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THE LAW OF AMERICAN HEALTH CARE

Second Edition

Wolters Kluwer

The Law of AMERICAN HEALTH CARE

Aspen Casebook Series

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Second Edition

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For our students, who inspired us;
our families, who supported us;
and our colleagues, who taught us.

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PREFACE

At its inception, health care law was primarily state-based common law, rooted in "Law and Medicine," the original term for the field. Over time, private health insurance became the dominant payment mechanism, and its close cousin, managed care, became the leading cost control tool, but regulatory developments still continued to be largely state-based. Meanwhile, the role of the federal government in health care has grown slowly but consistently, both in public programs like Medicare and Medicaid, and through major federal laws that preempted some state-based rules. Traditionally, health care law has been taught as state-based case law with a significant federal overlay, and administrative law was merely a relevant detail.

The time had come to shift the emphasis and fully recognize that health care is a highly regulated industry with a substantial federal administrative law superstructure, just like railroad and airline transportation, financial services, oil and gas, and telecommunications, to name a few examples. After the passage of the Patient Protection and Affordable Care Act of 2010 (ACA), federal statutory and administrative law dominate the field of health care law. You will learn in the following pages about the ACA's rather complicated history, yet for all the challenges and objections, the law remains largely in place and represents the most sweeping transformation of U.S health care in a generation. The ACA was the farthest reaching in a long line of federal laws that enshrines choices about America's long-debated approaches to health insurance — private versus public provision of care, medical assistance eligibility, and the state-federal relationship in health care, among other themes. Likewise, most of the challenges to the law have operated in federal courts, Congress, and federal agency rule and policymaking, reflecting the increasingly dominant role of federal health care law. This book is the first health care law casebook to reflect that gravitational shift to the federal domain.

This second edition reflects important changes and key updates that have occurred since the 2016 election, including an adjusted framework for Chapter 1's introductory material; adding federal endorsement of work requirements in the Medicaid program in Chapter 2 (public insurance); and addressing repeal of the tax penalty associated with the individual health insurance mandate in Chapter 3 (private insurance). The individual mandate and Medicaid work requirements are significant, because they have spillover effects on other parts of the ACA, and they represent a philosophical shift regarding the role of government and individual responsibility for health. In addition to the reframing and updating of Chapters 1, 2, and 3, other updates include Chapter 5 (tax-exempt organizations) to reflect recent IRS enforcement activity around 501(r) Community Health Needs Assessment compliance; Chapter 6 (fraud and abuse) to include the U.S. Supreme Court's *Universal Health Services v. United States ex rel. Escobar* opinion, issued just after our

first edition went to press; Chapter 9 (regulating the beginning and end of life), to incorporate the U.S. Supreme Court opinion in *Whole Woman's Health v. Hellerstedt* and related developments.

The book retains its distinctive features, including its emphasis on primary source materials beyond appellate cases, which are the bread and butter of most first-year law school courses. Health care law abounds with other forms of legal authority, including statutory, regulatory, and sub-regulatory guidance. We use secondary sources sparingly, including only canonical commentary on the field and data-driven empirical research, which are uniquely important for the practicing health care lawyer. The primary source materials are the focal point, with longer excerpts and light editing, providing an experience that foreshadows the work that our students must do when they become practicing lawyers.

We do not attempt to cover all topics comprehensively. Instead, we chose our key topics carefully, making use of guidelines suggested by practicing attorneys and health law professors in the American Health Lawyers Association, the preeminent professional organization for health law practitioners. While surveying fewer topics than some other health law casebooks, we engage the selected topics in more depth, so students emerge with an understanding of the most important features for the practice of health care law. The result is a three- or four-credit-hour book that is shorter but leaves room for professors to supplement with additional topics they are keen to teach.

Finally, we have listened carefully to students' comments about classroom materials over the years and have used that feedback in structuring the book. First, we avoided extensive notes, moving most references to scholarly articles and other secondary sources to the teachers' manual. Second, we use three different kinds of problems throughout the book: "Questions," which engage an excerpt directly; "Problems," which offer a practice-like scenario, hypothetical, or policy question to consider; and "Capstone Problems," which are designed to facilitate integrative and summative mastery of the chapter. While we firmly believe that the sometimes tedious, technical reading of statutes, regulations, cases, and other sources is the real work of health care lawyers, for pedagogical purposes, we highlight key issues, background, and other points of interest through boxed side notes, which enrich understanding in the moment of digesting a key source.

Health care law is complex, but teaching it needn't be. We hope you enjoy our labor of love.

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The Law of AMERICAN HEALTH CARE

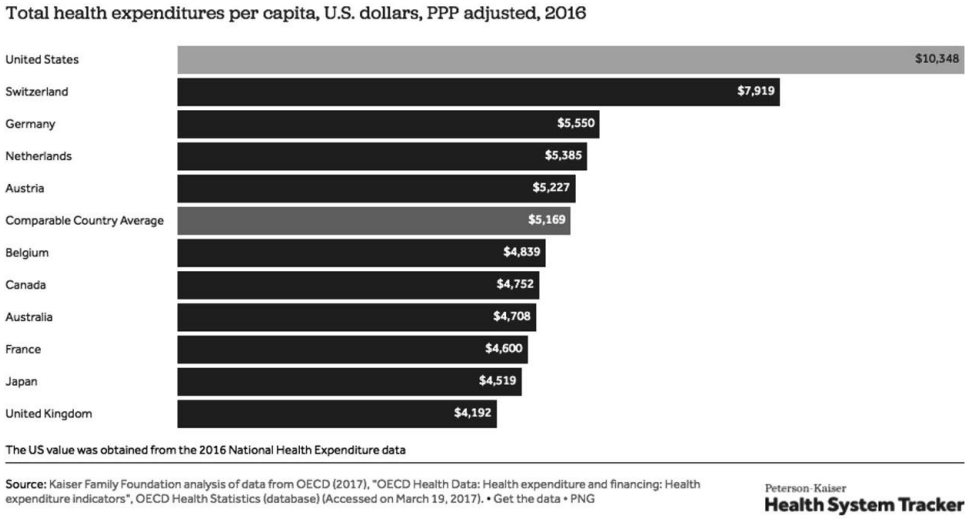
CHAPTER 1

Introduction to American Health Care Law

A. INTRODUCTION

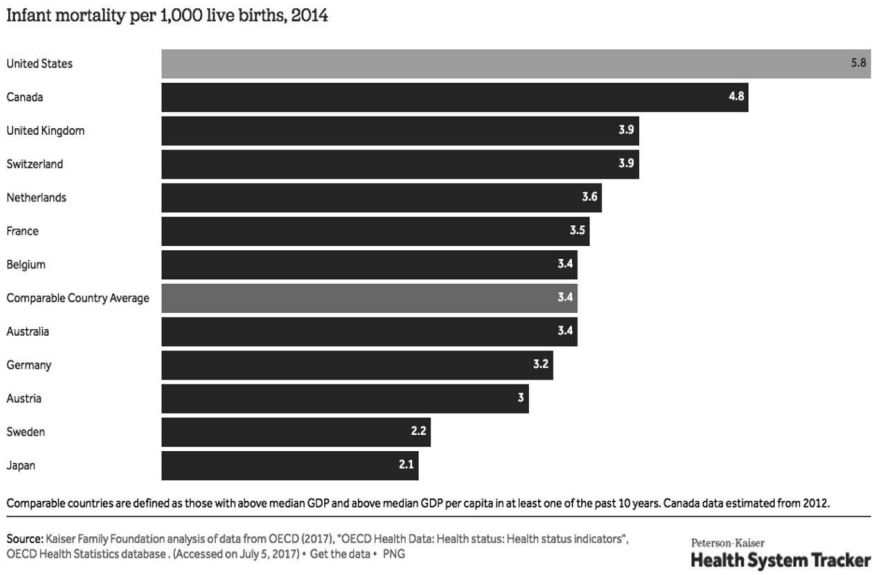
Health care is a vast, complex industry that will soon approach one-fifth of the U.S. economy, with more than $4 trillion in total spending expected in 2020. The United States is projected to spend on average more than $12,000 per capita on total health care expenses in 2020. Of course, this does not mean that each person in the United States will actually receive $12,000 in health care during the course of the year. Actual health care expenditures vary dramatically by age, sex, and other factors such as health status.

Health care is a growth industry, with costs steadily rising over time and accounting for an ever-increasing share of our nation's gross domestic product (GDP). In 2020, health care spending is projected to reach 18.4 percent of GDP, compared to just 5.5 percent of GDP in 1965 when Medicare and Medicaid began. Government spending on health care is projected to be 45 percent of total national health expenditures by 2020, though that does not account for federal tax benefits to private entities that provide health insurance as an employment benefit. The following chart shows U.S. health care spending, compared to certain other wealthy countries.

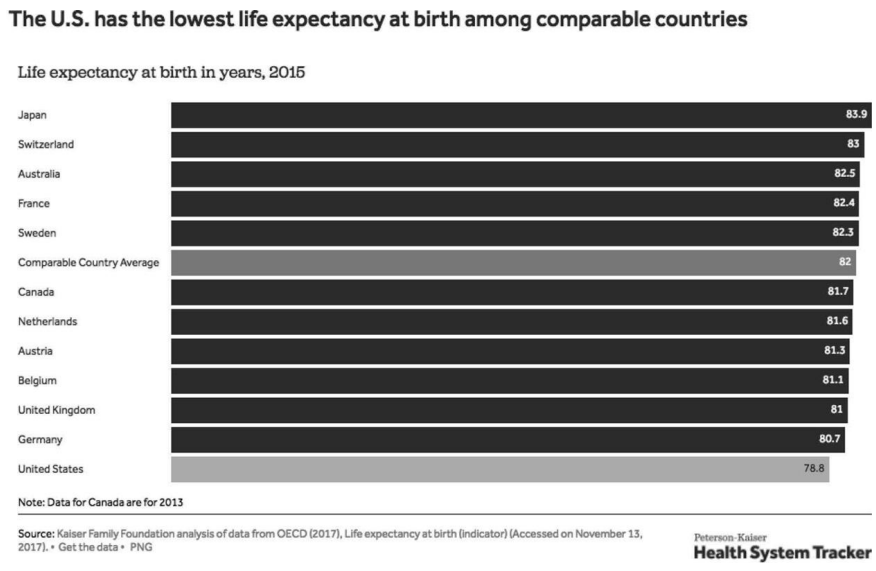


Those data might lead to the conclusion that the United States has an especially robust health care sector. Perhaps we value health care more highly than other comparable countries and spend accordingly. But what are we getting for our money? Health care law often operates within the larger sphere of health policy, which means that statistical methods are increasingly prominent in discussions on health care law. Two common ways to measure the relative health of a population are infant mortality and life expectancy. On both those measures, the United States performs poorly compared to other wealthy countries.

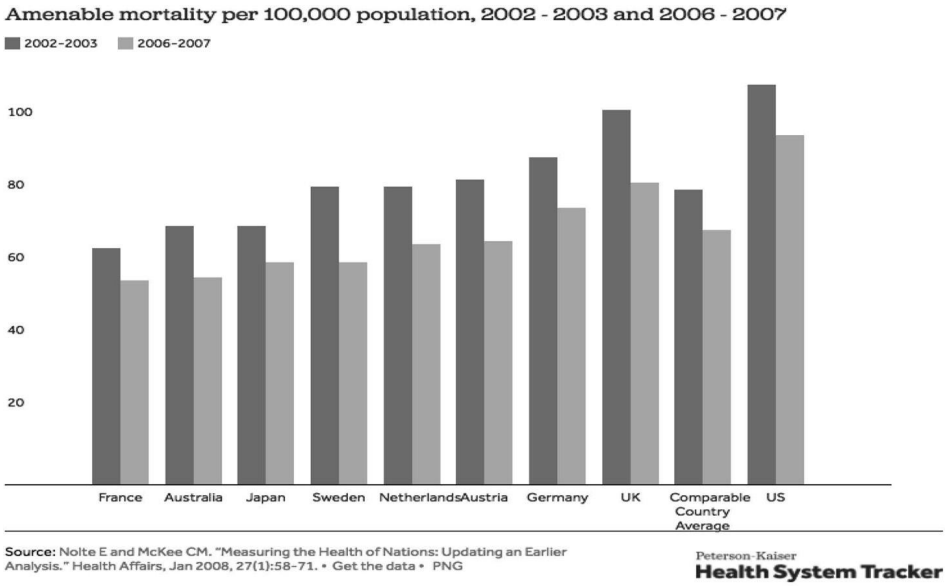
First, on infant mortality:



U.S. life expectancy at birth also lags by several years:



In addition, for all of that spending, the United States also has the highest rate of deaths that could be prevented by basic health care and preventive services, a measure called "mortality amenable to health care." The rate of mortality amenable to health care is even higher than the graphic below depicts, when measured based on demographic factors such as race and poverty. The United States has been ranked last among high-income nations on this measure since 2003.

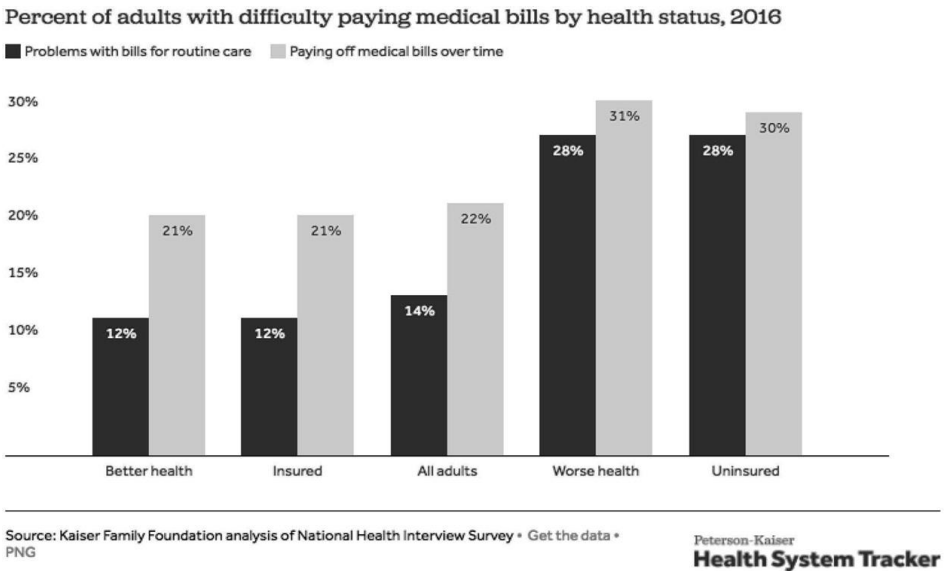


The Affordable Care Act (ACA) succeeded in its central objective of greatly reducing the percentage of uninsured Americans, but even near-universal insurance coverage does not ensure better health. Rates of insurance coverage in the United States reached their highest levels so far in 2016 at 91.1 percent and are projected to fall somewhat (to 89.3 percent) by 2026 under the Trump Administration's reduced enrollment efforts. But the direct health impact of insurance coverage should not be overstated. Insurance facilitates access to health care; but, it guarantees neither access nor affordability. Studies show that even those who have health insurance coverage are likely to struggle with the cost of medical care and to make sacrifices to pay for medical care.

Even more fundamentally, access to health care does not automatically lead to improved health. Many other socioeconomic factors such as wealth, employment, and housing may have greater direct effect on health, as do relatively inexpensive public health programs.

As you consider the snapshot of America's health care landscape on the next page and learn more details of its operation in the following chapters, it is important to recognize that America does not really have a health care "system," although that terminology is often used. In reality, the United States is better described as having a health care "non-system," or health care business "sector" or "space," which is complex, multifaceted, fragmented, and often poorly coordinated.

This fragmentation exists in part because the U.S. Constitution does not contain a right to health care or anything that looks like it, which can be contextualized by



history — such a right would have meant a "right" to bloodletting, fatal surgeries, and other remedies that today are considered barbaric. Medicine looked very different in 1787. This helps to explain why the Constitution does not squarely address the question of an affirmative right to health care, except in the prison context, where the Supreme Court of the United States held that total deprivation of medical care may violate the Eighth Amendment's prohibition on cruel and unusual treatment.

Estelle v. Gamble

429 U.S. 97 (1976)

Mr. Justice MARSHALL delivered the opinion of the Court.

. . . We therefore conclude that deliberate indifference to serious medical needs of prisoners constitutes the "unnecessary and wanton infliction of pain," Gregg v. Georgia, proscribed by the Eighth Amendment. This is true whether the indifference is manifested by prison doctors in their response to the prisoner's needs or by prison guards in intentionally denying or delaying access to medical care or intentionally interfering with the treatment once prescribed. Regardless of how evidenced, deliberate indifference to a prisoner's serious illness or injury states a cause of action under §1983.

For prisoners, the Constitution guarantees only a minimal right to health care, with quality decisions left to state law.

This conclusion does not mean, however, that every claim by a prisoner that he has not received adequate medical treatment states a violation of the Eighth Amendment. An accident, although it may produce added anguish, is not on that basis alone to be characterized as wanton infliction of unnecessary pain. . . . [I]n the medical context, an inadvertent failure to provide adequate medical care cannot be said to constitute "an unnecessary and wanton infliction of pain" or to be "repugnant to the conscience of mankind." Thus, a complaint that a physician has been negligent in diagnosing or treating a medical

condition does not state a valid claim of medical mistreatment under the Eighth Amendment. Medical malpractice does not become a constitutional violation merely because the victim is a prisoner. In order to state a cognizable claim, a prisoner must allege acts or omissions sufficiently harmful to evidence deliberate indifference to serious medical needs. It is only such indifference that can offend "evolving standards of decency" in violation of the Eighth Amendment.

Gamble's claims against Dr. Gray, both in his capacity as treating physician and as medical director of the Corrections Department, are not cognizable. . . . Gamble was seen by medical personnel on 17 occasions spanning a 3-month period: by Dr. Astone five times; by Dr. Gray twice; by Dr. Heaton three times; by an unidentified doctor and inmate nurse on the day of the injury; and by medical assistant Blunt six times. They treated his back injury, high blood pressure, and heart problems. Gamble has disclaimed any objection to the treatment provided for his high blood pressure and his heart problem; his complaint is "based solely on the lack of diagnosis and inadequate treatment of his back injury." The doctors diagnosed his injury as a lower back strain and treated it with bed rest, muscle relaxants and pain relievers. Respondent contends that more should have been done by way of diagnosis and treatment, and suggests a number of options that were not pursued. The Court of Appeals agreed, stating: "Certainly an x-ray of (Gamble's) lower back might have been in order and other tests conducted that would have led to appropriate diagnosis and treatment for the daily pain and suffering he was experiencing." But the question whether an X-ray or additional diagnostic techniques or forms of treatment is [*sic*] indicated is a classic example of a matter for medical judgment. A medical decision not to order an X-ray, or like measures, does not represent cruel and unusual punishment. At most it is medical malpractice, and as such the proper forum is the state court under the Texas Tort Claims Act.

QUESTION

Should everyone have the same constitutional right of access to health care enjoyed by prisoners?

The lack of a unifying right to health care facilitates complexity and fragmentation, both of which invite legal regulation. Thus, we will see that the health care sector is heavily regulated through statutes, regulations, common law, and other authority, leading to the set of legal doctrines commonly called health care law.

B. COMMON THEMES IN HEALTH CARE LAW

Health care law is one of the more complex subjects taught in law school, given that it contains a high degree of interaction with nonlegal actors and institutions, including doctors, patients, health insurers, hospitals, drug and device companies, and federal and state governments. Each of these groups has interests to defend, and many have highly specialized knowledge that uses special language, which a health care lawyer must be able to understand. As you approach this course and the materials included in this casebook, appreciate that they may be unfamiliar and

challenging at times. The objective, however, is to give you ample opportunity to practice reading and digesting the wide range of sources that you might encounter practicing this area of law.

One way to facilitate an ongoing understanding of the disparate field of health care law, despite its often rapidly changing landscape, is to introduce its consistent themes. These themes include:

- **Federalism** (the relationship between the federal government and states);
- **Individual rights** (protected by the U.S. Constitution, state constitutions, and common law, but limited by certain governmental powers and societal needs);
- **Fiduciary relationships** (between patients and providers, insurers and insureds, corporate officers and directors and the public, to name a few);
- **The modern administrative state** (including inherent tensions between coordinate legislative, executive, and judicial branches of government); and
- **Markets and regulation** (operating from the premise that health care markets are marred by various "imperfections" that invite legal interventions).

We offer the following three examples to elucidate these themes and introduce some substantive topics that we will consider more systematically throughout the course. Our purpose here is not to cover these topics exhaustively but rather to offer a brief introduction to laws and concepts that animate the field of health care law. We close the chapter with two theoretical approaches to health care, rooted first in economics and then in distributive justice. These insights and vocabulary will reappear in your studies as well.

1. INDIVIDUAL RIGHTS AND GOVERNMENTAL POWERS

The following case illustrates two inherent tensions in health law: the interests of individuals versus society at large, and the overlapping spheres of state and federal law that regulate health care. The U.S. Constitution recognizes certain individual rights, including liberty, property, free speech, freedom of religion, and privacy. But these rights are not absolute; the government may intrude upon them for justifiable reasons. Throughout the course, you will see numerous examples testing the scope of government power vis-à-vis individual rights. The federal government's powers are enumerated in the Constitution, while all other powers are reserved to the states. The states' reserved powers have long been called the "police powers," which includes authority to protect public health and safety. In the field of health care, it can have a great impact on individual autonomy. For example, in 2014, governors from New Jersey and Maine limited the freedom of a Doctors Without Borders nurse, Kaci Hickox, who returned from treating Ebola patients in West Africa. Global outbreaks of Ebola spurred fears and provoked the states' governors to exert their police powers to quarantine Hickox, despite lack of a clear medical or epidemiological basis for believing that she was infected. Quarantines are just one example of direct state control over a person, ostensibly to protect the public's health.

This early U.S. Supreme Court decision in the realm of medicine is still good law, frequently cited for the propositions it contains.

Jacobson v. Commonwealth of Massachusetts

197 U.S. 11 (1905)

Mr. Justice HARLAN delivered the opinion of the court:

This case involves the validity, under the Constitution of the United States, of certain provisions in the statutes of Massachusetts relating to vaccination.

The Revised Laws of that commonwealth provide that "the board of health of a city or town, if, in its opinion, it is necessary for the public health or safety, shall require and enforce the vaccination and revaccination of all the inhabitants thereof, and shall provide them with the means of free vaccination. Whoever, being over twenty-one years of age and not under guardianship, refuses or neglects to comply with such requirement shall forfeit $5."

An exception is made in favor of "children who present a certificate, signed by a registered physician, that they are unfit subjects for vaccination."

. . . Jacobson[ ] was proceeded against by a criminal complaint in one of the inferior courts of Massachusetts. The complaint charged that on the 17th day of July, 1902, the board of health of Cambridge, being of the opinion that it was necessary for the public health and safety, required the vaccination and revaccination of all the inhabitants thereof who had not been successfully vaccinated since the 1st day of March, 1897, and provided them with the means of free vaccination; and that the defendant, being over twenty-one years of age and not under guardianship, refused and neglected to comply with such requirement.

The defendant, having been arraigned, pleaded not guilty. The government put in evidence the above regulations adopted by the board of health, and made proof tending to show that its chairman informed the defendant that, by refusing to be vaccinated, he would incur the penalty provided by the statute, and would be prosecuted therefor; that he offered to vaccinate the defendant without expense to him; and that the offer was declined, and defendant refused to be vaccinated. . . .

There is some evidence that Reverend Jacobson refused to be vaccinated because he had already suffered a bad reaction to a vaccine.

A verdict of guilty was thereupon returned . . . and thereafter, pursuant to the verdict of the jury, he was sentenced by the court to pay a fine of $5. And the court ordered that he stand committed until the fine was paid. . . .

Is the statute . . . inconsistent with the liberty which the Constitution of the United States secures to every person against deprivation by the state?

The authority of the state to enact this statute is to be referred to what is commonly called the police power, a power which the state did not surrender when becoming a member of the Union under the Constitution. Although this court has refrained from any attempt to define the limits of that power, yet it has distinctly recognized the authority of a state to enact quarantine laws and "health laws of every description"; indeed, all laws that relate to matters completely within its territory and which do not by their necessary operation affect the people of other states. According to settled principles, the police power of a state must be held to embrace, at least, such reasonable regulations established directly by legislative enactment as will protect the public health and the public safety. . . .

We come, then, to inquire whether any right given or secured by the Constitution is invaded by the statute as interpreted by the state court. The defendant insists that

his liberty is invaded when the state subjects him to fine or imprisonment for neglecting or refusing to submit to vaccination; that a compulsory vaccination law is unreasonable, arbitrary, and oppressive, and, therefore, hostile to the inherent right of every freeman to care for his own body and health in such way as to him seems best; and that the execution of such a law against one who objects to vaccination, no matter for what reason, is nothing short of an assault upon his person. But the liberty secured by the Constitution of the United States to every person within its jurisdiction does not import an absolute right in each person to be, at all times and in all circumstances, wholly freed from restraint. There are manifold restraints to which every person is necessarily subject for the common good. On any other basis organized society could not exist with safety to its members. Society based on the rule that each one is a law unto himself would soon be confronted with disorder and anarchy. Real liberty for all could not exist under the operation of a principle which recognizes the right of each individual person to use his own, whether in respect of his person or his property, regardless of the injury that may be done to others. This court has more than once recognized it as a fundamental principle that "persons and property are subjected to all kinds of restraints and burdens in order to secure the general comfort, health, and prosperity of the state; of the perfect right of the legislature to do which no question ever was, or upon acknowledged general principles ever can be, made, so far as natural persons are concerned." In Crowley v. Christensen, 137 U.S. 86, 89, we said:

> The possession and enjoyment of all rights are subject to such reasonable conditions as may be deemed by the governing authority of the country essential to the safety, health, peace, good order, and morals of the community. Even liberty itself, the greatest of all rights, is not unrestricted license to act according to one's own will. It is only freedom from restraint under conditions essential to the equal enjoyment of the same right by others. It is, then, liberty regulated by law.

In the Constitution of Massachusetts adopted in 1780 it was laid down as a fundamental principle of the social compact that the whole people covenants with each citizen, and each citizen with the whole people, that all shall be governed by certain laws for "the common good," and that government is instituted "for the common good, for the protection, safety, prosperity, and happiness of the people, and not for the profit, honor, or private interests of any one man, family, or class of men." The good and welfare of the commonwealth, of which the legislature is primarily the judge, is the basis on which the police power rests in Massachusetts.

Applying these principles to the present case, it is to be observed that the legislature of Massachusetts required the inhabitants of a city or town to be vaccinated only when, in the opinion of the board of health, that was necessary for the public health or the public safety. . . . To invest such a body with authority over such matters was not an unusual, nor an unreasonable or arbitrary, requirement. Upon the principle of self-defense, of paramount necessity, a community has the right to protect itself against an epidemic of disease which threatens the safety of its members. . . .

> There is, of course, a sphere within which the individual may assert the supremacy of his own will, and rightfully dispute the authority of any human government, especially of any free government existing under a written constitution, to interfere with the exercise of that will. But it is equally true that in every well-ordered society charged with the duty of conserving the safety of its members the rights of the individual in

> respect of his liberty may at times, under the pressure of great dangers, be subjected to such restraint, to be enforced by reasonable regulations, as the safety of the general public may demand. An American citizen arriving at an American port on a vessel in which, during the voyage, there had been cases of yellow fever or Asiatic cholera, he, although apparently free from disease himself, may yet, in some circumstances, be held in quarantine against his will on board of such vessel or in a quarantine station, until it be ascertained by inspection, conducted with due diligence, that the danger of the spread of the disease among the community at large has disappeared. The liberty secured by the 14th Amendment, this court has said, consists, in part, in the right of a person "to live and work where he will"; and yet he may be compelled, by force if need be, against his will and without regard to his personal wishes or his pecuniary interests, or even his religious or political convictions, to take his place in the ranks of the army of his country, and risk the chance of being shot down in its defense. It is not, therefore, true that the power of the public to guard itself against imminent danger depends in every case involving the control of one's body upon his willingness to submit to reasonable regulations established by the constituted authorities, under the sanction of the state, for the purpose of protecting the public collectively against such danger. . . .

Looking at the propositions embodied in the defendant's rejected offers of proof, it is clear that they are more formidable by their number than by their inherent value. Those offers in the main seem to have had no purpose except to state the general theory of those of the medical profession who attach little or no value to vaccination as a means of preventing the spread of smallpox, or who think that vaccination causes other diseases of the body. What everybody knows the court must know, and therefore the state court judicially knew, as this court knows, that an opposite theory accords with the common belief, and is maintained by high medical authority. We must assume that, when the statute in question was passed, the legislature of Massachusetts was not unaware of these opposing theories, and was compelled, of necessity, to choose between them. It was not compelled to commit a matter involving the public health and safety to the final decision of a court or jury. It is no part of the function of a court or a jury to determine which one of two modes was likely to be the most effective for the protection of the public against disease. That was for the legislative department to determine in the light of all the information it had or could obtain. It could not properly abdicate its function to guard the public health and safety. The state legislature proceeded upon the theory which recognized vaccination as at least an effective, if not the best-known, way in which to meet and suppress the evils of a smallpox epidemic that imperiled an entire population. Upon what sound principles as to the relations existing between the different departments of government can the court review this action of the legislature? If there is any such power in the judiciary to review legislative action in respect of a matter affecting the general welfare, it can only be when that which the legislature has done comes within the rule that, if a statute purporting to have been enacted to protect the public health, the public morals, or the public safety, has no real or substantial relation to those objects, or is, beyond all question, a plain, palpable invasion of rights secured by the fundamental law, it is the duty of the courts to so adjudge, and thereby give effect to the Constitution.

The Court sidestepped the factual issue of whether these vaccinations are safe and effective.

Whatever may be thought of the expediency of this statute, it cannot be affirmed to be, beyond question, in palpable conflict with the Constitution. Nor, in view of the methods employed to stamp out the disease of smallpox, can anyone confidently

assert that the means prescribed by the state to that end has no real or substantial relation to the protection of the public health and the public safety. Such an assertion would not be consistent with the experience of this and other countries whose authorities have dealt with the disease of smallpox.[1] And the principle of vaccination as a means to prevent the spread of smallpox has been enforced in many states by statutes making the vaccination of children a condition of their right to enter or remain in public schools.

The latest case upon the subject of which we are aware is *Viemester v. White*, decided very recently by the court of appeals of New York. That case involved the validity of a statute excluding from the public schools all children who had not been vaccinated. One contention was that the statute and the regulation adopted in exercise of its provisions was [*sic*] inconsistent with the rights, privileges, and liberties of the citizen. The contention was overruled, the court saying, among other things:

> Smallpox is known of all to be a dangerous and contagious disease. If vaccination strongly tends to prevent the transmission or spread of this disease, it logically follows that children may be refused admission to the public schools until they have been vaccinated. The appellant claims that vaccination does not tend to prevent smallpox, but tends to bring about other diseases, and that it does much harm, with no good. It must be conceded that some laymen, both learned and unlearned, and some physicians of great skill and repute, do not believe that vaccination is a preventive of smallpox. The common belief, however, is that it has a decided tendency to prevent the spread of this fearful disease, and to render it less dangerous to those who contract it. While not accepted by all, it is accepted by the mass of the people, as well as by most members of the medical profession. It has been general in our state, and in most civilized nations for generations. It is generally accepted in theory, and generally applied in practice, both by the voluntary action of the people, and in obedience to the command of law. Nearly every state in the Union has statutes to encourage, or

1. "State-supported facilities for vaccination began in England in 1808 with the National Vaccine Establishment. In 1840 vaccination fees were made payable out of the rates. The first compulsory act was passed in 1853, the guardians of the poor being intrusted with the carrying out of the law; in 1854 the public vaccinations under one year of age were 408,824 as against an average of 180,960 for several years before. In 1867 a new act was passed, rather to remove some technical difficulties than to enlarge the scope of the former act; and in 1871 the act was passed which compelled the boards of guardians to appoint vaccination officers. The guardians also appoint a public vaccinator, who must be duly qualified to practise medicine, and whose duty it is to vaccinate (for a fee of one shilling and sixpence) any child resident within his district brought to him for that purpose, to examine the same a week after, to give a certificate, and to certify to the vaccination officer the fact of vaccination or of insusceptibility. . . . Vaccination was made compulsory in Bavarla in 1807, and subsequently in the following countries: Denmark (1810), Sweden (1814), Wu«rttemberg, Hesse, and other German states (1818), Prussia (1835), Roumania (1874), Hungary (1876), and Servia (1881). It is compulsory by cantonal law in 10 out of the 22 Swiss cantons; an attempt to pass a Federal compulsory law was defeated by a plebiscite in 1881. In the following countries there is no compulsory law, but governmental facilities and compulsion on various classes more or less directly under governmental control, such as soldiers, state employees, apprentices, school pupils, etc.: France, Italy, Spain, Portugal, Belgium, Norway, Austria, Turkey. . . . Vaccination has been compulsory in South Australia since 1872, in Victoria since 1874, and in Western Australia since 1878. In Tasmania a compulsory act was passed in 1882. In New South Wales there is no compulsion, but free facilities for vaccination. Compulsion was adopted at Calcutta in 1880, and since then at 80 other towns of Bengal, at Madras in 1884, and at Bombay and elsewhere in the presidency a few years earlier. Revaccination was made compulsory in Denmark in 1871, and in Roumania in 1874; in Holland it was enacted for all school pupils in 1872. The various laws and administrative orders which had been for many years in force as to vaccination and revaccination in the several German states were consolidated in an imperial statute of 1874." 24 Encyclopaedia Britannica (1894), *Vaccination*.

> directly or indirectly to require, vaccination; and this is true of most nations of Europe. . . . A common belief, like common knowledge, does not require evidence to establish its existence, but may be acted upon without proof by the legislature and the courts. . . . The fact that the belief is not universal is not controlling, for there is scarcely any belief that is accepted by everyone. The possibility that the belief may be wrong, and that science may yet show it to be wrong, is not conclusive; for the legislature has the right to pass laws which, according to the common belief of the people, are adapted to prevent the spread of contagious diseases. In a free country, where the government is by the people, through their chosen representatives, practical legislation admits of no other standard of action, for what the people believe is for the common welfare must be accepted as tending to promote the common welfare, whether it does in fact or not. Any other basis would conflict with the spirit of the Constitution, and would sanction measures opposed to a Republican form of government. While we do not decide, and cannot decide, that vaccination is a preventive of smallpox, we take judicial notice of the fact that this is the common belief of the people of the state, and, with this fact as a foundation, we hold that the statute in question is a health law, enacted in a reasonable and proper exercise of the police power.

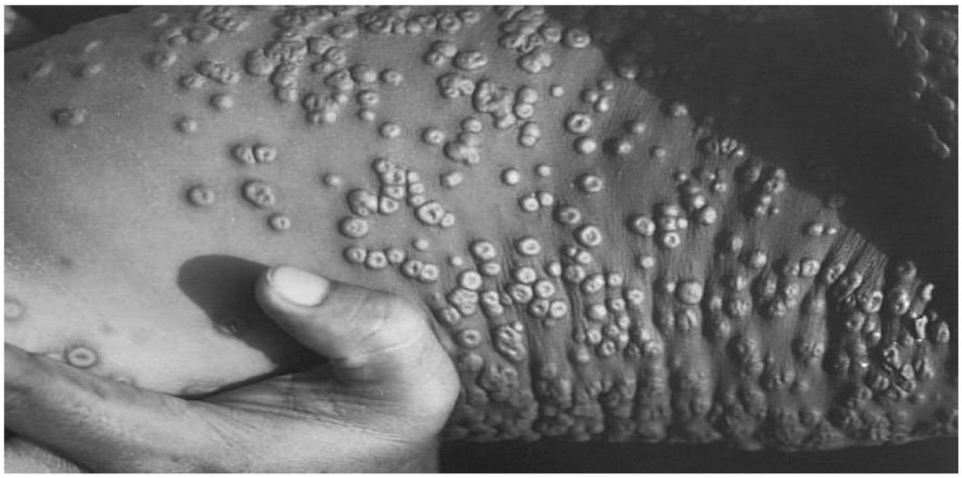
Since, then, vaccination, as a means of protecting a community against smallpox, finds strong support in the experience of this and other countries, no court, much less a jury, is justified in disregarding the action of the legislature simply because in its or their opinion that particular method was — perhaps, or possibly — not the best either for children or adults. . . .

It seems to the court that [Jacobson's arguments] would practically strip the legislative department of its function to care for the public health and the public safety when endangered by epidemics of disease. Such an answer would mean that compulsory vaccination could not, in any conceivable case, be legally enforced in a community, even at the command of the legislature, however widespread the epidemic of smallpox, and however deep and universal was the belief of the community and of its medical advisers that a system of general vaccination was vital to the safety of all.

We are not prepared to hold that a minority, residing or remaining in any city or town where smallpox is prevalent, and enjoying the general protection afforded by an organized local government, may thus defy the will of its constituted authorities, acting in good faith for all, under the legislative sanction of the state. If such be the privilege of a minority, then a like privilege would belong to each individual of the community, and the spectacle would be presented of the welfare and safety of an entire population being subordinated to the notions of a single individual who chooses to remain a part of that population. We are unwilling to hold it to be an element in the liberty secured by the Constitution of the United States that one person, or a minority of persons, residing in any community and enjoying the benefits of its local government, should have the power thus to dominate the majority when supported in their action by the authority of the state. While this court should guard with firmness every right appertaining to life, liberty, or property as secured to the individual by the supreme law of the land, it is of the last importance that it should not invade the domain of local authority except when it is plainly necessary to do so in order to enforce that law. The safety and the health of the people of Massachusetts are, in the first instance, for that commonwealth to guard and protect. They are matters that do not ordinarily concern the national government. So far as they can be

reached by any government, they depend, primarily, upon such action as the state, in its wisdom, may take; and we do not perceive that this legislation has invaded any right secured by the Federal Constitution.

Before closing this opinion we deem it appropriate, in order to prevent misapprehension as to our views, to observe — perhaps to repeat a thought already sufficiently expressed, namely — that the police power of a state, whether exercised directly by the legislature, or by a local body acting under its authority, may be exerted in such circumstances, or by regulations so arbitrary and oppressive in particular cases, as to justify the interference of the courts to prevent wrong and oppression. Extreme cases can be readily suggested. Ordinarily such cases are not safe guides in the administration of the law. It is easy, for instance, to suppose the case of an adult who is embraced by the mere words of the act, but yet to subject whom to vaccination in a particular condition of his health or body would be cruel and inhuman in the last degree. We are not to be understood as holding that the statute was intended to be applied to such a case, or, if it was so intended, that the judiciary would not be competent to interfere and protect the health and life of the individual concerned. "All laws," this court has said, "should receive a sensible construction. General terms should be so limited in their application as not to lead to injustice, oppression, or an absurd consequence. It will always, therefore, be presumed that the legislature intended exceptions to its language which would avoid results of this character. The reason of the law in such cases should prevail over its letter." Until otherwise informed by the highest court of Massachusetts, we are not inclined to hold that the statute establishes the absolute rule that an adult must be vaccinated if it be apparent or can be shown with reasonable certainty that he is not at the time a fit subject of vaccination, or that vaccination, by reason of his then condition, would seriously impair his health, or probably cause his death. No such case is here presented. It is the cause of an adult who, for aught that appears, was himself in perfect health and a fit subject of vaccination, and yet, while remaining in the community, refused to obey the statute and the regulation adopted in execution



Skin lesions caused by smallpox, courtesy of the Centers for Disease Control and Prevention.

of its provisions for the protection of the public health and the public safety, confessedly endangered by the presence of a dangerous disease.

We now decide only that the statute covers the present case, and that nothing clearly appears that would justify this court in holding it to be unconstitutional and inoperative in its application to the plaintiff in error.

The judgment of the court below must be affirmed.

It is so ordered.

QUESTIONS

1. Did Massachusetts force Jacobson to be vaccinated?
2. Justice Harlan deferred to state legislative judgments about the efficacy of smallpox vaccination as an appropriate exercise of state police power. Why then did the Court review the dominant views in the United States and Europe?
3. Would the Court have decided the case differently if Jacobson had convinced the justices he had a well-founded fear of harm from vaccination?

One justification for the result in *Jacobson* is that the police power can intrude on cognizable individual liberty when the benefit to the public outweighs the risk of harm to the individual. Vaccination hinders the spread of infectious disease. Each vaccination carries a small risk of side effects for the individual, but society is better off with mass vaccination that reaches a high enough level to protect the population (sometimes called "herd immunity"). An unvaccinated individual exposes the entire community to a risk, a negative externality in the language of economics. Even though epidemiologists find that vaccinating 100 percent of the population is rarely necessary, it is also difficult to know when enough of the population has been vaccinated to ensure protection from further disease. The safest path from a population perspective is to attempt to achieve very high levels of vaccination compliance lest a dread disease like smallpox, measles, or polio be permitted to flower into an epidemic.

PROBLEM

You represent a client in Boston, Massachusetts, who believes that the measles vaccine causes autism and, therefore, has not vaccinated his school-aged child. Relying on the guidance below, the Massachusetts Department of Public Health has blocked the child from attending school until he has received all scheduled vaccinations, including measles. What advice do you have for your client about whether he will succeed in challenging the constitutionality of the state's regulations?

MASSACHUSETTS DEPARTMENT OF PUBLIC HEALTH

Immunization Exemptions and
Vaccine Preventable Disease Exclusion Guidelines in School Settings

Definition of Allowable Exemptions

There are two situations in which children who are not appropriately immunized may be admitted to school:

1) **a medical exemption** is allowed if a physician submits documentation attesting that an immunization is medically contraindicated; and
2) **a religious exemption** is allowed if a parent or guardian submits a written statement that immunizations conflict with their sincere religious beliefs.

The law states that medical exemptions must be presented at the beginning of each school year. MDPH recommends also requesting religious exemptions on an annual basis, in writing, at the beginning of each school year.

Philosophical exemptions are not allowed by law in Massachusetts, even if signed by a physician. Only medical and religious exemptions are acceptable. These exemptions must be kept in the students' files at school (105 CMR 220.000 and M.G.L. c.76, ss. 15, 15C and 15D).

Policies for Exclusion at School Entry

While the laws and regulations state that **unimmunized** children who do not meet criteria for medical or religious exemption "shall **not** be admitted to school," policies around enforcement of exclusion for unimmunized or partially immunized children are developed by individual schools/school districts.

The only exception for exclusion of unimmunized or partially immunized children who do not have documentation of a medical or religious exemption is in the case of homeless children, whereby they cannot be denied entry to school if they do not have their immunization records. The federal McKinney-Vento Homeless Assistance Act states that if a homeless student does not have proper documentation of immunizations or any medical records, the Homeless Education Liaison at your school must immediately assist in obtaining them, and the student must be enrolled and permitted to attend school in the interim (as cited in the McKinney-Vento Homeless Assistance Act of 2001).

Exclusion During Disease Outbreaks

In situations when one or more cases of a vaccine-preventable or any other communicable disease are present in a school, all susceptibles, **including those with medical or religious exemptions**, are subject to exclusion as described in the Reportable Diseases and Isolation and Quarantine Requirements (105 CMR 300.000).

The reporting and control of diseases identified as posing a risk to the public health is prescribed by state regulation and law. The Isolation and Quarantine Requirements establish isolation and quarantine requirements for cases of certain diseases and their contacts in certain high-risk situations, including the school setting. The following table outlines several of the more common childhood vaccine-preventable diseases identified in the requirements that may occur in schools and the corresponding exclusion requirements.

2. HEALTH CARE RELATIONSHIPS AND FIDUCIARY DUTIES

Patients visit doctors for expert advice and treatment. But because the doctor is an expert who almost certainly knows much more about available treatments for the patient's medical condition, the patient is vulnerable and must trust the advice that a physician offers. While trust is a core element of the doctor-patient relationship, it is also a major topic in health care law. Under common law, an agent cannot have an undisclosed conflict of interest against his or her principal. But health care is big business, and therefore a wide range of considerations influences health care providers, including insurance company administrators, government regulators, health care corporate officers and directors, and even shareholders, in some cases. Many health care laws attempt to police the actions of providers when they face potential or actual financial conflicts of interest. Some of the most important health care practice areas, including fraud and abuse, regulate financial self-interest by providers, prohibiting financial and other arrangements that are perfectly acceptable in other industries. When a physician recommends surgery, patients understandably want that advice to be based on best medical advice, not the surgeon's desire to make money. By contrast, most consumers recognize that a salesperson's recommendation regarding which car to purchase includes a host of considerations irrelevant to the customer's driving pleasure.

The following example of fiduciary duties and market regulation in health law is illustrated with a collection of materials, including a media report, a court opinion, and an empirical research study. Together, these documents introduce the dynamic interplay of fiduciary rules and their various legal vehicles in the context of questionably necessary heart surgery.

Tenet Physicians Settle Case over Unnecessary Heart Procedures at Redding Medical Center, USA

Med. News Today, Nov. 17, 2005

Federal prosecutors on Tuesday said they have settled civil claims against physicians at Redding Medical Center — formerly owned by Dallas-based Tenet Healthcare — accused of performing unnecessary heart surgeries, the Los Angeles Times reports. In October 2002, federal officials launched an investigation into Drs. Chae Hyun Moon and Fidel Realyvasquez, two physicians at Redding Medical Center who allegedly performed unnecessary surgeries and defrauded Medicare. Federal officials alleged that the physicians participated in a "scheme to cause patients to undergo unnecessary invasive coronary procedures," such as artery bypass and heart valve replacement surgeries. In August 2003, Tenet agreed to pay $54 million to settle the federal case. In addition, the company in December 2004 announced plans to establish a $395 million fund for more than 769 cardiac patients and their families to settle a civil lawsuit filed over the allegations. The latest settlement pertains to Realyvasquez, Moon and two other doctors accused of performing the unnecessary heart procedures. According to the Sacramento Bee, FBI officials had sought to bring criminal charges against the doctors, but federal prosecutors "conceded [on Tuesday] they could not prove a criminal case and settled the matter with a series of civil fines."

Settlement Terms

Under the terms of the settlement, Moon and Realyvasquez each agreed to pay $1.4 million in fines. Kent Brusett, another surgeon in Realyvasquez's group, agreed to pay $250,000 over 10 years. Moon and Realyvasquez also agreed not to perform any procedures or surgeries on patients covered by Medicare, TRICARE or Medi-Cal, California's Medicaid program. In addition, Realyvasquez, Brusett and Ricardo Javier Moreno-Cabral agreed to ask their insurer to pay out $24 million to victims in the case, who have brought a civil lawsuit against the doctors in Shasta County Superior Court. The insurer will decide whether to pay the $24 million or contest the litigation, the San Francisco Chronicle reports. Tenet also agreed to pay an additional $5.5 million to settle claims against the company, U.S. Attorney McGregor Scott said. Tenet also will pay $1 million to California to settle a related state case filed by two of the whistleblowers in the federal investigation. Scott valued the overall settlement at $32.5 million. Tenet has admitted no wrongdoing in the case. The settlement does not resolve a civil lawsuit brought by 647 plaintiffs saying they underwent unnecessary heart surgeries. The first trial in the lawsuit is scheduled to begin on Tuesday.

Reaction

Assistant U.S. Attorney Michael Hirst said, "The evidence shows these doctors ran a high turnover, high volume surgery mill. While the evidence did not establish beyond a reasonable doubt that the doctors intended to perform unnecessary heart surgeries, the evidence was convincing that the doctors showed a reckless disregard for whether those surgeries were necessary or in their patients' best interests." Scott said, "The question at the end of the day becomes, 'Can you convict?' We came to the conclusion that we could not in good conscience go forward." Tenet said in a

statement, "Tenet and its subsidiaries have expressly denied that Redding Medical Center submitted false claims to government health care programs for cardiac procedures at Redding." "This settles all significant litigation and investigations having to do with Redding," Tenet spokesperson Harry Anderson, said. Malcolm Segal, Realyvasquez's lawyer, said, "Today's outcome reflects what we have said all along and what renowned heart specialists across the country have testified to under oath — Dr. Realyvasquez provided only necessary surgical care to save and prolong the lives of his patients." Moon's attorneys issued a statement saying, "[W]e appreciate the objectivity of the U.S. attorney for coming to the conclusion that Dr. Moon has no criminal liability."

QUESTIONS

1. Did the government prove that Dr. Moon performed unnecessary surgeries?
2. Did Dr. Moon physically or financially harm patients?
3. Although Dr. Moon avoided criminal prosecution, should he be allowed to continue to practice medicine in California?

The Redding-related litigation proceeded under several statutes, including the False Claims Act, which forbids anyone from submitting a false bill (or claim) to the federal government (discussed in greater detail in Chapter 6). The law applies to any government contractor and has become a key component of the government's oversight of federal health care programs such as Medicare and Medicaid. Private health care providers, including hospitals, physicians, clinical laboratories, pharmacies, and nursing homes, contract with the government to provide care and treatment to individual citizens enrolled in those programs. Each time that a provider submits a bill to the government for services rendered to those patients, significant penalties may be imposed due to violation of the Act.

The False Claims Act also offers substantial rewards to successful whistleblowers, known as *qui tam* relators. *Qui tam* relators receive a share of any money the government recovers as a "bounty" for bringing the matter forward. Accordingly, strong incentives exist for these individuals, and their attorneys, to identify wrongdoers, but the whistleblowers may be wrongdoers as well. The following opinion did not address the merits of the allegations regarding Dr. Moon. Rather, the court was sorting out which whistleblowers qualified for rewards.

Campbell v. Redding Medical Center

421 F.3d 817 (9th Cir. 2005)

I. Factual and Procedural Background

This lawsuit arises out of a scheme involving the performance of thousands of unnecessary invasive cardiac procedures at the Redding Medical Center ("RMC") for the purposes of fraudulently billing Medicare. On October 30, 2002, Magistrate Judge Peter Nowinski issued a medical records search warrant authorizing the FBI to investigate RMC and the medical offices of the defendant doctors. The FBI executed the search warrant at RMC that same day. The U.S. Attorney's Office also released the Search Warrant Affidavit to the public and the press on October 30.

On November 5, 2002, John Corapi, a former RMC patient, and Joseph Zerga, his friend, filed a sealed qui tam complaint pursuant to the False Claims Act, 31 U.

S.C. §3729-3733 ("FCA"), and the California False Claims Act in the United States District Court for the Eastern District of California against RMC; Tenet Healthcare Corporation; Chae Moon, RMC's director of Cardiology; and Fidel Realyvasquez, the Chairman of RMC's Cardiac Surgery Program. The Corapi/Zerga complaint alleged that the defendants had submitted false claims to federal and state medical insurance programs and stated that they had direct and independent knowledge of the facts underlying the complaint and had brought that information to the attention of the United States government. The Corapi/Zerga suit was assigned to Judge William Shubb.

Three days later, on November 8, 2002, Patrick Campbell, a local physician, filed his own complaint under the FCA and the California statute in the same court against the same defendants. Campbell later amended his complaint to accuse the defendants of engaging in a scheme to defraud state- and federally-funded health care insurance programs, including Medicare, Medicaid, and MediCal, by submitting claims for cardiac care that the defendants knew to be medically unnecessary or inappropriate. The complaint alleged that the defendants had performed medically unjustified invasive diagnostic coronary artery imaging tests and then misrepresented the results of these tests to patients so that they would undergo invasive cardiac procedures. . . .

Both cases were filed after the Oct. 30, 2002 press release.

The United States subsequently announced that it had settled its civil claims against RMC and Tenet Healthcare Corporation for payment of $54 million. . . .

III. Discussion

A. The False Claims Act

The False Claims Act imposes liability on those who submit a false or fraudulent claim for payment to the United States Government. The qui tam provisions of the False Claims Act encourage private parties who are aware of fraud against the government to sue for a civil penalty on behalf of the government. If the government intervenes and the action is successful, such parties will share in up to 25% of the government's recovery.

A private party, referred to as the "relator," may bring a civil action in the name of the government to recover damages against a person who has defrauded the government. . . .

Section 3730(e)(4)(A) states that "[n]o court shall have jurisdiction over an action under this section based upon the public disclosure of allegations or transactions . . . unless . . . the person bringing the action is an original source of the information." This subsection prevents opportunistic individuals from bringing qui tam actions — and sharing in the government's recovery — when they have done nothing to expose the allegations of fraud. For a court to have jurisdiction over a FCA case brought by a private party after the allegations have been made public, the relator must have been "an original source" of the allegations. An "original source" is someone who has "direct and independent knowledge of the information on which the allegations are based" and has voluntarily provided it to the government before filing suit.

. . . This is the first-to-file bar, which encourages prompt disclosure of fraud by creating a race to the courthouse among those with knowledge of fraud. We previously have held that §3730(b)(5) bars without exception a subsequent related action, even if the first action had been dismissed on the merits. The question before us is

whether the first-to-file bar also precludes the filing of a subsequent related action when the first complaint is subject to dismissal solely on jurisdictional grounds — i.e., because the relator is not an original source of allegations that already have been publicly disclosed.

B. The First-to-File Bar

. . . .

2. Legislative History and Underlying Purpose of the False Claims Act

. . . The legislative history also does not resolve the dispute before us, although the congressional intent to encourage whistleblowers to come forward is clear. Because that example is not instructive with respect to the case before us, we consider the history of the FCA.

The FCA was originally enacted in 1863 to address fraud by defense contractors during the civil war. . . . Congress . . . amended the statute again in 1986. "[T]he purpose of the 1986 amendments was to repeal overly-restrictive court interpretations of the qui tam statute, which had prohibited not only suits by private citizens based on information obtained by the government, but also suits brought by those who had information independently of the government." The 1986 Amendments also sought to "encourage more private enforcement suits."

3. Section 3730(b)(5) Does Not Create an Absolute First-to-File Bar When the First Complaint Is Jurisdictionally Defective

Both the history of the FCA and the legislative history of the 1986 Amendments demonstrate the effort to achieve "the golden mean between adequate incentives for whistle-blowing insiders with genuinely valuable information and discouragement of opportunistic plaintiffs who have no significant information to contribute of their own."

Even where allegations have already been publicly disclosed, the original source requirement seeks to reward those who came to the government with information about fraud before the public disclosure.

The FCA reflects the strong congressional policy of encouraging whistleblowers to come forward by rewarding the first to do so. In amending the FCA, Congress sought to create incentives for insiders with information that would be particularly valuable to the government.

The 1986 amendments succeeded in encouraging more private enforcement suits.

Construing §3730(b)(5) to create an absolute bar would permit opportunistic plaintiffs with no inside information to displace actual insiders with knowledge of the fraud. The government conceded at oral argument that under its interpretation of §3730(b)(5), a purely frivolous sham complaint filed in an instance where the allegations had been publicly disclosed would bar a subsequently filed action by an original source. This cannot be what Congress intended. We have previously noted that, "[i]n earlier versions of the FCA, the statute was abused by qui tam suits brought by private plaintiffs who had no independent knowledge of fraud." Although the addition of §3730(e)(4) would now prevent these plaintiffs from recovering in a public disclosure case, the simple fact that the sham complaint was filed before a meritorious complaint brought by a real original source would effectively prevent anyone from bringing a qui tam suit related to those claims. Such an interpretation would have

the effect of reducing the number of qui tam suits in public disclosure cases, directly contravening the express intent of Congress. . . .

To summarize: . . . we hold that in a public disclosure case, the first-to-file rule of §3730(b)(5) bars only subsequent complaints filed after a complaint that fulfills the jurisdictional prerequisites of §3730(e)(4).

As noted previously, the district court assumed for purposes of the motion to dismiss that Corapi and Zerga were not original sources, ruling that all that matters was whether Corapi and Zerga were the first to file. As we have shown, that is not all that matters. Accordingly, we remand so that the district court can determine if Corapi and Zerga were, indeed, original sources. . . .

REVERSED AND REMANDED.

QUESTIONS

1. How large is the potential reward for the *qui tam* relators in this case?
2. Should a doctor who participates in unnecessary heart surgeries be permitted to act as a whistleblower under the False Claims Act? Do you think physicians would be motivated to be more or less attentive to their fiduciary responsibilities in light of your answer?

Many surgeries in the United States occur in ambulatory surgery centers (ASCs), which is an outpatient care setting. Surgeons who practice in ASCs frequently own part of the company, which enables the surgeon to make money from both their professional fees (the surgery itself) and also from the facility fee (the separate charge for the ASC's operating room, equipment, and the like). Researchers have found empirical evidence that physician ownership changes referral patterns and that physicians refer differently when the facility fee is at stake. Federal and state lawmakers have enacted many laws, including fraud and abuse laws, in response to such empirical data. As you read an example of the research supporting limitations on physician referral behavior, pay close attention to the numbers in the chart demonstrating changes in referral patterns depending on ownership, which includes bias (intentional or implicit) against certain types of patients.

Jon R. Gabel et al., Where Do I Send Thee? Does Physician-Ownership Affect Referral Patterns to Ambulatory Surgery Centers?

27 Health Aff. w165 (2008)

Background. Recent congressional unease about physician financial conflict of interest has focused on specialty hospitals, but historically, Congress has also turned its attention to physicians' ownership of laboratories, imaging centers, pharmacies, and other facilities. One concern is whether physician-ownership leads to unfair competitive advantages relative to nonphysician-owned facilities. At issue is whether physician-owners refer more-lucrative patients to their own facilities and less-lucrative patients to their competitors. A second issue is that when physicians receive payment for nonprofessional services, they have added incentives to induce demand for these services, without the constraint of their own time as they would when they provide services in their own offices. Proponents of physician ownership see direct ownership of facilities leading to more-efficient management and scheduling.

This paper examines the first of these concerns: physicians' referral patterns when physicians own health care facilities. Current law prohibits physicians from referring their patients to facilities that they own in ten different categories. One . . . exception is ambulatory surgery centers (ASCs), where the rationale for the exemption is that ASCs deliver services at a lower cost than hospitals.

ASCs play an important and growing role in the U.S. health care delivery system. An estimated 3,800 ASCs were operational in 2003, with more than 40 percent of them owned by physicians and another 40 percent owned in joint physician-hospital or physician-corporate ventures. These ASCs competed with 3,998 hospital outpatient departments. From 2000 to 2006, the number of ASCs grew 55 percent, and total Medicare payments to ASCs rose 13.3 percent per year.

This paper explores how physician-ownership of ASCs affects referral patterns to ASCs. For a set of Pennsylvania physicians and ASCs, we analyzed whether physicians who are leading referrers to ASCs are more likely to send Medicaid and uninsured patients to hospital outpatient departments and refer privately insured patients to physician-owned facilities. We compared the referral patterns of "high referrers" to physician-owned ASCs, a proxy for physician-ownership, with patterns for physicians who are "high referrers" to non-physician-owned ASCs. . . .

Other patient characteristics. African Americans constituted 16 percent of the population in the study regions in 2003. Nearly 4 percent of patients cared for in

EXHIBIT 3
Distribution Among Payers, For Physicians Who Accounted For The Top 50 Percent Of Physician Referrals To Hospital Outpatient Departments, Not-For-Profit Ambulatory Surgery Centers (ASCs), For-Profit ASCs, And Physician-Owned ASCs In Pennsylvania, 2003

Category	Hospital outpatient department (%)	Not-for-profit ASC (%)	For-profit ASC (%)[a]	Physician-owned ASC (%)
Top 50% of referrals to physician-owned ASCs				
Total (n = 26,249)	8.7	0.0	0.2	91.3
Medicaid (n = 368)	44.6	0.0	0.0	55.4
Uninsured/self-pay (n = 447)	1.6	0.0	0.0	98.2
Commercial/Blue Cross (n = 17,321)	7.9	0.0	0.0	92.1
Medicare (n = 7,969)	9.1	0.0	0.0	90.8
Top 50% of referrals to hospital outpatient departments				
Total (n = 336,527)	95.5	1.7	0.5	2.0
Medicaid (n = 26,526)	97.6	1.0	0.3	0.2
Uninsured/self-pay (n = 12,026)	98.0	0.1	0.1	1.8
Commercial/Blue Cross (n = 191,789)	95.5	1.5	0.3	2.3
Medicare (n = 103,103)	94.5	2.6	0.9	1.9
Top 50% of physician referrals to not-for-profit ASCs				
Total (n = 17,712)	27.8	54.7	4.4	1.2
Medicaid (n = 1,578)	41.5	26.4	0.4	0.1
Uninsured/self-pay (n = 110)	44.6	23.6	5.5	10.0
Commercial/Blue Cross (n = 9,601)	23.8	56.9	1.3	1.6
Medicare (n = 6,293)	30.3	59.2	9.9	0.6
Top 50% of physician referrals to for-profit ASCs				
Total (n = 10,148)	20.0	5.7	73.9	0.3
Medicaid (n = 154)	38.3	0.0	61.0	0.7
Uninsured/self-pay (n = 19)	31.6	0.0	63.2	0.0
Commercial/Blue Cross (n = 6,151)	20.4	1.5	77.7	0.3
Medicare (n = 3,710)	18.8	13.1	67.7	0.3

Source: Pennsylvania Health Cost Containment Commission, Outpatient File, 2003.
[a] ASCs owned by for-profit corporations with no identified physician ownership.

physician-owned ASCs were African Americans, compared to 13 percent in hospital outpatient departments. . . .

. . . .

Discussion

Role of patients' payer status. This study analyzed more than one million discharge abstracts from hospital outpatient departments and ASCs located in the Pittsburgh and Philadelphia metropolitan areas. Our most important findings pertain to physicians who referred many patients to physician-owned ASCs. These physicians referred very few Medicaid patients at all — about 1.2 percent of their total referrals. However, when these physicians referred a Medicaid patient, that patient was referred to the physician-owned ASC about 55 percent of the time and to the outpatient department about 45 percent of the time. In contrast, this same set of physicians referred other patients — commercial/Blue Cross, Medicare, and self-pay/indigent — 90-98 percent of the time to the physician-owned facility. . . .

QUESTIONS

1. Why are the racial characteristics of the physician-owned ASC patients different?
2. Does the study suggest that Congress should prohibit physician ownership of ASCs?
3. Are patients in danger if they are referred to physician-owned facilities? If not, what is the concern?
4. Would a requirement that physicians disclose to their patients their ownership interests in the facilities to which they refer address these concerns?

3. THE MODERN ADMINISTRATIVE HEALTH CARE STATE

As this chapter has already demonstrated, health care law does not evolve solely through judge-made common law, the approach to legal study which traditionally dominates the first-year curriculum. Rather, much of the law exists in a complex and iterative process including legislative debate and enactment, administrative rulemaking and guidance, and sometimes but not always judicial or administrative adjudication.

In the following pages, you will follow the saga of the so-called "contraceptive coverage mandate" regulations. Administrative law develops over time and, as here, may involve complex interplay of the executive, legislative, and judicial branches. We will return to employer-sponsored health insurance and coverage mandates in more detail in Chapter 3. For now, the example is here to expose you to the complexity of the modern health care administrative state. While the particular legal principles discussed below are important, it is also vital to see how the larger machine operates.

The ACA was the most comprehensive reform of U.S. health insurance in a generation. Passage of the ACA triggered many regulatory processes but also political reactions. One example is the federal law that, effective 2014, required most health insurance plans to cover certain preventive health care services without any cost (no copayments or deductibles) to the insured, other than their monthly premiums. Congress did not specify which preventive services must be covered but rather delegated

to executive branch agencies the task of fleshing out the details of the new statutory requirement. One of these delegated questions involved whether to require coverage for contraception. After an expert-driven administrative rulemaking process, all forms of contraception approved by the federal Food and Drug Administration (FDA) for women were included, including birth control pills, tubal ligation (which involves a medical device), and emergency contraception.

Some churches and other religious organizations objected to the executive branch's inclusion of contraceptive coverage within the ACA's preventive care coverage requirements. The ACA expressly exempted churches and houses of worship from the requirement to cover contraceptive methods and counseling for their employees. But the rules were not as clear for religiously affiliated employers such as hospitals and universities with religious missions, including Catholic hospitals and universities. In response, federal agencies promulgated rules allowing an expanded group of "religious organizations" to refuse to cover contraceptives by submitting a form to the Department of Health and Human Services (HHS). The Preamble to that February 15, 2012, rule explains the multistep regulatory process.

Group Health Plans and Health Insurance Issuers Relating to Coverage of Preventive Services Under the Patient Protection and Affordable Care Act

T.D. 9578, 77 Fed. Reg. 8725-01 (Feb. 15, 2012)

RULES and REGULATIONS
DEPARTMENT OF THE TREASURY
DEPARTMENT OF LABOR
DEPARTMENT OF HEALTH AND HUMAN SERVICES

I. Background

. . . Section 2713 of the PHS Act, as added by the Affordable Care Act and incorporated into ERISA and the Code, requires that non-grandfathered group health plans and health insurance issuers offering group or individual health insurance coverage provide benefits for certain preventive health services without the imposition of cost sharing. These preventive health services include, with respect to women, preventive care and screening provided for in the comprehensive guidelines supported by the Health Resources and Services Administration (HRSA) that were issued on August 1, 2011 (HRSA Guidelines). As relevant here, the HRSA Guidelines require coverage, without cost sharing, for "[a]ll Food and Drug Administration [(FDA)] approved contraceptive methods, sterilization procedures, and patient education and counseling for all women with reproductive capacity," as prescribed by a provider. Except as discussed below, non-grandfathered group health plans and health insurance issuers are required to provide coverage consistent with the HRSA Guidelines, without cost sharing, in plan years (or, in the individual market, policy years) beginning on or after August 1, 2012. These guidelines were based on recommendations of the independent Institute of Medicine, which undertook a review of the evidence on women's preventive services.

The Departments of Health and Human Services, Labor, and the Treasury (the Departments) published interim final regulations implementing PHS Act section

2713 on July 19, 2010 (75 FR 41726). In the preamble to the interim final regulations, the Departments explained that HRSA was developing guidelines related to preventive care and screening for women that would be covered without cost sharing pursuant to PHS Act section 2713(a)(4), and that these guidelines were expected to be issued no later than August 1, 2011. Although comments on the anticipated guidelines were not requested in the interim final regulations, the Departments received considerable feedback regarding which preventive services for women should be covered without cost sharing. Some commenters, including some religiously-affiliated employers, recommended that these guidelines include contraceptive services among the recommended women's preventive services and that the attendant coverage requirement apply to all group health plans and health insurance issuers. Other commenters, however, recommended that group health plans sponsored by religiously-affiliated employers be allowed to exclude contraceptive services from coverage under their plans if the employers deem such services contrary to their religious tenets, noting that some group health plans sponsored by organizations with a religious objection to contraceptives currently contain such exclusions for that reason.

In response to these comments, the Departments amended the interim final regulations to provide HRSA with discretion to establish an exemption for group health plans established or maintained by certain religious employers (and any group health insurance coverage provided in connection with such plans) with respect to any requirement to cover contraceptive services that they would otherwise be required to cover without cost sharing consistent with the HRSA Guidelines. The amended interim final regulations were issued and effective on August 1, 2011. The amended interim final regulations specified that, for purposes of this exemption, a religious employer is one that: (1) Has the inculcation of religious values as its purpose; (2) primarily employs persons who share its religious tenets; (3) primarily serves persons who share its religious tenets; and (4) is a non-profit organization described in section 6033(a)(1) and section 6033 (a)(3)(A)(i) or (iii) of the Code. Section 6033(a)(3)(A)(i) and (iii) of the Code refers to churches, their integrated auxiliaries, and conventions or associations of churches, as well as to the exclusively religious activities of any religious order. In the HRSA Guidelines, HRSA exercised its discretion under the amended interim final regulations such that group health plans established and maintained by these religious employers (and any group health insurance coverage provided in connection with such plans) are not required to cover contraceptive services.

To assist in the regulatory process, the agencies commissioned a report from the Institute of Medicine (now the National Academy of Medicine), an independent, nonprofit, private association with significant influence on health care policy.

In the preamble to the amended interim final regulations, the Departments explained that it was appropriate that HRSA take into account the religious beliefs of certain religious employers where coverage of contraceptive services is concerned. The Departments noted that a religious exemption is consistent with the policies in some States that currently both require contraceptive services coverage under State law and provide for some type of religious exemption from their contraceptive services coverage requirement. Comments were requested on the amended interim final regulations, specifically with respect to the definition of religious employer, as well as alternative definitions.

II. Overview of the Public Comments on the Amended Interim Final Regulations

The Departments received over 200,000 responses to the request for comments on the amended interim final regulations. . . .

Some commenters recommended that the exemption for the group health plans of a limited group of religious organizations as formulated in the amended interim final regulations be maintained. Other commenters urged that the definition of religious employer be broadened so that more sponsors of group health plans would qualify for the exemption. Others urged that the exemption be rescinded in its entirety. The Departments summarize below the major issues raised in the comments that were received.

Public comments are an important aspect of rulemaking under the Administrative Procedure Act. The entire process is made transparent by being posted at http://www.regulations.gov. Anyone can comment on proposed regulations.

Some commenters supported the inclusion of contraceptive services in the HRSA Guidelines and urged that the religious employer exemption be rescinded in its entirety due to the importance of extending these benefits to as many women as possible. For example, one provider association commented that all group health plans and group health insurance issuers should offer the same benefits to plan participants, without a religious exemption for some plans, and that religious beliefs are more appropriately taken into account by individuals when making personal health care decisions. Others urged that the exemption be eliminated because making contraceptive services available to all women would satisfy a basic health care need and would significantly reduce long-term health care costs associated with unplanned pregnancies. . . .

Commenters opposing any exemption stated that, if the exemption were to be retained, clear notice should be provided to the affected plan participants that their group health plans do not include benefits for contraceptive services. In addition, they urged the Departments to monitor plans to ensure that the exemption is not claimed more broadly than permitted.

On the other hand, a number of comments asserted that the religious employer exemption is too narrow. These commenters included some religiously-affiliated educational institutions, health care organizations, and charities. Some of these commenters expressed concern that the exemption for religious employers will not allow them to continue their current exclusion of contraceptive services from coverage under their group health plans. Others expressed concerns about paying for such services and stated that doing so would be contrary to their religious beliefs.

Commenters also claimed that Federal laws, including the Affordable Care Act, have provided for conscience clauses and religious exemptions broader than that provided for in the amended interim final regulations. Some commenters asserted that the narrower scope of the exemption raises concerns under the First Amendment and the Religious Freedom Restoration Act.

Other commenters, however, disputed claims that the contraceptive coverage requirement infringes on rights protected by the First Amendment or the Religious Freedom Restoration Act. These commenters noted that the requirement is neutral and generally applicable. They also explained that the requirement does not substantially burden religious exercise and, in any event, serves compelling governmental interests and is the least restrictive means to achieve those interests.

Some religiously-affiliated employers warned that, if the definition of religious employer is not broadened, they could cease to offer health coverage to their employees in order to avoid having to offer coverage to which they object on religious grounds.

Commenters supporting a broadening of the definition of religious employer proposed a number of options, generally intended to expand the scope of the exemption to include religiously-affiliated educational institutions, health care organizations, and charities. In some instances, in place of the definition that was adopted in the amended interim final regulations, commenters suggested other State insurance law definitions of religious employer. In other instances, commenters referenced alternative standards, such as tying the exemption to the definition of "church plan" under section 414(e) of the Code or to status as a nonprofit organization under section 501(c)(3) of the Code.

III. Overview of the Final Regulations

In response to these comments, the Departments carefully considered whether to eliminate the religious employer exemption or to adopt an alternative definition of religious employer, including whether the exemption should be extended to a broader set of religiously-affiliated sponsors of group health plans and group health insurance coverage. For the reasons discussed below, the Departments are adopting the definition in the amended interim final regulations for purposes of these final regulations while also creating a temporary enforcement safe harbor, discussed below. During the temporary enforcement safe harbor, the Departments plan to develop and propose changes to these final regulations that would meet two goals — providing contraceptive coverage without cost-sharing to individuals who want it and accommodating non-exempted, non-profit organizations' religious objections to covering contraceptive services as also discussed below.

PHS Act section 2713 reflects a determination by Congress that coverage of recommended preventive services by non-grandfathered group health plans and health insurance issuers without cost sharing is necessary to achieve basic health care coverage for more Americans. Individuals are more likely to use preventive services if they do not have to satisfy cost sharing requirements (such as a copayment, coinsurance, or a deductible). Use of preventive services results in a healthier population and reduces health care costs by helping individuals avoid preventable conditions and receive treatment earlier. Further, Congress, by amending the Affordable Care Act during the Senate debate to ensure that recommended preventive services for women are covered adequately by non-grandfathered group health plans and group health insurance coverage, recognized that women have unique health care needs and burdens. Such needs include contraceptive services.

Because nearly *half* of all pregnancies in the United States are unintended, the findings about the need for contraception and planning for prenatal care were especially important.

As documented in a report of the Institute of Medicine, "Clinical Preventive Services for Women, Closing the Gaps," women experiencing an unintended pregnancy may not immediately be aware that they are pregnant, and thus delay prenatal care. They also may not be as motivated to discontinue behaviors that pose pregnancy-related risks (e.g., smoking, consumption of alcohol). Studies show a greater risk of preterm birth and low birth weight among unintended pregnancies compared with pregnancies that were planned. Contraceptives also have medical benefits for women who are contraindicated for pregnancy, and there are

demonstrated preventive health benefits from contraceptives relating to conditions other than pregnancy (e.g., treatment of menstrual disorders, acne, and pelvic pain).

In addition, there are significant cost savings to employers from the coverage of contraceptives. A 2000 study estimated that it would cost employers 15 to 17 percent more not to provide contraceptive coverage in employee health plans than to provide such coverage, after accounting for both the direct medical costs of pregnancy and the indirect costs such as employee absence and reduced productivity. In fact, when contraceptive coverage was added to the Federal Employees Health Benefits Program, premiums did not increase because there was no resulting health care cost increase. Further, the cost savings of covering contraceptive services have already been recognized by States and also within the health insurance industry. Twenty-eight States now have laws requiring health insurance issuers to cover contraceptives. A 2002 study found that more than 89 percent of insured plans cover contraceptives. A 2010 survey of employers revealed that 85 percent of large employers and 62 percent of small employers offered coverage of FDA-approved contraceptives. . . .

Nothing in these final regulations precludes employers or others from expressing their opposition, if any, to the use of contraceptives, requires anyone to use contraceptives, or requires health care providers to prescribe contraceptives if doing so is against their religious beliefs. These final regulations do not undermine the important protections that exist under conscience clauses and other religious exemptions in other areas of Federal law. Conscience protections will continue to be respected and strongly enforced.

This approach is consistent with the First Amendment and Religious Freedom Restoration Act. The Supreme Court has held that the First Amendment right to free exercise of religion is not violated by a law that is not specifically targeted at religiously motivated conduct and that applies equally to conduct without regard to whether it is religiously motivated — a so-called neutral law of general applicability. The contraceptive coverage requirement is generally applicable and designed to serve the compelling public health and gender equity goals described above, and is in no way specially targeted at religion or religious practices. Likewise, this approach complies with the Religious Freedom Restoration Act, which generally requires a federal law to not substantially burden religious exercise, or, if it does substantially burden religious exercise, to be the least restrictive means to further a compelling government interest. . . .

QUESTIONS

1. Why did the regulations narrowly define the scope of religious employers entitled to the exemption?
2. Does the information regarding cost savings appear to fit within the charge given to the administrative agencies?
3. How does the rule support the government's interest in requiring coverage of contraception as preventive care?

Despite federal agencies' conclusion that the final regulations balanced religious freedom and congressional intent to maximize access to core preventive health services, a group of small for-profit businesses owned by religious families challenged the rule, which culminated in the following Supreme Court case.