

Providers do not possess market power.

Providers do not influence consumers' decisions, over and above their role as hired, perfect experts or agents.

Bruce C. Vladeck and Thomas Rice, *Market Failure and the Failure of Dis-course: Facing Up to the Power of Sellers*, 28 *Health Affairs* 1305 (2009).

How well does the market for medical care and health care services measure up against Rice and Vladeck's criteria? Can you match up Enthoven's description of the nature of medical care with these criteria for functional markets? Rice and Vladeck argue that where these and other classic economic assumptions are not met, "reliance on the marketplace is likely to lead to outcomes that are not in society's best interest." So, does that mean that government regulation necessarily will lead to better outcomes? What sorts of regulation might help improve the market in health care?

3. The "system" we have for delivering health care services is hardly systematic. Instead, services are offered in fragmented and inefficient segments, as any patient who has dealt with even a relatively simple episode understands. See Davis, *supra*, Section II.B. With physicians practicing primarily in solo practices or small groups and group practices often not coordinating across specialty lines or with inpatient facilities, care delivery is extraordinarily uncoordinated and episodic. See generally *The Fragmentation of U.S. Health Care: Causes and Solutions* (Einer R. Elhauge, ed., 2010). Fragmentation causes serious deficiencies in quality through uncoordinated care and discontinuity of care that leads to misdiagnosis and duplicative testing, among other problems. Fragmented delivery also produces markets that impair effective bargaining and comparative shopping. See Thomas L. Greaney, *Competition Policy and Organizational Fragmentation in Health Care*, 71 *U. Pitt. L. Rev.* 217, 229 (2009). The absence of vertical integration (for example, integration between physician services offered in clinical offices and hospital services) frustrates the capacity of managed care, or any payer, to negotiate for cost-effective bundles of services. In hospital markets, most patients delegate choice to their physicians but do not internalize the hospitals' costs and are insensitive to costs of care that they do not bear directly. In this context, hospitals benefit more by competing for physician affiliation through various forms of nonprice competition than by economizing for the benefit of efficient contracting.

Regulation and government payment policies, which strongly influence the practices and norms in the private sector, also bear significant responsibility for market inefficiencies in health care. Most notably, the longstanding reliance on fee-for-service methods of payment has spawned an ethos of provider payment that rewards volume rather than selectivity and efficiency. Fee-for-service payment also creates a disincentive for providers to consider cost-benefit tradeoffs of particular interventions. See Uwe E. Reinhardt, *Can Efficiency in Health Care Be Left to the Market?*, 26 *J. Health Pol. Pol'y & L.* 967 (2001).

Is the fragmentation of the health care system a problem that can be fixed? How would you fix it? If you could create one regulation that would have a significant impact, what might it be? Could you instead stimulate competition among providers to improve the situation? How might that happen? Can you do anything as a consumer of services? What if you were a payer?

#### IV. WHAT IS ILLNESS?

We all have an operational definition of health and sickness. I know when I am depressed, have a broken leg, a headache or a hangover. In these circumstances I consider myself to be in ill health because I am not functioning as well as I usually do, even though I may lack a scientific medical explanation of my malaise. But am I in poor health because my arteries are gradually becoming clogged, a process that probably began when I was a teenager? Am I sick or in poor health if I am obese, or addicted to alcohol or drugs, or becoming very old and enfeebled, or struggling with my sexual identity?

We need some definition of health in order to assess the quality of care needed to promote or restore it. A malpractice suit or medical quality audit depends on an ability to distinguish a bad from a good medical care outcome. An understanding of the nature of sickness and health is required to determine what health care society should provide the poor and how much society ought to spend on health care. Should Medicaid (a federal/state health care program for the poor) or a commercial insurer, for example, cover in vitro fertilization or abortions? If the state of being old becomes a state of sickness, does it mean that sickness must be "cured" at public expense? Finally, the definition of health raises questions of autonomy, responsibility and personhood. Should health be defined by the doctor as scientist or the patient as person, or both? Is the drunkard or serial killer diseased or sinning or both or neither?

The Constitution of the World Health Organization defines health as "[a] state of complete physical, mental and social well-being and not merely the absence of disease or infirmity." When did you last feel that way? Can health ever be achieved under this definition, or is everyone always in a state of ill health? How much can physicians and hospitals contribute to health under this definition? A further provision of the WHO Constitution provides that "Governments have a responsibility for the health of their peoples which can be fulfilled only by the provision of adequate health and social measures." What are the political ramifications of these principles?

Health can be viewed in a more limited sense as the performance by each part of the body of its "natural" function. Definitions in terms of biological functioning tend to be more descriptive and less value-laden. As Englehardt writes, "The notion required for an analysis of health is not

that of a good man or a good shark, but that of a good specimen of a human being or shark." H. Tristam Engelhardt, "The Concepts of Health and Disease," in *Concepts of Health and Disease* 552 (Arthur Caplan, H. Tristam Engelhardt, and James McCartney, eds. 1981) (hereafter Concepts).

Boorse compares health to the mechanical condition of a car, which can be described as good because it conforms to the designers' specifications, even though the design is flawed. Disease is then a biological malfunction, a deviation from the biological norm of natural function. Illness can be defined as a subset of disease. Boorse writes:

An illness must be, first, a reasonably serious disease with incapacitating effects that make it undesirable. A shaving cut or mild athlete's foot cannot be called an illness, nor could one call in sick on the basis of a single dental cavity, though all these conditions are diseases. Secondly, to call a disease an illness is to view its owner as deserving special treatment and diminished moral accountability \*\*\*. Where we do not make the appropriate normative judgments or activate the social institutions, no amount of disease will lead us to use the term "ill." \*\*\*

There are, then, two senses of "health". In one sense it is a theoretical notion, the opposite of "disease." In another sense it is a practical or mixed ethical notion, the opposite of "illness."

Christopher Boorse, "On the Distinction between Disease and Illness," in Concepts, *supra* at 553.

Illness is thus a socially constructed deviance. Something more than a mere biological abnormality is needed. To be ill is to have deviant characteristics for which the sick role, as Parsons has described it, exempts one from normal social responsibilities and removes individual responsibility. See Talcott Parsons, *The Social System* (1951). Our choice of words reflects this: an alcoholic is sick; a drunkard is not.

A sick person can be assisted by treatment defined by the medical model. He becomes a patient, an object of medical attention by a doctor. The doctor has the right and the ability to label someone ill, to determine whether the lump on a patient's skin is a blister, a wart or a cancer. The doctor can thus decide whether a patient is culpable or not, disabled or malingering. Illness also enjoins the physician to action to restore the patient to health.

Illness thus has many ramifications. First, it affects the individual. It relieves responsibility. The sick person need not report for work at 8:00; the post-traumatic stress syndrome or premenstrual syndrome victim may be declared not guilty of an assault. Sickness means loss of control. The mild pain may have disproportionate effects on the individual who

sees it as the harbinger of cancer or a brain tumor. The physician can restore control by providing a rational explanation for the experience of impairment. Illness costs the patient money, in lost time and in medical expenses. And someone receives that money for trying to treat that patient's illness.

Our understanding of illness also affects society. Defining a condition as an illness to be aggressively treated, rather than as a natural condition of life to be accepted and tolerated, has significant economic effects. Medical care is an object of economic choice, a good that many perceive to be different from other goods, with greater, sometimes immeasurable value. Some people are willing to pay far more for medical care than they would for other goods, or, more typically, to procure insurance that will deliver them from ever having to face the choice of paying for health care and abandoning all else. Society may also feel a special obligation to pay for the medical expenses of those who need treatment but lack resources to pay for it.

#### KATSKEE V. BLUE CROSS/BLUE SHIELD OF NEBRASKA

Supreme Court of Nebraska, 1994.  
245 Neb. 808, 515 N.W.2d 645.

##### WHITE, JUSTICE.

This appeal arises from a summary judgment issued by the Douglas County District Court dismissing appellant Sindie Katskee's action for breach of contract. This action concerns the determination of what constitutes an illness within the meaning of a health insurance policy issued by appellee, Blue Cross/Blue Shield of Nebraska. We reverse the decision of the district court and remand the cause for further proceedings.

In January 1990, upon the recommendation of her gynecologist, Dr. Larry E. Roffman, appellant consulted with Dr. Henry T. Lynch regarding her family's history of breast and ovarian cancer, and particularly her health in relation to such a history. After examining appellant and investigating her family's medical history, Dr. Lynch diagnosed her as suffering from a genetic condition known as breast-ovarian carcinoma syndrome. Dr. Lynch then recommended that appellant have a total abdominal hysterectomy and bilateral salpingo-oophorectomy, which involves the removal of the uterus, the ovaries, and the fallopian tubes. Dr. Roffman concurred in Dr. Lynch's diagnosis and agreed that the recommended surgery was the most medically appropriate treatment available. After considering the diagnosis and recommended treatment, appellant decided to have the surgery. In preparation for the surgery, appellant filed a claim with Blue Cross/Blue Shield. Both Drs. Lynch and Roffman wrote to Blue Cross/Blue Shield and explained the diagnosis and their basis for recommending the surgery. Initially, Blue Cross/Blue Shield

sent a letter to appellant and indicated that it might pay for the surgery.

Two weeks before the surgery, Dr. Roger Mason, the chief medical officer for Blue Cross/Blue Shield, wrote to appellant and stated that Blue Cross/Blue Shield would not cover the cost of the surgery. Nonetheless, appellant had the surgery in November 1990.

Appellant filed this action for breach of contract, seeking to recover \$6,022.57 in costs associated with the surgery. Blue Cross/Blue Shield filed a motion for summary judgment. The district court granted the motion. It found that there was no genuine issue of material fact and that the policy did not cover appellant's surgery. Specifically, the court stated that (1) appellant did not suffer from cancer, and although her high-risk condition warranted the surgery, it was not covered by the policy; (2) appellant did not have a bodily illness or disease which was covered by the policy; and (3) under the terms of the policy, Blue Cross/Blue Shield deserved the right to determine what is medically necessary. Appellant filed a notice of appeal to the Nebraska Court of Appeals, and on our motion, we removed the case to the Nebraska Supreme Court.

Appellant contends that the district court erred in finding that no genuine issue of material fact existed and granting summary judgment in favor of appellee.

\* \* \*

Blue Cross/Blue Shield contends that appellant's costs are not covered by the insurance policy. The policy provides coverage for services which are medically necessary. The policy defines "medically necessary" as follows: "The services, procedures, drugs, supplies or Durable Medical Equipment provided by the Physician, Hospital or other health care provider, in the diagnosis or treatment of the Covered Person's Illness, Injury, or Pregnancy, which are: 1. Appropriate for the symptoms and diagnosis of the patient's Illness, Injury or Pregnancy; and 2. Provided in the most appropriate setting and at the most appropriate level of services[.] and 3. Consistent with the standards of good medical practice in the medical community of the State of Nebraska; and 4. Not provided primarily for the convenience of any of the following: a. the Covered Person; b. the Physician; c. the Covered Person's family; d. any other person or health care provider; and 5. Not considered to be unnecessarily repetitive when performed in combination with other diagnoses or treatment procedures. We shall determine whether services provided are Medically Necessary. Services will not automatically be considered Medically Necessary because they have been ordered or provided by a Physician. (Emphasis supplied.) Blue Cross/Blue Shield denied coverage because it concluded that appellant's condition does not constitute an illness, and thus the treatment she received was not medically necessary. Blue Cross/Blue Shield has not raised any other basis for its denial, and we therefore will limit

our consideration to whether appellant's condition constituted an illness within the meaning of the policy.

The policy broadly defines "Illness" as a "bodily disorder or disease." The policy does not provide definitions for either bodily disorder or disease.

An insurance policy is to be construed as any other contract to give effect to the parties' intentions at the time the contract was made. When the terms of the contract are clear, a court may not resort to rules of construction, and the terms are to be accorded their plain and ordinary meaning as the ordinary or reasonable person would understand them. In such a case, a court shall seek to ascertain the intention of the parties from the plain language of the policy. [1]

Whether a policy is ambiguous is a matter of law for the court to determine. If a court finds that the policy is ambiguous, then the court may employ rules of construction and look beyond the language of the policy to ascertain the intention of the parties. A general principle of construction, which we have applied to ambiguous insurance policies, holds that an ambiguous policy will be construed in favor of the insured. However, we will not read an ambiguity into policy language which is plain and unambiguous in order to construe it against the insurer. [1]

When interpreting the plain meaning of the terms of an insurance policy, we have stated that the "natural and obvious meaning of the provisions in a policy is to be adopted in preference to a fanciful, curious, or hidden meaning." [2] We have further stated that "[w]hile for the purpose of judicial decision dictionary definitions often are not controlling, they are at least persuasive that meanings which they do not embrace are not common." [1]

Applying these principles, our interpretation of the language of the terms employed in the policy is guided by definitions found in dictionaries, and additionally by judicial opinions rendered by other courts which have considered the meaning of these terms. Webster's Third New International Dictionary, Unabridged 648 (1981), defines disease as an impairment of the normal state of the living animal or plant body or of any of its components that interrupts or modifies the performance of the vital functions, being a response to environmental factors . . . to specific infective agents . . . to inherent defects of the organism (as various genetic anomalies), or to combinations of these factors. Sickness, Illness. The same dictionary defines disorder as "a derangement of function: an abnormal physical or mental condition: Sickness, Ailment, Malady." [1]

These lay definitions are consistent with the general definitions provided in Dorland's Illustrated Medical Dictionary (27th ed. 1988). Dorland's defines disease as any deviation from or interruption of the normal structure or function of any part, organ, or system . . . of the body that is

manifested by a characteristic set of symptoms and signs and whose etiology [theory of origin or cause], pathology [origin or cause], and prognosis may be known or unknown. [ ] Dorland's defines disorder as "a derangement or abnormality of function; a morbid physical or mental state." [ ]

\* \* \*

[The court looked at similar definitional disputes in other jurisdictions, noting that hemophilia, aneurysms, and chronic alcoholism had been held to be diseases or illnesses under insurance policies.]

We find that the language used in the policy at issue in the present case is not reasonably susceptible of differing interpretations and thus not ambiguous. The plain and ordinary meaning of the terms "bodily disorder" and "disease," as they are used in the policy to define illness, encompasses any abnormal condition of the body or its components of such a degree that in its natural progression would be expected to be problematic; a deviation from the healthy or normal state affecting the functions or tissues of the body; an inherent defect of the body; or a morbid physical or mental state which deviates from or interrupts the normal structure or function of any part, organ, or system of the body and which is manifested by a characteristic set of symptoms and signs.

The issue then becomes whether appellant's condition—breast-ovarian carcinoma syndrome—constitutes an illness.

Blue Cross/Blue Shield argues that appellant did not suffer from an illness because she did not have cancer. Blue Cross/Blue Shield characterizes appellant's condition only as a "predisposition to an illness (cancer)" and fails to address whether the condition itself constitutes an illness. This failure is traceable to Dr. Mason's denial of appellant's claim. Despite acknowledging his inexperience and lack of knowledge about this specialized area of cancer research, Dr. Mason denied appellant's claim without consulting any medical literature or research regarding breast-ovarian carcinoma syndrome. Moreover, Dr. Mason made the decision without submitting appellant's claim for consideration to a claim review committee. The only basis for the denial was the claim filed by appellant, the letters sent by Drs. Lynch and Roffman, and the insurance policy. Despite his lack of information regarding the nature and severity of appellant's condition, Dr. Mason felt qualified to decide that appellant did not suffer from an illness.

Appellant's condition was diagnosed as breast-ovarian carcinoma syndrome. To adequately determine whether the syndrome constitutes an illness, we must first understand the nature of the syndrome.

The record on summary judgment includes the depositions of Drs. Lynch, Roffman, and Mason. In his deposition, Dr. Lynch provided a thorough discussion of this syndrome. In light of Dr. Lynch's extensive research and clinical experience in this particular area of medicine, we

consider his discussion extremely helpful in our understanding of the syndrome.

According to Dr. Lynch, some forms of cancer occur on a hereditary basis. Breast and ovarian cancer are such forms of cancer which may occur on a hereditary basis. It is our understanding that the hereditary occurrence of this form of cancer is related to the genetic makeup of the woman. In this regard, the genetic deviation has conferred changes which are manifest in the individual's body and at some time become capable of being diagnosed.

At the time that he gave his deposition, Dr. Lynch explained that the state of medical research was such that detecting and diagnosing the syndrome was achieved by tracing the occurrences of hereditary cancer throughout the patient's family. Dr. Lynch stated that at the time of appellant's diagnosis, no conclusive physical test existed which would demonstrate the presence of the condition. However, Dr. Lynch stated that this area of research is progressing toward the development of a more determinative method of identifying and tracing a particular gene throughout a particular family, thus providing a physical method of diagnosing the condition.

Women diagnosed with the syndrome have at least a 50-percent chance of developing breast and/or ovarian cancer, whereas unaffected women have only a 1.4-percent risk of developing breast or ovarian cancer. In addition to the genetic deviation, the family history, and the significant risks associated with this condition, the diagnosis also may encompass symptoms of anxiety and stress, which some women experience because of their knowledge of the substantial likelihood of developing cancer.

The procedures for detecting the onset of ovarian cancer are ineffective. Generally, by the time ovarian cancer is capable of being detected, it has already developed to a very advanced stage, making treatment relatively unsuccessful. Drs. Lynch and Roffman agreed that the standard of care for treating women with breast carcinoma syndrome ordinarily involves surveillance methods. However, for women at an inordinately high risk for ovarian cancer, such as appellant, the standard of care may require radical surgery which involves the removal of the uterus, ovaries, and fallopian tubes.

Dr. Lynch explained that the surgery is labeled "prophylactic" and that the surgery is prophylactic as to the prevention of the onset of cancer. Dr. Lynch also stated that appellant's condition itself is the result of a genetic deviation from the normal, healthy state and that the recommended surgery treats that condition by eliminating or significantly reducing the presence of the condition and its likely development.

Blue Cross/Blue Shield has not proffered any evidence disputing the premise that the origin of this condition is in the genetic makeup of the individual and that in its natural development it is likely to produce devastating results. Although handicapped by his limited knowledge of the syndrome, Dr. Mason did not dispute the nature of the syndrome as explained by Dr. Lynch and supported by Dr. Roffman, nor did Dr. Mason dispute the fact that the surgery falls within the standard of care for many women afflicted with this syndrome.

In light of the plain and ordinary meaning of the terms "illness," "bodily disorder," and "disease," we find that appellant's condition constitutes an illness within the meaning of the policy. Appellant's condition is a deviation from what is considered a normal, healthy physical state or structure. The abnormality or deviation from a normal state arises, in part, from the genetic makeup of the woman. The existence of this unhealthy state results in the woman's being at substantial risk of developing cancer. The recommended surgery is intended to correct that morbid state by reducing or eliminating that risk.

Although appellant's condition was not detectable by physical evidence or a physical examination, it does not necessarily follow that appellant does not suffer from an illness. The record establishes that a woman who suffers from breast-ovarian carcinoma syndrome does have a physical state which significantly deviates from the physical state of a normal, healthy woman. Specifically, appellant suffered from a different or abnormal genetic constitution which, when combined with a particular family history of hereditary cancer, significantly increases the risk of a devastating outcome.

We are mindful that not every condition which itself constitutes a predisposition to another illness is necessarily an illness within the meaning of an insurance policy. There exists a fine distinction between such conditions \* \* \*.

\* \* \*

The issue raised in Fuglsang [ ] was whether the disease from which the plaintiff suffered constituted a preexisting condition which was excluded from coverage by the terms of the policy. Blue Cross/Blue Shield relied on the following rule from Fuglsang as a definition of "disease": A disease, condition, or illness exists within the meaning of a health insurance policy excluding preexisting conditions only at such time as the disease, condition, or illness is manifest or active or when there is a distinct symptom or condition from which one learned in medicine can with reasonable accuracy diagnose the disease. [ ]

This statement concerns when an illness exists, not whether the condition itself is an illness. If the condition is not a disease or illness, it would be unnecessary to apply the above rule to determine whether the

condition was a preexisting illness. In the present case, Blue Cross/Blue Shield maintains that the condition is not even an illness.

Even assuming arguendo that the rule announced in Fuglsang is a definition of "disease," "Illness," and "condition," the inherent problems with the argument put forth by Blue Cross/Blue Shield undermine its reliance on that rule. Blue Cross/Blue Shield emphasizes the fact that appellant was never diagnosed with cancer and therefore, according to Blue Cross/Blue Shield, appellant did not have an illness because cancer was not active or manifest. Appellant concedes that she did not have cancer prior to her surgery. The issue is whether the condition she did have was an illness. Blue Cross/Blue Shield further argues that "[n]o disease or illness is 'manifest or active' and there is no 'distinct symptom or condition' from which Dr. Lynch or Dr. Roffman could diagnose a disease." We stated above that lack of a physical test to detect the presence of an illness does not necessarily indicate that the person does not have an illness.

When the condition at issue—breast-ovarian carcinoma syndrome—is inserted into the formula provided by the Fuglsang rule, the condition would constitute an "illness" as Blue Cross/Blue Shield defines the term. The formula is whether the breast-ovarian carcinoma syndrome was manifest or active, or whether there was a distinct symptom or condition from which one learned in medicine could with reasonable accuracy diagnose the disease. The record establishes that the syndrome was manifest, at least in part, from the genetic deviation, and evident from the family medical history. The condition was such that one learned in medicine, Dr. Lynch, could with a reasonable degree of accuracy diagnose it. Blue Cross/Blue Shield does not dispute the nature of the syndrome, the method of diagnosis, or the accuracy of the diagnosis.

In the present case, the medical evidence regarding the nature of breast-ovarian carcinoma syndrome persuades us that appellant suffered from a bodily disorder or disease and, thus, suffered from an illness as defined by the insurance policy. Blue Cross/Blue Shield, therefore, is not entitled to judgment as a matter of law. Moreover, we find that appellant's condition did constitute an illness within the meaning of the policy. We reverse the decision of the district court and remand the cause for further proceedings. [ ]

#### NOTES AND QUESTIONS

1. Why did the court hold that Katskee was ill when she had no symptoms and no cancer? Can we have a variable definition of illness? For example, could Katskee be ill for purposes of payment for the surgery but not ill for purposes of pre-existing condition exclusions or excusal from work? What about treatment for high blood pressure or arteriosclerosis? The medications to prevent heart attacks are expensive, and are typically covered by health

insurance plans. For discussion of genetic conditions and notions of illness and health, see Chapter 16.

**Why would Blue Cross resist covering this treatment for this problem?**

2. The syndrome in *Katskee*, if it materializes, is a medical problem for which the patient bears no responsibility. A more difficult problem area in defining "disease" involves those conditions or syndromes within some control by the individual. Consider for example alcoholism as a "disease". What difference does such a label make? What characteristics of alcohol consumption justify the label "disease"? See H. Thomas Milhorn, *The Diagnosis of Alcoholism*, ARP 175 (June 1988) ("... alcoholism can be defined as the continuation of drinking when it would be in the patient's best interest to stop.") See *Taylor v. Turnage*, 485 U.S. 535, 108 S.Ct. 1372, 99 L.Ed.2d 618 (1988) (considering alcoholism as attributable to "willful misconduct" under Veterans' Administration rules). See also Herbert Fingarette, *Heavy Drinking: The Myth of Alcoholism as a Disease* (1988); contra, see George Vaillant, *The Natural History of Alcoholism* (1983).

3. What other emerging clinical "syndromes" or diseases can you think of that raise troubling problems for the medical model of disease? How about anorexia? Obesity? Battered wife syndrome? Restless leg syndrome? Parental alienation syndrome? What forces have led to the proliferation of these new syndromes or diseases? See discussion of genetic traits as illness in Chapter 16.

4. Disputes over insurance coverage of treatments are the most common legal battleground over the meanings of "disease" and "treatment". Other legal contexts however also give rise to definitional battles, such as the Internal Revenue Code and taxpayer claims that their medical expenses should be allowable deductions. In *O'Donnabhain v. Commissioner of Internal Revenue*, 134 T.C. 34 (2010), the IRS determined a deficiency in petitioner's Federal income tax. The issue was whether the petitioner could deduct as a medical care expense amounts paid in 2001 for hormone therapy, sex reassignment surgery, and breast augmentation surgery that she contended she incurred to treat her gender identity disorder, totaling over \$60,000. None of petitioner's expenses were covered by insurance or other sources of reimbursement. Rhiannon G. O'Donnabhain (petitioner) was born a genetic male with unambiguous male genitalia. She was, however, uncomfortable as a male from childhood and she first wore women's clothing secretly around age 10. Her gender discomfort increased as a teenager, and she continued to dress in women's clothing secretly. After completing university and military service, she married, but the marriage ended finally after more than 20 years. After separating from her spouse in 1992, petitioner's feelings that she wanted to be female intensified and grew more persistent. Her discomfort with her male gender and her strong desire to be female intensified, and she sought a psychotherapist to address them. She found a therapist who specialized in gender identity disorder (GID), and had twenty individual therapy sessions with the therapist, who then concluded that petitioner needed

treatment. The court recounted the therapist's diagnostic description of the petitioner as follows:

Petitioner was a transsexual suffering from severe gender identity disorder (GID), a condition listed in the Diagnostic and Statistical Manual of Mental Disorders (4th ed. 2000 text revision) (DSM-IV-TR), published by the American Psychiatric Association. The DSM-IV-TR states that a diagnosis of GID is indicated where an individual exhibits (1) a strong and persistent desire to be, or belief that he or she is, the other sex; (2) persistent discomfort with his or her anatomical sex, including a preoccupation with getting rid of primary or secondary sex characteristics; (3) an absence of any physical intersex (hermaphroditic) condition; and (4) clinically significant distress or impairment in social, occupational, or other important areas of functioning as a result of the discomfort arising from the perceived incongruence between anatomical sex and perceived gender identity.

The standard of care, described by the Tax Court,

[consisted] of (1) hormonal sex reassignment; i.e., the administration of cross-gender hormones to effect changes in physical appearance to more closely resemble the opposite sex; (2) the "real-life" experience (wherein the individual undertakes a trial period of living full time in society as a member of the opposite sex); and (3) sex reassignment surgery, consisting of genital sex reassignment and/or nongenital sex reassignment. \*\*\*. These standards also required the recommendation of a licensed psychotherapist for these treatments, with evidence of transsexualism for a period of at least 2 years.

Petitioner underwent hormone therapy, and followed these treatments with "real-life" experience, presenting in public as a female on a full-time basis, including at work. While this made petitioner feel better, her anxiety as a result of having male genitalia persisted. The therapist concluded that sex reassignment therapy was therapeutically desirable, given petitioner's anxiety, and helped petitioner arrange the surgery. Petitioner then underwent sex reassignment surgery in 2001. Her surgeon performed procedures that included surgical removal of the penis and testicles and creation of a vaginal space using genital skin and tissue, designed to create female genitalia both in appearance and in function, capable of sexual arousal and intercourse. He also performed breast augmentation surgery and subsequent surgery on petitioner's face to "feminize her facial features".

The court noted that

\*\*\* since the inception of the medical expense deduction, the definition of deductible "medical care" has had two prongs. The first prong covers amounts paid for the "diagnosis, cure, mitigation, treatment, or prevention of disease" and the second prong covers amounts paid "for the purpose of affecting any structure or function of the body."

The court undertook a careful analysis of the meaning of "disease," and concluded:

"\*\*\*GID is a "disease" within the meaning of section 213 [of the Internal Revenue Code]. \*\*\* In view of (1) GID's widely recognized status in diagnostic and psychiatric reference texts as a legitimate diagnosis, (2) the seriousness of the condition as described in learned treatises in evidence and as acknowledged by all three experts in this case; (3) the severity of petitioner's impairment as found by the mental health professionals who examined her; (4) the consensus in the U.S. Courts of Appeal that GID constitutes a serious medical need for purposes [prison medical care], we conclude and hold that GID is a "disease" for purposes of section 213.

After a dictionary-based definitional analysis of "treat", the court found in favor of the petitioner. The therapy and surgery were accepted treatments of GID; they have positive results according to psychiatric experts, so they alleviate suffering within the definitions of treatment. The court continued: "We therefore conclude and hold that petitioner's hormone therapy and sex reassignment surgery "[treated] \*\*\* disease" within the meaning of section 213(d)(9)(B) and accordingly are not "cosmetic surgery" as defined in that section." The court finally held that the surgery was medically necessary. The court rejected petitioner's deduction for breast augmentation surgery, since she failed to show that her surgery treated GID, finding it was "cosmetic surgery" and not deductible.

How does the Tax Court determine that O'Donnabhain's condition is a "disease"? Is GID treatment distinguishable from psychiatric treatments for depression or schizophrenia? The use of hormones, which have side effects, is certainly similar to the use of drugs in psychotherapy, which sometimes work moderately well but with side effects. The surgical removal of healthy body parts on the other hand does not resemble other medical therapies for treating diseases, does it? Would the *Katskee* court's definition of disease apply to this case?

Critics of GID therapy contend that it is an example of a personal problem that has been medicalized. What do they mean by that? Can you think of any good examples of a medicalized problem? See *Lauren Herman, A Non-Medicalized Medical Deduction?* *O'Donnabhain v. Commissioner & the I.R.S.'s Understanding of Transgender Medical Care*, 35 Harv. J. L. & Gender 487 (2012) (noting that a diagnosis of GID is required before a deduction is possible, which has the effect of medicalizing a person's personal choice).

#### **PROBLEM: THE COUPLE'S ILLNESS**

You represent Thomas and Jill Henderson, a couple embroiled in a dispute with their health insurance plan over coverage of infertility treatments. The Hendersons have been having trouble getting pregnant. Thomas has a low sperm count and motility, while Jill has irregular ovulation. They have undergone infertility treatment successfully in the past and have one child.

They again sought further treatment, in order to have a second child. A simple insemination procedure failed. The health and disability group benefit plan of Thomas's employer, Clarion, paid their health benefits for this procedure.

They were then advised to try a more complex and expensive procedure, called Protocol I, which involved treating Thomas' sperm to improve its motility. Drug therapy was prescribed for Jill to induce ovulation. Semen was then taken from Thomas, and put through an albumin gradient to improve its motility. The semen was then reduced to a small pellet size and injected directly into the uterine cavity at the time of ovulation.

The Hendersons underwent Protocol I and submitted a bill to Clarion, which refused to pay it. Clarion cited a provision in its plan, Article VI, section 6.7, which provided:

If a covered individual incurs outpatient expenses relating to injury or illness, those expenses charged, including but not limited to, office calls and for diagnostic services such as laboratory, x-ray, electrocardiography, therapy or injections, are covered expenses under the provisions of [the plan].

Under section 2.24 of the plan, "illness" was defined as "any sickness occurring to a covered individual which does not arise out of or in the course of employment for wage or profit." Clarion denied the Hendersons' claim on the grounds that the medical services were not performed because of any illness of Jill or Thomas, as required under section 6.7. No provisions in the plan specifically excluded fertilization treatments like Protocol I.

What arguments can you make on behalf of the Hendersons that their situation is an "illness"? What arguments can you make for the insurance company that it is not?

#### **V. FROM DEFINING QUALITY TO REGULATING PATIENT SAFETY**

Lawyers are involved with quality of health care issues through a variety of routes. They file, or defend against, malpractice suits when a patient is injured during the course of medical treatment. They handle medical staff privileges cases that frequently turn on the quality of the staff doctor's performance. They represent the government in administering programs that aim to cut the cost of health care and improve its quality as well as providers who must adjust to these programs. They contest insurer refusals to pay claims, or represent insurers who don't want to pay for poor quality or unproven treatments.

##### **A. THE NATURE OF QUALITY IN MEDICINE**

The Institute of Medicine has developed a definition that is a useful starting point:

\* \* \* quality of care is the degree to which health services for individuals and populations increase the likelihood of desired health outcomes and are consistent with current professional knowledge. Institute of Medicine, Medicare: A Strategy for Quality Assurance, Vol. I, 20 (K. Lohr, Ed.1990).

Unnecessary care that causes harm is poor in quality, since unnecessary harm is not counterbalanced by any expectation of benefit. How about care that is unnecessary yet harmless, like over-the-counter medicines that contain no therapeutic ingredients? Or medical interventions that have no proven value? Such care also fails a quality test, because it yields no benefits, wastes resources, and indicates poor judgment or ignorance on the part of the practitioner. See *Riser v. American Medical International, Inc.*, 620 So.2d 372 (La.App. 5th Cir., 1993), where the doctor performed a femoral arteriogram on the patient, who suffered a stroke and died. The court found that the physician had breached the standard of care by subjecting the patient to a technology that he should reasonably have known would be of "no practical benefit to the patient".

Much of American medical practice does not improve health. In controlled trials, many cherished practices have been found unhelpful and even harmful. Treatments effective for one indication are frequently extended to other indications where effectiveness data do not exist. See, e.g., William B. Borden et al., Patterns and Intensity of Medical Therapy in Patients Undergoing Percutaneous Coronary Intervention, 305 JAMA 1882, 1886 (2011).

Higher quality care may cost more, raising the question of cost-effectiveness. Or it might be obtained for less money, cutting out inefficiencies. Or quality care may be less expensive. See Charles Andel, et al., The Economics of Health Care Quality and Medical Errors, 39 J. Health Care Finance 39, 48 (2012), contending that quality care "is better, more efficient, and by definition, less wasteful. It is the right care, at the right time, every time. It should mean that far fewer patients are harmed or injured." See also Peter S. Hussey, et al., The Association Between Health Care Quality and Cost: A Systematic Review, 158 Ann. Int. Med. 27 (2013) (concluding that "the association between cost and quality is small to moderate, regardless of whether the direction is positive or negative. Future studies should focus on what types of spending are most effective in improving quality and what types of spending represent waste.")

Should patient engagement in her care be part of an expanded definition of quality medical care? This shared decision making model of the doctor-patient relationship certainly maximizes patient autonomy. See Chapter 4 for a discussion of major developments in "shared decision making" models of informed patient consent and Chapter 18 for patient decision making in end-of-life care.

How do cost considerations fit into this individualized definition of quality? If the patient has no insurance and probably cannot pay for an expensive surgical procedure, or if the patient decides to forego a treatment after making his or her own cost tradeoffs, how should the doctor respond? Must the doctor be satisfied with giving the patient less medical care than would be possible and would in fact help the patient?

Even in a society with comprehensive social benefits, such as a national health insurance program, costs must be considered by the practitioner, who is still constrained by the resources available for health care. The doctor as citizen must choose whether to help the patient as much as possible, with the taxpayers absorbing the costs; or to stop short of giving the individual the maximum help. See the *Wickline* and *Murray* cases in Chapter 5 for a discussion of these tensions.

The distribution of benefits within a population is another important dimension of quality. Patients' insurance status significantly affects the procedures they receive to treat various medical problems. Lack of insurance can reduce the length of one's life: mortality studies suggest a reduction in the uninsured's mortality as high as 20% to 25%. The uninsured receive fewer preventive and diagnostic services, tend to be more severely ill when diagnosed, and receive less therapeutic care. Other literature suggests that improving health status from fair or poor to very good or excellent would increase both work effort and annual earnings by approximately 15% to 20%. Jack Hadley, Sicker and Poorer—The Consequences of Being Uninsured: A Review of the Research on the Relationship between Health Insurance, Medical Care Use, Health, Work, and Income, 60 The Urban Institute Medical Care Research and Review, 2 suppl, 3S-75S (2003). See discussion in Chapter 8.

### 1. Medical Practice Variation

The phenomenon of medical practice variation highlights the role of uncertainty in the setting of medical standards. John Wennberg, whose studies in this area are often cited, has analyzed states and regions within states for variation in surgical and other practices:

[I]n Maine by the time women reach seventy years of age in one hospital market the likelihood they have undergone a hysterectomy is 20 percent while in another market it is 70 percent. In Iowa, the chances that male residents who reach age eighty-five have undergone prostatectomy range from a low of 15 percent to a high of more than 60 percent in different hospital markets. In Vermont the probability that resident children will undergo a tonsillectomy has ranged from a low of 8 percent in one hospital market to a high of nearly 70 percent in another.

John E. Wennberg, Dealing with Medical Practice Variations: A Proposal for Action, 3 Health Affairs 6, 9 (1984).

Wennberg is one of the creators of the *Dartmouth Atlas*, which uses Medicare data to track medical practice variation over the country, by procedure. Physician variation in treatment approaches is greatest with aging-related conditions, where the outcomes of conservative treatment are unknown. Procedures least subject to variation are those for which there is a professional consensus on the preferred place or style of treatment. Wennberg gives the example of patient time in intensive care units in the last six months of life in selected teaching hospitals. The number of days ranged from 11.4 at UCLA Medical Center to as low as 2.8 at Massachusetts General Hospital.

Wennberg's studies of medical practice variation are based on studies of three categories of care: effective care, preference-sensitive care, and supply-sensitive care.

(1) "Effective Care": interventions that are viewed as medically necessary on the basis of clinical outcomes evidence and for which the benefits so outweigh the risks that virtually all patients with medical need should receive them.

(2) "Preference-sensitive Care": treatments, such as discretionary surgery, for which there are two or more valid treatment alternatives, and the choice of treatment involves tradeoffs that should be based on patients' preferences. Variation in such care is typified by elective surgeries, such as hip fracture, knee replacement, or back surgery. Surgeons in adjoining counties in Florida, for example, may operate at very different levels for the same condition and patient.

(3) "Supply-sensitive Care": services such as physician visits, referrals to specialists, hospitalizations, and stays in intensive care units involved in the medical (non-surgical) management of disease. In Medicare, the large majority of these services are for patients with chronic illness.

Wennberg concluded that "system" causes of unwarranted variation include misuse of preference-sensitive care; poor communication between the doctor and patient regarding the risks and benefits of alternative treatments; patient dependency on a physician's opinion in sorting out preferences; inadequate evaluation of (evolving) treatment theory; and the effects of our health care finance system that rewards procedures, not time spent with patients or the quality of decision making.

See generally John E. Wennberg, Variation in Use of Medicare Services Among Regions and Selected Academic Medical Centers: Is More Better?, Commonwealth Fund Pub. No. 874, at 4 (Dec. 2005) (noting "striking regional variations in the proportion of early stage breast cancer patients who undergo lumpectomy" and identifying "idiosyncratic practice style" as the "major source of such widely varying discretionary surgery

"rates"). For a graphic depiction of the variation, see John E. Wennberg, Understanding Practice Patterns: A Focus on What the Quality Movement Can Do to Reduce Unwarranted Variations. The Institute for Healthcare Improvement), Orlando, FL. (2005). See also John E. Wennberg, et al., Evaluating The Efficiency Of California Providers In Caring For Patients With Chronic Illnesses, *Health Affairs* (November 16, 2005) Web Exclusive 10.1377. See also Lars Noah, Medicine's Epistemology: Mapping the Haphazard Diffusion of Knowledge in the Biomedical Community, 44 Ariz. L. Rev. 373, 382 (2002) (recognizing physicians' traditional reliance on personal experience and anecdotal information).

The attitudes of individual doctors influence the range of variation where consensus is lacking. Wennberg has termed this the "practice style factor." This style can exert its influence in the absence of scientific information on outcomes; in other cases it may be unrelated to controversies. Physicians in some hospital markets practice medicine in ways that have extremely adverse implications for the cost of care, motivated perhaps by reasons of their own or their patients' convenience, or because of individualist interpretations of the requirements for defensive medicine. See John E. Wennberg, The Paradox of Appropriate Care, 258 J.A.M.A. 2568 (1987). See generally John Eisenberg, Doctors' Decisions and the Cost of Medical Care (1986).

Some critics have contended that medical practice variation is overstated by Wennberg. Economic disparities in regional populations, not physician practice patterns, may drive health care utilization and therefore health care spending. Poorer people are demonstrably sicker and cost more to treat than do more economically stable people by a large margin. Therefore, the key to lowering health care costs is to reduce poverty and increase wealth. See e.g. Louise Sheiner, Why the Geographic Variation in Health Care Spending Can't Tell Us Much about the Efficiency or Quality of our Health Care System, Federal Reserve Board of Governors, December 20, 2012 ("This paper examines the geographic variation in Medicare and non-Medicare health spending and finds little support for the view that most of the variation is attributable to differences in practice styles. Instead, I find that socioeconomic factors that affect the need for medical care, as well as interactions between the Medicare system, Medicaid, and private health spending, can account for most of the variation in Medicare health spending.") For responses to these criticisms, see Reflections on Variation, Dartmouth Atlas of Health Care.

Several approaches to quality improvement can be pursued. We can rely on the traditional forces of professional ethics and socialization. We can expand the role of the marketplace, using dissemination of quality information to consumers and buyers of health, on the theory that prudent buyers will reject lower quality providers. See discussion of regulation and competition in Section III, above. We can improve the current

modes of self-regulation of the medical profession and the industry, which include accreditation, medical staff privileges, and medical licensing actions. The process by which a patient sues for malpractice can be improved. And the government, as a primary source of financing for much health care in the United States, can intervene, setting standards and demanding better processes and outcomes. We will examine each of these methods of quality improvement in later sections and chapters.

## 2. Quality and the Patient Protection and Affordable Care Act of 2010

The ACA has an astonishing variety of provisions aimed at improving the quality of the U.S. health care system, reducing errors, and generally promoting patient safety. These provisions include new centers, demonstration projects, and funding awards for a wide range of quality improvement projects.

The ACA has a variety of quality definitions and measurements. Quality is defined in Section 3013 of the ACA as "a standard for measuring the performance and improvement of population health or of health plans, providers of services, and other clinicians in the delivery of health care services."

Section 3013 contains a range of useful benchmarks for defining quality. Good quality care is care that improves patient health outcomes and their functional status. It provides management and coordination of care across episodes of care and care transitions across providers, settings, and plans. It makes patients part of the decision making process through a variety of tools. It uses health information technology effectively. The care provided must be safe, effective, patient-centered, patient satisfying, appropriate, timely, efficient, and innovative. The ACA also has a strong focus on population health, and one of its quality tests is whether care given promotes "the equity of health services and health disparities across health disparity populations [ ] and geographic areas." ACA, section 3013, subsections A through J. See discussion of population health in Section VI, below.

Other programs such as payment bundling, section 3023, use more specific tests for quality improvement or shortcomings; patient functional status improvement; reduction in the rates of avoidable hospital readmissions; rates of discharge to the community; rates of admission to an emergency room after a hospitalization; incidence of health care acquired infections; efficiency measures; measures of patient-centeredness of care; and patient perception of care.

Quality improvement is central to the ACA. Section 3501 mandates the Director of the Center for Quality Improvement Programs to "identify, develop, evaluate, disseminate, and provide training in innovative methodologies and strategies for quality improvement practices in the

delivery of health care services that represent best practices in health care quality, safety, and value" in collaboration with other Federal agencies.

The Center for Quality Improvement and Patient Safety of the Agency for Healthcare Research and Quality sets quality priorities. These include improving health outcomes, efficiency, and patient-centeredness of health care for all populations; identifying areas that can be rapidly improved; addressing gaps in information about outcomes; improving Federal payment policy to improve quality and efficiency; addressing patients with high-cost chronic diseases; improving research and dissemination of strategies and best practices to improve patient safety and reduce medical errors; preventable admissions and readmissions, and health care infections; and reducing health disparities.

The Center's research goals include, among others, reducing preventable morbidity, mortality, and associated costs of morbidity and mortality by building capacity for patient safety research; supporting the discovery of processes for the reliable, safe, efficient, and responsive delivery of health care; taking into account discoveries from clinical research and comparative effectiveness research; allowing communication of research findings and translating evidence into practice recommendations that are adaptable to a variety of settings; analyzing reports from patient safety reporting systems and patient safety organizations, and developing responses; reviewing existing practices and how to improve them; and examining how to measure and evaluate the progress of quality and patient safety activities.

Excess readmissions are presumed to indicate lower quality care by hospitals. The ACA creates the Hospital Readmission Reduction Program. Section 3025 ties excess readmissions (however defined) to a reduction in Medicare payments that would otherwise be made to that hospital. Information on all patient readmission rates shall be made available on the CMS Hospital Compare website in a form and manner determined appropriate by the Secretary. The Secretary may also make other information determined appropriate available on such website. See Chapter 10 for a fuller discussion of value-based purchasing and Medicare readmission policies.

The ACA directs the Secretary of HHS to develop provider-level outcome measures for hospitals and physicians, as well as other providers. Section 1033. Such measures will include at least ten outcome measurements for acute and chronic diseases, including the five most prevalent and resource-intensive conditions, within two years; and for primary and preventative care, ten measurements for distinct populations, within three years.

Section 3021 establishes a new Center for Medicare and Medicaid Innovation (CMI) within the Centers for Medicare & Medicaid Services (CMS). The purpose of the Center will be to research, develop, test, and expand innovative payment and delivery arrangements to improve the quality and reduce the cost of care provided to patients in each program. Dedicated funding is provided to allow for testing of models that require benefits not currently covered by Medicare. The expectation is that successful models would then be expanded nationally.

The goals of the models to be researched and tested include promoting payment and practice reform, including patient-centered medical homes and models that move toward comprehensive payment or salary payment; direct contracting with groups of providers, through risk-based or salary-based payments; care coordination; patient decision making support tools; hospital care using specialists linked by electronic monitoring at integrated systems; and payments to Healthcare Innovation Zones. The Medicare Shared Savings Program (Section 3022) creates Accountable Care Organizations (ACOs). ACOs are discussed in Chapter 10.

#### NOTES AND QUESTIONS

1. The ACA presents a confusing, sometimes overlapping and inconsistent, approach to patient quality and improvements to patient safety. It is a grab bag of existing health policy ideas about what quality means, how to measure it, reduce uncertainty, and then maximize health care quality. What are the strategies that the ACA employs to generate new outcomes data and best practices information, from a regulatory perspective? Consider the range of regulatory tools that you can find in the various provisions that will serve the ends of quality as you read through the casebook. Who is likely to seek the grants that the federal government makes available in these provisions? Is this morass of provisions really just a disguise for what will ultimately be a top-down national health system? Or is it a design that promotes maximum flexibility and the ability of a system to evolve through consensus and buy-in by all parties?
2. Many of the payment strategies are just a more aggressive expansion of Medicare payment reforms now in place. Will providers respond positively to these incentive-based devices to promote quality and standardization? What kinds of strategies might you expect from providers, as they push back against both the pressures toward standardization, and the intensified linkage of payment to performance?
3. Tools are already available to improve clinical performance. One obvious example is checklists. See generally Atul Gawande, *Annals of Medicine: The Checklist, The New Yorker* (December 10, 2007). Gawande writes about the tension between the model of expert audacity (the doctor as medical hero) and the model of regimentation, drawn from management of complex systems. He notes that in the ICU you have a very sick patient who requires that hundreds of things are done right, every day, to keep him alive. He ar-

gues that checklists have tremendous advantages in the complex world of the ICU. First, they help with memory recall. Second, they make clear and explicit the "the minimum, expected steps in complex processes." Even experienced providers don't always understand the critical important of some precautions, such as the use of antacid medication for ventilated patients. In Gawande's words, "[c]hecklists established a higher standard of baseline performance." He continues:

We have the means to make some of the most complex and dangerous work we do—in surgery, emergency care, and I.C.U. medicine—more effective than we ever thought possible. But the prospect pushes against the traditional culture of medicine, with its central belief that in situations of high risk and complexity what you want is a kind of expert audacity—the right stuff, again. Checklists and standard operating procedures feel like exactly the opposite, and that's what rankles many people.

#### PROBLEM: DEFINING "QUALITY"

The ACA has several provisions that attempt to define quality, primarily by listing quality measures, as noted above. As CEO of a large multi-hospital system, you are developing standards for quality to improve patient safety at the thirty-five hospitals in your system. The hospitals range from small inner-city hospitals to large tertiary care hospitals. Review the various quality measures described in the ACA. How will you begin to prioritize these measures for your system? What other elements of the ACA will guide your decisions about what measures to focus on?

#### PROBLEM: BATTLING STANDARDS I

As the CEO of the large integrated health system described in the previous problem, you are well aware that cardiac care is an important and profitable component of patient care. You have recently begun a study of cardiac care in your system, with particular attention to the treatment of heart patients with clogged arteries. Cardiologists routinely use stents for stable coronary artery disease (CAD). In angioplasties, doctors guide a narrow tube through a blood vessel near the groin up toward the heart, inflate a tiny balloon to flatten blockages, and insert a stent to keep arteries propped open. The procedure costs about \$20,000, based on average Medicare reimbursement for doctor and hospital fees, and generally requires an overnight hospital stay. You are aware of the COURAGE study, a major research study in 2007 that concluded that intensive drug treatment in non-emergency patients with chest pain (aspirin, beta blockers, and statins) worked as well as angioplasty in preventing heart attacks, improving survival and relieving discomfort in the long run. In a seven-year follow-up, the study found that the outcomes were the same for stents and drug therapies.

The use of stents by cardiologists in your system hospitals has continued at about the same level in 2011 as in 2007, in spite of their much higher costs

and identical outcomes. You would like to change the practice patterns of the cardiologists in your system. How should you proceed? What kind of approach do you advise to deal with the problem of variation in practice approaches in cardiology? What ideas do you have to reduce such conflicts and to guide providers into the best practices? Given the structure of most hospitals, how will you orchestrate a unified approach to cardiology practice? Are you likely to be conflicted about this choice, given the likelihood of substantial hospital revenue from interventions like angioplasty?

What mechanisms might be used to resolve such possible conflicts among best practices, comparative effectiveness research findings, practice guidelines, and other standards of ACA? To what extent do variations inherent in medical practice styles confound such research? And what about the confounding effects of variations in patients, physician and support teams, and available resources? See William B. Borden et al., Patterns and Intensity of Medical Therapy in Patients Undergoing Percutaneous Coronary Intervention, 305 J.A.M.A. 1882 (2010), reporting that fewer than half of patients undergoing percutaneous coronary intervention (PCI) are receiving optimal medical therapy (OMT), despite the guideline-based recommendations to maximize OMT and the clinical logic of doing so before PCI.

## B. EVIDENCE-BASED MEDICINE (EBM) AND COMPARATIVE EFFECTIVENESS RESEARCH (CER)

Evidence-based medicine (EBM) has been defined as “the conscientious, explicit, and judicious use of current best evidence in making decisions about the care of individual patients.” David L. Sackett et al., Evidence-Based Medicine: What It Is and What It Isn’t, 312 Brit. Med. J. 71, 71 (1996). EBM incorporates clinical expertise and patient values as well, but the emphasis is on the use of current best evidence. EBM assumes that the physician will keep up with and incorporate the best evidence into his practice in advance of the development of a clinical practice guideline. See generally Carter Williams, Evidence-Based Medicine in the Law Beyond Clinical Practice Guidelines: What Effect Will EBM Have on the Standard of Care? 61 Wash. & Lee L. Rev. 479 (2004).

Comparative effectiveness research (CER) is a natural outgrowth of EBM. It is a major component of current federal health policy. This “effectiveness initiative” in modern medicine is based on three premises. First, many current medical practices either are ineffective or could be replaced with less expensive substitutes. Wennberg’s medical practice variation studies support this premise to a large extent.

Second, physicians often select more expensive treatments because of bias, fear of litigation, or financial incentives. Physician defensive medical practices like unnecessary tests, motivated by fear of litigation, supports this premise. So do payment incentives like fee-for-service medicine, where the more a physician does, the more she gets paid.

Third, patients would often choose different options from those recommended by their physicians if they had better information about treatment risks, benefits, and costs. The burgeoning literature on shared decision making and the use of decision aids supports this idea that patient choices might often lead to conservative treatment or no treatment at all. See Chapter 4.

The goal of evidence-based medicine and comparative effectiveness research is to narrow variation in medical practice by developing guidelines and best practices for clinicians. See David Eddy, Evidence-Based Medicine: A Unified Approach, 24 Health Affairs 9 (2005); Alan M. Garner, Evidence-Based Guidelines As a Foundation For Performance Incentives, 24 Health Affairs 174 (2005); M.C. Weinstein & J.A. Skinner, Comparative Effectiveness and Health Care Spending: Implications for Reform, 326 NEJM 460 (2010).

The federal government has a range of CER programs that predate the ACA. The Federal Coordinating Council for Comparative Effectiveness Research was created and funded by the American Recovery and Reinvestment Act of 2009 (ARRA) to promote optimum coordination of comparative effectiveness research conducted or supported by federal departments and agencies. The Council in its first report defines comparative effectiveness research:

\*\*\*the conduct and synthesis of research comparing the benefits and harms of different interventions and strategies to prevent, diagnose, treat and monitor health conditions in “real world” settings. The purpose of this research is to improve health outcomes by developing and disseminating evidence-based information to patients, clinicians, and other decision-makers, responding to their expressed needs, about which interventions are most effective for which patients under specific circumstances.

See Federal Coordinating Council for Comparative Effectiveness Research, Report to the President and the Congress 5, June 30, 2009.

The ACA continues the strong emphasis in federal health policy on comparative effectiveness research. Section 6301 of the ACA defines “comparative clinical effectiveness research” to mean research evaluating and comparing health outcomes and the clinical effectiveness, risks, and benefits of two or more medical treatments, services, and items. These include “health care interventions, protocols for treatment, care management, and delivery, procedures, medical devices, diagnostic tools, pharmaceuticals (including drugs and biologics), integrative health practices, and any other strategies or items being used in the treatment, management, and diagnosis of, or prevention of illness or injury in, individuals.”

The ACA created several entities to further CER. The primary new entity is a nonprofit corporation, the Patient-Centered Outcomes Research Institute (PCORD). The Institute's purpose is:

\*\*\* to assist patients, clinicians, purchasers, and policymakers in making informed health decisions by advancing the quality and relevance of evidence concerning the manner in which diseases, disorders, and other health conditions can effectively and appropriately be prevented, diagnosed, treated, monitored, and managed through research and evidence synthesis that considers variations in patient subpopulations, and the dissemination of research findings with respect to the relative health outcomes, clinical effectiveness, and appropriateness of the medical treatments, services, and other items.

For a full list of federal programs, see National Information Center on Health Services Research and Health Technology (NICHSR), Comparative Effectiveness Research.

Critics of comparative effectiveness research note several problems with the enterprise, primarily the difficulties inherent in clinical adoption of research findings as to what works. They note that historically, medical practices are very slow to change in the face of new scientific evidence about what works. Timbie et al. list five sources of resistance to the adoption of research findings: “\*\*\* financial incentives, such as fee-for-service payment, that may militate against the adoption of new clinical practices; ambiguity of study results that hamper decision making; cognitive biases in the interpretation of new information; failure of the research to address the needs of end users; and limited use of decision support by patients and clinicians.” See Justin W. Timbie et al., Five Reasons That Many Comparative Effectiveness Studies Fail To Change Patient Care And Clinical Practice, 31 Health Affairs 2168 (2012) (The authors offer a note of optimism: “Policies that encourage the development of consensus objectives, methods, and evidentiary standards before studies get under way and that provide strong incentives for patients and providers to use resources efficiently may help overcome at least some of these barriers and enable comparative effectiveness results to alter medical practice more quickly.”)

See also Eleanor D. Kinney, Comparative Effectiveness Research under the Patient Protection and Affordable Care Act: Can New Bottles Accommodate Old Wine? 37 Am. J. Law & Med. 522 (2011) (providing an excellent history of comparative effectiveness research and a detailed discussion of the Patient-Centered Outcomes Research Institute, and its potential strengths and problems.); Richard S. Saver, Health Care Reform’s Wild Card: The Uncertain Effectiveness of Comparative Effectiveness Research, 159 U. Pa. L. Rev. 2147 (2011) (discussing the limitations of CER as rolled out under the ACA, and concluding that “to even begin fulfilling some of its promise, CER must be deployed under better starting condi-

tions. This means paying a great deal more attention to how physicians, the critical gatekeepers, will likely respond and directly confronting the serious risks of physician tune-out and indifference.”)

### C. THE PROBLEM OF MEDICAL ERROR

#### 1. Adverse Events: Definition and Scope

Injury caused by doctors and health care institutions, or iatrogenesis, is the inverse of quality medicine. The literature on adverse events is growing rapidly as the patient safety movement begins to permeate federal health policies. What is an adverse event?

The Institute of Medicine developed working definitions of “adverse event” and “medical error” in *To Err Is Human*. The IOM defined an adverse event as “an injury caused by medical management rather than the underlying condition of the patient,” and a medical error as “the failure of a planned action to be completed as intended . . . or the use of a wrong plan to achieve an aim. . . .” Institute of Med., *To Err Is Human: Building a Safer Health System* 28 (Linda T. Kohn, et al., eds., 2000) [hereinafter, IOM Report].

The U.S. Agency for Healthcare Research and Quality (AHRQ) defines an adverse event as “Any negative or unwanted effect from any drug, device, or medical test,” essentially the same as the IOM’s definition. AHRQ cites the following examples of adverse events: “pneumothorax from central venous catheter placement,” “anaphylaxis to penicillin,” “postoperative wound infection,” and “hospital-acquired delirium (or ‘sun-downing’) in elderly patients.”

The law has historically focused on physician “error.” Until recently, malpractice cases were brought against the treating physician and not his institution because of a variety of legal rules that shielded the hospital. State licensing boards brought disciplinary actions against the individual errant doctor. Staff privileges cases involved the individual doctor’s qualifications. The narrow focus on individual error facilitated a clear definition of “bad medicine.” Bad medicine was what bad doctors did. The “bad apples” were doctors whose incompetence was obvious.

The larger problem of quality in medical care must also address systematic failures, poor administrative design for review of health care, inaccuracy in training of physicians, and the nature of practice incentives. The concept of “error” often misses the point of quality improvement, which requires a look at many other facets of health care delivery. See Chapter 6.

## CHAPTER 1

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### COST, QUALITY, ACCESS, AND CHOICE

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#### V. FROM DEFINING QUALITY TO REGULATING PATIENT SAFETY

##### A. THE NATURE OF QUALITY IN MEDICINE

2. Quality and the Patient Protection and Affordable Care Act of 2010

Add at page 34 at the end of Note 2:

The payment strategies under Medicare provide incentives for hospitals to reduce unnecessary readmissions and otherwise lower their adverse event rates. The problem is that surgical complications lead to higher hospital contribution margins (except for Medicaid and self-pay), since historically the cost of fixing patients after the fact could be billed at the prevailing rates. Hospitals will experience substantial adverse near-term financial consequences of reducing overall complication rate since they will now be financially penalized for readmissions. See generally Sunil Eappen et al., Relationship Between Occurrence of Surgical Complications and Hospital Finances, 309 JAMA 1599 (2013).

#### C. THE PROBLEM OF MEDICAL ERROR

##### 2. The Extent of Medical Misadventures

Add at page 43 the following new Note 7:

7. Assessing the frequency of medical errors and their contribution to patient deaths continues to be a difficult problem. One recent study concluded that medical errors are now the third leading cause of death in United States, claiming up to 251,000 lives every year—more than respiratory disease, accidents, stroke and Alzheimer's. The authors analyzed four large studies, including ones by the Health and Human Services Department's Office of the Inspector General and the Agency for Healthcare Research and Quality that took place between 2000 and 2008. They used broad categories that included everything from bad doctors to issues such as communication breakdowns when patients are handed off from one department to another.

The authors noted the high degree of variability in evaluating and tabulating data on medical errors—the Centers for Disease Control and Prevention (CDC), for example, does not require reporting of errors in the data it collects about deaths through billing codes. This lack of national standardization in reporting medical errors increases the difficulty in both assessing and reducing such errors. They proposed a national approach to properly fund studies of national patterns of medical errors. Martin A. Makary and Michael Daniel, Medical Error—the Third Leading Cause of Death in the U.S., 353 BMJ i2139 (2016).

The level of severe patient injuries resulting from medical errors has been projected as high as 40 times the death rate. See Frederick van Pelt, quoted in Ariana Burung Cha, Medical Errors Now Third Leading Cause of Death in United States, Washington Post (May 3, 2016), <https://www.washingtonpost.com/news/your-health/wp/2016/05/03/researchers-medical-errors-now-third-leading-cause-of-death-in-united-states/>.

Drug adverse events also continue to occur at a surprisingly high rate in spite of initiatives over the past decade in improving drug administration. A recent study of the problem concluded:

We found that approximately 1 in 20 perioperative medication administrations and every second operation resulted in an ME and/or an ADE. More than one third of these errors led to observed patient harm, and the remaining two thirds had the potential for patient harm. More than two thirds of the harm or potential harm was classified as serious. Thus, there is a substantial potential for medication-related harm and a number of opportunities to improve safety in the perioperative setting.

Karen C. Nauij et al., Evaluation of Perioperative Medication Errors and Adverse Drug Events, 124 Anesthesiology 25, 31 (2016).

## E. REGULATING TO REDUCE MEDICAL ADVERSE EVENTS

### 3. Federal Reimbursement Strategies

#### b. *Federal Quality Incentive Strategies*

Add at page 63 following subsection b:

CMS has continued to refine its value-based purchasing strategies, as described in Chapter 10 at page 789. The three broad models are as follows:

- Pay-for-performance—a payment arrangement in which providers are rewarded (bonuses) or penalized (reductions in payments) based on meeting pre-established targets or benchmarks for measures of quality and/or efficiency.

- Accountable care organizations—models of coordinated care in which doctors, hospitals, and other health care providers voluntarily associate to provide coordinated care, with payment tied to overall costs and quality of care for an assigned population of patients. Payment is tied to performance on quality measures and reductions in the total cost of care. This risk sharing model allows providers to choose varying levels of risk in order to gain a share of the savings achieved through improved care delivery, if quality and spending targets are met.
  - Bundled payments—payments to health care providers are based on the expected costs for a clinically defined episode or bundle of related health care services, with financial and quality performance accountability for episodes of care.
- Cheryl L. Damberg et al., Measuring Success in Health Care Value-Based Purchasing Programs Findings from an Environmental Scan, Literature Review, and Expert Panel Discussions (RAND CORPORATION (2014), [http://www.rand.org/content/dam/rand/pubs/research\\_reports/RR300/RR306/RAND\\_RR306.pdf](http://www.rand.org/content/dam/rand/pubs/research_reports/RR300/RR306/RAND_RR306.pdf))
- What are the assumptions on which these payment models are based? What problems can you foresee in using reimbursement models as the preferred regulatory tool to achieve high quality care? What other regulatory strategies might you consider along with, or instead of, payment mechanisms?