CHAPTER 2

Introduction to Health Law

"We the People of the United States, in Order to form a more perfect Union, establish Justice, insure domestic Tranquility, provide for the common defense, promote the general Welfare, and secure the Blessings of Liberty to ourselves and our Posterity, do ordain and establish this Constitution for the United States of America."

— **Preamble**, Constitution of the United States of America (1776)

IN BRIEF

This chapter describes how the U.S. legal system functions through the separation of governmental powers that is central to the U.S. Constitution. The role of "the People" and the agencies the federal government uses to administer and enforce U.S. health laws is reviewed. Particular attention is directed to the U.S. Department of Health and Human Services and the Food and Drug Administration, the agency that regulates about one-fourth of the U.S. economy. Crucial public health issues currently facing relevant federal agencies are outlined in the Law Notes and subsequently addressed in greater detail throughout this text.

LEARNING OBJECTIVES

Upon completion of this chapter readers should be able to:

1. Explain the general concept of the separation of powers.
2. Outline the principles flowing from the Declaration of Independence that form the basis of the Constitution and Bill of Rights.
3. Describe the difference between enumerated rights and unenumerated rights and the function of the Ninth Amendment in resolving these with *tacit rights*.
4. Show how the Bill of Rights was conceived to meet various objections to the original Constitution.
5. Describe the three separate but equal branches of government.
6. Discuss the distribution of powers between the federal and state governments.
7. Differentiate among various types of laws: common, statutory, administrative, and constitutional.

KEY TERMS

Affordable Care Act of 2010
Adversarial system
Adverse Events Reporting System
Agency guidelines
Appellate courts
Autonomy
Ballot measures
Bicameralism
Bill of Rights
Boycotts
Budget reconciliation
Case of first impression
Common law
Compassion
Competition
Complementary health care practices
Consent of the governed
Democratic legitimacy
Earmarking
Emergency Medical Treatment and Labor Act of 1986
Enumerated rights
Equality of opportunity
Exclusive dealing
Exclusive jurisdiction
Expressed powers
Food, Drug, and Cosmetic Act of 1938
Gainsharing agreements

Horizontal price fixing
Illegal combinations of competitors
Illegal monopoly
Inalienable rights
Initiatives
Joint ventures
Justice
Legislative measures
Liberty
Limited government
Market discrimination
Medical devices
Medical product error
Medicare Advantage
MedWatch
Nanotechnology
Natural rights
Necessary and Proper clause
Ninth Amendment
Nonbinding policy statements
Nonvaccine biologics
Offset
Part D prescription drug plans
Pay-as-you-go
People, the
Personal health records
Price-fixing agreements
Pricing discrimination
Referendums
Representative democracy
Retail-based health clinics
Rule of law
Separation of powers doctrine
Tax expenditures
Therapeutic inequivalence
Trade restraints
Tradition
Trial courts
Truth in Lending Simplification and Reform Act of 1980
Tying arrangements
Unenumerated rights
Unfair methods of competition
Valid insurance claim
Value-based payment system

FACT OR FICTION

Comprehensive Health Care Reform

Should comprehensive health care reforms, as well as repeal of the reforms, be passed through Congress's budget reconciliation process?

Created in 1974, the omnibus **budget reconciliation** process allows federal legislation dealing with entitlement programs, such as parts of the health care reform, to be enacted by Congress upon a simple majority vote after 20 hours of debate. This process precludes a filibuster in the Senate and makes it more difficult for individual Senators to amend legislation on the floor, which might unravel deals struck in congressional committees (Cannan, 2013). Critics of budget reconciliation maintain the process is an attack on federalism, since the Senate has historically been the arena where smaller states have significant influence. One issue being debated is whether the budget reconciliation process shifts too much power to congressional committees and away from members of Congress.

Under the principle of federalism, one of the founding principles of the U.S. Constitution, the federal and state governments should share the power to govern. The federal government has certain **expressed powers** (also called *enumerated powers*). The Constitution's **Necessary and Proper clause** gives Congress (and by delegation the executive branch) the implied power to pass any law *necessary and proper* for the execution of its express powers (*McCulloch v. Maryland*, 17 U.S. 316 (U.S. Supreme Court 1819); Sassman, 2015). Opponents of universal health care believe the federal government has grown beyond the bounds permitted by its expressed powers. One fear is the federal government may be increasing too greatly in both its size and its influence on the everyday lives of Americans and in its expansion relative to the state governments. One side of this debate asserts the provision of universal health care by the federal government may exceed Congress' power, a power rightly belonging to the states. The other side maintains the states are legally subject to the dictates of the federal government when there is a national need to regulate an industry such as the health and insurance industries that span state borders.

It appears a large majority of Americans believe the U.S. Constitution implies that every member of society has a fundamental right to medically necessary care. If so, then the country may be ready for the federal government to comprehensively overhaul U.S. health care and provide access to affordable health insurance for everyone. While implementation of health care reform legislation will require significant intergovernmental mandates for decades to come, the current debate centers on whether there should be a social consensus in Congress for comprehensive reform, or whether health care reform is too important to be stalled by congressional protocol.

—*See* Law Fact at the end of this chapter for the answer.

Data from: 2 U.S.C.A. §§ 601-688, 900-907d.

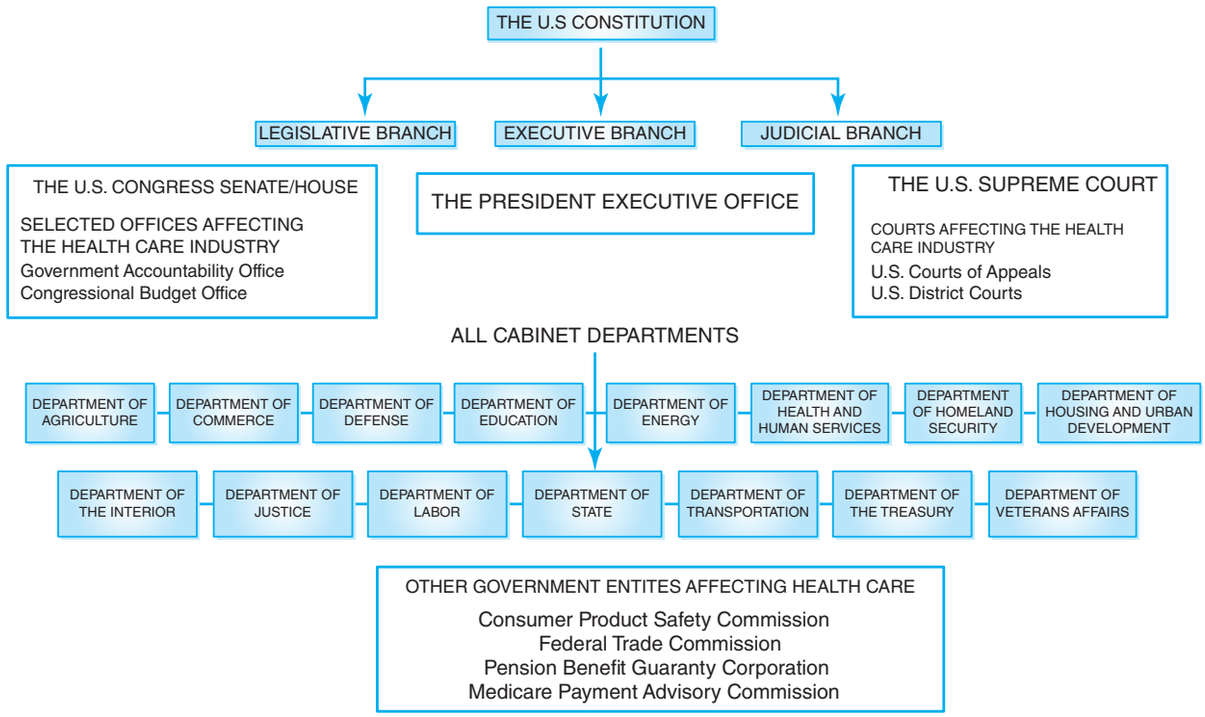

FIGURE 2-1 Organization of the Federal Government

Modified from: Government Manual, The U.S. (2016). Washington, DC: U.S. Government Printing Office.

Principles and Applications

To understand health law, it helps to have a basic understanding of the following:

- **Bill of Rights** (the first 10 Amendments to the U.S. Constitution)
- Declaration of Independence
- Distribution of governmental powers between the federal and state governments
- Three separate branches of government: judicial, legislative, and executive
- U.S. Constitution

This chapter focuses on the facets of the federal government with the most impact on the health care industry as illustrated in **FIGURE 2-1**. Most of the 50 states have created similar organizations and government agencies.

The Declaration of Independence

The Declaration of Independence is the nation's keystone document (Presser & Zainaldin, 2013); its principles form the basis of the U.S. Constitution and the Bill of Rights. The **inalienable rights** concept, embodied in the Declaration of Independence, is the foundation of the fundamental rights of all Americans and the basis for the concept of a **limited government** in the United States.

> *We hold these truths to be self-evident, that all men are created equal, that they are endowed by their Creator with certain unalienable Rights, that among these are Life, Liberty and the pursuit of Happiness.—That to secure these rights, Governments are instituted among Men, deriving their just powers from the consent of the governed.*
>
> — The Declaration of Independence, paragraphs 2–3 (1776)

Three fundamental and inherent rights are listed: *life, liberty,* and *the pursuit of happiness* (meaning a life lived to its full potential); these are basic rights to which everyone is equally entitled. The very idea that people have rights that precede and are superior to government is based on the self-evident truths articulated in the Declaration of Independence (Hamburger, 2015).

U.S. Constitution and Bill of Rights

The U.S. Constitution and Bill of Rights, along with the Declaration of Independence, are salient expressions of the unique character of American democracy (Smith & Gallena, 2014). When the U.S. Constitution was sent to the states for ratification, several states insisted a Bill of Rights be added, but no such bill could list all of the rights intended to be protected; the failure to do so, however, raised the implication that only the **enumerated rights** were to be preserved in this emerging democracy. So the **Ninth Amendment** was ratified, stating **unenumerated rights** are protected in addition to the rights enumerated and protected in the Bill of Rights.

The Ninth Amendment states individuals have tacit rights, in addition to the rights explicit in the Bill of Rights. The legislative branch was given the authority to enumerate the unenumerated rights by using the power to set forth laws that would bring the rights to fruition through the executive branch and that would be subject to review through the judicial branch. These creative powers are not unique to the Ninth Amendment; for instance, the First Amendment's enumerated rights also require the three separate branches of government to balance and protect the rights to freedom of speech, property, and due process of law.

Underlying this **separation of powers doctrine** regarding enumerated and unenumerated rights are the Constitution's **natural rights** and **common law** foundations. When laws become removed from these foundations, the result is often divisive controversies, such as the right to life-sustaining drugs and the right-to-die debates, and even the right to health care debate itself. Confusion reigns until the balance is restored to its grounding in the consent of the governed.

Judicial Branch

In any democracy, there are many sides to the evolving debate over rights. On one side of this ongoing debate is the judicial branch with judges who sometimes become impatient (often justifiably) with the founding principles of the U.S. Constitution and who use their powers to create rights based on their self-conceptions of evolving social values. On the other side of this debate are judges who go overboard in recognizing only those rights specifically expressed in the Constitution. Both extreme sides of this democratic debate ignore the presumptions at the very foundation of the Constitution (Fishkin & Forbath, 2014). These are the uniquely American beliefs in:

- Free markets
- Independence (limited government)
- Individual **autonomy** (personal responsibility)
- Individual freedom
- **Liberty** (**representative democracy**)

The Constitution no more authorizes the judicial branch to invent rights than it allows the judiciary to ignore rights meant to be protected when it addresses the most difficult, sometimes divisive, cases that arise. Nevertheless, the law must be ascertained and applied by the bench, as opposed to invented from behind it (Blackstone, 2011/1765). Generally the judicial branch gets it right, even if a case must go through several levels of appeal to arrive at the correct interpretation of the law.

Organization of the Judicial Branch

The judicial branch is divided into **trial courts** (courts of first instance) and **appellate courts**. Trial courts function with a judge and often a jury. Juries make findings of fact while judges decide conclusions of law (jury trials), or judges make decisions of both fact and law without a jury (bench trials). Whether or not a jury is selected depends upon the case and whether any of the parties has requested a jury. In the common law system, courts follow the **adversarial system**. Procedural law governs the rules by which courts operate: civil procedure for private disputes; criminal procedure for violation of criminal laws; and administrative procedure for government proceedings.

Federal Courts

The federal courts, as illustrated in **FIGURE 2-2**, are composed of:

- U.S. Courts of Appeals
- U.S. District Courts
- The U.S. Supreme Court

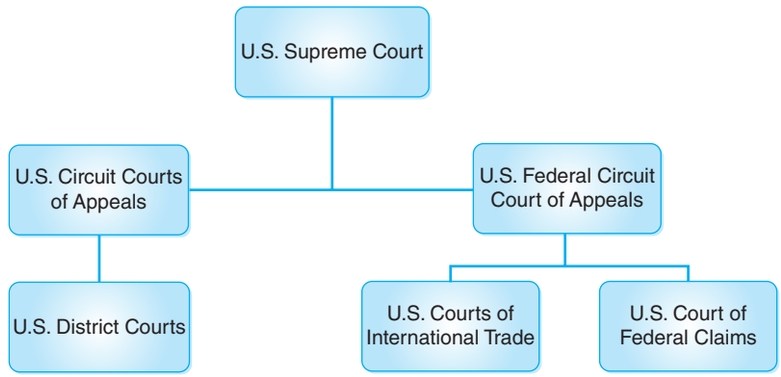

FIGURE 2-2 Organization of the Federal Court System

Modified from: Government Manual, The U.S. (2016). Washington, DC: U.S. Government Printing Office.

Every health law **case of first impression** that has been decided by the U.S. Courts of Appeals within the last five years is summarized in the *Principles and Applications* sections of this text or its ancillary materials. The health law cases decided by the U.S. Supreme Court within the past five years are also examined.

U.S. Supreme Court Article III, § 1 of the U.S. Constitution provides that the "judicial Power of the United States, shall be vested in one supreme Court, and in such inferior Courts as the Congress may from time to time ordain and establish." The U.S. Supreme Court was created in accordance with this provision in 1790 and is comprised of the Chief Justice and such number of Associate Justices as may be determined by Congress, which in 2016 was eight, for a total of nine Justices (*See* 28 U.S.C.A. § 1). The President nominates the Justices with the advice and consent of the Senate.

The term of the U.S. Supreme Court begins on the first Monday in October and lasts until the first Monday in October of the following year. Approximately 8,000 cases are filed with the Court in the course of a term; some 1,000 applications are filed each year that can be acted upon by a single Justice (*Government Manual*, 2016). While appellate jurisdiction has been conferred upon the U.S. Supreme Court by Congress, Congress has no authority to change the original jurisdiction of the Court as defined in Article III, § 2 of the U.S. Constitution (*See* 28 U.S.C.A. §§ 1251, 1253–1254, 1257–1259, and various special laws). This means that the Supreme Court can only review certain kinds of cases and has no authority to review other kinds, and Congress cannot alter the Supreme Court's authority to hear certain kinds of cases.

U.S. Courts of Appeals The 94 District Courts are organized into 12 circuits, each of which has a corresponding U.S. Court of Appeals. Courts of Appeal hear appeals from the District Courts located within their regional circuit, as well as appeals from decisions of federal administrative agencies, the Bankruptcy Courts, and the U.S. Tax Court. In addition, the U.S. Federal Circuit Court of Appeals hears appeals in specialized cases:

- U.S. Court of Customs and Patent Appeals (such as disputes between providers of medical products)
- U.S. Court of Federal Claims (such as vaccine injury claims)
- U.S. Court of International Trade (such as counterfeit medical product cases)

U.S. District Courts The U.S. District Courts are the trial courts of the federal court system. Within limits set by Congress and the U.S. Constitution, the District Courts hear civil and criminal federal cases.

MANAGEMENT AND LAW ISSUES

1. Should Americans be concerned about the fact that the average tenure of U.S. Supreme Court Justices has increased to almost 30 years, when every other major court of its kind in the world has rejected life tenure and 49 out of 50 states have rejected it for their state supreme courts?
2. Is life tenure for a U.S. Supreme Court Justice a good idea or is it an 18th-century anachronism?

U.S. Bankruptcy Courts and the U.S. Vaccine Court are separate units of the District Courts. Federal courts have **exclusive jurisdiction** over bankruptcy and vaccine cases, which means bankruptcy and vaccine cases cannot be filed in state courts. The Vaccine Court, with one chief special master and seven associate special masters, hears cases of children injured as a result of compulsory childhood vaccines and, like the Bankruptcy Courts, was established by Congress to bypass traditional civil malpractice litigation (*See* National Childhood Vaccine Injury Act of 1986, 42 U.S.C.A. §§ 300aa-2 *et seq.*).

State Courts

The organization of each state's judiciary is patterned after the federal judicial system. As in the federal courts, every health law case of first impression that has been decided by the highest state courts within the last five years is summarized in this text and its ancillary materials.

The People and the Judicial Branch

Americans have always been interested in questions related to **the People**, which is the Constitution's term of art referring to the citizenry, and the judicial branch. With hundreds of **ballot measures** in almost every state, **initiatives**, **referendums**, and **legislative measures** are becoming more a part of political discourse than ever before, with spending on such polling approaching a half-billion dollars each election year (Smith, 2014). What role the People retain in the U.S. Constitutional order is not just a theoretical issue; the increasing number of ballot measures addressed to voters has made it a debate with real consequences. The breadth of this debate is not limited to the topic of the right to gay marriage. The People may also play a role in deciding health care issues such as the following:

- Abortion rights
- Food regulations
- Physician-assisted death
- Right to basic health care
- Right to end-of-life medical treatments
- Right to medical marijuana
- Rights of adolescents
- Rights of women to contraception, including the morning-after pill
- Smoking measures

Although there is no provision for legislative measures at the national level, initiatives and referendums are available in thousands of counties, cities, and towns across the nation and are used far more frequently than their statewide counterparts (Smith, 2014 Perhaps more important, the way ordinary Americans choose to live and die gives meaning to the **rule of law**. Because the U.S. legal system often takes its cue from **tradition**, it is critical to decide when the judicial branch should defer to customary practice, both when interpreting the U.S. Constitution and when applying legislation and the rules of law that govern most health care decisions in the United States.

Legislative Branch

Congress makes the controlling choices in policy debates and establishes the acknowledged standards of law (*See Panama Refining Co. v. Ryan*, 293 U.S. 388, 426 (U.S. Supreme Court 1935)). This principle of legislation is grounded in the notion of **democratic legitimacy** (Barnard, 2003). Democratic legitimacy is the concept, first coined by F. M. Barnard, professor emeritus at the University of Western Ontario, that political accountability is as important to the democratic ethic as political participation. Barnard argues that laws must be tempered by a sense of universal humanity. In a democracy, the People's role does not begin and end in the voting booth when members of Congress are elected to take legislative action on behalf of the public; legitimacy assumes ongoing public involvement and regular public deliberation regarding issues of national concern. Democratic legitimacy depends on the nature of the congressional debate that precedes decision-making as much as the actual vote to enact legislation. To be legitimate, laws adopted by the legislative branch should comply with well-reasoned and recognized rules and tradition. The legitimacy of laws is challenged, as need be, through the judicial branch.

These democratic principles extend equally to the executive and judicial branches when they execute and apply the laws emanating from the legislative branch. Execution of the legislative laws by the executive branch should be

well-reasoned and in compliance with recognized standards of **compassion**, **justice**, and **equality of opportunity** (Rawls, 1999/1971). The judicial branch's interpretation of the policy choices made by both the legislative and executive branches should comply with well-reasoned rules that are consistent with the democratic traditions in the U.S. Constitution, which, in turn, reflects the Founders' beliefs in the universality of the human race (Nozick, 2013/1974).

Failure to comply with a health law does not necessarily indicate malicious intent or lack of compassion. Compliance with the law is required simply because the legislative branch of government has determined it is the law. The law is the policy choice made by Congress based on what it, as the People's representative, determines to be in the nation's best interests.

Organization of the U.S. Congress

Congress was created by Article I, § 1, of the U.S. Constitution, providing that "All legislative Powers herein granted shall be vested in a Congress of the U.S., which shall consist of a Senate and House of Representatives." The Senate is composed of 100 Senators, two from each state elected by its citizens to serve for six-year terms. There are three classes of Senators; a new class is elected every two years. The House of Representatives is composed of 435 members, a number determined by the population in each state. Representatives are elected by their state's citizens for two-year terms, all terms running for the same period.

Delegated Enactment of Laws

Congress cannot transfer the power of making laws to any other hands, for it is a delegated power from the People. They who have it cannot pass it over to others (Locke, 2015/1689). This principle is a fundamental democratic concern arising out of the ideal that significant policy decisions should be grounded in the **consent of the governed**.

Government Accountability Office

The Government Accountability Office (GAO), established in 1921, is the investigative arm of Congress charged with examining all matters relating to the receipt and disbursement of government funds (*See* 31 U.S.C.A. § 702). An independent, nonpartisan agency, the GAO works for Congress and is often referred to as the congressional watchdog because it investigates how the federal government spends society's dollars. The GAO gathers information to help Congress determine how effectively the executive branch is doing its job. The GAO's work routinely answers such basic questions as whether government health care programs are meeting their legislative objectives or providing effective service to the public (*Government Manual*, 2016).

With virtually the entire federal government subject to its review (*Government Manual*, 2016), the GAO issues a steady stream of reports and testimonies by its officials. Its reports help Congress better understand newly emerging issues with far-reaching impacts. For instance, privacy of the National Health Information Network has always been a GAO concern (GAO, 2015, 2014(a-c) and 2007).

Congressional Budget Office

The Congressional Budget Office, established in 1974, provides Congress with economic analyses of fiscal, budgetary, and program policy issues, as well as with information and estimates required for the congressional budget process (*See* 2 U.S.C.A. § 601 (2004)). This enables Congress to have an overview of the federal budget and to make overall decisions regarding spending and taxing levels and the deficit these levels incur.

One of the most controversial activities of the Congressional Budget Office is its projection of costs and savings from proposed legislation. Congressional budget rules allow the rate of mandatory spending and tax spending to grow automatically. If the cost of health care grows, spending will automatically grow. Instead of limiting the growth of health care programs, Congress has limited itself in its ability to pass legislation that would increase spending, known as **pay-as-you-go** (Paygo) (Kamin, 2015).

Paygo restricts Congress to passing only legislation with a net estimated cost of zero, or projected to result in additional revenue for the government. If a new program would increase spending above the current level (a term that,

incidentally, has never been defined), Congress would have to either reduce other programs or increase tax revenues. While total government borrowing, in the form of Treasury bonds and notes, could pass $544 billion in 2016 (76% of the gross national product), borrowed funds are not an **offset** for Paygo (CBO, 2016). Paygo estimates the official costs of legislation; a score that is too costly makes new programs harder to pass. Paygo assumes that the future effects of programs can be estimated. For instance, if legislation is proposed to make a new health service available under Medicare, the Congressional Budget Office estimates the increased costs of this proposal over the expected year-to-year automatic increases. In doing so, the Congressional Budget Office also offsets increases with any expected decreases. For instance, if legislation would require Medicare coverage for a drug, scorekeeping would include both the costs of the drug and any offsetting reductions in the need for hospital care (Kamin, 2015). It is debatable whether any supposed cost offsets ever materialize.

Executive Branch

Three issues face the executive branch. They include its:

- Encroachment into the judicial and legislative branches of a federal system established on the Separation of Powers doctrine
- Long-term fiscal gap resultant from expansion of social spending and congressional **earmarking** Unprecedented growth of entitlement programs

(CBO, 2015; Lowi et al., 2013).

Expansive Growth and Resultant Long-Term Fiscal Gap

The executive branch faces a long-term fiscal gap driven largely by health care and Social Security entitlements and interest payments (CBO, 2015). Meanwhile, the federal government continues to expand with congressional earmarking without regard for merit, need, or any scrutiny (Nussle & Orszag, 2015). Earmarks skyrocketed to over 16,000 in the middle of the last decade according to the Congressional Research Service (Orszag, 2010; White House, 2009). As a result of these forces, federal expenditures have increased from $1.8 trillion in 2000 to $3.9 trillion in 2016 (CBO, 2016).

Decline of Governance by Separation of Powers

With the growth of the executive branch, agency-promulgated guidelines have become universal in the federal government. There is debate, however, over whether **agency guidelines** and **nonbinding policy statements** are resulting in a diminution of the separation of powers doctrine, particularly for the judicial branch. The actual impact of agency guidelines and their voluntary and cooperative enforcement procedures is often unspoken. Often the issuing agencies declare the guidelines to be nonbinding, even for themselves. Notwithstanding this disclaimer, the health care industry and the judicial branch frequently rely upon agency guidelines in a precedent-like manner. The guidelines often become valued far more than the persuasive power of their ideas. This raises the more general concern as to whether the judicial branch is ceding its role as the check on the executive branch (Moncrieff, 2010). Such questions regarding the judiciary's role in the separation of powers are broadly analogous to those raised regarding Congress's role in the legislative process. Congress is often criticized for writing nonspecific legislation with delegation that arguably transfers legislative power to the executive and judicial branches (Lowi et al., 2013).

MANAGEMENT AND LAW ISSUES

3. Should the independent federal regulatory agencies be truly independent and free of executive and legislative branch control?

Executive Branch Departments and Agencies Affecting the Health Care Industry

Eleven departments exist in the executive branch that are part of the President's Cabinet and report to the President. The U.S. Department of Health and Human Services has the most direct impact on the health care industry, particularly the Food and Drug Administration (FDA) and the Centers for Medicare and Medicaid Services. The Internal Revenue Service (IRS), within the U.S. Department of the Treasury, and the Federal Trade Commission also have significant impacts on health care.

Organization of the U.S. Department of Health and Human Services

Funding for the U.S. Department of Health and Human Services is greater than all the other federal agencies combined, with 86% of the outlays for government health insurance programs (*Government Manual*, 2016). The $1.1 trillion size of the departmental budget is more than double the size of the budget of global retailer Walmart; by comparison and in terms of revenue, the department is equal to more than 13 IBMs.[1] Created in 1798 as a Cabinet-level department, the Department of Health and Human Services is composed of the following 11 agencies that report to the Secretary:

- Administration for Children and Families
- Administration on Aging
- Agency for Healthcare Research and Quality
- Agency for Toxic Substances and Disease Registry
- Centers for Disease Control and Prevention (CDC)
- Centers for Medicare and Medicaid Services (CMS)
- Food and Drug Administration (FDA)
- Health Resources and Services Administration
- Indian Health Service
- National Institutes of Health (NIH)
- Substance Abuse and Mental Health Services Administration

Administration for Children and Families

The Administration for Children and Families is the second largest agency in the Department of Health and Human Services. The agency deals primarily with:

- Adoptions
- Child abuse and neglect
- Child support
- Developmental disabilities
- Family assistance (welfare)
- Foster care[LN1]
- Head Start
- Human trafficking
- Legalized aliens
- Native American assistance
- Refugee resettlement and unaccompanied children's services

(*Government Manual*, 2016).

Today, welfare programs are substantially controlled by federal legislation. Every five years, the agency conducts reviews of state programs to ensure they are in conformity with federal requirements; most states are not. At the same time, the agency is criticized for failing to adequately monitor state programs and its inability to sufficiently hold states accountable. Although states may be penalized for noncompliance or failure to comply with federal reporting requirements, a state would only lose a small portion of its federally allotted money for noncompliance. Congressional influence on the agency's oversight role, without exception, results in new promises of future compliance by the noncompliant states but no cutbacks in funding.

[1]In 2015, the revenue of IBM was $81.7 billion (IBM, 2015); the revenue of Walmart was $485 billion (Walmart, 2016).

Administration on Aging

The Administration on Aging helps Americans aged 65 and over to maintain independence in their homes through comprehensive community-based systems of care. This population of 45 million comprised about 14% of the population in 2014 and is expected to more than double by 2060 (AOA, 2014). Three health care issues are of special importance to the population served by the agency. They include the following:

- Inadequate efficacy and affordability of medicines[LN2]
- Limited access to and increased non-affordability of basic health care[LN3]
- Unreported elder abuse and neglect with lack of protective services[LN4]

In partnership with the National Aging Network (which consists of over 50 state agencies on aging, almost 900 area agencies on aging, and 29,000 service providers), the Administration on Aging seeks to promote the development of all-inclusive structures encompassing:

- Home health care
- Hospice services
- Long-term nursing care

Agency for Healthcare Research and Quality

Since 2005, the Agency for Healthcare Research and Quality has issued comprehensive annual reports that address statistical compliance on a range of issues and highlight how the United States could improve the quality, safety, efficiency, and effectiveness of the nation's health care.[LN5] In addition, health services research to improve the quality of health care and promote evidence-based decision-making is supported by the agency, including research on:

- Access to quality health care for minorities and people of lower socioeconomic status;
- Emerging standards in national health care information technology
- Patient injuries caused by medical errors[LN6]
- Payments for the routine costs of clinical trials and treatment of trial-related complications[LN7]
- Physician compliance with clinical guidelines[LN8]
- Provision of emergency contraception in the nation's hospital emergency rooms[LN9]

Centers for Disease Control and Prevention

The Centers for Disease Control and Prevention is charged with protecting the public health of the nation by providing leadership and direction in the prevention and control of diseases and preventable conditions, and responding to public health emergencies (*Government Manual*, 2016). Within the Centers for Disease Control and Prevention are the following centers, institutes, and offices:

- CDC Washington Office
- Center for Global Health
- Office for State, Tribal, Local and Territorial Support
- Office of Equal Employment Opportunity
- Office of Infectious Diseases
  - National Center for Emerging and Zoonotic Infectious Diseases
  - National Center for HIV/AIDS, Viral Hepatitis, STD, and TB Prevention
  - National Center for Immunization and Respiratory Diseases
- Office of Minority Health and Health Equity
- Office of Noncommunicable Diseases, Injury and Environmental Health
  - National Center for Chronic Disease Prevention and Health Promotion
  - National Center for Environmental Health/Agency for Toxic Substances and Disease Registry
  - National Center for Injury Prevention and Control
  - National Center on Birth Defects and Developmental Disabilities

- Office of Public Health Preparedness and Response
- Office of Public Health Science Services
  - Center for Surveillance, Epidemiology and Laboratory Services
  - National Center for Health Statistics
- Office of the Associate Director for Communication
- Office of the Associate Director for Laboratory Science and Safety
- Office of the Associate Director for Policy
- Office of the Associate Director for Science
- Office of the Chief of Staff
- Office of the Chief Operating Officer

Health law is a foundational public health tool for disease prevention and health promotion. For many traditional public health problems, both acute and chronic, the role of law has been crucial in attaining public health goals, both framing and complementing the roles of epidemiology and laboratory science. Recently, law has played a fundamental role in the control and prevention of emerging health problems such as the threat of pandemic influenza, food safety, and gun violence. The agency's Public Health Law Program assists the centers, institutes, and offices to improve their understanding and use of law as a public health tool. CDC law initiatives have been developed in **personal health records** and **retail-based health clinics**.

Centers for Medicare and Medicaid Services

The Centers for Medicare and Medicaid Services administers Medicare, Medicaid, and related government health insurance programs. These programs serve one in three Americans, with over 1.2 billion claims per year, making the federal government the nation's largest purchaser of health care (*Government Manual*, 2016). The definition of what constitutes a **valid insurance claim** for payment by the government is an ever-present source of contention.[LN10]

The agency is attempting to transition its $927.7 billion insurance program to a **value-based payment system** (CMS, 2015). Hospitals are being solicited to enter into **gainsharing agreements** with physicians in order to reduce costs while also improving care. Under standard gainsharing agreements, hospitals pay physicians a share of any reduction in a hospital's costs attributable to the physicians' cost-saving efforts in providing care (Greaney, 2014). The merits of value-based payments are controversial (Santo, 2014).

On one hand, properly structured arrangements could offer opportunities for hospitals to reduce costs without causing inappropriate reductions in health care or rewarding patient referrals. On the other hand, gainsharing could reduce physician choice of medical devices and diagnostic tests and thus limit access to the most appropriate care (Fendell, 2014). The medical device and diagnostic industries claim gainsharing decreases incentives to invest in newer, more expensive technology and treatment procedures. While the U.S. Department of Justice, which enforces health care fraud and abuse laws, does not prosecute gainsharing agreements authorized by the Centers for Medicare & Medicaid Services (Farringer, 2015), this conditioned exception could vanish should gainsharing not produce positive results.

Food and Drug Administration

The Food and Drug Administration (FDA), the oldest federal regulatory agency in the nation, has garnered more than a century of scientific expertise. Federal concern for drugs started with the establishment of U.S. customs laboratories to administer the Import Drugs Act of 1848 (*See* 9 Stat. 237). The agency's roots date back to 1862, when the Division of Chemistry was created in the newly formed U.S. Department of Agriculture to analyze the food supply and provide advice on agricultural chemistry.

Regulation of a $4.4 Trillion Market

Growth in the medical products and food industries has resulted in the FDA regulating about $4.4 trillion of the U.S. economy (*Government Manual*, 2016; World Bank, 2015). The FDA is responsible for protecting the public health by ensuring the safety, efficacy, and security of the nation's food supply and the following eight categories of products:

- Biologics
- Cosmetics (including color additives found in makeup and other personal care products, skin moisturizers and cleansers, nail polish and perfume)

- Foods (including dietary supplements, bottled water, food additives, and infant formulas)
- Pharmaceuticals or human therapeutic drugs
- Medical devices (simple items, complex technologies such as heart pacemakers, dental devices, and surgical implants and prosthetics)
- Products that emit radiation
- Tobacco products (including cigarettes, cigarette tobacco, roll-your-own tobacco, and smokeless tobacco)
- Veterinary products (including livestock feeds, pet foods, and veterinary drugs and devices)

The FDA plays a significant role in addressing the following functions:

- Advertising of medical products with the Federal Trade Commission
- Consumer products that pose a hazard with the Consumer Product Safety Commission
- Counterterrorism capabilities
- Drinking water standards with the Environmental Protection Agency
- Security of the nation's food supply with the U.S. Department of Agriculture's Food and Safety Service

(*Government Manual*, 2016).

Incremental Regulation

In the last 70 years, the federal **Food, Drug, and Cosmetic Act of 1938** has been amended several hundred times to narrow the broad mandates the FDA was originally given. This incremental approach to regulation has resulted in enormously complex ambiguities.[LN11] Yet, Congress has not engaged in a comprehensive review of the Food, Drug, and Cosmetic Act since 1938, choosing instead to revise it word by word, provision by provision (Melnick, 2014). Today, the Food, Drug, and Cosmetic Act has slowly become inconsistent in both its terms and scope, specifically:

- Conflicting enforcement powers are provided for comparable violations
- Different words are used to mean the same thing in different parts of the law
- Inconsistent types of authority are granted with respect to similar matters
- Relationships among all of the provisions in the law are increasingly ambiguous.

Drug Safety: Premarket Approval Process

Before a new medical product is introduced into the marketplace, the FDA must be provided reasonable assurances that the product is both safe and effective (Kramer et al., 2014). These assurances may be provided through the FDA's premarket approval process. The process permits the FDA to demand the submission of detailed information regarding the safety and effectiveness of the product under review (*See* 21 U.S.C.A. § 360e (describing the required contents of a premarket approval application)). The FDA then spends substantial time and resources reviewing these applications, with the average submission requiring 1,200 hours of review (over nine months of review time). Ordinarily, the FDA refers the product to an independent panel of experts, which prepares a report and recommendation on whether to approve marketing of the product. The FDA may also advise a medical products firm of any measures necessary to put its product in approvable form. Once the FDA determines the required reasonable assurances have been provided, an order is issued permitting product marketing, exactly as approved. Thereafter, changes affecting the safety or effectiveness of the product may not be made to the approved labeling, manufacturing process, or product design. The FDA may withdraw its marketing approval if any such changes are made without prior approval. The U.S. Court of Appeals for the 11th Circuit provided a summary description of the premarket approval process in *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369-70 (U.S. Court of Appeals for the 11th Circuit 1999) that has since been cited by federal courts and the U.S. Supreme Court.

Post-Marketing Surveillance

Despite premarket review of medical products, active post-marketing surveillance for adverse effects is essential. Because all possible side effects of a product cannot be anticipated based on preapproval studies involving only several hundred to several thousand patients, the FDA maintains a system of post-marketing surveillance to identify adverse events that did not appear during the approval process. The FDA monitors adverse events such as reactions and poisonings and uses this information to update labeling and, on rare occasions, to reevaluate or revoke product approvals or marketing decisions.

Product Safety and Adverse Event Reporting

The FDA's **MedWatch** program provides an avenue for health care professionals and the public to voluntarily report serious reactions and problems with medical products. It also ensures that new safety information is rapidly communicated to the health care community. All data contained on the MedWatch form is entered into the **Adverse Events Reporting System**, a computerized information database of safety reports that supports the FDA's post-marketing safety surveillance program for all approved medical products.

Industry Surveillance

After a product is approved and marketed, FDA field investigators and analysts conduct unannounced inspections of drug production and control facilities to assure that firms adhere to the terms and conditions of approval described in the application. Investigators also determine if the drug or product is manufactured in a consistent and controlled manner.

Product Errors

Drug manufacturers are required by regulation to submit adverse event reports to the FDA. The MedWatch website provides information on mandatory reporting by manufacturers. In addition, manufacturers must submit either error and accident reports or drug quality reports when deviation from current good manufacturing practice regulations occurs.

The FDA receives error reports on marketed human drugs (including brand-name and generic prescription drugs as well as non-prescription over-the-counter drugs) and **nonvaccine biologics** and **medical devices**. A **medical product error** is defined as any preventable event that may cause or lead to inappropriate product use or patient harm. Such events may be related to professional practice or the medical products (including prescribing, product labeling, packaging, compounding, dispensing, distribution, administration, education, monitoring, and use).

Medical Product Shortages

It is the FDA's policy to attempt to prevent or alleviate shortages of medically necessary products. Medical product shortages may arise from varying causes, such as the unavailability of raw materials or packaging components, marketing decisions, and enforcement issues.

Drug Therapeutic Inequivalence Reporting

In the past 10 years, the FDA has received an increase in reports of **therapeutic inequivalence** or medical products that fail to work in patients because they simply have no effect or are toxic. These problems are usually attributed to switching brands of pharmaceuticals (brand-name to generic or one generic to another generic manufacturer). As a result, the FDA created the Therapeutic Inequivalence Action Coordinating Committee to identify and evaluate reports of therapeutic failures and toxicity that could indicate that one medical product is not equivalent to another similar product.

National Institutes of Health

The National Institutes of Health is the largest source of funding for medical research in the world. As the nation's medical research agency, the National Institutes of Health:

- Conducts research in its own campus laboratories and clinics across the United States
- Distributes public health information
- Facilitates the integration of safe and effective **complementary health care practices** into mainstream Western or conventional medicine
- Supports biomedical and behavioral research domestically and abroad
- Trains research scientists internally, as well as at universities and other institutions across the United States

Most of the agency's $30 billion in funding is awarded through competitive grants to more than 300,000 researchers at over 3,000 universities, medical schools, and other research institutions in every state and around the world (*Government Manual*, 2016). There are 27 national institutes and centers, including the following 18 national institutes that focus on particular diseases or body systems:

- Aging
- Alcohol Abuse and Alcoholism
- Allergy and Infectious Diseases

- Arthritis and Musculoskeletal and Skin Diseases
- Biomedical Imaging and Bioengineering
- Child Health and Human Development
- Deafness and Other Communication Disorders
- Dental and Craniofacial Diseases
- Diabetes and Digestive and Kidney Diseases
- Drug Abuse
- Environmental Health Sciences
- Eye (Ophthalmological Diseases)
- General Medical Sciences
- Heart, Lung, and Blood Diseases
- Human Genome Research
- Mental Health
- Neurological Disorders and Strokes
- Nursing Research

Internal Revenue Service within the U.S. Department of the Treasury

U.S. tax laws have a significant effect on the health care industry, affecting the payment for and delivery of health care. Many of the provisions in the internal revenue laws and related laws are direct government expenditures but are not included in the federal budget. For this reason, they are termed **tax expenditures**. In recent years, tax expenditures have amounted to almost half the federal budget outlays. For instance, employer-paid health insurance benefits are nontaxable income. The federal government is forgoing taxes on health insurance premiums to promote a policy of encouraging employers to provide their workers with health insurance as opposed to higher salaries and wages. This policy was implemented after World War II in the 1950s when the economy shifted from workers being self-employed or working in family-run farms or businesses to industrial and urban wage-based jobs instead.

Limited Government

The architects of the U.S. Constitution took great care to form a limited government founded on personal responsibility and individual liberty. A fundamental policy issue facing the nation right now is whether the U.S. internal revenue laws promote or undermine these founding principles. When more than $3.3 trillion is collected in federal tax revenue each year, by over 100,000 government employees, the meaning of *limited* arguably takes on an altogether different connotation (*Government Manual*, 2016; OMB, 2016).

MANAGEMENT AND LAW ISSUES

4. Do Americans still have a limited government that exists to preserve freedom, and, for the most part, does this principle still apply to health care?

Social Policy Vehicle

An ongoing debate is whether the U.S. internal revenue laws are an appropriate vehicle for implementing sweeping social policies. If tax fairness is placed ahead of economic progress, will either be achieved? The perennial question is whether the wealthiest class of Americans and corporations should pay higher tax rates to help the poor and middle classes. Congress first received authority to levy taxes on the income of individuals and corporations in 1913, pursuant to the Sixteenth Amendment of the U.S. Constitution. The percentage of tax filers paying no federal taxes has risen from about 18% in the 1980s to over 45% in 2015 (CBO, 2016). The Tax Policy Center estimated that in 2015 nearly 78 million filers had no federal income tax liability (TPC, 2015). There is serious debate about whether the removal of millions of taxpayers from the federal tax rolls is wise social policy.

MANAGEMENT AND LAW ISSUES

5. Should health care regulation authority be consolidated into one executive agency, or are there benefits to having multiple agencies involved?

Other Government Entities Affecting Health Care

Debate about whether the 59 independent federal regulatory agencies and government corporations are truly independent is ever-present. There are at least three such agencies that significantly impact and regulate the health care industry:

- Federal Trade Commission (FTC)
- National Science and Technology Council, which regulates emerging technologies such as **nanotechnology**[FN13]
- The Consumer Product Safety Commission, which tries to prevent harms before they occur; nevertheless, over 36,000 deaths and almost 14 million injuries are related to consumer products each year

By placing limits on the President's power to appoint and remove independent agency heads as well as mandating limits on the number of the President's own partisans that can be appointed, Congress has sought to limit presidential control of independent agencies (Krotoszynski et al., 2015; Lewis & Selin, 2015). Whether this independence is effective is debatable.

Federal Trade Commission

The Federal Trade Commission (FTC) was established by the Federal Trade Commission Act, 15 U.S.C.A. §§ 41–58. The following eight principal FTC functions affect the health care industry:

- Barring interlocking directorates' or officers' positions that may restrain **competition**
- Compelling hospitals and other health care providers to disclose in writing certain cost information, such as the annual percentage rate for deferred payments, before patients enter into credit transactions, as required by the **Truth in Lending Simplification and Reform Act of 1980** (*See* 15 U.S.C.A. §§ 1601 *et seq.*)
- Prohibiting the dissemination of false or deceptive advertisements of health care products and services as well as other unfair or deceptive practices
- Promoting competition through the prevention of general **trade restraints** such as **price-fixing agreements**, **boycotts**, **illegal combinations of competitors**, and other **unfair methods of competition**
- Proscribing **pricing discrimination**, **exclusive dealing**, **tying arrangements** (where buyers desiring to purchase one product must purchase a second product that they may or may not want), and **market discrimination** among competing health care providers and medical products firms
- Protecting patients with medical debt against circulation of inaccurate or obsolete credit reports and ensuring that credit bureaus, consumer reporting agencies, credit grantors, and bill collectors exercise their responsibilities in a fair and equitable manner
- Safeguarding the privacy of patients' personal information to prevent illegal or unwanted use of health data
- Stopping corporate mergers, acquisitions, or **joint ventures** that may substantially lessen **competition** or tend to create an **illegal monopoly**

(*Government Manual*, 2015).

Competition in Health Care

One of the two major missions of the FTC is to encourage competition in the delivery of health care. The FTC seeks to prevent unfair practices that undermine competition and attempts to prevent mergers or acquisitions of health care systems if the results would inappropriately lessen competition. It is the only federal agency with jurisdiction to enhance health care welfare and protect competition in broad sectors of the health care economy by:

- Enforcing laws that prohibit industry practices that are anticompetitive, deceptive, or unfair to health care entities if the results would inappropriately lessen competition

- Challenging attempts by independent practice associations, hospital-contracting networks, physician-contracting networks, and preferred provider organizations to impede competition and prohibiting physicians from discriminating among themselves in terms of price or other services provided
- Denying payment to physicians providing services to consumer-driven health care organizations
- Negotiating jointly with the health insurance industry and health care providers when they act in a manner that constitutes unlawful **horizontal price-fixing**

(DOJ & FTC, 2004; FTC, 2013).

The FTC is the only federal agency from which the American Medical Association has sought special exemption from jurisdiction (Blair & Durrance, 2015). The House passed a bill placing a moratorium on FTC investigations and lawsuits against physicians until Congress expressly approved such activity, but the bill was defeated in the Senate when the FTC challenged the rules banning physicians from engaging in contract medicine.

Health Care Advertising and Marketing

Health care consumer protection is the second of the two main missions of the FTC. The FTC works to:

- Ensure advertising is truthful and not false or misleading
- Prevent hospital and other health care providers from using unlawful practices when granting credit, maintaining credit information, collecting debts, and/or operating credit systems
- Reduce instances of fraudulent, deceptive, or unfair marketing and promotional practices

(DOJ & FTC, 2004).

The FTC initiates investigations in areas of concern to consumers of health care, including health and nutrition claims in advertising. The rapid expansion of medical testing, especially the direct-to-consumer advertising of genetic testing, raises questions about the accuracy of such tests and their consequences for even the most educated of consumers (Hartzog & Solove, 2015).

Medicare Advantage and Part D Prescription Drug Plan Compliance Activities

The deceptive sales tactics of private insurers running **Medicare Advantage** and **Part D prescription drug plans** victimize Medicare beneficiaries (Reiss et al., 2013). FTC audits of health-benefit options approved by Medicare, but sold and administered by private insurers, show widespread violations of patients' rights. Since 2006, when private Medicare coverage began, abuse of Medicare beneficiaries has grown as access to needed drugs or coverage of medical treatments has been restricted under the private Medicare plans. This problem is not limited to a few rogue insurance agents; rather, insurers provide lucrative incentives to producers who sell the private plans and then fail to supervise their agents (Pasquale & Ragone, 2014).

Unfortunately, weak federal regulations preempt stronger state law protections (*See* 42 U.S.C.A. §§ 139w-26(b)(3)-112(g) (pre-empting all state laws and regulations related to private Medicare plans)). Through systematic review of the marketing of Medicare's private plans, the FTC is obtaining and maintaining compliance with its cease-and-desist orders. All private insurers against whom such orders have been issued are required to file reports with the FTC to substantiate their compliance. In the event compliance is not obtained or if the order is subsequently violated, civil penalty proceedings may be instituted.

Agency Guidelines and Cooperative Procedures

Since the late 1960s, the FTC (like the FDA and Consumer Products Safety Commission) has relied increasingly on guidelines (Krishnakumar, 2015). A debate is ensuing in the health care industry about whether greater transparency is needed in the FTC's use of discretion. In carrying out its congressional directive to prevent unfair methods of competition or unfair or deceptive practices, the FTC makes extensive use of voluntary and cooperative procedures. Through these procedures, the health care industry obtains authoritative guidance and a substantial measure of certainty as to what it may do under the laws administered by the FTC. Guidelines provide the basis for voluntary abandonment of unlawful practices, while failure to comply with the guidelines may result in corrective action by the FTC.

Agency Investigations

Investigations by the FTC may originate through a complaint by a health care provider, competitor, Congress, or from federal, state, or local government agencies. Also, the FTC itself may initiate an investigation into possible violations

MANAGEMENT AND LAW ISSUES

6. How should the benefits of private development and public regulation be balanced?

of the laws it administers. No formality is required in submitting a complaint. It is the general policy of the FTC not to disclose the identity of the health care provider of any complainant, except as required by law or FTC rules. Upon receipt of a complaint, various criteria are applied in determining whether the particular matter should be investigated. An order issued after an administrative proceeding that requires the respondent to cease and desist or take other corrective action may be appealed. Appeals may go as far as the U.S. Supreme Court. In addition to, or in lieu of, the administrative proceeding initiated by a formal complaint, the FTC may request a U.S. district court to issue a preliminary or permanent injunction to:

- Halt the use of unfair or deceptive practices
- Prevent an anticompetitive merger or unfair methods of competition
- Stop violations of any law enforced by the FTC

Recently, the FTC initiated an investigation into children's advertising practices and the link between unhealthy food ads and childhood obesity. The consolidation of generic drug manufacturers is another area of ongoing FTC investigation as generics face a growing pressure to reduce costs. Lastly, the FTC is investigating the entire private equity industry, which may impact the pace of future acquisition deals.

Use of Governmental Powers

The federal government is continually developing new health care programs and expanding its regulation of the health care industry. However, this evolution has created overlap and excessive complexity in administrative responsibilities and regulatory powers. Further, there is confusion regarding how the federal government should construct health care spending plans that meet long-term objectives while helping put the economy on a path to budget balance. This is particularly true following the comprehensive health care reforms that were instituted with the Affordable Care Act of 2010 (42 U.S.C.A. §§ 18001 *et seq*.).

LAW FACT

Comprehensive Health Care Reform

Should comprehensive health care reforms, as well as repeal of the reforms, be passed through Congress's budget reconciliation process?

No, generally but not always necessarily. The Supremacy Clause of the U.S. Constitution is a powerful protection of the principle of federalism because it allows federal action only if the precise procedures for lawmaking are followed (Rubenstein, 2015). Budget reconciliation eliminates and lessens some of the major hurdles to enacting comprehensive federal legislation. Omnibus budget reconciliation acts, which typically include changes to revenue laws and entitlement programs, cannot be filibustered in the Senate; instead, a reconciliation bill is considered under rules that limit debate and allow passage by a simple majority (Perkins, 2014). While budget reconciliation bills still must meet the constitutional requirements of **bicameralism** and presentment to the President for enactment, congressional passage is more likely because it eliminates internal impediments of the minority (Kysar, 2014).

— 2 U.S.C.A. §§ 601-688, 900-907d (primary governing laws for the federal budget process).

Data from: 2 U.S.C.A. §§ 601-688, 900-907d.

CHAPTER SUMMARY

- U.S. health care law has evolved out of the interpretation and application by the judicial, legislative, and executive branches of government of the fundamental principles contained in the country's founding documents: the Declaration of Independence, the U.S. Constitution, and the Bill of Rights.
- The separation of governmental powers is central to the U.S. Constitution.
- Americans have rights beyond those enumerated in the founding documents; this is based on the notions that it would be impossible to set forth every possible right and that some rights supersede the government.
- It is the province and duty of the judicial branch to interpret and apply the laws enacted by the legislative branch; the judiciary sometimes struggles to say what the law is, not what it should be.
- The U.S. Supreme Court is the nation's highest court, but it may only hear certain kinds of cases.
- The People are attempting to increase their influence upon their government, particularly through ballot initiatives and citizen movements.
- The legislative branch consists of Congress, which is comprised of the U.S. Senate and House of Representatives, who jointly draft and enact legislation.
- The Government Accountability Office and the Congressional Budget Office help to advise Congress and provide oversight and guidance.
- The executive branch is comprised of the President and various government agencies that administer and enforce legislation; two ongoing priorities have been to address health care fraud and drug safety issues.
- The U.S. Department of Health and Human Services has a pervasive influence on the U.S. health care industry; its budget is greater than all of the other federal agencies combined.
- The nine Department of Health and Human Services agencies that significantly impact the U.S. health care industry are the Administration for Children and Families, Administration on Aging, Agency for Healthcare Research and Quality, Centers for Medicare and Medicaid Services, Food and Drug Administration, Health Resources and Services Administration, National Institutes of Health, Public Health Service, and Substance Abuse and Mental Health Services Administration.
- The Food and Drug Administration regulates approximately one-fourth of the U.S. economy by ensuring the safety and efficacy of food, cosmetics, dietary supplements, therapeutic drugs, medical devices, radioactive products, and veterinary drugs.
- Beyond the U.S. Department of Health and Human Services, federal tax laws also influence how health care is paid for and delivered.
- Nanotechnology provides the first opportunity since the formation of the Food and Drug Administration for governance to develop simultaneously with emerging technology.
- The Federal Trade Commission protects U.S. health care by preventing unfair competition and deceptive business practices and protecting consumers.
- The Food and Drug Administration further protects consumers by requiring medical products manufacturers to prove that their products are safe and effective prior to marketing.

LAW NOTES

1. For decades, the Administration for Children and Families has met criticism for the nation's lack of oversight of state-administered foster programs. Recent concerns have been directed at how foster youth are generally unable to live independently once they reach 18 years of age, with some youth resorting to sleeping in hospital emergency rooms (Beam, 2014; Dixon et al., 2011). Today, a child welfare issue involving transitions out of foster care has evolved into a health care issue.
2. Medicines produced by the medical products industry have helped to increase the life expectancy of Americans 65 and over, to 20 years longer than their predecessors (NBER, 2016). Therefore, as a significant portion of the U.S. population grows older, the Administration on Aging will be placed under greater scrutiny to ensure the nation's medical products are safe, as well as efficacious and affordable for older Americans.
3. Americans 65 and over spend twice as much on health care compared to the rest of the population (Kaiser, 2014). While the majority Americans over 65 have health insurance coverage through Medicare, nearly half of all health care costs come from non-Medicare sources. This places a heavy burden on this population, considering that nearly 45% of Americans over the age of 65 are also socioeconomically deprived with limited access to health care (Cubanski et al., 2015 and 2014).

4. Elder abuse is so pervasive it qualifies as a major public health problem in the United States (Marcus, 2015). The Administration on Aging estimates that over 4 million Americans 65 and older have been the victims of some form of abuse. At the same time, the National Center on Elder Abuse believes the reporting of elder abuse and neglect is as low as 1 in 14 cases, despite mandatory reporting in all 50 states. Systems to address this public health issue simply do not exist in most communities (Kapp, 2014).
5. The Quality and Disparity Report measures differences in the availability and use of health care services in various populations. Differences in quality and access to health care do exist. People of lower socioeconomic status are less likely to receive high-quality health care; they also spend more money to get inferior care, suffer poorer health outcomes, and die earlier than their more affluent peers (AHRQ, 2014; Matthew, 2015).
6. New research estimating the rate of injuries caused by medical errors suggests that U.S. hospitals and health care providers bear some of the responsibility for as many as 440,000 deaths each year (James, 2013); a finding consistent with studies by the Agency for Healthcare Research and Quality (Landrigan, 2010), the Office of the Inspector General at the U.S. Department of Health and Human Services (Levinson, 2012; OIG-HHS, 2010), and the Institute of Medicine (IOM, 2010). The Agency for Healthcare Research and Quality continuously monitors this phenomenon using outcomes research. For instance, the Agency for Healthcare Research and Quality and the Centers for Disease Control and Prevention recently found that two-thirds of the serious injuries and deaths to newborn infants in the delivery room are the result of human error (CDC, 2013). Once the Agency for Healthcare Research and Quality makes discoveries like this, national guidelines for common medical procedures are produced to address the problem (*See* Welch et al., 2012). Compliance with applicable guidelines is in turn monitored by The Joint Commission on Accreditation of Healthcare Organizations. Noncompliance could cause a health care provider to lose accreditation, which could provide grounds for insurers to deny payment for medical treatments provided to patients (including government insurance programs like Medicare and Medicaidinsurance).
7. Health insurance coverage for the routine costs of qualifying clinical trials, and medically reasonable and necessary services used to diagnose and treat clinical trial-related complications, is inconsistent and denials are plentiful. The General Accounting Office estimates that the medical coverage denial rate for experimental and investigational treatment is one in four of all claims (GAO, 2011). The Agency for Healthcare Research and Quality, the Centers for Medicare and Medicaid Services, and the FDA are working with the health insurance industry and patients to resolve this payment issue (Lee, 2014).
8. Quality and Disparity Reports, from the Agency for Healthcare Research and Quality, on the terms of statistical compliance with clinical guidelines has demonstrated that even with clear-cut clinical guidelines, physicians ignore the guidelines more times than not. As a result, Americans receive the care that is recommended by the best available information only about 54% of the time (IOM, 2012). To improve physician compliance, the Agency for Healthcare Research and Quality and the Institute of Medicine have recommended the need for a conceptual framework to analyze physician performance (Avraham, 2014 and 2011; IOM, 2012).
9. Research from the Agency for Healthcare Research and Quality found the personal beliefs of physicians often supersede the proper care of sexual assault victims (Hrobak & Wilson, 2014; Mulla, 2014). Although the FDA approved over-the-counter access to emergency contraception for those over age 18 in the pharmacy setting, few states have enacted explicit emergency contraception laws to require hospital emergency rooms to provide sexual assault victims with information regarding emergency contraception and then to furnish it in the hospital upon request. The Agency for Healthcare Research and Quality has been clear in advising states that hospital emergency rooms must inform rape survivors of the availability of emergency contraception and provide information on how to access it, even though they may refer the patient to another facility to secure it (Deutsch, 2015).
10. Across the nation hospital debts are mounting due to the unreimbursed care that is given to the 11 million undocumented immigrants (Berlinger et al., 2015; Gusmano, 2012). While the Centers for Medicare and Medicaid Services funds Emergency Medicaid and promulgates policies the states must follow in administration of their own plans, defining emergency care has proven to be a problem (*See* **Emergency Medical Treatment and Labor Act of 1986**, 42 U.S.C.A. § 1395dd). Several states are funding chemotherapy for immigrants regardless of status and are requesting payment from the federal government. This argument over whether chemotherapy should be covered under Emergency Medicaid highlights the ambiguity of the government policy of only offering financial assistance for emergencies. Immigrants diagnosed with cancer suffer emergencies as the disease takes its course, but any emergency care given ultimately does little good because necessary follow-up treatment is unavailable. Hospitals often wind up with large bills of uncompensated care if chemotherapy is part of any treatment intervention (Price, 2012).

11. The FDA prohibits the medical products industry from promoting the unapproved use of its pharmaceutical, biologic, and device products, maintaining that this information is detrimental to public health (Abbott & Ayres, 2014). At the same time, the FDA mandates that the industry provide open access to available data about unapproved uses so medical decision-making can be safe (LaSalle, 2011). One policy prohibits the same speech that another policy mandates. Despite these regulatory inconsistencies, the significance of the FDA's role in the U.S. economy continues to increase.
12. Nanotechnology offers the possibility of revolutionizing health care. Though a number of nanotechnology products are already on the market, the major developments are yet to come. Most discussion presents a polarized debate between those seeking rapid development unfettered by excessive regulation and those who advocate a stringent regulatory regime to protect against nanotechnology risks. For the second time in history, there is the opportunity for a federal governance system to develop simultaneously with an emerging technology, the first time being the FDA (Cortez, 2014). The governance model that is emerging for nanotechnology could provide important insights for reforming governance systems in general.
13. The FTC's law enforcement work falls into two general categories: actions to foster voluntary compliance with the law, and formal administrative or federal court litigation leading to mandatory orders against offenders. Compliance with the law may be obtained through:

    - Formal advisory opinions;
    - Guides and policy statements outlining legal requirements as to industry practices; and
    - Voluntary and cooperative action in response to nonbinding staff advice.

Formal litigation is instituted either by issuing an administrative complaint or by filing a federal district court complaint charging a health care provider or a medical products firm with violating one or more of the laws administered by the FTC. If the charges in an administrative matter are not contested, or if the charges are found to be true after an administrative hearing in a contested case, an order may be issued requiring discontinuance of the unlawful practices.

REFERENCES

Abbott, R., & Ayres, I. (2014). Evidence and extrapolation: Mechanisms for regulating off-label uses of drugs and devices. *Duke Law Journal*, *64*, 377–435.

AHRQ (Agency for Healthcare Research and Quality). (2014). *National Healthcare Quality and Disparities Report*. Rockville, MD: AHRQ.

AOA (Administration on the Aging). (2014). *A profile of older Americans*. Washington, DC: AOA.

Avraham, R. (2014). Overlooked and underused: Clinical practice guidelines and malpractice liability for independent physicians. *Connecticut Insurance Law Journal*, *20*, 273–333.

Barnard, F. M. (2003). *Democratic legitimacy: Plural values and political power*. Montreal, Canada: McGill-Queen's University Press.

Beam, C. (2014). *To the end of June: The intimate life of American foster care*. Boston, MA: Mariner Books-Houghton Mifflin Harcourt.

Berlinger, N., et al. (2015). *Undocumented immigrants and access to health care in New York City: Identifying fair, effective, and sustainable local policy solutions*. New York, NY: New York Immigration Coalition and Garrison, NY: Hastings Center.

Blackstone, W. (2011). *The commentaries of Sir William Blackstone, Knight, on the laws and constitution of England*. Chicago, IL: American Bar Association (Original work published 1765).

Blair, R. D., & Durrance, C. P. (2015). Licensing health care professionals, state action and antitrust policy. *Iowa Law Review*, *100*, 1943–1967.

Cannan, J. (2013). A legislative history of the Affordable Care Act: How legislative procedure shapes legislative history. *Law Library Journal*, *105*, 131–173.

CBO (Congressional Budget Office). (2016). *The budget and economic outlook: 2016 to 2026*. Washington, DC: CBO.

___. (2015). The 2015 long-term budget outlook

CDC (Centers for Disease Control and Prevention). (2013, August 9). CDC grand rounds: Public health approaches to reducing U.S. infant mortality. *Morbidity and Mortality Weekly Report (MMWR)*, *62*(31), 625–628.

Cortez, N. (2014). Regulating disruptive innovation. *Berkeley Technology Law Journal*, *29*, 175–228.

Cubanski, J., et al. (2015). *Poverty among seniors: An updated analysis of national and state level poverty rates under the official and supplemental poverty measures*.

___. (2014). *Health care on a budget: The financial burden of health care spending by Medicare households*.

Deutsch, E. B. (2015). Expanding conscience, shrinking care: The crisis in access to reproductive care and the Affordable Care Act's nondiscrimination mandate. *Yale Law Journal*, *124*, 2470–2514.

Dixon, J., et al. (2011). The politics of protecting children. *Tennessee Journal of Law and Policy*, *7*, 218–263.

DOJ & FTC (U.S. Department of Justice & Federal Trade Commission). (2004). *Improving health care: A dose of competition*. Washington, DC: DOJ & FTC.

Farringer, D. R. (2015). Keeping our eyes on the prize: Examining Minnesota as a means for assuring achievement of the "triple aim" under the ACA. *Hamline Law Review*, *38*, 177–225.
Fendell, S. (2014). The unintended results of payment reform and electronic medical records. *Health and Biomedical Law Society*, *10*, 173–200.
Fishkin, J., & Forbath, W. E. (2014). The great society and the constitution of opportunity. *Drake Law Review*, *62*, 1017–1054.
FTC (Federal Trade Commission). (2013). *Overview of FTC antitrust actions in health care services and products*. Washington, DC: FTC.
GAO (General Accountability Office). (2015). *Cybersecurity: Recent data breaches illustrate need for strong controls across federal agencies*. Washington, DC: GAO.
___. (2014a). *Healthcare.Gov: Information security and privacy controls should be enhanced to address weaknesses*.
___. (2014b). *Healthcare.Gov: Actions needed to address weaknesses in information security and privacy controls*.
___. (2014c). *Electronic health records: HHS strategy to address information exchange challenges lacks specific prioritized actions and milestones*.
___. (2011). *Private health insurance: Data on application and coverage denials*.
Government Manual, The U.S. (2016). Washington, DC: U.S. Government Printing Office.
Greaney, T. L. (2014). Regulators as market-makers: Accountable care organizations and competition policy. *Arizona State Law Journal*, *46*, 1–40.
Gusmano, M. K. (2012). *Undocumented immigrants in the United States: U.S. health policy and access to care*. Garrison, NY: The Hastings Center.
Hamburger, P. (2015). The inversion of rights and power. *Buffalo Law Review*, *63*, 731–832.
Hartzog, W., & Solove, D. J. (2015). The scope and potential of FTC data protection. *The George Washington Law Review*, *83*, 2230–2300.
Hrobak, R. M., & Wilson, R. F. (2014). Emergency contraceptives or "abortion-inducing" drugs? Empowering women to make informed decisions. *Washington and Lee Law Review*, *71*, 1385–1428.
IBM. (2015). *Annual report*, Armonk, NY: IBM.
IOM (Institute of Medicine). (2012). *Best care at lower cost: The path to continuously learning health care in America*. Washington, DC: The National Academies Press.
___. (2010). *Redesigning continuing education in the health professions*.
James, J. T. (2013). A new, evidence-based estimate of patient harms associated with hospital care. *Journal of Patient Safety*, *9*(3), 122–128.
Kaiser Family Foundation. (2014). *Medicare at a glance*. Menlo Park, CA: Kaiser.
Kamin, D. (2015). Basing budget baselines. *William and Mary Law Review*, *57*, 143–219.
Kapp, M. B. (2014). Home and community-based long-term services and supports: Health reform's most enduring legacy? *Saint Louis University Journal of Health Law and Policy*, *8*, 9–32.
Kramer, D. B., et al. (2014). Ensuring medical device effectiveness and safety: A cross-national comparison of approaches to regulation. *Food and Drug Law Journal*, *69*, 1–23.
Krishnakumar, A. S. (2015). Longstanding agency interpretations. *Fordham Law Review*, *83*, 1823–1903.
Krotoszynski, R. J., et al. (2015). Partisan balance requirements in the age of new formalism. *Notre Dame Law Review*, *90*, 941–1017.
Kysar, R. M. (2014). The shell bill game: Avoidance and the origination clause. *Washington University Law Review*, *91*, 659–720.
Landrigan, C. P. (2010). Temporal trends in rates of patient harm resulting from medical care. *New England Journal of Medicine*, *363*, 2124–2134.
LaSalle, K. (2011). A prescription for change: *Citizens United's* implications for regulation of off-label promotion of prescription pharmaceuticals. *Journal of Law and Policy*, *19*, 867–911.
Lee, W. B. (2014). Recalibrating "experimental treatment exclusion": An empirical analysis. *University of Cincinnati Law Review*, *83*, 171–201.
Levinson, D. R. (2012). *Hospital incident reporting systems do not capture most patient harm*. Washington, DC: U.S. Department of Health and Human Services, Office of the Inspector General.
Lewis, D. E., & Selin, J. L. (2015). Political control and the forms of agency independence. *The George Washington Law Review*, *83*, 1487–1516.
Locke, J. (2015). *The second treatise of civil government*. Peterborough, Canada: Broadview Press (Original work published 1689).
Lowi, T. J., et al. (2013). *American government: Power and purpose* (13th ed.). New York, NY: W. W. Norton and Company.
Marcus, I. (2015). Gaps and barriers: Elder abuse qualifies as a major public health problem in the United States. *Montana Lawyer*, *40*(7), 20–22.
Matthew, D. B. (2015). Toward a structural theory of implicit racial and ethnic bias in health care. *Health Matrix: Journal of Law Medicine*, *25*, 61–85.
Melnick, R. S. (2014). Has the Constitution exacerbated the crisis of governance? The conventional misdiagnosis: Why "gridlock" is not our central problem and constitutional revision is not the solution. *Boston University Law Review*, *94*, 767–793.
Moncrieff, A. R. (2010). The Supreme Court's assault on litigation: Why (and how) it might be good for health law. *Boston University Law Review*, *90*, 2323–2382.
Mulla, S. (2014). *The violence of care: Rape victims, forensic nurses, and sexual assault intervention*. New York, NY: New York University Press.
NBER (National Bureau of Economic Research). (2016). *The impact of new drug launches on longevity: Evidence from longitudinal, disease-level data from 52 countries*. Cambridge, MA: NBER.
Nozick, R. (2013). *Anarchy, state, and utopia*. New York, NY: Basic Books-Perseus Book Group (Original work published 1974).
Nussle, J., & Orszag, P. (2015). *Moneyball for government* (2nd ed.). Disruption Books: Amazon Digital Services.
OIG-HHS (Office of the Inspector General, U.S. Department of Health and Human Services). (2010). *Adverse events in hospitals: National incidence among Medicare beneficiaries*. Washington, DC: HHS, OIG.
OMB (Office of Management and Budget). (2016). *Budget of the U.S. government*. Washington, DC: OMB.
Orszag, P. R. (2010). *Changing the trend for earmarks*. Washington, DC: Office of Management and Budget.
Pasquale, F., & Ragone, T. A. (2014). Protecting health privacy in an era of big data processing and cloud computing. *Stanford Technology Law Review*, *17*, 595–653.
Perkins, R. H. (2014). Breaking the spell of tax budget magic. *Columbia Journal of Tax Law*, *6*, 1–32.
Presser, S. B., & Zainaldin, J. S. (2013). *Cases and materials on law and jurisprudence in American history* (8th ed.). St. Paul, MN: West Academic Publishing.

Price, R. (2012). The killer mandate: EMTALA and its financial effects on hospitals and immigrants. *UMKC [University of Missouri-Kansas City] Law Review*, *80*, 881–903.
Rawls, J. (1999). *Theory of justice*. Cambridge, MA: Belknap Press-Harvard University Press (Original work published 1971).
Reiss, J. B., et al. (2013). Your business in court and at federal agencies. *Food and Drug Law Journal*, *68*, 1–51.
Rubenstein, D. S. (2015). Administrative federalism as separation of powers. *Washington and Lee Law Review*, *72*, 171–254.
Santo, C. (2014). Walking a tightrope: Regulating Medicare fraud and abuse and the transition to value-based payment. *Case Western Reserve Law Review*, *64*, 1377–1417.
Sassman, W. G. (2015). Applying originalism. *UCLA Law Review Discourse*, *63*, 154–171.
Smith, Jr., F. O. (2014). Due process, republicanism, and direct democracy. *New York University Law Review*, *89*, 582–665.
Smith, G. P., & Gallena, R. P. (2014). Re-negotiating a theory of social contract for universal health care in America or, securing the regulatory state? *Catholic University Law Review*, *63*, 423–463.
TPC (Tax Policy Center). (2015). *The numbers: Tax units with zero or negative income tax*. Washington, DC: Urban Institute and Brookings Institution.
Walmart. (2016). *Annual report*. Bentonville, AR: Walmart
Welch, H. G., et al. (2012). *Over-diagnosed—Making people sick in the pursuit of health*. Boston, MA: Beacon Press.
White House, The. (2009). *Press release: Remarks by the President on earmark reform*. Washington, DC: The White House.
World Bank. (2015). *GDP at market prices (current US$)*. Washington, DC: World Bank.