LEARNING OBJECTIVES:

Upon completion of this text, the student should be able to:

- Describe the two dominating philosophies that have shaped the U.S. healthcare system
- Understand and appreciate the contributions of pharmacy and pharmacists in the U.S. healthcare delivery system
- Explain the political and economic forces that have shaped the growth and development of the profession and industry
Introduction

Pharmacy has always played a vital role in the delivery of health care within the U.S. and around the world. For example, according to the Centers for Disease Control, between 2005 and 2008, about half of the population used at least one prescription drug per month in the United States and 74% of physician office visits resulted in at least one prescribed medication (CDC, 2012). Pharmacy has made an enormous impact on our health and healthcare system, ranging from prevention and treatment of diseases to the management of chronic diseases.

Overview of the U.S. Healthcare Delivery System

The U.S. healthcare delivery system is not centralized and it has been described as fragmented in terms of how it is organized, structured, and delivered (McCarthy & Schafermeyer, 2007). The fragmentation has been an outcome of several factors including political, social, and economic forces. Politically, there are two schools of thought on how health care should be structured and delivered. One group strongly believes that health is an individual’s right and so the government should be actively involved in ensuring that every individual has equitable access to affordable health care. Dr. John Bowman, a director of the American College of Surgeons in 1918, best expresses this viewpoint. He commented, “as a people we are accustomed to hospital service; we look upon that service no longer as a luxury which we may buy, but rather as an inherent right” (Barr, 2007). Such a system operates similarly to most European countries and
Canada where the government has central control both as a regulator and financier, which supposedly enhances coordination of care. The major drawback of this approach has been increasing cost to taxpayers leading to cost containment measures including rationing of care and some operational inefficiencies.

The other school of thought strongly believes health is a commodity left best to the free market economy. This view is reflected in a statement by Dr. Sade, who reported in the *New England Journal of Medicine* in 1971 that, “Medical care is neither a right nor a privilege: it is a service provided by doctors and others to people who wish to purchase it” (Barr, 2007). The free market traditionally has been known to enhance the distribution of goods and services through competition, often resulting in efficiency, quality of products, and affordable goods for many people. Unfortunately, health is not a perfect good, so perfect competition has not been achieved, partly due to government interference and the unique characteristics of health and health care.

Commodities are often produced and targeted to meet the needs of different segments of the market economy. For example, there are numerous brands of automobiles, used automobiles, bus systems, and subways to cater to the needs of different groups of people based on convenience, price, and taste, so the market and the government has worked hand in hand in meeting the transportation needs of the majority of people. Such a solution cannot be fully replicated in the healthcare industry because ‘subpar’ or ‘cheap’ treatment could have a devastating outcome. It can be argued that, to some extent, the market tried to respond to this problem by offering patients the choice between generic and brand name drugs, different tiers and levels of coverage of insurance products, and different types of hospitals. However, the disparities that resulted from this approach have created negative externalities (including increased uncompensated care and higher rates of the uninsured), which have ultimately contributed to the increasing cost of health care (something the market is supposed to be able to fix). There are other causes of market failures including monopoly of the market: pharmaceutical companies and patency rights, and in some cases only one hospital in some small markets, and some insurance companies having a monopoly due to their size. Some have blamed interference by the government for the market failures, but others believe without government interference the level of disparity would have been much greater.

Economically, the healthcare industry had traditionally been organized around the entrepreneurship of the medical professionals; physicians had their own practices, pharmacists operated their own pharmacies, and hospitals were mainly privately owned by religious entities. Most people treated health care as a commodity, visited
and paid for physician services when they required medical expertise. Moreover, the responsibility for the cost of medications, laboratory work, and hospital stays was left to the individual patient.

Corporatization, the introduction of health insurance, and advancement in both medical technologies and medicine changed the dynamics and ushered in a fragmented system that benefits the individual components of the healthcare delivery system more than the patient. However, the patient has benefited from these new arrangements in several ways. For instance, health insurance has insulated the patient from the real cost of health care (and therefore, has increased the demand for health care by patients), corporatization and advancement in medicine and medical technologies have improved the quality, convenience, and efficiency of delivery (such as the advent of CT-scans, MRIs, bypass surgeries, etc). Notwithstanding such potential benefits, the economic interests of various stakeholders within the healthcare industry have helped to spur the increasing costs of health care and the fragmentation in the delivery system. There are, however, ongoing reforms and debates to curb the rising cost of health care and to centralize the delivery of care.

Curbing the rising cost of healthcare continues to dominate healthcare debates and reforms. In 2009, it was estimated healthcare expenditure was about 17.6% of the U.S. gross domestic product (GDP), which translates to about $2.5 trillion annually (or about $8,160 per resident) (Kaiser, 2009). By way of contrast, in 1970 healthcare expenditure was 7.2% of GDP (about $75 billion annually or $356 per resident). The top three drivers of healthcare expenditure are hospital care (31.1%), physician/clinical services (21.4%), and prescription drugs (10.1%) (Kaiser, 2009). Most reforms have targeted these sectors with programs such as prospective payment systems with diagnosis-related groups (DRGs), capitation systems, and the proposed bundled payment systems. Reforms aimed at controlling prescription drug cost will be addressed elsewhere in this text.

Until recently, the focus had been more on quality control than cost containment. This followed reports by the Institute of Medicine (IOM) about the impact of medical errors on mortality and healthcare expenditure in the United States. For example, in IOM’s 1999 report “To Err is Human,” it was estimated that the occurrence of deaths due to medical errors was about 100,000. It was further estimated that, on the average, it cost the healthcare system between $28.4 to $33.8 billion dollars annually to treat most hospital-acquired infections. The report also mentioned system issues that needed to be addressed to reduce medication errors occurring within pharmacies (Kohn, Corrigan, & Donaldson, 2000).
The Patient Protection and Affordable Care Act of 2010 (popularly known as “Obamacare”) has shifted the focus from quality of care to cost and increasing access to health care by expanding health insurance coverage to the millions of Americans without health insurance. It was estimated in 2004 that there were approximately 46 million Americans without health insurance (McCarthy & Schafermeyer, 2007). The passage and implementation of Obamacare has been met with a great deal of resistance because of the perception that it increases government control over health care and will increase the cost of health care to individuals and employers.

Currently, the government acts as a provider, regulator, and financier of health care. As a provider, the government provides health care directly to veterans (VA hospitals), active military members and their families, and state and community health centers (i.e., through a partnership with private companies). As a regulator, the government controls healthcare delivery through laws, regulations, recommendations, and policies via government agencies like the
Food and Drug Administration (FDA) and the Centers for Medicare & Medicaid Services (CMS). As a financier, the government finances about 50% of health care through Medicare (i.e., insurance for mostly the elderly over 65 years old), Medicaid (i.e., means-test insurance for low income Americans jointly financed by states and the federal government), and TRICARE (i.e., insurance for the military). The government also influences health care through the funding of research in areas such as public health, health policy, and medicines through agencies like the Centers for Disease Control and Prevention (CDC), National Science Foundation (NSF), and the National Institutes of Health (NIH).

Pharmacy Within the U.S. Healthcare Delivery System

Pharmacy has operated largely under the free market model dominated by private ownership. However, a market once dominated by “mom and pop”-type independent pharmacies is now dominated by corporate and chain ownership. For example, the top two retail giants in the market, Walgreens and CVS, have over 7,000 stores each across the nation (www.cvs.com, www.Walgreens.com). It is suggested there is a retail pharmacy within a 5-minute drive of most Americans. Although this development has decreased the control and power of pharmacists over the practice of their profession, it has increased the access of pharmacy services in the community. Most of these pharmacies come with a drive-thru service and some have a 24-hour operation for patient convenience.

Pharmacies have responded to rising healthcare costs with extensive generic drug substitution and prescription loyalty discount programs. Walmart initiated a $4 per prescription program for several generic drugs that was replicated by most supermarket pharmacies, which further drove down medication costs. There are pharmacy benefit managers (PBMs) who act as middlemen for insurance companies by negotiating for lower prices and lower dispensing fees from pharmacies, another mechanism to control cost. At the same time, technology has improved the quality of work of the pharmacist. There has been improved access to online resources for education and reference, and new dispensing technologies to help reduce medication errors.

Although about 40% of every dollar spent on drugs goes to the retail sector, most of the national policy reform efforts are geared toward manufacturers. Unlike the retail pharmacy sector, there is lower competition at the manufacturer’s level. The sector is dominated by a few large research-based companies, which often are referred to as Big PhRMA (Pharmaceutical Research Manufacturers of America),
like Pfizer, Merck, and GlaxoSmithKline, some Biotech companies, and a few generic-producing companies like Abbott, Mylan, and Teva. The FDA is the federal agency responsible for regulating food, drugs, medical devices, and cosmetics (activities that directly or indirectly impacts pharmacies) at the federal level. Their primary goal is drug safety, so they regulate the introduction of new drug products into the market through a rigorous four-phase process. The initial phase, the animal studies and the basic sciences, is evaluated first, followed by three phases of clinical investigation. The clinical phases evaluate the safety and efficacy of the new drug in healthy people (for safety) and then among a sample of the target population. At the end of the process, if the drug is approved, the drug company gets patency rights to their product to safeguard their investment and to spur further innovation. There is a post-marketing surveillance phase where practitioners and patients can report any side effects or problems of concern about the approved drug. Although this four-phase process is considered the most stringent in the world, the FDA often comes under criticism when certain drugs are later found to be harmful. A case in point is the recall of some COX2 inhibitors (a new generation of anti-inflammatory drugs), which were found to be linked to heart attacks. These necessary processes and provisions add to the oligopoly in the market and the limited competition we see in the drug industry. There have been policy reform efforts to reduce the patency duration and to allow quicker introduction of generic drugs as a cost containment measure.

Lawmakers over the years have tried to regulate drug prices because of the higher prices charged by drug companies in the United States as compared to other countries, especially Canada (the Canadian government as a single payer negotiates for cheaper prices). Such efforts have failed partly due to the divide among lawmakers pertaining to the impact such regulations may have on research and development.

The pharmaceutical industry has traditionally marketed their products directly to physicians through medical journals and “detailing” (the direct introduction of medications to physicians at their offices) because the American Medical Association was able to convince Congress to restrict advertisement to physicians since they are the prescribers. This arrangement changed in 1995 when the Federal Trade Commission allowed drug companies to advertise directly to consumers. The rationale behind this decision was to involve patients more in the management of their health by increasing their knowledge of the existence of new and alternative medications. Opponents believe this has added to the increased demand for newer medications, which has contributed to rising healthcare costs.
PHARMACIST ROLE IN THE U.S. HEALTHCARE DELIVERY SYSTEM

Until recently, the clinical or medical team has been comprised of the physician and the nurse. They form the clinical core and the pharmacist was considered an auxiliary member similar to the imaging and laboratory staffs. The clinical team made decisions, and the auxiliary members provided services to support their decisions. The retail pharmacist was a drug product and delivery expert who worked mainly in the community setting with minimal contact with the medical team except when receiving medication orders and calling to get clarification for the orders. The hospital pharmacist had more contact with the clinical team, but mainly with nurses coming for inpatient medications and admixtures compounded by the pharmacist, as well as some minimal drug monitoring activities. Pharmacist training, the economic environment, and the prevailing healthcare policies together helped to create this work environment.

Earlier pharmacy curricula emphasized pharmacognosy, medical chemistry, pharmaceutics, and pharmacology much more than the clinical practice of pharmacy. Despite these emphases, most pharmacists ended up working in the community and hospital settings where drug dispensing and some compounding constituted the bulk of the practice. A survey conducted in 2000 shows that pharmacists devoted about 56% of their practice to drug dispensing, only 19% to consultation-related services, 9% to drug use management, and the rest to business-related management issues (Schomer et al., 2002).

With the shift to the doctor of pharmacy program and residencies, the emphasis has moved to an increased involvement of the pharmacist in clinical practice. A mail survey of 1,173 pharmacy directors at U.S. general, children, and surgical hospitals indicated that pharmacists in 95.3% of these institutions were involved in regular monitoring of medication therapy, and most of them (78%) had computer access to laboratory information to assist them in this function (Petersen et al., 2004). Other practicing pharmacist’s functions included detection and reporting of adverse drug events (84%), medication counseling (75%), and inpatient medication education (26%).

Today, pharmacists in hospital settings are also actively involved in pharmacy and therapeutic committees where they assist in the selection and revision of their hospital’s drug formularies. Such committees are normally made up of physicians, pharmacists, nurses, and representatives from other clinical services. Their purpose is to act as a communication link between the pharmacy and medical staff, and such committees are responsible for rational and safe drug therapy in their institution. These committees are involved with drug utilization review, drug formulary creation and maintenance, as well as
formulation of drug policies and procedures to be adopted by the institution. One survey found that about 87.7% of hospitals have closed formularies and that most changes are initiated by the medical staff, but about 62.4% of pharmacy directors said pharmacy staffs also initiate changes (Mannebach et al., 1999).

Another clinical practice area where pharmacists have become increasingly involved both at the retail and hospital levels is through Medication Therapy Management (MTM). MTM is a concept that has been in practice since the 1990s but was given official recognition and definition in the Medicare Modernization Act of 2003 and Medicare Part D (Barnett et al., 2009). The IOM, in their report, has stated that it costs the United States over $177 billion due to about 1.5 million morbidity- and mortality-related cases of adverse medication errors annually. The IOM suggested a healthcare system that is patient-centered, timely, efficient, and safe. Such a system will revolve around pharmacists—the drug product experts in the healthcare delivery team.

Not only is MTM recognized by the Centers for Medicare and Medicaid Services (CMS), but also by many third party insurance companies. The goal is to involve the pharmacist actively in drug management through consultation with prescribers in appropriate drug selection (including unnecessary prescriptions), the choice of cost-effective medications, and the promotion of patient adherence to drug therapy. There have been several studies showing the benefit of MTM on health outcomes. For example, a review of 10 years’ experience of a large integrated healthcare system that uses MTM found that MTM was cost effective and offered cost savings; for example, the healthcare system saved $86 for every $67 they spent on MTM per encounter (Ramalho de Olivera et al., 2010).

The challenges of MTM for pharmacies include justifying their services for reimbursement and getting other stakeholders to buy into the value of these services. The biggest challenge for pharmacists is that currently pharmacies are licensed as providers but not pharmacists. This means that pharmacies can submit services for reimbursement to federal programs, as physicians and other healthcare providers do, but pharmacists cannot. Moreover, the Social Security Act of 1935 does not recognize pharmacists as healthcare providers like physicians, physician assistants, nurse practitioners, clinical psychologists, dentists, and other healthcare professionals. Therefore, CMS, which administers the Medicare Part D program (where MTM is advocated), does not reimburse pharmacists for their MTM services (Giberson, Yoder & Lee, 2011). However, various pharmacists (including the Pharmacist Services Technical Advisory Coalition) have made changes based on extensive evidence of positive patient outcomes with MTM services by pharmacists. Pharmacists are able to apply for National Provider
Identifier (NPI) numbers, which are given to providers under the HIPAA Act of 1997 and required for reimbursement purposes by CMS and other private insurers. Pharmacists with NPIs are able to bill federal programs using CPT Category 1 codes (Milenkovich, 2011).

Additionally, pharmacists are now involved in disease management, health promotion, and even some primary patient-care services including immunization services. Pharmacists are also increasingly serving as advocates for drug safety and drug cost-effectiveness considerations, and therefore, becoming an active force in improving our healthcare delivery system.

Discussion Questions:

1. Should the government directly regulate the price of pharmaceuticals?
2. How can we improve the fragmentation in our healthcare delivery system?
3. Is the pharmacist effective as a healthcare team member?
4. Is pharmacy a success story of the free market?
5. How well has pharmacy adapted to changing healthcare demands and challenges?

References


