United States Court of Appeals
FOR THE EIGHTH CIRCUIT

No. 10-1326

Allen LeFaivre, Individually and on behalf of all others similarly situated,	*	
Appellant,	*	
	*	Appeal from the United States
v.	*	District Court for the
	*	Eastern District of Missouri.
KV Pharmaceutical Company; Ethex Corporation; Ther-Rx Corporation,	*	
Appellees.	*	

Submitted: September 21, 2010
Filed: January 19, 2011

Before BYE, BEAM, and SMITH, Circuit Judges.

SMITH, Circuit Judge.

Allen Lefaivre, individually and on behalf of all others similarly situated, brought this potential class action suit against KV Pharmaceutical Company, ETHEX Corporation, and Ther-Rx Corporation (collectively, "KV"). KV manufactures a hypertension medication called Metoprolol Succinate ER. Lefaivre alleged that KV breached its implied warranty of merchantability and violated the Missouri Merchantability Practices Act (MMPA) by failing to manufacture the medication in compliance with federal regulations. In response, KV moved to dismiss the suit, asserting that the claims were essentially claims for violation of federal regulations

themselves and that no private cause of action existed. The district court held that Lefaivre's state law claims were preempted by federal law because the claims were based entirely on violations of federal regulations, and the enforcement of federal regulations is solely the province of the federal government. We hold that Lefaivre's claims are not impliedly preempted and accordingly reverse and remand.

I. *Background*

KV manufactures Metoprolol Succinate ER in Missouri, and markets and distributes it throughout the United States. Lefaivre, a resident of Rhode Island, had a prescription for the medication and purchased it several times at retail pharmacies in Rhode Island.

On March 2, 2009, the Food and Drug Administration (FDA) filed a complaint against KV alleging that KV had not manufactured the medication in compliance with FDA standards under certain provisions of Chapter V of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. § 351(a)(2)(B). On March 6, 2009, the FDA and KV jointly filed a Consent Decree of Permanent Injunction ("Consent Decree") that settled the FDA's complaint with KV. In the Consent Decree, KV neither admitted nor denied the FDA's claims.

KV stipulated as part of the Consent Decree that it had sold drugs that were "adulterated" as defined by 21 U.S.C. § 351(a)(2)(B), meaning that the drugs were manufactured, processed, packed, labeled, held, and distributed in violation of the FDA's current good manufacturing practice (cGMP) requirements. KV acknowledged that it had not used proper quality control procedures when manufacturing the medication. It also stipulated that some of the medication sold to retail pharmacies had been misbranded in violation of federal regulations. KV agreed to destroy the remaining stock of "adulterated" drugs and issue a recall for all stocks of the medication sold to retailers between May 2008 and February 3, 2009. KV issued the recall notice "at the retail level." A retail-level recall instructs all retailers that had

purchased the medication to return all unsold product to KV. The Consent Decree did not require KV to distribute its recall notice to individual purchasers of the medication, and it did not do so.

Lefaivre filed suit against KV alleging (1) a breach of the implied warranty of merchantability and (2) violations of the MMPA. Specifically, Lefaivre alleged that the medication was "unmerchantable" because it was "not manufactured, marketed and/or distributed in compliance with cGMP and [was] accordingly adulterated as a matter of law." Lefaivre sought damages "in the amount of the difference between the values of the [medication] as warranted (their values if they were manufactured in full compliance with cGMP) and the values of the [medication] as actually received (adulterated)." With regard to the MMPA claim, Lefaivre alleged that KV "concealed, suppressed and omitted to disclose the material fact that the [medication was] adulterated under federal law in connection with its sale of the [medication] in trade or commerce in and from the State of Missouri." Lefaivre requested an award of actual damages and punitive damages under the MMPA.

KV moved to dismiss the suit, asserting that the claims were essentially claims for violation of federal regulations themselves and that no private cause of action existed. The district court held that Lefaivre's state law claims were preempted by federal law because the claims were based entirely on violations of federal regulations and the enforcement of federal regulations is solely the province of the federal government.

II. *Discussion*

On appeal, Lefaivre asserts that the district court's ruling leaves him and all other purchasers of the adulterated medication without a legal remedy for economic injuries. According to Lefaivre, the district court's determination that the FDCA impliedly preempts his state law causes of action is without legal support and contrary to *Wyeth v. Levine*, 129 S. Ct. 1187 (2009), in which the Supreme Court held that the

FDCA does not preempt state law claims against drug manufacturers for failure to adequately warn of potential hazards. Additionally, Lefaivre asserts that the district court erred in relying on the Supreme Court's decision in *Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), as support for its finding of preemption. Lefaivre distinguishes *Buckman* arguing it concerned "fraud-on-the-FDA" claims not present here.

In response, KV maintains that the district court simply applied a basic legal doctrine—that Lefaivre may not convert FDCA violations into private causes of action—to dismiss Lefaivre's claims. According to KV, the Supreme Court in *Wyeth* left this doctrine intact.

"The general law of preemption is grounded in the Constitution's command that federal law 'shall be the supreme Law of the Land.'" *In re Aurora Dairy Corp. Organic Milk Mktg. & Sales Practices Litig.*, 621 F.3d 781, 791 (8th Cir. 2010) (quoting U.S. Const. art. VI, cl. 2). As a result, any state law conflicting with federal law "has no effect." *Id*. (internal quotation and citations omitted). "Whether a particular federal statute preempts state law depends upon congressional purpose." *Id*. We "entertain two presumptions" when "interpreting the presence and scope of preemption." *Id*. at 792.

> First, Congress does not cavalierly pre-empt state-law causes of action. In all pre-emption cases, and particularly in those in which Congress has legislated in a field which the States have traditionally occupied, 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. Second, congressional purpose is the ultimate touchstone in every preemption case.

Id. (internal quotations, alterations, and citation omitted).

The express language of a statute or its structure and purpose may indicate Congress's preemptive intent. *Id*. "A state law is expressly preempted when a federal statute states the congressional intention to preempt state law by defining the scope of preemption." *Id*. Here, KV has not asserted, nor do we find any evidence of, "explicit pre-emptive language" in the FDCA to bar Lefaivre's present claims. *Id*. (internal quotation and citation omitted). Therefore, we need only consider whether Lefaivre's claims are impliedly preempted.

> Implied preemption exists where a federal statutory or regulatory scheme is so pervasive in scope that it occupies the field, leaving no room for state action—this is termed field preemption. Implied preemption also occurs where state law has not been completely displaced but is superseded to the extent that it conflicts with federal law—this is known as conflict preemption.

Id. (internal quotation and citation omitted). There are two types of conflict preemption—impossibility preemption and obstruction preemption. *See Wis. Pub. Intervenor v. Mortier*, 501 U.S. 597, 605 (1991). Impossibility preemption "arises when compliance with both federal and state regulations is a physical impossibility." *Id*. (internal quotation and citation omitted). "Impossibility pre-emption is a demanding defense." *Wyeth*, 129 S. Ct. at 1199. Obstruction preemption exists "when a state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Wis. Pub. Intervenor*, 501 U.S. at 605 (internal quotation and citation omitted).

In determining whether Lefaivre's claims are impliedly preempted, we must determine Congress's purpose and intent in enacting the FDCA. To determine Congress's intent, we "may consider the statute itself and any regulations enacted pursuant to the statute's authority." *Aurora*, 621 F.3d at 792. A tension exists "between the presumption against preemption and the possibility of implied preemption"; as a result, "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." *Id*. (internal quotation, alteration, and citation omitted).

Fortunately, the Court extensively discussed Congress's purpose with regard to drugs and drug labeling in *Wyeth*, stating:

> In 1906, Congress enacted its first significant public health law, the Federal Food and Drugs Act, ch. 3915, 34 Stat. 768. *The Act, which prohibited the manufacture or interstate shipment of adulterated or misbranded drugs, supplemented the protection for consumers already provided by state regulation and common-law liability*. In the 1930's, Congress became increasingly concerned about unsafe drugs and fraudulent marketing, and it enacted the Federal Food, Drug, and Cosmetic Act (FDCA), ch. 675, 52 Stat. 1040, as amended, 21 U.S.C. § 301 et seq. The Act's most substantial innovation was its provision for premarket approval of new drugs. It required every manufacturer to submit a new drug application, including reports of investigations and specimens of proposed labeling, to the FDA for review. Until its application became effective, a manufacturer was prohibited from distributing a drug. The FDA could reject an application if it determined that the drug was not safe for use as labeled, though if the agency failed to act, an application became effective 60 days after the filing. FDCA, § 505(c), 52 Stat. 1052.
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> As it enlarged the FDA's powers to "protect the public health" and "assure the safety, effectiveness, and reliability of drugs," [76 Stat.] 780, Congress took care to preserve state law. The 1962 amendments added a saving clause, indicating that a provision of state law would only be invalidated upon a "direct and positive conflict" with the FDCA. § 202, *id*., at 793. Consistent with that provision, state common-law suits "continued unabated despite . . . FDA regulation." *Riegel v. Medtronic, Inc*., 552 U.S.___,___, 128 S. Ct. 999, 1017, 169 L. Ed.2d 892 (2008) (GINSBURG, J., dissenting); *see ibid*., n. 11 (collecting state cases). *And*

when Congress enacted an express pre-emption provision for medical devices in 1976, see § 521, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)), it declined to enact such a provision for prescription drugs.

* * *

Building on its 1906 Act, Congress enacted the FDCA *to bolster consumer protection against harmful products. See Kordel v. United States*, 335 U.S. 345, 349, 69 S. Ct. 106, 93 L. Ed. 52 (1948); *United States v. Sullivan*, 332 U.S. 689, 696, 68 S. Ct. 331, 92 L. Ed. 297 (1948). *Congress did not provide a federal remedy for consumers harmed by unsafe or ineffective drugs in the 1938 statute or in any subsequent amendment. Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings.*

If Congress thought state-law suits posed an obstacle to its objectives, it surely would have enacted an express pre-emption provision at some point during the FDCA's 70-year history. But despite its 1976 enactment of an express pre-emption provision for medical devices, *see* § 521, 90 Stat. 574 (codified at 21 U.S.C. § 360k(a)), *Congress has not enacted such a provision for prescription drugs.* See *Riegel*, 552 U.S., at ___, 128 S. Ct., at 1009 ("Congress could have applied the pre-emption clause to the entire FDCA. It did not do so, but instead wrote a pre-emption clause that applies only to medical devices"). *Its silence on the issue, coupled with its certain awareness of the prevalence of state tort litigation, is powerful evidence that Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.* As Justice O'Connor explained in her opinion for a unanimous Court: "The case for federal pre-emption is particularly weak where Congress has indicated its awareness of the operation of state law in a field of federal interest, and has nonetheless decided to stand by both concepts and to tolerate whatever tension there [is] between them." *Bonito Boats, Inc. v. Thunder Craft Boats, Inc.*, 489 U.S. 141, 166–167, 109 S. Ct. 971, 103 L. Ed.2d 118 (1989) (internal quotation marks

omitted); *see also supra*, at 1194 (discussing the presumption against pre-emption).

* * *

In keeping with Congress' decision not to pre-empt common-law tort suits, it appears that *the FDA traditionally regarded state law as a complementary form of drug regulation*. The FDA has limited resources to monitor the 11,000 drugs on the market, and manufacturers have superior access to information about their drugs, especially in the postmarketing phase as new risks emerge. *State tort suits uncover unknown drug hazards and provide incentives for drug manufacturers to disclose safety risks promptly. They also serve a distinct compensatory function that may motivate injured persons to come forward with information*. Failure-to-warn actions, in particular, lend force to the FDCA's premise that manufacturers, not the FDA, bear primary responsibility for their drug labeling at all times. *Thus, the FDA long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation*.

129 S. Ct. at 1195–96; 1199–1200, 1202 (emphasis added) (footnotes omitted).

The Court's comments in *Wyeth* regarding drugs and drug labeling strongly imply that field preemption does not apply in the present case. Specifically, in relating the history of federal regulation of drugs and drug labeling, the Court recognized that when Congress first enacted the Federal Food and Drugs Act, Congress "supplemented the protection for consumers already provided by state regulation and common-law liability." *Id*. at 1195. Furthermore, when Congress enacted an express preemption provision for medical devices, it declined to do so for prescription drugs. *Id*. at 1196. Nor has Congress ever provided a federal remedy for consumers harmed by ineffective drugs. "Evidently, it determined that widely available state rights of action provided appropriate relief for injured consumers. It may also have recognized that state-law remedies further consumer protection by motivating manufacturers to produce safe and effective drugs and to give adequate warnings." *Id*. at 1199–1200.

Thus, we conclude the "federal statutory or regulatory scheme" in the present case is *not* "so pervasive in scope that it occupies the field." *Aurora*, 621 F.3d at 792 (internal quotation and citation omitted). To the contrary, "the FDA [has] traditionally regarded state law as a complementary form of drug regulation" and has "long maintained that state law offers an additional, and important, layer of consumer protection that complements FDA regulation." *Wyeth*, 129 S. Ct. at 1202 (footnote omitted).

Nor does conflict preemption—impossibility or obstacle—apply in the present case. First, it is not physically impossible for KV to comply with both federal and state law. *See Wis. Pub. Intervenor*, 501 U.S. at 605 (1991). In fact, Lefaivre's state law claims—breach of the implied warranty of merchantability and MMPA claims—admittedly rest on KV's admission in the Consent Decree that it had sold drugs that were "adulterated," as defined by 21 U.S.C. § 351(a)(2)(B), and had failed to manufacture, process, pack, label, hold, and distribute the drugs in compliance with the FDA's cGMP requirements. Second, Lefaivre's state law claims do not "stand[ ] as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress" because, as the Court explained in *Wyeth*, state law is complimentary to federal drug regulation and serves as an additional "layer of consumer protection." 129 S. Ct. at 1202.

Nevertheless, KV maintains that *Buckman* forecloses Lefaivre's state law claims. In *Buckman*, the plaintiffs claimed injuries arising from the use of orthopedic bone screws in their spines. 531 U.S. at 343. The defendant was a consulting company that assisted the screws' manufacturer in obtaining approval for the devices from the FDA. *Id*. The plaintiffs asserted that the consulting company "made fraudulent representations to the . . . FDA . . . in the course of obtaining approval to market the screws." *Id*. Additionally, they claimed that the fraudulent representations were a "but for cause" of their injuries. *Id*.

The Court held "that the plaintiffs' state-law fraud-on-the-FDA claims conflict[ed] with, and [were] therefore impliedly pre-empted by, federal law." *Id*. at 348. The Court applied the doctrine of field preemption, explaining that "*[p]olicing fraud against federal agencies* is hardly a *field* which the States have traditionally occupied, such as to warrant a presumption against finding federal pre-emption of a state-law cause of action." *Id*. at 347 (emphasis added) (internal quotation and internal citation omitted). Instead, the federal agency's relationship with the entity that it regulates "is inherently federal in character because the relationship originates from, is governed by, and terminates according to federal law." *Id*. According to the Court, the consulting company's "dealings with the FDA were prompted by the MDA [the Medical Device Amendments of 1976 (MDA)], and the very subject matter of [the consulting company's] statements were dictated by that statute's provisions." *Id*. at 347–48. Therefore, "in contrast to situations implicating federalism concerns and the historic primacy of state regulation of matters of health and safety," the Court concluded that "no presumption against pre-emption obtains in this case." *Id*. at 348 (internal quotation and internal citation omitted).

Thereafter, the Court explained that the "state-law fraud-on-the-FDA claims" conflicted with federal law because "the federal statutory scheme amply empowers the FDA to *punish and deter fraud against the Administration*, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives." *Id*. at 348 (emphasis added). According to the Court, these claims

> inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives. As a practical matter, complying with the FDA's detailed regulatory regime in the shadow of 50 States' tort regimes will dramatically increase the burdens facing potential applicants—burdens not contemplated by Congress in enacting the FDCA and the MDA. Would-be applicants may be discouraged from seeking § 510(k) approval of devices with potentially beneficial off-label uses for fear that such use might expose the manufacturer or its associates (such as petitioner) to unpredictable

> civil liability. In effect, then, fraud-on-the-FDA claims could cause the Administration's reporting requirements to deter off-label use despite the fact that the FDCA expressly disclaims any intent to directly regulate the practice of medicine, *see* 21 U.S.C. § 396 (1994 ed., Supp. V), and even though off-label use is generally accepted.

Id. at 350–51. Additionally, such claims would "cause applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court." *Id*. at 351. Furthermore, "Congress intended that the MDA be enforced exclusively by the Federal Government." *Id*. at 352 (citing 21 U.S.C. § 337(a)).

Finally, the Court rejected the plaintiffs'

> attempt to characterize both the claims at issue in *Medtronic[, Inc. v. Lohr*, 518 U.S. 470 (1996)] (common-law negligence action against the manufacturer of an allegedly defective pacemaker lead) and the fraud claims here as "claims arising from violations of FDCA requirements." Brief for Respondent 38. Notwithstanding the fact that *Medtronic* did not squarely address the question of implied pre-emption, it is clear that the *Medtronic* claims arose from the manufacturer's alleged failure to use reasonable care in the production of the product, not solely from the violation of FDCA requirements. *See* 518 U.S., at 481, 116 S. Ct. 2240. In the present case, however, the fraud claims exist solely by virtue of the FDCA disclosure requirements. Thus, although *Medtronic* can be read to allow certain state-law causes of actions that parallel federal safety requirements, it does not and cannot stand for the proposition that any violation of the FDCA will support a state-law claim.
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> In sum, were plaintiffs to maintain their fraud-on-the-agency claims here, they would not be relying on traditional state tort law which had predated the federal enactments in questions. On the contrary, the existence of these federal enactments is a critical element in their case. For the reasons stated above, we think this sort of litigation would exert an

> extraneous pull on the scheme established by Congress, and it is therefore pre-empted by that scheme.

Id. at 352–53.

Justice Stevens, joined by Justice Thomas, concurred in the judgment, explaining that

> [t]his would be a different case if, *prior to the instant litigation, the FDA had determined that petitioner had committed fraud during the § 510(k) process and had then taken the necessary steps to remove the harm-causing product from the market*. Under those circumstances, respondent's state-law fraud claim would not depend upon speculation as to the FDA's behavior in a counterfactual situation *but would be grounded in the agency's explicit actions. In such a case, a plaintiff would be able to establish causation without second-guessing the FDA's decisionmaking or overburdening its personnel*, thereby alleviating the Government's central concerns regarding fraud-on-the-agency claims.
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> *If the FDA determines both that fraud has occurred and that such fraud requires the removal of a product from the market, state damages remedies would not encroach upon, but rather would supplement and facilitate, the federal enforcement scheme. Cf. Medtronic, Inc. v. Lohr*, 518 U.S. 470, 495, 116 S. Ct. 2240, 135 L. Ed.2d 700 (1996) (holding that the presence of a state-law damages remedy for violations of FDA requirements does not impose an additional requirement upon medical device manufacturers but "merely provides another reason for manufacturers to comply with . . . federal law"); *id.*, at 513, 116 S. Ct. 2240 (O'CONNOR, J., concurring in part and dissenting in part) (same).

Id. at 354 (Stevens, J., concurring) (emphasis added).

The hypothetical scenario that Justice Stevens conceived of in *Buckman* is virtually identical to the present case. Here, the Consent Decree between the FDA and

KV established that KV had, in fact, manufactured "adulterated" medication in violation of cGMP requirements. In compliance with the Consent Decree, KV destroyed its remaining stock of "adulterated" drugs and issued a recall for all stocks of the medication sold to retailers. Thus, Lefaivre's state law claims are not "depend[ent] upon speculation as to the FDA's behavior" but instead are "grounded in the agency's explicit actions. In such a case, [Lefaivre] would be able to establish causation without second-guessing the FDA's decisionmaking or overburdening its personnel . . . ." *Id*. (Stevens, J., concurring).

Furthermore, the present case is distinguishable from *Buckman* because Lefaivre's state-law claims are not fraud-on-the-FDA claims, as they "focus on [harm] that is allegedly perpetrated against [consumers] rather than the FDA." *Couick v. Wyeth, Inc.*, No. 3:09-cv-210-RJC-DSC, 2009 WL 4644394, at *5 (W.D.N.C. Dec. 7, 2009) (unpublished) (holding that *Buckman* did not apply to plaintiff's state-law claims, including claims for unfair trade practices and breach of warranties); *see also Fulgenzi v. Wyeth, Inc.*, 686 F. Supp. 2d 715, 724 (N.D. Ohio 2010) (holding that *Buckman* did not apply to plaintiff's "multiple state law tort claims, including several claims sounding in fraud"). "The misrepresentation at issue in *Buckman* was not made to the plaintiff—or consumers at large—but to the FDA itself." *In re Bayer Corp. Combination Aspirin Prod. Mktg. & Sales Practices Litig.*,701 F. Supp. 2d 356, 369 (E.D.N.Y. 2010). And, "simply because conduct violates the FDCA does not mean a state-law claim based on that same conduct depends on the FDCA's existence." *Couick*, 2009 WL 4644394, at *5.

The Court in *Buckman* specifically applied field preemption to state-law fraud-on-the-FDA claims because policing fraud against federal agencies "is hardly a field which the States have traditionally occupied." *Buckman*, 531 U.S. at 347 (internal quotation and internal citation omitted). The present case involves no such claims, and, as explained *supra*, implied preemption does not bar Lefaivre's state law claims.

III. *Conclusion*

Accordingly, we reverse the judgment of the district court and remand for further proceedings consistent with this opinion.
