needs of their community pharmacy customers, pharmaceutical manufacturers work diligently to provide the best possible pricing and maintain supply chain links. Firms that are successful in these functions typically have the marketing department working closely with both the pricing department (if it exists; at some companies the marketing department decides pricing issues) and the manufacturing division. In these cases, sudden changes in pricing or supply in the marketplace can be quickly communicated through marketing to the rest of the company. The company can then efficiently act to solve any customer problems as well as reconduct its own analyses for forecasting and planning purposes.
CASE IN POINT 2-2
Various Pharmacy Customer Types

Pharmaceutical manufacturers primarily meet pharmacy customer needs associated with price on a customer-by-customer basis. By negotiating with a national chain pharmacy differently from how they negotiate with smaller, regionally located independent pharmacy buying groups, manufacturers base the price variable on customer buying power and how much market share the customer can drive.

One primary categorization for manufacturers as a starting point in pricing negotiations is whether the chain pharmacy has its own warehouse for medications. If so, the pharmacy is classified as a warehousing chain that buys medications directly from the manufacturer, has the product shipped to its own warehouse, and then subsequently distributes the medications to its individual stores when necessary. Pharmacy chain customers that do not have warehouses, nonwarehousing chains, typically negotiate directly with the manufacturer and then work through a wholesaler for day-to-day shipments of medication. Independently owned pharmacies often negotiate through a buying group, or multiple pharmacies banding together as a single unit to buy medications directly from pharmaceutical manufacturers, so as to increase their buying power (i.e., lower prices) and, ultimately, improve their bottom-line profits.

Most manufacturers set prices based on customer type, for example, categorizing the different types of chain customers, wholesalers, mail-order pharmacies, hospital buying groups, and others into different pricing levels. Then, as with any item bought in bulk or at large-dollar volumes, the pricing level is only that—a starting point for negotiation.

Wholesalers

How do drugs reach the pharmacy? Do manufacturers deliver their medications to individual pharmacies? Logistically, that would be next to impossible given the thousands upon thousands of community pharmacies throughout the United States. Thus, the role of the wholesaler is created, and the need for supply chain management. For medications made in manufacturing facilities around
the world to end up in a local community pharmacy, wholesalers serve as the warehousing and distribution arm and are vital to the success and survival of the pharmaceutical industry.

Over time, the pharmaceutical wholesale industry evolved in a very similar fashion to pharmaceutical manufacturers. In the 1960s and 1970s, without the aid of today’s technologies, pharmaceutical wholesaling was primarily a retail business driven by sales representatives who made daily or weekly sales visits to pharmacies and called in medication orders to the warehouse. Once the order was placed, the product was then delivered within a few days. The core business of wholesalers revolved around the pick, pack, and ship model. As technology advanced and enabled ordering and delivery to become more efficient, wholesalers began to expand their service offerings into, for example, reimbursement, packaging, and consulting, otherwise known as value-added services.

As buyers of medications and customers of pharmaceutical manufacturers, wholesalers need the best available pricing and a consistent supply of medications. Given the continual pricing pressure applied by manufacturers and the competition, the years have brought constant profit erosion, and it has become generally accepted knowledge that the pick, pack, and ship component of the wholesale industry works off very small margins (profit), typically in the 2–4% range. Further, wholesalers traditionally bought, held, and then sold medications as their main revenue model. Recently, the model has evolved into a fee-for-service (FFS) model in which manufacturers pay wholesalers a fee based on the

CASE IN POINT 2-3
AmerisourceBergen

In keeping with the evolution of the industry, AmerisourceBergen Corporation (ABC)—created in 2001 with the merger of Amerisource Health and Bergen Brunswig—has expanded its reach outside of the core pick, pack, and ship model for pharmaceutical products. ABC also has a specialty group that handles various biologic medications and their distribution, consulting services companies that work with manufacturers and healthcare providers to maximize efficiency in all areas, and World Courier, which specializes in logistics for global clinical trial administration and distribution.
services (e.g., ordering technology, emergency shipments, contract administra-
tion, returns processing) provided (Baumer, 2005).

In addition to price erosion, the wholesale industry was marked by increasing
competition in the marketplace, leading to the same fate as befell the pharmaceu-
tical manufacturer industry: increased consolidation through mergers. Currently,
the wholesale industry is dominated by three large, multi-billion-dollar firms that
have eliminated or bought up a majority of the competition: AmerisourceBergen,
Cardinal Health, and McKesson. At this point, the “Big 3” wholesalers control
approximately 85% of the market share in the United States (Fein, 2011).

**General Consumers/Patients**

In 1997, in response to a growing use by manufacturers of direct-to-consumer
(DTC) advertising for medications, the FDA released a “Draft Guidance for
Industry” document addressing the DTC issue and, in particular, television-
based medication advertisements (final version released in August 1999) (Food
and Drug Administration, 1999). These new regulations (broadcast advertising
had been greatly restricted prior to this) allowed manufacturers to advertise their
specific medications in television commercials and led to an extreme growth
period in pharmaceutical advertising directed at general consumers. In fact, the
average American television viewer is exposed to as much as 30 hours of prescrip-
tion drug advertisements annually (Brownfield et al., 2004), and television ad
spending accounts for the majority of DTC spending (Arnold, 2006).

This expansion of television advertising coupled with the evolution of com-
munication, information availability, and the Internet has led to a new age model
of healthcare dynamics and shared decision making. No longer are information,
knowledge, and choice of drugs driven by the physician/prescriber, but typically
the consumer/patient actively participates and works with the physician/pre-
scriber to determine the best treatment choice based on the individual’s unique
wants and desires. Given this change, the general consumer/patient has become
a primary customer of pharmaceutical manufacturers, with both healthcare and
information needs.

Pharmaceutical manufacturers’ products are intended to meet the most basic
needs of consumers with healthcare issues: improved health outcomes, increased
quality of life, and prevention (or cure) of long-term complications and dis-
ease. Although the types of products researched and eventually produced vary
by manufacturer and market conditions, each product aims to affect one of the
areas described. (Here, *products* refers to branded and innovator products rather
than generic products, for which the primary focus is making sure the quality of the drug is equivalent to the branded/innovator product.) Even medications viewed primarily as lifestyle choices (e.g., Viagra [sildenafil]) can work to enhance quality of life and well-being of the individuals taking them. Pharmaceutical manufacturers spend billions annually on product research and development to discover new entities to meet consumer/patient needs and improve the efficacy and effectiveness of existing therapies. In fact, in 2011, PhRMA members spent approximately $49.5 billion on product research and development (PhRMA, 2012). With this investment over time, manufacturers have made great advancements in all treatment areas, particularly in the areas of cancer, HIV, rheumatoid arthritis, and multiple sclerosis. Further, as the industry moves forward, pharmacogenomics and the ability to tailor a medication to an individual’s (or group of individuals’) DNA offers endless possibilities.

A driving force behind consumer information needs has been the expansion of consumerism and general consumer involvement (referred to as shared decision making) in healthcare decisions. With consumers playing a greater role in healthcare decisions, including the choice of a drug product, pharmaceutical manufacturers have learned they must provide much more nontechnical medical information to the general consumer. One way manufacturers have accomplished this has been the proliferation of DTC ads since the late 1990s. The use of DTC ads has created a far more consumer-driven pharmaceutical manufacturer than ever before. In addition to the information provided to consumers, pharmaceutical manufacturers continue to expand the channels of communication with consumers, including use of personal electronic technology and social media.

**Third-Party Payers**

One dynamic unique to healthcare (and the insurance business in general) is when insurance is involved in the payment for services; often patients are not responsible for the greatest majority of payment. Thus, a patient can use physician services at little or no cost. In general, well exams might be covered 100% or be zero cost to the patient. This means a patient can go to the physician for an annual checkup and leave the office without paying a penny, with the health insurance company, or third-party payer, paying the physician fees. To clarify the terminology, the *first party* is the patient/consumer, the *second party* is the physician, and the *third party* is the insurance company that pays for the services rendered. The same low/no-cost possibilities exist for obtaining a prescription. Just as the
insurance company pays the physician, the prescription health insurance payer, typically called a pharmacy benefits manager, or PBM, pays the pharmacy a contracted amount for the prescription dispensed. In their current form, third-party payers are not “direct” customers of pharmaceutical manufacturers because they do not actually buy, stock, dispense, and sell medications (except for PBM-owned mail-order pharmacies, which do buy, stock, and dispense medication). They are, however, manufacturer customers given their ultimate responsibility for prescription claim payment and the dynamics of the U.S. reimbursement system.

Third-party payers reimburse pharmacies based on a variety of mechanisms, including reimbursement formulas, usual and customary prices, reimbursement based on the “lower of” a series of potential reimbursement rates, a maximum allowable cost (MAC), or an upper limit on product cost (also called a federal upper limit, or FUL). Third-party reimbursement to pharmacies is based on benchmark prices created, controlled, and published by pharmaceutical manufacturers for third-party payers to use in reimbursement formulas. These benchmark prices include the following:

- **Average wholesale price (AWP):** Typical reimbursement formula of AWP minus a discount plus a fee paid to the pharmacy for dispensing the prescription, calculated as follows:

  \[ \text{Reimbursement} = \text{AWP} - \% \text{ Discount} + \text{Dispensing fee} \]

- **Wholesale acquisition cost (WAC):** Typical reimbursement formula of WAC plus a percentage plus the dispensing fee, calculated as follows:

  \[ \text{Reimbursement} = \text{WAC} + \% + \text{Dispensing fee} \]

Pharmacy profit margin then depends on the difference between the negotiated acquisition cost with the manufacturer or wholesaler and the reimbursement amount.

Pharmaceutical marketers operating in the industry need to be aware of the various aspects of third-party reimbursement. For products to be reimbursed by third-party payers, manufacturers must report benchmark prices to the pricing compendia, such as First DataBank and Redbook. Failure to publish benchmark prices (either AWP or WAC) effectively excludes manufacturers’ products from coverage by third-party insurers and, in turn, decreases their market share dramatically.

The primary third-party payer is the federal government. Through the Medicare (for older adults and persons with disabilities) and Medicaid (for individuals below a specific income level) programs, the federal government pays for approximately
40% of all prescription drug expenditures (Kaiser Family Foundation, n.d.). Other entities functioning as third-party payers are private insurers/insurance companies, such as BlueCross BlueShield, Aetna, and United Healthcare, and pharmacy benefits managers (PBMs), such as CVS Caremark and Express Scripts.

CASE IN POINT 2-4
AWP Litigation

When manufacturers do not follow the OIG guidelines for price reporting of benchmark prices, a situation could exist in which the actual price paid by the customer (e.g., chain pharmacy) greatly differs from the amount reimbursed by the government as payer. The difference between the price paid for the product and the amount reimbursed for the product is referred to as the reimbursement spread.

Prudent pharmaceutical marketers know the dynamics of the marketplace, including what customers want, price levels, costs, and other barriers to entry (patents and other regulatory barriers such as exclusivity, production and supply issues), before the manufacturer enters the market, and they monitor these variables continually. When market conditions deteriorate to the point where a manufacturer can no longer profitably meet the competition and win sales, the manufacturer must decide whether to continue production and remain in the market. This kind of decision is common in industry and must be continually evaluated. Creating a differential product advantage by reporting inflated benchmark prices to enhance reimbursement spread disrupts marketplace dynamics and shifts the burden of financing a product’s benefit from the manufacturer to Medicaid and other third-party payers.

Over the past decade, whistleblowers have filed lawsuits based on a provision of the federal False Claims Act. Through these lawsuits, the federal government and various state Medicaid programs have recovered billions of dollars from pharmaceutical manufacturers that reported inflated AWPs in comparison to actual acquisition costs (Harris, 2008; Voreacos, 2012; Voreacos & Fisk, 2012).
Given their role as payers in the healthcare and pharmaceutical industries, these customers focus on price as their primary need. Associated with price are the reimbursement benchmark prices. In accordance with the Office of Inspector General compliance guidance of May 2003, manufacturers must set and publish reimbursement benchmarks that reflect prices generally and currently paid in the marketplace (OIG, 2003). Therefore, third-party payers, in particular the federal government, need pharmaceutical manufacturers to comply with the OIG guidance and report accurate prices.

ISSUES UNIQUE TO THE PHARMACEUTICAL MARKET

Just as in any other industry, external factors and pressures apply to the pharmaceutical industry on a daily basis. Whether it is the latest round of negative press on the rise of prescription drug costs or the passing of new healthcare reform laws, the external environment in which the pharmaceutical industry operates changes on a daily and weekly basis. This section discusses the specific positive and controversial issues unique to the pharmaceutical industry and market, focusing on the industry’s various social, ethical, legal, and political environments.

Social Environment

“Do more, feel better, live longer” and “to serve patients.” These simple statements are the mission statements of global pharmaceutical manufacturer GlaxoSmithKline and global biotechnology/pharmaceutical company Amgen, respectively. While countless space and time could be used to discuss the advances and innovations of the pharmaceutical industry in areas such as cancer, HIV/AIDS, and cardiovascular disease, from the societal perspective, the pharmaceutical industry and its discoveries have not only saved countless lives, but improved health outcomes (which provides a positive economic impact) and quality of life for millions of people.

In addition to its impact on patient health and welfare, the pharmaceutical industry is a massive economic engine. The most recent published data show the industry is directly responsible for more than 670,000 jobs and indirectly responsible for another 3.4 million, bringing the total to more than 4 million jobs produced (Battelle Technology Partnership Practice, 2011). Further, with the average annual wage of more than $105,000 in pharmaceuticals, the jobs created supply almost double the salary of the next highest group among all U.S.
manufacturing sectors, with $85 billion in tax revenue also created for local, state, and federal governments. The overall economic impact of the U.S. biopharmaceutical industry is estimated to be approximately $918 billion (Archstone Consulting & Burns, 2009; Battelle Technology Partnership Practice, 2011).

Even with these positive economic benefits, the pharmaceutical industry is often criticized for increasing overall healthcare costs through rising prescription drug prices. The exponential rise in direct-to-consumer advertising spending over the last 15 years has sparked the debate about its effect on increasing drug use and whether DTC advertising has created a world in which the company with the best ad agency—not the best drugs—gets the attention of consumers and prescribers. Empirical research suggests a positive correlation between DTC advertising spending and prescription drug demand and utilization, with an almost 40% increase in utilization from 1999 to 2009 and price increases over that same time span annually, on average, of 3.6% (Donohue, 2007; Kaiser Family Foundation, n.d.; Kravitz, 2005; Wilkes, 2000).

The pharmaceutical industry battles daily to try to overturn its negative public perception. For many years, the pharmaceutical industry has been at the bottom of the public approval list, typically rated as above only the tobacco industry (Arnst, 2005). The general consumer sees the large profits made by the pharmaceutical industry coupled with high and increasing prices (especially with brand medications) and does not view this favorably (FierceBiotech, 2007; Kaiser Family Foundation, 2008; Robinson, 2004).

The peak of general negativity toward the industry culminated with the removal of Vioxx (rofecoxib) from the marketplace. After a heavy DTC advertising and physician detailing campaign, the medication quickly became popular and sales soared (over 80 million doses prescribed during its time on the market). Amid mounting evidence of cardiovascular issues and media pressure, the product’s manufacturer, Merck, removed the product from the market in September 2004. Numerous plaintiffs eventually took legal action against Merck, and in November 2007 Merck settled the lawsuits for $4.85 billion (Prakash & Valentine, 2007). This debacle led society to question the safety level within the pharmaceutical industry (Kaiser Family Foundation, 2008; Olsen & Whalen, 2009; Sillup & Porth, 2008).

**Ethical Environment**

Sell what I invent, or invent what I can sell? This question underlies the primary ethical dilemma within the pharmaceutical industry with respect to new drug
discovery and the allocation of resources within the industry. As mentioned previously, pharmaceutical discoveries have saved, prolonged, and improved countless lives. However, as in any industry, the business exists to be profitable for itself and its shareholders in addition to existing over time. The pharmaceutical industry must work daily to find the right balance of profitability and not lose sight of its mission to discover new medications to alleviate pain and disease in the effort to offer consumers improved health and quality of life.

From a marketing perspective, the ethical issues and influencers within the industry center on the various communications by manufacturers. Whether it is sales reps or MSL interactions with physicians or advertising aimed at the general consumer, the pharmaceutical industry walks a fine line in promoting products yet still being able to promote the best healthcare decisions for patients. The following examples describe various ethical issues:

- **Interactions with healthcare professionals.** Many professions and professional organizations have guidelines on how to interact with the pharmaceutical industry, including, for example, the American College of Clinical Pharmacy (ACCP, 2008). The guidelines are primarily based on the PhRMA Code on Interactions with Healthcare Professionals (PhRMA, n.d.). Updated in 2009, the code lays out how pharmaceutical manufacturers should proceed ethically in their communications with all healthcare professionals. Areas covered include dealing with speakers, support of continuing medical education (CME), prohibition against entertainment and recreation (e.g., avoid offering trips or tickets to the big game to physicians or others), and representative training.

- **Off-label promotion/communication.** One area not covered directly by the PhRMA code is off-label communications. In all their communications, pharmaceutical manufacturers can discuss only approved indications; otherwise, they may (and have) become involved in a lawsuit by knowingly communicating and promoting a medication for non-FDA-approved uses. During the period from January 2001 to March 2009, pharmaceutical manufacturers paid almost $3 billion to settle cases involving off-label marketing/promotion of certain medications (Kesselheim, 2010).

- **Price reporting/communication.** As mentioned earlier, manufacturers must report to the pricing compendia prices that reflect values generally and currently paid in the marketplace (OIG, 2003). Failure to do so has led to numerous lawsuits from which payers have recovered billions from pharmaceutical manufacturers.
• *Publication practices.* Pharmaceutical manufacturers’ relationships with providers, particularly physicians, must walk a fine line. This is especially true when it comes to the publication of clinical trial results. Clinical trials are conducted for new drugs to show safety and efficacy for FDA approval. Clinical trials are also typically published in the medical literature. Over the years, the publishing practices of pharmaceutical manufacturer–sponsored literature have been scrutinized, particularly with the issue of ghost writing. **Ghost writing** refers to the process when the work of an original creator or contributor is then credited to another author. In the pharmaceutical industry, outside writers (unaffiliated with the pharmaceutical company) often draft articles for publication in medical journals based on data provided by pharmaceutical manufacturers. Various guidelines exist for the publication process, including those from the International Committee of Medical Journal Editors and Wager et al. (2003) in *Current Medical Research and Opinion*.

**Political and Legal/Regulatory Environment**

Legal constraints and influences are also a part of the daily changes taking place in and around the pharmaceutical industry. Closely intertwined with this area is the political arena. Since the early 1900s, political leaders have enacted laws greatly affecting health care in the United States, including the original Food, Drug, and Cosmetic Act and its amendments and, most recently, the Patient Protection and Affordable Care Act signed into law in March 2010 and upheld by the Supreme Court. Prompted by citizen concern over access and quality, health care is typically always a part of state and federal political discussions and campaigns.

Not only do the legal and political environments affect the industry from a regulatory standpoint, but the government also functions as a large payer in the marketplace (through Medicare, Medicaid, and the Department of Defense), thus creating a situation in which politics and legislation could possibly be altered heavily given that role. State laws and regulations also influence the industry, chiefly with regard to how the Medicaid program is run in each state. Manufacturers are continually in contact with all state providers to ensure preferred formulary status for their medications. Overall, the political and legal environment in which the pharmaceutical industry exists has changed over time with regard to the manner in which drugs come to market, are distributed, and are dispensed.
As discussed earlier, marketing is a process that works to create value for customers through the exchange process. Although all pharmaceutical marketers must recognize and work within the bounds of the unique nature of the external environment, they must differentiate in terms of how drugs are marketed based on classification, specifically whether a medication is prescription or over-the-counter (OTC) and whether it is a brand or generic medication. Each of these situations offers differing sets of primary customers and needs.

**Prescription vs. Over-the-Counter Drugs**

Given that both prescription and OTC drugs are medications used to treat many of the same conditions, one might assume the products are marketed using the same tactics and promotional ideas. However, although there are similarities to the underlying messaging, the primary customers and their needs are different for each type of medication. In the prescription environment, pharmaceutical manufacturer customers include physicians, consumers, pharmacies, wholesalers, and third-party payers. All customers work, albeit not necessarily together, to decide which product is ultimately dispensed. For OTC medications, however, the customer base is quite different.
The physician and third-party payer are not a primary concern to an OTC marketer. Even though a physician is usually aware of an OTC product (especially if it was previously a prescription product, such as Prilosec [omeprazole]), the OTC manufacturer typically does not detail or call on physicians because of physicians’ low level of choice power. Instead, the OTC marketer focuses on the customer with the highest level of choice power: the general consumer.

Given the lack of an intermediary in the OTC market space (i.e., physician/prescriber), the OTC market behaves much like the traditional consumer goods market. Thus, the primary focus of the OTC product marketer is creating a recognizable and remembered brand, such as the “nighttime, sniffling, sneezing, coughing, aching, best-sleep-you-ever-got-with-a-cold medicine” or the “Mucinex in, mucus out” medication. As with other consumer goods, numerous private-label and store brands exist on the shelf right next to the branded product, with great price differences among them. For example, Sam’s Club’s “Simply Right” private-label brand loratadine costs approximately $13 for two 200-count bottles, while the brand-name Claritin costs approximately $35 for one 90-count bottle. From a marketing perspective, this situation is common in almost every consumer good category, and is why OTC marketers work hard to place their brand and its quality above reproach and to remove the price variable from the consumers’ choice equation.

OTC marketing and promotions are focused on the consumer as well as the pharmacist. Given their accessibility within community pharmacies and mass merchandisers (the “place” for OTC products) and their role in product recommendation, it makes sense for OTC marketers to call on pharmacists and advertise in community pharmacy–focused magazines and publications such as Drug Topics.

**Brand vs. Generic**

In 1984, the Drug Price Competition and Patent Term Restoration Act (1984), better known as the Hatch-Waxman Act, gave rise to the modern-day generic pharmaceutical industry. No longer did generic manufacturers have to go through the same approval process as their innovator/brand counterparts, but could execute approvals in a fraction of the time. In fact, prior to the passing of the Hatch-Waxman Act, approximately 35% of innovator drugs had generics available even with an expired patent (Rouhi, 2002). Generic manufacturers now continue to climb the sales rankings even given the lower prices of their medications.

As noted earlier, the primary customer and marketing focus of brand manufacturers and innovator companies is the physician. In addition, general consumers and third-party payers are important target audiences so that specific drugs can develop brand loyalty and maintain preferred status on a given formulary.
However, in the generics industry, medications are considered to be a commodity (i.e., interchangeable), and thus the marketing of these products differs from that of other consumer goods because the focus of the marketing mix (i.e., the four Ps: price, place, product, and promotion) is on price. The other primary difference in generic manufacturers’ customer and marketing mixes is the absence of the physician as a primary focus. The product selected by the physician is usually available from a number of manufacturers, each competing for market share. Although physicians still choose which medications patients need, pharmacy providers select the company that will supply the medication. Other members of the distribution channel can also affect the pharmacy’s supplier decision by participating in buying groups and wholesaler source programs. Consequently, pharmaceutical manufacturers of generics focus their marketing efforts on pharmacy providers.

Regardless of product type, though, effective marketing in the pharmaceutical industry is based on being able to meet customer needs. For generic medications, pharmacy buyers must also seek consistency of supply and high product quality. Other product benefits, such as a company’s ability to supply a full line of generic products, or “one-stop shopping,” can also be important to generic pharmaceutical purchasers. Thus, price is the most salient evaluative criterion, and pharmacy providers seek out the lowest prices for products that meet quality requirements and

**CASE IN POINT 2-6**

**Pfizer’s Unique Strategy for Lipitor**

Recently, in an effort to overlap the brand and generic pharmaceutical industries, Pfizer used a unique marketing strategy when its multi-billion-dollar blockbuster medication Lipitor (atorvastatin) was about to become generically available. To maximize profits as long as possible for the highly successful medication, Pfizer basically sold the medication to consumers using a $4 copay card backed up with a heavy DTC advertising campaign, as well as to insurers/payers through deep discounts and rebates. Although Pfizer still lost a large portion of market share, it lost it at a rate much slower than a typical blockbuster drug coming off patent. Given the financial success of Pfizer’s marketing strategy, an increased use of this tactic is likely as many more blockbuster medications come off patent in the coming years (Fein, 2012; Silverman, 2011).
that can be adequately and consistently supplied. Commodity manufacturers, such as those in the generics industry, might hold to a more product oriented rather than customer oriented marketing philosophy. A customer (or market) orientation implies that a firm seeks to understand a market, develop an awareness of customer needs and wants, and then strive to develop a product or product line that satisfies these needs. A product orientation indicates that a generic manufacturer first produces a product, and then seeks to sell in the marketplace as much of the product as possible, recognizing that the focus in the marketplace is primarily on the price variable.

CASE IN POINT 2-7
How Does a Drug Get Its Names, Both Brand and Generic?

Lipitor, Viagra, Tylenol, and Prozac. Branding in the pharmaceutical industry is just as important as it is for any consumer good. But how does a chemical entity that started in the laboratory referred to as, for example, ABC-123, eventually become Ambien or Prozac? Further, where do the generic names, such as zolpidem and fluoxetine, originate?

First, a group known as the United States Adopted Name Council (USANC) initiates the generic/chemical name of a new drug (zolpidem and fluoxetine, in this example). This council is made up of five representatives, one each from the American Medical Association, United States Pharmacopoeia (USP), American Pharmacists Association (APhA), the FDA, and an at-large member (American Medical Association [AMA], n.d.b). When a manufacturer applies for a name, usually during Phase II clinical trials, the USANC works until a name agreeable to the council, manufacturer, and International Nonproprietary Names Expert Group is determined (World Health Organization, 2012). There can be only one name used around the globe for a generic/active ingredient.

The USANC considers three primary issues in the naming process: whether the name reflects the medication’s mechanism, the name’s ability to be translated to other languages, and the general ease of pronunciation of the name (AMA, n.d.a). In addition to the prefixes and infixes used to complete the name, the core component is the stem, which typically identifies the medication’s class/group. For
example, “oxetine” is the stem for *fluoxetine* and identifies the drug class known as selective serotonin reuptake inhibitors (SSRIs). Another example is “pril,” which is the stem for the names of angiotensin-converting enzyme (ACE) inhibitors used for blood pressure and cardiovascular health.

To create brand and trade names of drugs, pharmaceutical manufacturers complete extensive marketing research to identify the most beneficial name. Their own marketing departments and/or market research firms identify and test dozens of names for consumer response. For example, the name *Ambien* is formed from *am* (morning) and *bien* (good), aiming to enable the user to have a good morning after a great night’s sleep. Premarin’s name comes from where the product is derived: PREgnant MAre’s uRINe. Although not every medication can be named as cleverly as Ambien or Premarin, at least an exhaustive list of possibilities is explored before a name is picked.

**SUMMARY**

The pharmaceutical industry and market in which it exists create a complex interaction of environmental factors, including government regulations; cultures and norms; high technological barriers to entry; multiple primary customers, each with their own needs; and competition. From a marketing perspective, the key is to understand the various roles of these environmental factors and to design pharmaceutical products consistent with consumer needs. Although the pharmaceutical industry as a whole continues to grow and be profitable, the high growth volume seen in the 2000s has been replaced by fewer blockbuster drugs, declining sales, shrinking workforces, and increased scrutiny by those external to the industry. Yet, the industry remains largely profitable.

Various opinions have surfaced on what the industry can do to recapture its growth (Chase, 2012; Denning, 2012). Perhaps the pharmaceutical industry must take a lesson from the experiences of one of its customers: the wholesale industry. While maintaining its core pick, pack, and ship business model, the industry has continued to grow with the provision of value-added services (including technology). Knowledge of the components of the pharmaceutical industry helps identify areas for growth and opportunity.
It is clear that new models of operation in the industry are desired. Given the success of pharmaceutical companies over the last 50 years, it seems clear this industry will continue to prevail in the face of rapidly changing environmental factors, new technology, and an aging and needy world population.

**DISCUSSION QUESTIONS**

1. Describe the differences between physician needs versus patient needs with regard to pharmaceutical products. Whose needs are more important?
2. What is meant by the term *directed demand*, and how does this concept affect most everything a pharmaceutical manufacturer does to promote its medications? Are there any similarities in the OTC market?
3. The pharmaceutical manufacturer invents and markets the drugs that doctors prescribe and patients take. Explain why an insurance company should or should not be involved in this exchange transaction.
4. Should the large number of U.S. physicians be considered a marketing opportunity or threat to pharmaceutical manufacturers? Why?
5. What are the pros and cons of a pharmaceutical manufacturer downsizing its sales force and increasing its medical science liaison presence?
6. Why can it be considered a “death knell” for a pharmaceutical product to be excluded from formulary coverage?
7. The rise in DTC advertising has provided information to consumers that they can use to recognize a problem, seek care, and gain awareness of diseases, vaccines, and treatments. These all seem to be positive aspects of DTC advertising. Describe some possible negative consequences of providing increased information to consumers through pharmaceutical marketing.
8. Considering your response to question 7 and the marketing implications, what would pharmaceutical manufacturers do to promote their products if the FDA banned DTC advertising? What if the FDA banned only television commercials?
9. Should pharmaceutical manufacturers be able to justify spending similar amounts on research and development compared to marketing expenditures? (*Hint: Recall the three primary consumers and each consumer’s unique needs.*)
10. Comment on any ethical issues you might consider relevant to the funding of biomedical research by pharmaceutical manufacturers.
REFERENCES


