
ISSUE BRIEF

Why Failure-to-Market Claims Are Preempted Under Federal Law

Richard A. Epstein and Benjamin Flowers

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Pacific Research Institute
PO Box 60485
Pasadena, CA 91116
Tel: 415-989-0833
www.pacificresearch.org

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EXECUTIVE SUMMARY

A California appellate court invented out of whole cloth a new and troubling theory of tort liability. Specifically, the court held that drug companies have a duty to develop and bring to market drugs that are supposedly safer and more effective than another, FDA-approved drug the company sells already. The claim rested on factual premises contradicted by all publicly available information, the acceptance of which could seriously disrupt the FDA approval process. This disruption gives rise to an issue the parties did not raise on appeal and that the appeals court never addressed, notwithstanding the complex, comprehensive statutes governing drug approval: these state tort law claims are preempted under theories of both field and conflict (including obstacle) preemption. This White Paper explains why it is imperative for the federal government and private parties to advance these preemption arguments, and why the courts should accept them.

THE WHITE PAPER

This short White Paper addresses preemption arguments relevant to what we call “failure to market” claims, which cover those cases in which plaintiffs allege that drug companies may be held liable for failing to bring to market, as quickly as possible, drugs that present (allegedly) fewer side effects than other, FDA-approved drugs already on the market.

Background

Right now, an alarming development is working its way through the California state court system—a development that could have major adverse consequences for the development of new drugs and vaccines that are now subject to extensive regulation by the FDA. This development threatens to put drug companies in a no-win situation, in which they can be held liable in tort for both the drugs they sell and for those they decline to bring to market. This additional hurdle adds cost to the drug-development process while, at the same time, giving drug companies one of two undesirable incentives: either seek approval prematurely or abandon a promising line of research altogether. That Hobson’s choice benefits no one.

By way of background, drugs and vaccines take an enormous time to develop. Risks lurk in designing and testing them in animal and human markets. Innovators often must pursue multiple layers of clinical trials, many of which fail to pan out despite exhaustive planning and development. Once new chemical entities (sometimes called “NCEs”) are properly isolated, proprietary companies must manufacture these new products in accordance with the highest production standards, and then supply full and accurate warnings—approved by the Food and Drug Administration—that are statutorily required before the drugs will be deemed fit for human use. The cycle is both extensive and exhaustive, and today many delays occur in the production and marketing of NCEs that deny vital care to millions of sick or diseased individuals.

One of the many complexities in this area relates to the tangled law of preemption. Preemption rules stem from the principle that federal law trumps state law—a principle rooted in the Constitution’s Supremacy Clause, which makes “the laws of the United States ... the supreme law of the land,” the “laws of any State to the contrary notwithstanding.”¹ Congress may expressly preempt state law. But it may also preempt state law implicitly. Implicit preemption comes in three forms, conflict, field, and frustration of federal purpose (sometimes called “obstacle” preemption). Conflict preemption arises when state law prohibits what federal law requires, or requires what federal law prohibits. Field preemption bars states from regulating conduct in a field that “Congress, acting within its proper authority, has determined must be regulated by its exclusive governance.”²

Obstacle preemption arises in “those instances where the ... state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”³ This letter elaborates later on the various circumstances indicative of Congress’s intent to trump state law.

Preemption principles apply to more than just statutory laws and administrative rules. They apply equally to the pursuit of tort remedies, including remedies for injuries allegedly caused by FDA-approved products. This White Paper provides an analysis that attorneys and the government might use to argue that these failure-to-market claims are preempted. Such claims are especially salient in light of the *Gilead Tenofovir* cases,⁴ where the decision of the Court of Appeals (now on appeal to the California Supreme Court) endorsed the view that drug companies may be held liable for negligently failing to bring a drug to market. That theory poses unique risks to the drug development system, undermining the FDA’s authority and the drug-regulation framework more broadly. In a word, the theory is preempted by federal law. This White Paper explains why.

One of these authors, Richard A. Epstein has drafted both an *amicus* brief in the case, and an academic critique attacking it, which are attached to this White Paper as an appendix.

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The Plaintiffs’ Theory As Accepted by the California Appellate Court

The distinctive feature of the *Gilead Tenofovir* decision is that it deemed it unnecessary for the plaintiff in a product-liability case to show that a challenged product was defective in either warning or design. The case recognized a duty to develop new chemical entities from scratch, on pain of a heavy damage award if a jury concludes that some new drug is both safer and more effective than some FDA-approved drug that the defendant firm sells already. At this point, it is uncertain whether the California Supreme Court will affirm the decision below, though we think that the trend of the California cases has been to be cautious to create new tort duties.⁵

Nonetheless, this White Paper is critical because any final decision in California is not likely to come down any time soon, and no matter what its outcome, the same problem can resurface in other states at any time. The theory should not be allowed to metastasize. For one thing, the record in the *Gilead Tenofovir* cases reveals that the factual predicate on which these cases rest is woefully deficient. The courts have thus far allowed a group (not a class action) of some 25,000 plaintiffs to bring claims for kidney and bone damage that was allegedly caused by the well-known drug TDF, which has been a runaway success on the market for antiretrovirals since it was first marketed in 2001. The probability that TDF users would suffer from either of these conditions is vanishingly small, affecting 0.002% (bone) and 0.11% (renal) of the user populations.⁶ It was stipulated that Gilead supplied adequate warnings to both conditions, so that the novel theory of liability at work in these cases was simply that Gilead did not take some asserted golden opportunity in the year 2004 to develop an alternative product, TAF, that the plaintiffs asserted was superior to TDF in all relevant respects on safety and effectiveness. The plaintiffs say it was highly foreseeable that the development of TAF would have denied Gilead its alleged monopoly profits on TDF, which they claimed could be obtained until TDF went off patent in 2015.

There are no such profits. Plaintiffs’ novel theory is contradicted by every known fact available on the public record. TAF was launched, in 2015. Both TDF and TAF have remained top performers on the market ever since, even after TDF obtained generic status in 2017. Both drugs are listed as first-level treatments and are considered by the FDA and the medical profession to be complements as well as substitutes. Both drugs are subject to spirited market competition from third parties. Neither drug has ever held a monopoly position, as this table indicates by showing how TDF variants like Truvada and Atripla have kept their robust sales after TDF went generic and after TAF drugs entered the market in 2017:

Table⁷

				U.S. Revenues (\$ millions)												
Manufacturer	Drug	TDF / TAF	Generic Entry	2012	2013	2014	2015	2016	2017	2018	2019	2020	2021	2022	2023	Total
Gilead	Viread	TDF	Dec-17	387	428	484	541	591	514	50	32	14	11	6	8	6,381
Gilead	Truvada	TDF	Oct-20	1,612	1,570	1,787	2,057	2,384	2,266	2,605	2,640	1,376	314	113	82	25,798
Gilead	Atripla	TDF	Oct-20	2,252	2,355	2,357	2,222	1,898	1,288	967	501	307	121			22,265
Gilead	Complera	TDF	n/a	280	503	663	796	821	406	276	160	89	102	74	47	4,255
Gilead	Stribild	TDF	n/a	57	509	1,014	1,476	1,523	811	505	268	125	132	88	72	6,580
Gilead	Vemlidy	TAF	n/a						111	245	309	356	384	429	410	2,244
Gilead	Descovy	TAF	n/a					226	958	1,217	1,078	1,526	1,397	1,631	1,771	9,804
Gilead	Biktarvy	TAF	n/a							1,144	4,225	6,095	7,049	8,510	9,692	36,715
Gilead	Genvoya	TAF	n/a				44	1,301	3,033	3,631	2,984	2,605	2,267	1,983	1,752	19,600
Gilead	Odefsey	TAF	n/a					302	964	1,242	1,180	1,172	1,076	1,058	1,012	8,006
Gilead	Total TDF	TDF	n/a	4,588	5,365	6,305	7,092	7,217	5,285	4,403	3,601	1,911	680	281	209	65,279
Gilead	Total TAF	TAF	n/a	0	0	0	44	1,829	5,066	7,479	9,776	11,754	12,173	13,611	14,637	76,369
Gilead	Grand Total	TDF & TAF	n/a	4,588	5,365	6,305	7,136	9,046	10,351	11,882	13,377	13,665	12,853	13,892	14,846	141,648

In addition, other major drug companies were marketing antiretrovirals that were in direct competition with the Gilead products. Gilead’s own decisions show that, when TAF was first launched in 2017, monopolization was far from its mind:

Gilead chose to price Genvoya and Odefsey [its new brands] slightly lower than Stribild and Complera [its older TDF variants] in the US to encourage switching onto the TAF-based regimens, which are under patent protection for the foreseeable future. Apart from generic competition, the company must also face threats from other brands, as its competitors, ViiV Healthcare, Janssen, and Merck & Co., are currently working on developing new HIV treatments to supplement their already strong portfolios.⁸

Nonetheless, against this unambiguous background, plaintiffs falsely claim that the defendant achieved an enviable position by a combination of fraud and “product hopping.” The former claim rested an unsupported allegation that, in 2004, the defendants fudged in public reporting of their disappointing data on the initial TAF tests solely to keep that drug off the market for another seven years, notwithstanding Gilead’s detailed public statement to the industry explaining how current test results at the time did not support further testing. With respect to product hopping, the Federal Trade Commission’s recent *Report on Pharmaceutical Product Hopping* recognizes that product hopping consists of behavior that is not possible between two distinct chemical entities, such as TDF and TAF:

Product hopping is a strategy where a brand-name pharmaceutical company seeks to shift demand from a brand-name drug that faces generic competition to a newly patented and/or exclusivity protected drugs that do not face generic competition. For example, a product hop can be executed by making modest non-therapeutic changes to a product that offer little or no apparent medical benefit to consumers and moving demand to that product.⁹

There is no legal or economic way that product hopping can be executed from one successful new chemical entity, TDF, to another, TAF. It is a threat to the structure of the industry to assume that such a strategy is even plausible.

The Federal Preemption of These Novel State Law Tort Claims

Thus far the preemption issues have not been addressed by any of the parties to the current litigation, which is going forward on the question whether California law recognizes a duty to bring drugs to market. But even if the California Supreme Court rejects this claim on this occasion, the possibility of destructive and diverse state tort regimes remains a systematic risk to the innovation of new drugs.

It has been a long-standing policy under the Food and Drug Act that all New Drug Applications—known as “NDAs”—must be approved before these drugs may be commercialized. It is, in other words, illegal to market a drug without FDA approval; companies may not market until the FDA says they can. At the outset of the approval process, the NDA collects all the relevant information about any new drug including all the animal and clinical trials. “The NDA process is designed to confirm:

- Whether the drug is safe and effective in its proposed use(s), and whether the benefits of the drug outweigh the risks.
- Whether the drug’s proposed labeling (package insert) is appropriate, and what it should contain.
- Whether the methods used in manufacturing the drug and the controls used to maintain the drug’s quality are adequate to preserve the drug’s identity, strength, quality, and purity.¹⁰

Even this brief summary shows the sharp division of responsibility in the drug approval process between the applicant and the FDA. All of the basic research is to be done by the private firm in accordance with its own judgment. The drug company may start or stop any research project at any time, wholly without the need for any FDA approval. It is only when the drug company files its NDA that the review processes of the FDA kick in, so that the NDA is evaluated solely on the strength of the evidence presented. There is nothing in the NDA approval process that lets the federal government ask, or even consider, the research choices made by the individual firm prior to its submission of its NDA. Given the highly regulated nature of the pharmaceutical licensing process, that should be considered a deliberate choice by Congress—a choice to leave drug companies free to decide whether, for any new drug, to pursue the NDA-approval process. There is no room for state law to pressure initiation of that process. The assertion by the California Court of Appeals in the *Gilead Tenofovir* cases that in some, allegedly narrow circumstances, a tort remedy may be injected into the law is not supported by a single syllable found in the basic legal analysis of the FDA or in any of the complex procedures used for initial or amended NDAs.

Under this basic structure, one essential feature of the FDA law is to erect a barrier around these preliminary investigations so that they cannot be undermined or compromised under any unprecedented state legislative or common law scheme. This point is true whether the issue is viewed through the lens of field preemption, conflicts, including obstacle preemption.

The basic framework on preemption was set out in *Rice v. Santa Fe Elevator Company*,¹¹ a 1947 case that had to decide whether a federal rate regulation scheme superseded an Illinois ratemaking scheme that had different features but was enacted with the same basic purpose. The canonical test, citations omitted, reads as follows:

Congress legislated here in [a] field which the States have traditionally occupied. So we start with the assumption that the historic police powers of the States were not to be superseded by the Federal Act unless that was the clear and manifest purpose of Congress. Such a purpose may be evidenced in several ways. *The scheme of federal regulation may be so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.* Or the Act of Congress may touch a field in which the federal interest is so dominant that the federal system will be assumed to preclude enforcement of state laws on the same subject. Likewise, the object sought to be obtained by the federal law and the character of obligations imposed by it may reveal the same purpose. Or the state policy may produce a result inconsistent with the objective of the federal statute. It is often a perplexing question whether Congress has precluded state action or by the choice of selective regulatory measures has left the police power of the States undisturbed except as the state and federal regulations collide.¹²

In Rice, the Court held that the federal scheme preempted the state scheme:

the special and peculiar history of the Warehouse Act indicates to us that such a construction [that is, one allowing state regulation] would thwart the federal policy which Congress adopted when it amended the Act in 1931. Prior to that time, as we have pointed out, the Federal Act by reason of its express terms had been subservient to state laws relating to warehouses and warehousemen. Congress in 1931 found that condition unfavorable and undertook to change it.¹³

Similar logic applies to failure-to-market claims. The case for preemption in these failure to market cases is even stronger because the federal government has been the dominant player in regulating the safety and effectiveness of drugs from the earliest times. That history is outlined in Peter Barton Hutt's article, *The Transformation of United States Food and Drug Law*,¹⁴ which traces development of federal regulation through the 1902 Biologics Control Act,¹⁵ to the Pure Food and Drug Act of 1906,¹⁶ to the Federal Food, Drug and Cosmetic Act of 1938,¹⁷ to the Kefauver-Harris Amendment of 1962.¹⁸ The common thread of all these provisions is that each imposed ever more comprehensive FDA coverage of every stage of the process of drug investigation and approval.

Field preemption. Put simply, the process of obtaining FDA approval is “so pervasive as to make reasonable the inference that Congress left no room for the States to supplement it.” There is no room for an additional ad hoc system, variable by state, that interferes with the uniform standard that is necessary to make sure that the process of drug development and approval, which often takes place across state lines, can be carried out in the manner federal law dictates. It is imperative that this process not be slowed down by the fear of state tort liability, which commentators warned against as soon as the ink was dried on the decision from the Court of Appeals.¹⁹ Paradoxically, one way drug innovation may be slowed is by rushing: companies may submit NDAs that they know are not yet ready simply to build a record that will help them resist liability on a failure-to-market claim. That defensive posture wastes the time of FDA officials without doing anything to promote consumer welfare. The delay of good drugs coming on the market is something that should not be tolerated, let alone encouraged, especially when the premise of these potential lawsuits rests on a wholly inaccurate account the underlying scientific economic forces that drove the successful drug development at Gilead.

Conflict (and obstacle) preemption. Now consider the problem through the lens of conflict preemption. Focus, in particular, on obstacle preemption—the flavor of conflict preemption applicable when “state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress.”²⁰

There is little doubt that failure-to-market claims would stand as an obstacle to the drug-approval process. That complex process is engineered to avoid two equal yet opposite errors: mistaken approvals of dangerous drugs (“Type 1” errors) and mistaken failure to approve safe drugs (“Type 2” errors). Both errors can be deadly; patients can die from either consumption of a dangerous product or their inability to obtain safe products. The drug-approval process is supposed to accommodate these competing concerns by requiring that companies prove safety, without requiring so much proof that drugs must be held off the market for too long. (In practice the FDA overprioritizes Type 1 errors, but that is not relevant for purposes of our analysis.)

Recognizing failure-to-market claims—claims potentially subject to 50 different standards in 50 different states—would inject another unwelcome variable into this carefully calibrated system. In addition to securing for the FDA the evidence needed to assess drug safety, drug companies would have to take additional steps to ensure that they cannot later be accused of moving too slowly in bringing drugs to market. That will, as noted above, slow the development drugs, leading to an increase in Type 2 errors, and interfering with the smooth functioning of the federal drug-approval process.

This result holds even after we take into account *Wyeth v. Levine*,²¹ in which a majority of the Supreme Court held that a failure-to-warn claim was not preempted. The decision is unsound, as one of us has publicly argued.²² At issue was the use of two methods for administering Phenergan, a drug for treating nausea. The drug had been on the market since 1955, with various warnings, which in all cases contemplated that the drug could “be administered intramuscularly or intravenously, and it can be administered intravenously through either the ‘IV-push’ method, whereby the drug is injected directly into a patient’s vein, or the ‘IV-drip’ method, whereby the drug is introduced into a saline solution in a hanging intravenous bag and slowly descends through a catheter inserted in a patient’s vein.”²³ It was widely understood that the IV drip was both less dangerous and less effective. And the drug’s warning advised about the relatively higher dangers of the IV-push method.

In the case of Ms. Levine, the *Wyeth* plaintiff, the IV-drip did not work to stop her pain. So, the treating physician and his assistant in the afternoon resorted to the IV-push. Notwithstanding warnings about the danger of administering the IV-Push method correctly, the doctor botched the process. As a result, the compound was injected into an artery, where the resulting gangrene required the amputation of first the Ms. Levine’s right hand and then her right forearm, a massive loss for a professional musician. The medical malpractice actions against the doctor and his assistant were open and shut, but after they settled out for a smallish sum, the offending doctor testified against the company. He urged that the warning was inadequate—that it should have warned not to administer the push method at all. This theory went to the jury, which ruled for the plaintiff. The Supreme Court found no preemption.

That judgment has to be wrong, as it permitted Wyeth to be punished under state law for doing what federal law expressly requires: namely, marketing the drug with the FDA-approved warning. That should have given rise to conflict and obstacle preemption.²⁴ The Court concluded otherwise based on the speculative possibility that Wyeth *might* have obtained a different label had it asked for one. The Court then determined that allowing such suits would not stand as an obstacle to Congress’s statutory purposes. It based that determination upon a general observation that common-law torts and FDA regulation had long served a complementary function but only in duty to warn cases. Had Congress meant to upset that complementary relationship, the Court claimed, it could

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have included an express preemption clause.²⁵ This logic fails to appreciate the balance that FDA warnings are designed to strike; a balance that recognizes the danger of overwarning. That point was put this way by researchers observing the phenomenon in the context of HIV treatments: “Community groups, researchers, and providers have been raising alarms that ads for lawsuits that perpetuate rare side effects caused by TDF/FTC may be hindering progress to disseminate PrEP in the communities most heavily impacted by HIV,”²⁶ such that the advertisements trolling for new clients reduced the effectiveness of safe drugs. *Wyeth* found no obstacle based on its failure to appreciate the dangers of overwarning and the FDA’s role in preventing it.

In any event, as noted, *Wyeth v. Levin* applies only to duty-to-warn cases. There is not the slightest hint that the Supreme Court would ever entertain some far broader claim that allows state tort actions to displace the development and approval process, as in the *Gilead Tenofovir* cases.

The Role of the Federal Government in this Litigation

Private attorneys can and should raise the foregoing arguments in response to failure-to-market claims. But the federal government, by legislation if necessary, should also act to address this matter. We think it advisable and prudent for the United States to intervene in all failure-to-market cases, including the *Gilead Tenofovir* cases if they are remanded to trial. At that point, the United States can explain to the courts the immense obstacle that failure-to-market claims pose to the orderly development of new safe, effective, and much needed drugs. In this regard, it is important to remember that when new drugs are not available in the market, desperate physicians and patients cannot conjure them up out of whole cloth. But allowing new drugs on the market does not guarantee either their financial or medical success because patients, physicians, hospitals, and independent reviewers may lead to their rejection or limited acceptance in the marketplace, based on a full analysis of the choice. But it is far better that these active *ex post* mechanisms make decentralized judgments on drug safety than it is to tolerate a legal regime in which the prospect of private tort actions, demanding billions of dollars, are a threat against medical progress.

Endnotes

- 1 U.S. Const., art. VI, cl.2.
- 2 *Arizona v. United States*, 567 U.S. 387, 399 (2012).
- 3 *Id.* (quotation omitted).
- 4 98 Cal. App. 5th 911(2024), review granted *sub nom Gilead Tenofovir Cases*, 546 P.3d 1114 (2024).
- 5 See the two leading California cases that refused to create novel torts duties: *Sheen v. Wells Fargo Bank*, 12 Cal. 5th 905 (2022) (refusing to recognize new judicial remedies for defaulting debtors in an area heavily regulated by state statutes); *Brown v. USA Taekwando*, 11 Cal. 5th 204 (2021) (holding that USA Taekwando, and not the United States Olympic Committee, had the requisite control over abusive coaches to be liable for failing to prevent their misdeeds because only the former had direct oversight and thus effective contemporaneous control over coaches.)
- 6 Petitioner’s Opening Brief on the Merits at 12, *Gilead Tenofovir Cases*, No. S283862 (Cal., July 15, 2024).
- 7 Available at <https://perma.cc/LLB8-ZSDR>.
- 8 *Gilead’s aggressive promotion of its TAF-based HIV portfolio already yielding results*, *GlobalData* (March 23, 2017), available at <https://perma.cc/NL9S-ZNJ8> (formatting altered)
- 9 Federal Trade Commission, *Report of Product Hopping* at 1 (Oct. 2022), available at <https://perma.cc/766E-4HHC>.
- 10 U.S. Food and Drug Administration, *New Drug Application (NDA)* (current as of Jan. 21, 2022), available at <https://tinyurl.com/FDA-NDA>.
- 11 331 U.S. 218 (1947).
- 12 *Id.* at 230–31 (citations omitted, emphasis added).
- 13 *Id.* at 232
- 14 J. Ass’n Food and Drug Officials, Sept.1996 at 1.
- 15 Public Law 57-244, 32 Stat. 728 (1902).
- 16 Public Law 59-384; 34 Stat. 768 (1906).
- 17 Pub. L. No. 75-717, 52 Stat. 1040 (1938).
- 18 Pub. L. No. 87-781; 76 Stat. 780 (1962).
- 19 George Priest, *California’s Negligence Tort Empowers Juries, Hurts Innovation*, *Bloomberg News* (Feb. 14, 2024), available at <https://tinyurl.com/Priest-Innovation>.
- 20 *Arizona*, 567 U.S. at 399 (quotation omitted).

- 21 555 U.S.555 (2009)
- 22 Richard A. Epstein, *What Tort Theory Tells Us About Federal Preemption: The Tragic Saga of Wyeth v. Levine*, 65 N.Y.U. Ann. Surv. Am. L. 485 (2010).
- 23 *Wyeth*, 555 U.S. at 559.
- 24 See *Armstrong v. Exceptional Child Ctr., Inc.*, 575 U.S. 320, 326 (2015).
- 25 *Wyeth*, 555 U.S. at 568–81.
- 26 Christian Grev et al, *Marketing of Tenofovir disoproxil fumarate (TDF) lawsuits and social media misinformation campaigns' impact on PrEP uptake among gender and sexual minority individuals at 6*, available at <https://perma.cc/4JA4-5N2U> (manuscript of article published at *AIDS Behav.* 2021 May; 25(6): 1396).

About the Authors

Richard A. Epstein

Laurence A Tisch Professor of Law, The New York University School of Law, Senior Fellow The Civitas Institute at the University of Texas Austin, and the James Parker Hall Distinguished Professor of Law Emeritus and Senior Lecturer at the University of Chicago.

Benjamin Flowers

Partner, Ashbrook Byrne Kresge Flowers LLC; former Solicitor General of Ohio (2019–22).

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MAILING ADDRESS

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Pasadena, CA 91116

Tel 415-989-0833

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Sacramento, CA 95816
Tel 916-389-9774

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