tion could feature many of the real patients in intensive care units who, just before being intubated, express deep regret over failing to get vaccinated. Many of these patients only then request vaccination and are told it's too late. Unvaccinated people often assume that doctors and hospitals will always be available to them if they get sick. Messages could therefore also feature health care workers attesting to the strain that Covid-19 places on clinicians and on patients requiring treatment for any condition. There is an opportunity to mount a serious effort to provide accurate vaccination information using the same media channels on which people currently consume misinformation.

Vaccine mandates have helped boost vaccination rates in some places by making being vaccinated a social norm, similar to wearing a seat belt and pausing for security checks in airports. Regulations at the local and community levels, such as requiring proof of vaccination to enter public spaces and maintain local business functions, may be even more effective than federal mandates. Liability litigation seeking compensation for harm caused by businesses that don't require their workers to be vaccinated merits consideration, even though the Supreme Court rejected private-employer vaccine mandates from the Occupational Safety and Health Administration.

Trusted personal physicians remain the best source for the effective transmission of health information. But many people at risk of remaining unvaccinated have had less-than-optimal access to and experiences with the health care system, which has engendered mistrust. Furthermore, despite the extraordinary efforts of most physicians during the pandemic, not all physicians provide truthful information, and states have inadequately regulated the licenses of those who spread harmful misinformation.[5]

Public health practitioners knew for years that tobacco use causes cancer, but scientific knowledge alone had a minimal effect on smoking behavior. Just as the awareness that smokers endanger others marked a turning point for tobacco control, conveying the message that unvaccinated people endanger their family members, communities, and the health care system may be effective. A well-funded, multifaceted communications effort will again be required to change the behavior of some people who are still undecided.

Freedom of choice remains; people can still smoke cigarettes and decline vaccinations. But the roadmap drawn by tobacco-control efforts shows that the public mindset can be tilted toward public health and social good. With vaccination, this work shouldn't take decades; it needs to begin immediately.

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Physicians as Political Pawns — The Texas Directive on Gender-Affirming Care and Other Moves

Anna Kirkland, J.D., Ph.D.

On February 21, 2022, Texas Governor Greg Abbott (R) directed his Department of Family and Protective Services (DFPS) to treat as child abusers all parents seeking gender-affirming care for their transgender children. One targeted family sued, and on March 11 — after a court

hearing in which a DFPS official testified that there had been an order to prioritize these cases but not put anything in writing — the judge issued an injunction against enforcing the directive. The case is set for trial this summer.

The directive is not a state law because the legislature failed to pass a similar measure. The court found that Abbott had overstepped his powers by using the directive to accomplish what the legislature would not.[1] But the Texas directive is part of a flurry of recent activity in various states aiming to criminalize the seeking and provision of gender-affirming care for children and adolescents. Idaho lawmakers considered a bill that would have made provision of gender-affirming care to minors punishable by a maximum term of life in prison; similar bills have been passed in Arkansas and Tennessee. Alabama Governor Kay Ivey (R) signed a bill on April 8, 2022, that makes it a state felony to provide gender-affirming care to minors.

Since the directive was issued, Texas physicians have practiced under impossible conditions. Duties to avoid discrimination, protect privacy, meet standards of care, fulfill reporting requirements, and avoid committing crimes have been set up in direct conflict. There are accepted international standards for providing gender-affirming care to young people (https://www.wpath.org/policies). Care may include supporting a social transition and prescribing puberty blockers or hormones; genital surgeries are not recommended for minors. Physicians practicing in this area are professionally, legally, and ethically obligated to provide individualized care that is in keeping with those standards, crafted with parents, and delivered with privacy protections. But the directive labels many of these forms of care as child abuse and would obligate physicians to report any parent who sought them.

Secretary of Health and Human Services Xavier Becerra responded by reminding all state agencies that accept funding under Title IV-E and IV-B of the Social Security Act that they are bound by federal child-welfare law to support LGBTQI+ (lesbian, gay, bisexual, transgender, queer or questioning, or intersex) young people in accessing gender-affirming care. Gender identity is also protected under federal antidiscrimination law. Section 1557 of the Affordable Care Act forbids health care discrimination based on sex, and the 2020 ruling in *Bostock v. Clayton County* held that discrimination based on gender identity or sexual orientation is necessarily considered sex-based discrimination in the context of employment under Title VII of the Civil Rights Act. The Biden administration has concluded that this inclusive interpretation applies to Section 1557 as well, so covered entities (all hospitals and health systems) must avoid discriminating against LGBT patients. Categorical refusal of care based on gender identity is illegal discrimination. Alabama physicians who provide gender-affirming care face state felony charges if they follow federal nondiscrimination requirements.

Moreover, Department of Health and Human Services guidance released on March 2, 2022, explicitly notes that it may be a violation of Section 1557 to report a parent to authorities for seeking gender-affirming care for their child. The guidance also reminds covered entities that the Health Insurance Portability and Accountability Act (HIPAA) Privacy Rule "permits, *but does not require*" (emphasis in original) disclosures about patients without their permission when required by another law (such as a child-abuse reporting law).[2]

The American Medical Association has condemned state legislation criminalizing gender-affirming care, but to no avail. This conflicting mess of legal obligations demands additional immediate responses by hospital ethics committees, legal counsel, and the medical profession at large. The Abbott directive and other state anti-trans measures rely on physicians' risk aversion and uncertainty to drive overcompliance (such as providing HIPAA disclosures that are not required) and withdrawal from care provision. But risk is everywhere when medical, professional, and legal obligations are deliberately drawn into conflict with one another. Patients bear risks when physicians withdraw care or report them to police or child-welfare investigators, and we all share risk when trust in medical providers breaks down. Health systems' in-house counsel must be ready to support clinicians as they navigate conflicting obligations in more immediate and riskier ways than usual.

Criminalization in health care settings will increase mistrust and damage public health, as more people come to perceive doctors as pawns in harmful political campaigns. New relationships

with lawyers will have to be part of the answer. These legal issues go beyond typical malpractice concerns, and physicians will need to work with lawyers on privacy, nondiscrimination, employment, criminal law, and child-welfare issues. But the lawyers who know these issues best are most likely to represent institutions, not individual physicians; doctors would do well to invest in an attorney–client relationship of their own when their interests depart from their employer's stance. Patients' medical vulnerability also means legal vulnerability. Medical–legal partnerships that embed lawyers in health care settings can help patients and families understand, for example, that they don't have to answer questions from law enforcement in health care settings and that they can ask caregivers to decline to provide health information without consent.

The Texas directive is one move in a long-standing effort to govern the United States theocratically. Conservative legal activists and religious organizations have been working for decades to build capacity to bring lawsuits, nominate judges, write model bills, support candidates for office, and steer the legal and political agenda.[3] Governor Ivey explicitly invoked the will of God to justify the Alabama state law criminalizing gender-affirming care. There is even a religious conservative alternative to the American Academy of Pediatrics (AAP): the American College of Pediatricians (ACPeds), which split off from the AAP in 2002 when the AAP endorsed adoption by same-sex couples. Focus on the Family, a far-right religious organization that is active in anti-LGBT politics, advises Christian counseling when "faced with a child's transgenderism," holds up ACPeds as an expert source, and blames social media, stress, and other "complex results of sin within our social and familial systems" for children's confusion while "navigating these normal developmental phases."[4] This movement's ultimate goal is apparently to deny transgender people's legitimate existence and remove them from full participation in society.

This targeting of transgender young people and their families and physicians has an obvious political context. The 100-plus bills introduced in 35 states in 2021 to restrict sports participation and bathroom use by transgender children and adolescents and to cut them off from medical care originate from the Republican party. These bills come out of this theocratic conservative legal movement and have electoral motivations. Texas Republicans, for example, have been battling to mobilize their base with hot-button cultural issues during primary and runoff campaigns. Texas state Representative Matt Krause started the chain of events with an inquiry to state Attorney General Ken Paxton about whether "sex change" surgeries are child abuse. Both Krause and Paxton were competing in runoff Republican primary elections. Abbott won his Republican primary and faces Democrat Beto O'Rourke in November.

Health care for transgender young people is a salient issue for Republican politicians to use to mobilize conservative voters, which explains the timing of these divisive actions. Another key issue is abortion, which is expected to be illegal in as many as 26 states if and when *Roe v. Wade* is overturned. The pending Supreme Court case *Dobbs v. Jackson Women's Health Organization* will most likely deliver that result in June — another jolt that would drive uncertainty, create impossible binds for physicians, and teach patients to withhold information. Partisan gerrymandering and a far-right Supreme Court majority mean that Republican politicians needn't fear voter disapproval for taking unpopular actions such as criminalizing gender-affirming care and abortion, since they anticipate supportive court rulings for the medium-to-long term.

These political and legal struggles are occurring at a time when the U.S. medical profession is divided and changing.[5] Overall, U.S. physicians are evenly split between Republican and Democratic affiliations, but while specialists such as surgeons are more likely to be Republicans, physicians in infectious diseases, pediatrics, endocrinology, and obstetrics and gynecology are more likely to be Democrats. The latter specialties also include more women, receive lower pay, and are the ones most immediately affected by restrictions on gender-affirming care and abortion. These political and legal challenges to the profession will be felt unequally, but the reverberations of politicized mistrust will harm everyone who needs to be able to tell a doctor the truth about themselves, as well as any doctor who needs to hear it.

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Your Money or Your Life — The High Cost of Cancer Drugs under Medicare Part D

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Undergoing cancer treatment is physically, emotionally, and financially burdensome.[1] For people whose treatment regimens include orally administered anticancer drugs, the financial burden associated with these medications can be overwhelming. About half of anticancer drugs are orally administered. Such drugs provide distinct benefits for patients, since they can reduce the amount of time spent receiving infusions and traveling to appointments.

Orally administered drugs are nearly always offered under a health plan's prescription-drug benefit, rather than the medical benefit. For younger patients with cancer, this distinction may be of limited importance, since both pharmacy and medical spending count toward annual limits on in-network, out-of-pocket spending set by the Affordable Care Act for private plans. For Medicare beneficiaries (the population most likely to be diagnosed with cancer), however, there are considerable financial implications associated with medications being covered under Medicare's pharmacy benefit instead of the medical benefit. Most beneficiaries would be responsible for high (and unlimited) out-of-pocket spending for drugs filled under their pharmacy benefit (Medicare Part D). The same beneficiaries typically wouldn't face the prospect of unlimited spending for drugs that are covered under the medical benefit (e.g., physician-administered drugs offered as part of Medicare Part B), since 90% of Medicare beneficiaries have supplemental coverage that reduces or eliminates these out-of-pocket costs.

One way to illustrate this issue is to consider a Medicare beneficiary who has been newly diagnosed with metastatic breast cancer. For a patient with hormone receptor–positive, human epidermal growth factor receptor type 2 (HER2)–negative breast cancer, the preferred first-line therapy includes two orally administered anticancer drugs: an aromatase inhibitor and an inhibitor of cyclin-dependent kinases 4 and 6 (CDK4/6).[2] Aromatase inhibitors are low-cost hormonal therapies and have been available in generic form for several years. But the most commonly used CDK4/6 inhibitor, palbociclib, would cost approximately $3,100 out of pocket for the first fill and more than $10,500 for 1 year of use for a Medicare Part D beneficiary who doesn't qualify for low-income subsidies (see table).

For a similar patient who is diagnosed with HER2-positive metastatic breast cancer, one of the preferred first-line treatment options is a combination of trastuzumab, pertuzumab, and a taxane.[3] These drugs are administered by physicians and are therefore covered under Medicare's medical benefit; for beneficiaries with supplemental coverage, the medications would be subject to an out-of-pocket spending limit or would be covered with limited or no cost sharing.