Law and Medicine

Law and Medicine:

A Practical Text

By

Scott Tenner

Cambridge
Scholars
Publishing

Law and Medicine: A Practical Text

By Scott Tenner

This book first published 2024

Cambridge Scholars Publishing

Lady Stephenson Library, Newcastle upon Tyne, NE6 2PA, UK

British Library Cataloguing in Publication Data
A catalogue record for this book is available from the British Library

ISBN: 978-1-0364-1510-5
ISBN (Ebook): 978-1-0364-1511-2

With special thanks to my wife Elina Tenner who supported me through Law School, Monica Zucca who supported me through medical school, Brenda Tenner who proof-read the manuscript (finding so many errors), my children, especially Samantha Tenner who attended the class I teach at Fordham (giving me great feedback), and the many medical and law students who inspired me to write the book.

TABLE OF CONTENTS

CHAPTER 1

AN INTRODUCTION TO HEALTH LAW

Is Access to Health Care a Right?

"*Everyone has the right *to a standard of living adequate for the health and well-being of himself and of his family, including food, clothing, housing and* medical care*…"
—Article 25, Universal Declaration of Human Rights
United States Adopted, December 10, 1948

President Harry Truman had appointed Eleanor Roosevelt to the United States delegation to the United Nations in December 1945. She co-authored the Universal Declaration of Human Rights which she is showing to Time Magazine for this photograph.

"A tremendous amount of needless pain and suffering can be eliminated by ensuring that health insurance is universally available."
—C. Everett Koop, former Surgeon General of the United States, Republican, Appointed by Ronald Reagan

If Access to Health Care is a Right,
Are There Limits?
Who Decides?

How To Finance?
How and Should the Delivery of Health Care be Regulated?

These are the basic questions which are the essence of law and medicine. The doctor-patient relationship begins with access. Once there is access to the provider, the duties, and responsibilities of delivering health care to the patient begins. The relationship is complex as State and Federal laws, rules, and regulations come into play. Common law and insurance companies also deeply influence the relationship between the people, patients and the providers of healthcare. Multiple other parties are often involved including hospital administrators, pharmaceutical representatives, professional societies, accreditation groups, and the media. In the end, the relationship that appears simple, the patient seeking health care with the physician or other provider, is exceedingly complex resting on a foundation of law and medicine.

This book begins with the basic questions to you, to society, to the doctor-patient relationship. Is access to health care a right? Are there limits? Who decides what care should be provided? How do we finance health care? How and who should regulate the delivery of health care? Law and medicine work together to seek answers and structure rules and regulations to guide healthcare delivery. The answers are complex because there are multiple competing issues. At the end of this book, the questions will be asked again. The goal of the book is to raise awareness to the issues that affect healthcare delivery, and to assist you in thinking about the historic, concurrent and future of healthcare.

We have seen great advances in Medicine and Law over the last one hundred years. Both fields have in common the goal to “promote the general welfare”. Both fields rely on the activities of professionals: the individual doctor or lawyer who has a duty to a patient or client. The duty of both professions is similar, one of a fiduciary, to assist their patient/client with their well-being, whether physically, emotionally and/or economically with the utmost care and loyalty. Both the physician and the lawyer are skillfully trained with a large body of knowledge provided and maintained by universities, libraries and “learned experts”. Both the physician and the lawyer stand with their patient/client with one eye towards the fiduciary duty but also an allegiance to a healthcare or judiciary system. Both also work within the realm of professional societies and as members of an international forum.

The interaction between health law and health policy is compounded by a myriad of issues that often seem incompatible. Both law and medicine often have a limited view of global societal problems when focusing on the individual client or patient, the case or controversy, or the individual's disease. Too often the broad implications of decisions made on behalf of the individual do not reflect consideration of its benefit to society or damage to the overall health system. Lawyers and physicians are trained to focus on the individual and typically leave the larger questions to be addressed by law makers and/or medical societies.

If one even looks at the challenges to the Patient Protection and Affordable Care Act (ACA), discussed at length throughout this text, one sees challenges to the law based on focused issues such as the "individual mandate", the tax required for persons not participating in insurance plans. Here the individual mandate may seem to infringe on personal freedom, but the purpose of the "tax" or "penalty" that defines the individual mandate is (or now was) one for the public good. The burden of the tax was to ensure that the health care system has healthy young people who would not typically buy health insurance. The mandate had a financial motive that benefited society in general.

Also, consider the challenges to birth control coverage. After numerous studies showed the benefit in assisting woman in avoiding unwanted pregnancies, and the importance of access to birth control, the ACA included a provision requiring coverage. This reproductive health promotion of birth control is universally recommended by numerous physician groups, including the American College of Obstetrics and Gynecology (ACOG). Despite the benefit to society, multiple legal challenges from employers based on religious doctrine led to changes in the implementation of this requirement as a matter of law. The Court held that the societal benefit could not encroach on employers' religious freedom. See Burwell v. Hobby Lobby Stores, Inc. USC 354 2014.

This conflict between issues promoting public health, the benefits to society, against the freedom of patients, employers and corporations are an ongoing problem that will continue for the foreseeable future. Lawyers, physicians, scientists, and public health experts will continue to push for laws, rules and regulations that "promote the general welfare" while conservative groups will push back claiming individual rights, liberty and religious freedoms. Unfortunately, various persons and groups will also use "alternative facts" and false science. In the end, science must guide health and policy. Consider the push back by conservatives over the last 50 years

on tobacco legislation, seatbelts, airbags, vaccine mandates, even the environment. The Coronavirus pandemic exposed the failure of law and medicine to adequately address the problem of misinformation as over 200,000-300,000 Americans largely died because of a failure to be vaccinated when multiple vaccines were readily available. Tens of millions failed to heed to the experts in science who offered the safe and effective vaccines studied more than any vaccine in history, choosing to take nonsensical hydroxychloroquine, azithromycin, ivermectin, vitamin C and zinc.

Regardless of what intervention benefits individuals or society, cost is a serious issue that permeates health care policy and individual treatment. The cost of providing healthcare has risen more than inflation at 5-8 percent per year for almost 40 years. Where Medicare and Medicaid passed in 1965 largely financed healthcare for decades with little regulation, recent legislative attempts to regulate patient care have met great political and legal challenges. Claiming "fraud, abuse and waste", physicians and health care providers are on the defensive as multiple government agencies scrutinize care. Additionally, attempts to control costs through government partnerships with private corporations, "Advantage Managed Care", beginning in the 1990s have met higher costs, further profiteering and frustration by providers who are often paid less and burdened by pre-authorization requirements.

The cost of health care in the United States far exceeds that of other countries while not providing better health outcomes for its population. While the United States spends over $13,000 a person for healthcare, for less than a third of that amount, $3800 a person, the European Union provides similar care with better outcomes in a variety of important parameters. Despite intense policies to control costs, the price of caring for an American is continuing to rise largely due to increased demand in technologies and new, more expensive, medications:

Consider the FDA in 2023, approved Lecanemab to treat Alzheimer's disease. The medication only has a marginal benefit. The drug would be used in persons who already have Alzheimer's and typically in their 8th or 9th decade of life. The physician panel at the FDA recommended NOT approving the drug due to its marginal benefit. The drug costs over $25,000 per year. Over 6 million Americans have Alzheimer's. In a rare move, the FDA ignored the experts and approved the drug. The drug, FDA approved, must be covered by Medicare as a matter of law.

Consider this fact: many, if not most, persons working for the FDA eventually leave and join the pharmaceutical industry, including the top officials.

The US healthcare system now represents almost 1/5th of all spending in our country (1/5th of the GDP), 4.5 trillion dollars. Novel, more effective medications provide some real improvement in outcomes, but we need to weigh the individual benefit v. the cost to society. But even beyond the cost of the actual care, the administrative burden is massive in the United States, accounting for almost a quarter of health care spending, approximately 1 trillion dollars.

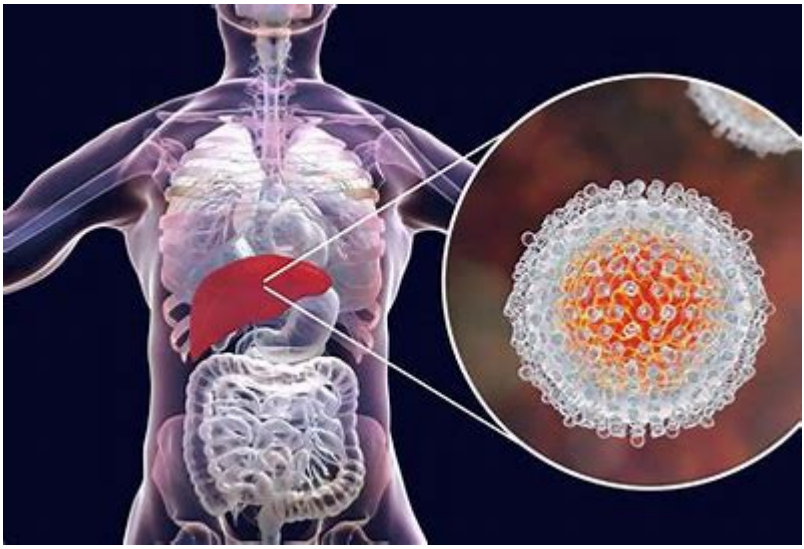
Consider that it costs a primary care physician over $20 just to bill the cost of a visit. There are almost 15 steps just to process each payment. For an individual physician, at least 2 persons need to be employed to bill and or authorize care (many insurance companies require an application to get approval for medications, procedures, radiologic tests). There are almost 600,000 unique codes to describe health care products and services. All this complexity is accompanied by 57 billion negotiated prices in the US market, and almost 100,000 different prices. Transaction costs for healthcare in the US are 10 times higher than the European Union. See Schulman KA et al. JAMA 2023; 330: 2159-2160.

Beyond these administrative costs, the cost of treating each disease is rising and will continue to rise for the foreseeable future. Consider the common new treatments in cardiology. Until recently, congestive heart failure (CHF) with reduced ejection fraction (EF) was treated with 3 inexpensive drugs

(beta-blocker, ACE or ARB, mineralocorticoid antagonist) but now two other drugs are added to the regimen: sacubitril/valsartan and SGLT-2 inhibitor. The health benefit is significant if you consider the individual patient, but the cost is also significantly higher which results in higher premiums that you pay! (See Kazi et al. JAMA; 2023: 330: 1619-1620.)

Disease	**Old Drug**	**Cost/Month**	**New Drug**	**Cost/Month**
Atrial Fibrillation	Warfarin	$ 4	DOACs	$378-$566
CHF	3 Drugs*	$10	5 Drugs*	$1200

Another example, consider the change in treating Chronic Hepatitis C (CHC) over the last decade. Depending on race, 1-2 percent of the US population has CHC. CHC is the most common bloodborne infection in the US and a leading cause of death from an infectious disease, primarily through cirrhosis, liver failure and liver cancer (hepatocellular carcinoma). Most persons who have CHC do not know they have the virus. There are no symptoms until the liver is severely damaged and the test is typically not part of routine blood work. Recently, the CDC has issued guidance to test all persons over age 18. CHC causes many deaths as a “silent killer”. Patients harboring the disease often have no symptoms until cirrhosis and complications of cirrhosis develop. It is one of the most common reasons a person has a liver transplant.



Treatment historically was difficult to tolerate (interferon), and often did not work. About a decade ago, a new series of medications became available which cured the disease 99 percent of the time, had no side effects but cost almost $1000 a pill and 60-90 pills for a 2-3 month course is needed! A course of treatment ranges from $70,000-90,000. When the medication became available after FDA approval, Medicare concerned at the cost announced that if every beneficiary who had CHC took the drug at that price, it would consume more than half of the budget for Medicare, approximately 400 million dollars. Fortunately, prices have come down but the cost to us, the people, through Medicare tax and private insurance premiums, continues to be significant. And this is just one disease!

At this point, another theme of this book needs to be introduced: systemic racism. Shame on the ignorant person who neglects American history and fantasizes that our country has not been forged by racism. The proof of systemic racism is embedded in our healthcare system, and this will be addressed throughout the text. You may be "turned off" by this topic. Your ignorance is forgiven as this is the beginning of the text. The purpose of this book is to educate the reader, painful as it may be but as John Adams stated defending the soldiers in the Boston Massacre: "facts are difficult things."

Since the cost of treating CHC was brought up in the last paragraph, some additional facts:

- Among 30 million black individuals in the US between 2013 and 2016, 1.8 % were found to be positive for CHC. Compare this to the prevalence of 0.5 % of whites.
- The mortality rate of CHC was three times higher in black individuals, 1/10,000 compared to 0.3/10,000.
- A person who is black is 10 times less likely to be tested and treated for CHC compared to a white individual.

Why? Multifactorial. These issues will be addressed further in the text. See Falade-Nwulia et al. Hepatitis C in Black Individuals in the US. JAMA 2023; 330: 2200-2208.

The American health care system is fragmented between public (Medicare and Medicaid) and private services (Blue Cross/Blue Shield, Oxford, United Healthcare, Aetna). Increasing the boundary between what is public and private is becoming vague as private-public ventures have evolved, such as Medicare Advantage, Managed Medicaid and ACA (Obamacare) plans. Overall, the health care policy in the United States prefers the dynamism of private markets, while respecting the doctor-patient relationship. One must ask: can the delivery of health care truly be fair in private markets, where profit motivations influence the action of providers, hospitals, and insurers? Afterall, the insurers need to answer to investors. Yes, there may be a desire for better quality care but the almighty dollar guides most corporate decisions. All the large carriers are on the New York Stock exchange selling shares for the profit to be distributed to shareholders. Do you think the executives of private carriers make decisions on the provision of health care influenced by the need to see profit fuel rising stock prices?

Compounding this problem, physicians are under increasing pressure to order tests and overtreat in order to make money in a fee-for-service system. Additionally, physicians are also typically under pressure to “do something” to satisfy patient expectations, and to avoid tort liability, medical malpractice. Failure to diagnose remains one, if not the most common claim against a physician in a medical malpractice action. Failure to treat is not far behind in numbers of claims against physicians. A common theme a physician faces at a malpractice trial is: if the doctor only did this or order that, the patient would not have had an adverse event. Thus, physicians do and order but do not simply comfort the patient as you were often taught under the same circumstances in medical school and/or residency. Thus, physicians practice in an environment where not only are there financial benefits to diagnosing and treating but legal pressure to focus on the individual patient and “do everything”.

The United States legal and medical community have created a system of professionalism in healthcare delivery that places the doctor-patient in an unrealistic relationship. The physician desires autonomy and the ability to care for the patient with unlimited resources. The patient expects the physician to provide perfect care, with no consideration to resources and costs. Worse, the expectation is that the doctor will deliver a cure and make no errors. This unrealistic relationship is then controlled by thousands of uncoordinated statutes, regulations, and judicial decisions. The limitations of what the physician can provide the patient with and what society can and should allow, including the costs involved are rarely discussed.

The unrealistic relationship of the 21st century American physician and patient will not improve in the current system. Failure of developing policy, long-term regulation, the provision of unconditional public subsidies, inadequate quality controls, and a fragmented insurance industry confined to small geographic areas has led to minimal price competition and the relatively poorly coordinated delivery of care. Large insurance companies and large provider hospitals and networks are largely entrenched. The benefits seen in free market competition do not exist in most of the healthcare industry. Worse, private equity, searching for profit is now infiltrating healthcare from all directions, hospitals, private practices, pharmacies, nursing homes, surgical centers, and anywhere profit can be realized. Afterall, the American health care system is the most profitable service industry in the world.

Alternatively, maybe we should abide by American capitalists who applaud the US health care industry as the most profitable service industry in the world. Afterall, the US is the leading market in health science innovation. A person with the right insurance coverage has unparalleled access to cutting edge diagnostic tests and treatments. The US government Medicare program is the most successful health insurance program in the world! The best medical centers, hospitals, teaching institutions worldwide are in the United States. Most Nobel prizes in medicine the last 50 years have gone to American physician scientists! No nation can combat disease, such as the Coronavirus pandemic, as the United States. The world envied the speed in which the United States developed the mRNA vaccines, massively produced the vaccines, and then distributed the vaccine quickly to those in need.

Undoubtedly, America can do better! Law and medicine can work together to transform healthcare delivery, to make it more equitable, more egalitarian. Tough choices will need to be made as the largest barrier to care needs to be removed, access. It will take a scientific basis, a public health focus and a legislative strategy. Only strong central regulations with a vision to public health can improve the current system. The individual decision making that occurs between a physician and patient will need to be more controlled in the future, forcing healthcare providers to adhere more to guidelines, to quality controls, focusing on efficiency rather than expediency and profit. Mandates to produce and disclose information from physicians, perhaps patients, insurers, hospital networks will need to be coupled to tax incentives, price control, and anti-trust remedies.

The public will need to be educated on more realistic expectations of healthcare delivery. This will be the most difficult task. The ignorance that led to 200,000 excess deaths from failure to receive the coronavirus vaccine reflects the pervasive misinformation that exists in health care. Education will be difficult but must be incorporated to achieve the greater good.

At the time this book is being written, the worst of the COVID-19 pandemic has ended. As the COVID tide recedes, many problems in our healthcare system need to be addressed. Life expectancy in the United States has not changed in the last decade but has steadily increased in other high-income countries. Mortality in the United States is rising in middle-aged adults for a variety of reasons, including alcohol liver disease, suicide and homicide. Injury related mortality has also increased. Among adults aged 25-64, motor vehicle and pedestrian injuries have steadily increased. Marginalized racial populations, African American, Hispanic and Indigenous, experienced the largest increases in mortality rates. This trend appears to be uniquely American. See Woolf, S. Increasing Mortality Rates in the US, but Not from COVID-19. 2024; JAMA 332: 959-960.

Lawyers and physicians need to work together in the legislature, in the courts, in the health care system. They will need to help guide the policies to restructure healthcare around old and new legal frameworks. Redistributive policies will need to be developed focusing more on population health rather than the individual. This may be difficult for America where individual liberty will undoubtedly need to be weighed against a public good, and fundamental principles of property ownership will need to take heed to distributive economic justice to achieve universal healthcare access for the purpose of a healthier society. How law and medicine will achieve these goals through public policy, discourse and law

will be difficult. As you go through this text, the cases will help you consider the issues and lead you to a better position, with increased knowledge and spiritual emanations to assist in the process of transforming health care delivery.

CASE: FAMILY LEAVE AND MATERNAL MORTALITY IN THE UNITED STATES

Both maternal and infant mortality in the US is much higher than in other developed countries. A key factor appears to be that the US is one of the only countries with no national paid parental leave policy. There are numerous epidemiologic studies that show that paid maternity leave is associated with better outcomes for mothers and newborn infants. There is evidence that short duration maternity leave is linked to poorer physical and mental health during the post-partum period.

One study found that women who took paid parental leave of any duration were 51% less likely to be readmitted to the hospital in the 12 months after childbirth. (See Jou J et al. Matern Child Health J. 2018; 22: 216-225).

Post-partum depression leading to maternal suicide accounts for 20% of post-partum mortality. Multiple studies have shown that 8-12 weeks of paid maternity leave is associated with less depression, less suicide. (See Bhatia R. JAMA 2023; 330: 1387).

Additionally, many studies have shown a link between longer duration of paid leave, eg greater than 10-12 weeks, leading to better health outcomes long term for both mothers and children. These studies also show no economic adverse effects to employers after the implementation of paid leave. (Scott K, et al. JAMA 2023; 329: 1819-1820).

Considering that the preamble of the Constitution states that one of the purposes of our government is to "promote the general welfare", should the Federal Government pass legislation requiring employers to provide paid maternity leave? Or should it be let to the States (NY and California already have such paid maternity laws).

Who should pay for it?

If a bill is introduced to both the House and Senate, would it pass? Why or why not?

Could an agency action simply accomplish the task, eg. Health and Human Services? Occupational Safety and Health Administration? Could you think of arguments that the agencies could make? Consider the recent Supreme Court decision in Loper Bright v. Raimondo, 2024.

If challenged in Federal Court as unconstitutional, would it be upheld? If you were drafting the bill, where in the Constitution is Congress provided the authority to pass such legislation?

"The law should be a consideration of the ordering of the good promulgated by one who has the power"
—Thomas Aquinas, Summa Theologica, circa 1268

"a woman's right to an abortion is covered under the fundamental right to privacy and how each fundamental right is subject to strict scrutiny (regulation must be justified by a compelling state interest and legislation must be narrowly tailored to further the stated interest)."
—Roe v. Wade, Supreme Court of the United States, (1973)

Overturned and Replaced:

"The Constitution makes no express references to abortion. Further, Court precedent holds that a state regulation of abortion is not a sex-based classification (and so is not subject to heightened scrutiny)." Dobbs v. Jackson Women's Health, Supreme Court of the United States (2022)

Abortion, the destruction of the human fetus in utero, typically by the healthcare provider, is one of the most common procedures/treatments performed in the United States. Almost a million of these procedures occur annually in the United States. Abortion is a medical procedure based on science. The argument against abortion is only based on theology. Social scientists, public health officials, healthcare providers as proponents of abortion have shown that the availability of abortion leads, in general, to increased maternal health. The availability of abortion empowers women in multiple ways, including family planning, pursuing professional opportunities and even more enjoyment of sex as the fear of its consequences are less burdensome. Also, the availability of abortion leads to less unwanted pregnancies leading to less financial burden. There is also less likely for unwanted children from restrictions on abortion to develop into criminals. The personal benefits for most women have been well documented. Abortion espoused by the concept of family planning has led to a societal benefit.

However, there is another side of the issue that cannot simply be ignored. One cannot deny the fact that abortion is viewed by some people as homicide, the taking of a human life by another human. Is the fetus a human deserving rights? Rights above the mother's right to self-determination of their bodily integrity? Should the State or Public be allowed to control such choices? We should not ignore the fact that there is a balancing of two choices, both are not optimal. Yet, as a society, we must recognize the historic burden and control women have faced. We must see that the two choices, freedom to reproductive care vs. restriction on the individual woman to choose what is done with their bodies overwhelming begs the question: how can anyone think that the government should define the reproductive health of a woman? Do we want unproven theology trump reproductive rights of an individual woman? Our constitution defines a citizen in the 14th amendment as a person "born or naturalized", not a fetus. Yet, despite the lack of clarity how Jesus, Buddha, Mohammed, Moses, Vishnu, etc. would have felt about abortion, the "right to life" movement has been well motivated for the last 50 years using the sword of religion and the shield of state regulation. Conservatives followed the liberal's success in the Court through the 50s, 60s and 70s beginning with Chief Justice Warren, by focusing on "changing the court" to the current "Robert's Court". Given the current Supreme Court conservative majority, and the pressure of organizations supporting them such as the Federalist Society, conservative decisions, often not based on science and social welfare will likely continue to reverse prior liberal successes. The last few years have shown numerous SCOTUS decisions vacating scientific agency rules and regulations promoting public health from the Environment Protection Agency (EPA), Health and Human Services (HHS) and the Occupational Health and Safety Administration (OSHA). Law and Medicine will need to work together to address these problems through Congressional Action. A deeply divided government unfortunately could lead to a failure "to promote the general welfare."

In Roe v, Wade, USC 1973, SCOTUS balanced interests by recognizing that there was no correct answer to the abortion issue. The Court concluded that the interest of the human mother who had privacy rights should be protected from State interference. Beyond the right and wrong of abortion, the issue became that of a woman's right to bodily integrity until the fetus became viable at which time the State could regulate abortion (by the way, every state in the United States regulated abortion strictly after the 24-26 weeks despite the misinformation on right wing media suggesting people routinely aborted babies in the third trimester or during birth). 98 percent of all abortions occurred in the first trimester and later terminations were almost

uniformly to protect the health of the mother and/or due to severe fetal abnormalities, such as chromosome deletions and anencephalous (baby has no brain). Despite multiple SCOTUS decisions upholding Roe v Wade, SCOTUS reversed and in Dobbs v. Jackson's Women's Health, USC 2023, gave the states the ability to regulate a women's choice.

While abortion was once largely an invasive procedure performed by a obstetrician-gynecologist (OB-GYN), the procedure has been replaced in most cases using a more simple two pill regimen (mifepristone and misoprostol). This is referred to a medication abortion (MA). Currently, MA accounts for more than half of all abortions in the US, and this number is rising very fast after the Dobbs v. Jackson decision. Guess why?

According to the American College of Obstetrics and Gynecology (ACOG) which advises the FDA, the medication for MA is so safe that it can be provided by any physician with minimal training. The FDA has been granted power by Congress through the Food, Drug and Cosmetic Act (FDCA) to regulate the approval, safe production, distribution, and use of medications. SCOTUS has over the last century continuously ruled in favor of the FDA regarding decisions made based on the available science.

Since the Dobbs decision overturning Roe, OB-GYNs and other physicians who proscribe MA have been fearful whether they practice or do not practice in the 16 States that have limited abortion for multiple reasons. Worse, MA is under litigation:

Alliance for Hippocratic Medicine, et al. v. United States Food and Drug

United States District Court, N.D. Texas, Amarillo Division. April 7, 2023

Justice Kacsmaryk

"The Organizations seek relief on behalf of their members, many of whom are OB/Gyns or emergency-room doctors. Many women face severe complications as a result of taking mifepristone. The Doctors allege that they are harmed when they treat those kinds of patients. According to the Doctors, when they treat women who are experiencing complications after taking mifepristone, they are required to perform or complete an abortion, or otherwise required to participate in a process that facilitates abortion. They maintain that personally conducting those procedures violates their sincerely held moral beliefs.

The Doctors also contend that treatment of mifepristone patients diverts time and resources away from their ordinary patients, causes substantial mental and emotional distress, and exposes them to heightened malpractice risk and increased insurance costs. Seeking to prevent those alleged injuries, the Medical Organizations and Doctors moved for preliminary injunctive relief."

HOLDING

1. **associations sufficiently alleged that interests at stake were germane to associations' purpose, as would support associational standing under Article III;**

2. **alleged injuries of physicians and associations were fairly traceable to the challenged conduct, supporting finding that physicians and associations had standing under Article III;**

3. **physicians and associations were within zone of interests sought to be protected by Federal Food, Drug, and Cosmetic Act (FFDCA), supporting finding that physicians and associations had standing to seek judicial review under Administrative Procedure Act (APA) of alleged violation of FFDCA by FDA;**

4. **Comstock Act, prohibiting the mailing of every "article, instrument, substance, drug, medicine, or thing which is advertised or described in a manner calculated to lead another to use it or apply it for producing abortion," does not require intent on the part of the seller that the mailed item be used unlawfully;**

5. **physicians and associations had substantial likelihood of prevailing on claim that FDA exceeded its authority by approving mifepristone, a pharmaceutical that effected abortion, as a drug studied for treatment of "serious or life-threatening illnesses" pursuant to rule which permitted accelerated approval of certain drugs; and**

6. **appropriate relief was a stay.**

Alliance for Hippocratic Medicine, et al. v. United States Food and Drug Administration: US 5th Circuit, October 20, 2023

HOLDING

"After extensive briefing and oral argument, we hold that the district court's stay order should be VACATED in part and AFFIRMED in part. We conclude that the Medical Organizations and Doctors' claim as to the 2000 Approval is likely barred by the statute of limitations. Accordingly, that component of the district court's order must be VACATED. This means that, until final judgment, Mifeprex will remain available to the public under the conditions for use that existed in 2016. We also VACATE the portion of the order relating to the 2019 Generic Approval because the Medical Organizations and Doctors have not shown that they are injured by that particular action. The generic version of mifepristone will also be available under the same conditions as Mifeprex. We AFFIRM the components of the stay order that concern the 2016 Amendments and the 2021 Non-Enforcement Decision. Those agency actions—which generally *223 loosen the protections and regulations relating to the use of mifepristone—will be stayed during the pendency of this litigation. Finally, we note that our holding is subject to the prior order of the Supreme Court, which stayed the district court's order pending resolution of this appeal and disposition of any petition for writ of certiorari. Danco Lab'ys, LLC v. All. for Hippocratic Med., —— U.S. ——, 143 S. Ct. 1075, 215 L.Ed.2d 667 (2023)"

Fact: Until this Case, Federal Courts Have Never Interfered with an FDA Decision on a Drug (Chevron deference)

SUPREME COURT OF THE UNITED STATES

Syllabus

FOOD AND DRUG ADMINISTRATION ET AL. *v.*
ALLIANCE FOR HIPPOCRATIC MEDICINE ET AL.
CERTIORARI TO THE UNITED STATES COURT OF APPEALS FOR THE FIFTH CIRCUIT

KAVANAUGH, J., delivered the opinion for a unanimous Court.

No. 23–235. Argued March 26, 2024—Decided June 13, 2024*

In 2000, the Food and Drug Administration approved a new drug application for mifepristone tablets marketed under the brand name Mifeprex for use in terminating pregnancies up to seven weeks. To help ensure that Mifeprex would be used safely and effectively, FDA placed

additional restrictions on the drug's use and distribution, for example requiring doctors to prescribe or to supervise prescription of Mifeprex, and requiring patients to have three in-person visits with the doctor to receive the drug. In 2016, FDA relaxed some of these restrictions: deeming Mifeprex safe to terminate pregnancies up to 10 weeks; allowing healthcare providers, such as nurs practitioners, to prescribe Mifeprex; and approving a dosing regimen that required just one in-person visit to receive the drug. In 2019, FDA approved an application for generic mifepristone. In 2021, FDA announced that it would no longer enforce the initial in-person visit requirement. Four pro-life medical associations and several individual doctors moved for a preliminary injunction that would require FDA either to rescind approval of mifepristone or to rescind FDA's 2016 and 2021 regulatory actions. Danco Laboratories, which sponsors Mifeprex, intervened todefend FDA's actions.

The District Court (Opinion Above) agreed with the plaintiffs and in effect enjoined FDA's approval of mifepristone, thereby ordering mifepristone off the market. FDA and Danco appealed and moved to stay the District Court's order pending appeal. As relevant here, this Court ultimately stayed the District Court's order pending the disposition of proceedings in the Fifth Circuit and this Court. On the merits, the Fifth Circuit held that plaintiffs had standing. It concluded that plaintiffs were unlikely to succeed on their challenge to FDA's 2000 and 2019 drug approvals, but were likely to succeed in showing that FDA's 2016 and 2021 actions were unlawful. This Court granted certiorari with respect to the 2016 and 2021 FDA actions.

Held: Plaintiffs lack Article III standing to challenge FDA's actions regarding the regulation of mifepristone. Pp. 5–25.

(a) Article III standing is a "bedrock constitutional requirement that this Court has applied to all manner of important disputes." United States v. Texas, 599 U. S. 670, 675. Standing is "built on a single basic idea—the idea of separation of powers." Ibid. Article III confines the jurisdiction of federal courts to "Cases" and "Controversies." Federal courts do not operate as an open forum for citizens "to press general complaints about the way in which government goes about its business." Allen v. Wright, 468 U. S. 737, 760. To obtain a judicial determination of what the governing law is, a plaintiff must have a "personal stake" in the dispute.

TransUnion LLC v. Ramirez, 594 U. S. 413, 423.

To establish standing, a plaintiff must demonstrate (i) that she has suffered or likely will suffer an injury in fact, (ii) that the injury likely was caused or will be caused by the defendant, and (iii) that the injury likely would be redressed by the requested judicial relief. See Summers v. Earth Island Institute, 555 U. S. 488, 493. The two key questions in most standing disputes are injury in fact and causation.

By requiring the plaintiff to show an injury in fact, Article III standing screens out plaintiffs who might have only a general legal, moral, ideological, or policy objection to a particular government action.

Causation requires the plaintiff to establish that the plaintiff 's injury likely was caused or likely will be caused by the defendant's conduct. Causation is "ordinarily substantially more difficult to establish" when (as here) a plaintiff challenges the government's "unlawful regulation (or lack of regulation) of someone else." Lujan v. Defenders of Wildlife, 504 U. S. 555, 560–561. That is because unregulated parties often may have more difficulty linking their asserted injuries to the government's regulation (or lack of regulation) of someone else. Pp. 5–12.

(b) Plaintiffs are pro-life, oppose elective abortion, and have sincere legal, moral, ideological, and policy objections to mifepristone being prescribed and used by others. Because plaintiffs do not prescribe or use mifepristone, plaintiffs are unregulated parties who seek to challenge FDA's regulation of others. Plaintiffs advance several complicated causation theories to connect FDA's actions to the plaintiffs' alleged injuries in fact. None of these theories suffices to establish Article III standing. Pp. 13–24.

(1) Plaintiffs first contend that FDA's relaxed regulation of mifepristone may cause downstream conscience injuries to the individual doctors. Even assuming that FDA's 2016 and 2021 changes to mifepristone's conditions of use cause more pregnant women to require emergency abortions and that some women would likely seek treatment from these plaintiff doctors, the plaintiff doctors have not shown that they could be forced to participate in an abortion or provideabortion-related medical treatment over their conscience objections. Federal conscience laws definitively protect doctors from being required to perform abortions or

to provide other treatment that violates their consciences. Federal law protects doctors from repercussions when they have "refused" to participate in an abortion. §300a–7(c)(1). The plaintiffs have not identified any instances where a doctor was required, notwithstanding conscience objections, to perform an abortion or to provide other abortion-related treatment

that violated the doctor's conscience since mifepristone's 2000 approval. Further, the Emergency Medical Treatment and Labor Act (or EMTALA) neither overrides federal conscience laws nor requires individual emergency room doctors to participate in emergency abortions. Thus, there is a break in any chain of causation between FDA's relaxed regulation of mifepristone and any asserted conscience injuries to the doctors. Pp. 14–17. (2) Plaintiffs next assert they have standing because FDA's relaxed regulation of mifepristone may cause downstream economic injuries to the doctors. The doctors cite various monetary and related injuries that they will allegedly suffer as a result of FDA's actions—in particular, diverting resources and time from other patients to treat patients with mifepristone complications; increasing risk of liability suits from treating those patients; and potentially increasing insurance costs. But the causal link between FDA's regulatory actionsin 2016 and 2021 and those alleged injuries is too speculative, lacks support in the record, and is otherwise too attenuated to establish standing. Moreover, the law has never permitted doctors to challenge the government's loosening of general public safety requirements simply because more individuals might then show up at emergency rooms or in doctors' offices with follow-on injuries. Citizens and doctors who object to what the law allows others to do may always take their concerns to the Executive and Legislative Branches and seek greater regulatory or legislative restrictions. Pp. 18–21. (3) Plaintiff medical associations assert their own organizational standing. Under the Court's precedents, organizations may have standing "to sue on their own behalf for injuries they have sustained,"Havens Realty Corp. v. Coleman, 455 U. S. 363, 379, n. 19, but organizations must satisfy the usual standards for injury in fact, causation, and redressability that apply to individuals, id., at 378–379. According to the medical associations, FDA has "impaired" their "ability to provide services and achieve their organizational missions." Brief for Respondents 43. That argument does not work to demonstrate standing. Like an individual, an organization may not establish standing simply

based on the "intensity of the litigant's interest" or because of strong opposition to the government's conduct, Valley Forge Christian College v. Americans United for Separation of Church and State, Inc., 454 U. S. 464, 486. The plaintiff associations therefore cannot establish standing simply because they object to FDA's actions. The medical associations claim to have standing based on their incurring costs to oppose FDA's actions. They say that FDA

has "caused" the associations to conduct their own studies on mifepristone so that the associations can better inform their members and the public about mifepristone's risks. Brief for Respondents 43 . . .

78 F. 4th 210, reversed and remanded.

CASE: A MEDICAL RESIDENT'S INTRODUCTION TO THE COMPLEXITY OF HEALTHCARE DELIVERY

Dr. Tenner was a medical resident in 1992 working at The George Washington University Health Maintenance Organization (GW HMO). A resident is a physician who graduated by still a student in the sense that there is multiyear training before they can actually practice. As a matter of employment, Dr. Tenner was by The George Washington University Medical Center which participates in the Federally Funded CMS program for resident training. The University was accredited by the American Board of Internal Medicine, a requirement to receive funding from the Federal Government. Despite being employed by the Medical Center, for his clinical rotation in outpatient care, he spent Thursday afternoons seeing patients in The George Washington Health Maintenance Organization (GW HMO).

The HMO was one of many new Managed Care Organizations developed to provide care efficiently and at a lower cost. Dr. Tenner chose a special "Primary Care" path at the GW HMO due to interests in primary care, preventative medicine, and health care reform. Having received a Master of Public Health, Dr. Tenner believed in a future where physicians and policy makers could work together to control costs and provide outstanding care. In 1990, US Healthcare spending was only 666 billion dollars. Dr. Tenner would never have believed that spending would grow to over 4.5 trillion dollars in 2024.

After attending a "drug lunch" where a pharmaceutical company paid for the residents to eat, provided a speaker to the hospital to teach for an hour, and go over new medications available, Dr. Tenner crossed over to the

HMO clinic to see patients. He felt a bit uncomfortable listening to representatives from the pharmaceutical companies making "pitches" for medications, typically new and expensive. As the representatives fed the hungry physicians, provided pens, cheap antics, and toys with the names of the new drug, even sometimes offering tickets to sporting events, most physicians did not believe there was any influence on their prescribing habits. Do you?

Ron Widen was a 38-year-old attorney working for the Organization of American States a few blocks away from the HMO. Married with two children, Bobby age 7 and Anne age 4, Mr. Widen was relatively healthy. He had joined the HMO after seeing the advertisement promising "the best quality care and best that medicine can offer". That Spring Day in 1992, Mr. Widen came to see a physician at the HMO with complaints of frequent urination at night. He had a minor fever. No abdominal pain, weight loss. He was otherwise healthy. Not knowing which physician to see when calling for an appointment, he was assigned to see Dr. Tenner, a resident who was supervised by Dr. Roth. This is common practice if you did not know who you wanted to see and/or if you had Medicaid. Resident physicians were the doctors of choice for the ignorant and the poor (and this practice largely continues today, especially at academic centers). Dr. Roth was attending physician at the HMO, not an employee of the hospital. Dr. Roth was a dedicated teacher. Many supervisory physicians do not interact with the Resident Physicians regarding the care of patients. They are largely seeing other patients of their own and are available if needed for questions from the Residents. However, Dr. Roth was different. He discussed, but did not see, every patient with Dr. Tenner.

"Prostatitis is likely. I will send off a UA (urine analysis)" Dr. Tenner informed Dr. Roth. Dr. Roth said, "given the fever, start him on sulfamethoxazole-trimethoprim, Bactrim." "Dr. Roth, I was just at a conference, a drug lunch, and there is a new drug Cipro which works with only 10 days of treatment and no side effects" Dr. Tenner boasted. "Scott, Cipro cost 20 times what generic Bactrim costs. . . save the healthcare system some dollars!" "Dr. Tenner thought to himself that he would want the Cipro if he was in Mr. Widen's position.

Dr Tenner felt he should discuss the existence of Cipro but felt compelled by Dr. Roth not to bring it up. Yet, Dr. Tenner was troubled, he did not like the number of patients he kept seeing with allergic reactions from the sulfa component of Bactrim. These reactions were always simple rashes and itchy throats. But, he also knew about the feared severe allergic reactions that

some patients develop, Steven-Johnsons syndrome where a person's allergic reaction can lead to death as the skin sloughs off the body.

Dr. Tenner took time with his patient Ron Widen discussing the diagnosis, the treatment and follow-up. He never offered Mr. Widen the opportunity to take the more expensive Cipro. He felt a little guilty knowing that the drug was a costly blockbuster with no side effects. He knew the benefit of the savings did not go to Mr. Widen but to the GW HMO. Mr. Widen paid a constant monthly fee for his access to the HMO, to the medications. At that time Dr. Tenner believed that his actions in cost savings in practice could slow down healthcare expenditures, allowing for better care through overall system savings. He understood physician's decisions could affect the overall expenditure of resources in healthcare. If every physician used generic Bactrim rather than the newer Cipro, an extra billion dollars annually would be available to that could be used toward more effective care, including preventable services. Dr. Tenner was not aware that executives of the GW HMO hoped to develop enough profit to attract investors, maybe even "go public" as many insurance companies had done or planned in the future.

It was three days later when Dr. Tenner received a page from the clinic. "Mr. Widen called and has a rash all over his body" he was told by the nurse. Dr. Tenner became fearful, upset with himself that he had given the sulfa containing Bactrim generic and not the Cipro. Dr. Tenner knew to stop the drug, but should he see Mr. Widen? Dr. Tenner was on call that night at another hospital. Should he have Mr. Widen go to the emergency room to be seen? Should he give Benadryl with little side effects or prednisone, stronger for an allergic reaction but with more possible side effects. Dr. Tenner called Mr. Widen who informed him that the rash was associated with many "bubbles on his skin and sores in his mouth." Dr. Tenner trembled; he knew it was Stevens-Johnsons syndrome!

Dr. Tenner saw Mr. Widen every day after he was admitted to the Intensive Care Unit at The George Washington University Medical Center. He tried to comfort Mr. Widen who had become delirious. Dr. Tenner felt terrible seeing his wife and children who could see that some catastrophic event had occurred. Dr. Tenner swore never to use a sulfa drug again and never consider cost when proscribing a drug if it was safer and more effective. It was too late. The ICU Fellow told Dr. Tenner "he is going to die within a week, seen it before, a dirty death." Dr. Tenner held back tears. Having recently published a paper in the New England Journal of Medicine about the importance of discussing DNR (do not resuscitate) status, Dr. Tenner