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Informed Consent and the First Amendment

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MYOCARDIAL INFARCTION

A 55-year-old man with no serious health conditions has a moderately severe myocardial infarction.

Management of myocardial infarction in China varies considerably between rural and urban areas, and Mr. Li lives in a rural area, where he's covered by rural health insurance. He develops chest pain around midday. An hour later, he calls the village doctor, who arrives at his home about 30 minutes later and administers nitroglycerin tablets. When the pain is not alleviated, the doctor calls a senior internist at the county hospital, who advises the patient to call an ambulance to transport him to the hospital, which is 30 minutes away. As is customary in China, however, Mr. Li waits for his daughter to come home from work so she can accompany him. He arrives at the hospital around 7 p.m.

There, electrocardiography and myocardial-enzyme tests confirm that he's having a myocardial infarction. He has two treatment options: intravenous thrombolysis at the county hospital or cardiac catheterization at a tertiary care hospital. His doctor recommends the latter, since it's too late for thrombolysis to be effective.

Mr. Li hesitates because of the added expense of care at the tertiary facility: treatment at the county hospital requires a $300-to-$600 copayment, as compared with $2,000 to $2,500 at the tertiary facility. His family's annual income is only $6,000. Nevertheless, he opts for the tertiary hospital.

Mr. Li undergoes angiography and receives two stents. He stays in the hospital for 2 weeks, spending half that time in the cardiac intensive care unit. He is discharged on aspirin, clopidogrel, an angiotensin-converting–enzyme inhibitor, a beta-blocker, spironolactone, and a statin. His insurance pays 60% of the cost of these medicines up to a maximum of $800, leaving him with out-of-pocket medication expenses of $700 to $800 per year.

Mr. Li receives very little counseling about preventive measures such as smoking cessation or hypertension or lipid management. He returns to his village with no arrangements for primary care follow-up.

easier to reform health insurance than delivery systems and that in creating effective delivery systems, primary care seems to play a vital role.

A review of China's health care journey reveals that its leadership has made significant errors but has also acted with flexibility and decisiveness in correcting its mistakes. China's willingness to undertake major health care experiments will make its system an interesting one to continue to observe in the future.

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Informed Consent and the First Amendment

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For more than two decades, states have been adding to the things that physicians must say and do to obtain "informed consent" — and thereby testing the constitutional limits of states' power to regulate medical practice. In 1992, the Supreme Court upheld states' authority to require physicians to provide truthful information that might encourage a woman to reconsider her decision to have an abortion, finding that such a requirement did not place an "undue burden" on the woman.[1]

Now, there is a potential vehicle for a new Supreme Court ex-

amination of informed consent: a recent decision by the U.S. Court of Appeals for the Fourth Circuit that conflicts with other appellate court decisions. The Fourth Circuit struck down a North Carolina statute, called the Display of Real-Time View Requirement, that required physicians to "perform an obstetric real-time view of the unborn child" that the patient could see; to simultaneously explain the display, including "the presence, location, and dimensions of the unborn child within the uterus and the number of unborn children depicted," as well as "the presence of external members and internal organs, if present and viewable"; and to offer the patient "the opportunity to hear the fetal heart tone." The woman undergoing ultrasonography, presumably partially unclothed, was permitted to avert her eyes and cover her ears, but the physician was required to speak. Penalties for noncompliance included liability for damages and disciplinary measures, including license revocation, by the North Carolina Medical Board. The appeals court concluded that the statute violated the First Amendment's prohibition on state-compelled speech.[2]

The First Amendment protects both the freedom to speak and the freedom not to speak. However, there are limits to both freedoms. As long as the law is viewpoint-neutral, the state can limit the time, place, and manner of speech for legitimate purposes. For example, government can limit loud rallies to daytime hours and require that they take place away from hospitals, but it cannot constitutionally allow only the Democratic Party and not the Republican Party to hold rallies.

The state can regulate the content of advertising ("commercial speech") to protect consumers from "commercial harms," such as false or misleading statements or claims, as long as the regulation is viewpoint-neutral. It can also require private entities to inform consumers of objective, accurate facts that may not be common knowledge, such as the ingredients in processed food, the true rate of interest on a mortgage, or the actual cost of attorneys' legal services.[3] But the state cannot entirely prohibit advertising of a legal product such as contraceptives or tobacco simply because it wants to discourage their sales.

Medical services are analogous to commercial practices for purposes of the First Amendment. The government has an interest in regulating medical practice to ensure safe and effective care. It also has an interest in ensuring that patients have enough accurate information to make voluntary, informed treatment decisions. Hence, it is the physician's duty under the doctrine of informed consent to provide material information about the benefits and risks of both the recommended treatment and its alternatives. However, the First Amendment prohibits the government from compelling people to make false or misleading statements or to express the government's point of view as their own.

Relying on the 1992 Supreme Court decision, North Carolina contended that the required fetal sonogram descriptions are merely statements of fact. The Fourth Circuit, however, found that North Carolina's display provision represented "quintessential compelled speech," calling the required description "ideological; it conveys a particular opinion."[2] The court, finding that the "state's avowed intent and the anticipated effect" were to discourage abortion, said that the provision compelled physicians to serve as a mouthpiece for the state's point of view.[2]

North Carolina also argued that it was not compelling speech, but simply regulating conduct — the practice of medicine — and that the law could therefore be justified under a more lenient standard of review. It cited a decision by the Fifth Circuit finding that similar, but somewhat less specific, information was truthful, nonmisleading, and relevant to abortion decisions and did not impose any particular viewpoint.[4]

The Fourth Circuit was unpersuaded. "Though the information conveyed may be strictly factual," it said, "the context surrounding the delivery of it promotes the viewpoint the state wishes to encourage."[2] The court emphasized that the context in which words are spoken can convert facts into propaganda. In this case, a woman in a vulnerable position lying partially disrobed on an examination table, who relies on her physician for objective medical information, must either listen to and watch the state's message or cover her eyes and ears. In such circumstances, the court concluded, "the state has . . . moved from 'encouraging' to lecturing, using health care providers as its mouthpiece."[2]

Do laws like the North Carolina statute improve the informed-consent process — or distort it by commandeering physicians to act as agents of the state? The answer will affect not only abortion services but all medical practice. As the Supreme Court

has made clear, "a requirement that a doctor give a woman certain information as part of obtaining her consent to an abortion is, for constitutional purposes, no different from a requirement that a doctor give certain specific information about any medical procedure."[1] If the state can require physicians to perform specific procedures and tell patients certain things about abortion, it can do the same for kidney transplantation, contraceptives, psychiatric treatment, and investigational therapies.

Last July, the Court of Appeals for the Eleventh Circuit upheld a Florida law forbidding physicians to ask patients about firearms in the home, finding that the prohibition did not violate physicians' First Amendment rights when the inquiry is "unnecessary to a patient's care."[5] The court did, however, note a fundamental reason for the doctrine of informed consent: "when a patient enters a physician's examination room, the patient is in a position of relative powerlessness."[5] The Fourth Circuit recognized this vulnerability, too, but drew a different conclusion. Instead of protecting patient autonomy, North Carolina's law forced the patient to take affirmative steps to protect herself against unwelcome, distressing, or unhelpful speech from the very physician she relies on for personalized care. This charade demeans both the physician and the patient.

An audio interview with Prof. Mariner is available at NEJM.org

These cases present two radically different views of informed consent: the traditional view that rational decision making and patient autonomy are best protected by allowing physicians to tailor disclosures to their patients' needs and preferences; and the view that government can use informed consent to encourage specific decisions by regulating what tests physicians must perform, what information they must present, and what information they cannot seek.

Laws prescribing exactly what physicians must say, regardless of patients' needs or preferences, make a mockery of informed consent and patient autonomy. Laws that compel physicians to speak for the state devalue physicians' professional judgment and responsibility to act in patients' best interests. The First Amendment was adopted to keep the government from controlling what people, including physicians, say. Protection of patients' rights should not be used as a pretext to promote partisan political purposes in the examining room.

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Market-Based Solutions to Antitrust Threats — The Rejection of the Partners Settlement

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Health care consumers won a significant victory when Massachusetts Suffolk County Superior Court Judge Janet Sanders blocked a settlement that would have allowed Partners HealthCare, the system that dominates the Boston area, to acquire three additional health care providers in eastern Massachusetts. Sanders concluded that the acquisitions "would cement Partners' already strong position in the health care market and give it the ability, because of this market muscle, to exact higher prices from insurers for the services its providers render."

If this decision is not overturned on appeal, consumers will now be spared those projected price increases. But there is an even bigger reason for New Englanders to celebrate the judge's ruling. The danger lay not only in Partners' expanded dominance but also in the degree to which the settlement would have shut out other innovative competitors.

Sanders's ruling closes the latest chapter in the saga of Partners HealthCare, a system formed in 1994 as a merger between the world-famous Massachusetts General and Brigham and Women's Hospitals. Beginning in 2010, then Massachusetts Attorney General Martha Coakley presciently warned of Partners' growing pricing