FOR PUBLICATION

UNITED STATES COURT OF APPEALS
FOR THE NINTH CIRCUIT

NEXUS PHARMACEUTICALS, INC., *Plaintiff-Appellant*, v. CENTRAL ADMIXTURE PHARMACY SERVICES, INC.; B. BRAUN HOLDING GMBH & CO. KG, *Defendants-Appellees.*	No. 20-56227 D.C. No. 8:20-cv-01506-CJC-JDE OPINION

Appeal from the United States District Court
for the Central District of California
Cormac J. Carney, District Judge, Presiding

Argued and Submitted October 18, 2021
Pasadena, California

Filed September 13. 2022

Before: Andrew J. Kleinfeld, Ryan D. Nelson, and Lawrence VanDyke, Circuit Judges.

Opinion by Judge Kleinfeld

SUMMARY*

Food, Drug, and Cosmetic Act / Preemption

The panel affirmed the district court's dismissal, for failure to state a claim, of state law claims brought by Nexus Pharmaceuticals, Inc., against Central Admixture Pharmacy Services, Inc., operator of a network of compounding pharmacies that sold the drug ephedrine sulfate pre-loaded into ready-to-use syringes without FDA approval.

Nexus developed the trademarked and FDA-approved drug Emerphed, ready-to-use ephedrine sulfate in a vial. Drug compounding by "outsourcing facilities" is permitted without FDA approval, but 21 U.S.C. § 353b, a part of the Food, Drug, and Cosmetic Act, excludes from this exception compounded drugs that are "essentially a copy of one or more approved drugs." To avoid the Act's bar on private enforcement, Nexus alleged violation of state laws that prohibit the sale of drugs not approved by the FDA.

The panel affirmed the district court's conclusion that, under the implied preemption doctrine, Nexus's state law claims were barred because they were contrary to the Food, Drug, and Cosmetic Act's exclusive enforcement provision, which states that proceedings to enforce or restrain violations of the Act, including the compounding statute, must be by and in the name of the United States, not a private party. The panel held that all of Nexus's claims depended on a determination of whether Central Admixture's ephedrine

* This summary constitutes no part of the opinion of the court. It has been prepared by court staff for the convenience of the reader.

sulphate was "essentially a copy" of Nexus's Emerphed, and the plain text of the Food, Drug, and Cosmetic Act left that determination in the first instance to the FDA and its enforcement process.

COUNSEL

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OPINION

KLEINFELD, Circuit Judge:

We address preemption, in the context of pharmaceutical compounding and the FDA's exclusive authority to enforce violations of the Food, Drug, and Cosmetic Act, and affirm the order of the district court.

BACKGROUND

The district court dismissed Nexus's claim for failure to state a claim upon which relief can be granted, under Federal Rule of Civil Procedure 12(b)(6). Accordingly, we take the

facts from the First Amended Complaint and assume for purposes of this decision that they would be proved.[1]

Ephedrine sulfate is a drug used to raise blood pressure immediately if an anesthetized surgical patient's blood pressure falls to a dangerously low level. Until 2020, the only version of the drug approved by the Food and Drug Administration ("FDA") was a concentrate, 50 milligrams per milliliter. It had to be diluted down to 5 milligrams per milliliter before administering it to a patient. Nexus Pharmaceuticals's ("Nexus") innovation, a trademarked and FDA-approved drug, is called Emerphed. Emerphed is ready-to-use ephedrine sulfate, provided by Nexus in a 5 milligram per milliliter vial. Emerphed eliminates the need for dilution at the hospital, with the attendant risks of delay and error.

The defendant, Central Admixture Pharmacy Services ("Central Admixture"), operates a network of compounding pharmacies. Central Admixture sells ephedrine sulfate pre-loaded into ready-to-use syringes. Nexus successfully obtained FDA approval for its drug, Emerphed. Central Admixture did not, because compounding pharmacies do not need FDA approval as a manufacturer of a new drug does. Pharmacists and some physicians have long combined,

[1] *Weston Fam. P'ship LLLP v. Twitter, Inc.*, 29 F.4th 611, 617 (9th Cir. 2022). The district court also considered a declaration from an FDA official after taking judicial notice of it as a document reflecting official acts of governmental agencies. Before us, Nexus challenges the district court's taking judicial notice of this declaration. Because Nexus did not object to the motion for judicial notice before the district court, the objection was waived. *See Marbled Murrelet v. Babbitt*, 83 F.3d 1060, 1066 (9th Cir. 1996). Accordingly, the declaration was properly considered at the motion to dismiss stage. *See Plaskett v. Wormuth*, 18 F.4th 1072, 1083 (9th Cir. 2021).

mixed, and altered ingredients in medicines to tailor them to individual patients—a practice known as compounding. For instance, patients allergic to something in the mass-produced, FDA-approved product may need an allergen-free version; patients unable to swallow pills may need a liquid form of the medicine; and children who refuse to take medications because of the taste may need a differently-flavored medicine. Congress does not subject compounded drugs to an approval process it uses for new drugs because valid compounding has traditionally been seen as an appropriate means of customizing existing drugs to the needs of individual patients.

For decades, Congress left regulation of compounding to the states because compounding was ordinarily done on a small scale by pharmacists and physicians, who were licensed and regulated by state governments.[2] Compounding expanded, though, and eventually, the FDA grew concerned that some pharmacies were turning into manufacturers of new drugs without going through the FDA-approval process for manufacturing.[3] The FDA issued a "Compliance Policy Guide" to clarify the line between compounding and manufacturing a new drug.[4]

Congress responded to this concern by promulgating the Food and Drug Administration Modernization Act of 1997,[5]

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[2] *See Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 362 (2002).

[3] *Id.* at 362–63.

[4] *Id.*

[5] Pub. L. No. 105-115, 111 Stat. 2296 (1997) (amended 2013).

codifying into law parts of the FDA's policy.[6] The new law permitted compounding but sought to prohibit unregulated large-scale drug manufacturing masquerading as compounding,[7] a difficult distinction to codify.

A drug catastrophe in 2012—a mass outbreak of deadly meningitis caused by contaminated compounded drugs—inspired Congress to pass the Drug Quality and Security Act of 2013,[8] which included the compounding provision before us in this case.[9] The exemption from the new drug approval process for compounded drugs remained, but the Act created a registration scheme for "outsourcing facilities."[10]

These "outsourcing facilities" are permitted to compound on a large scale and without a patient-specific prescription.[11] The new statutory criteria focus largely upon registration with the FDA, yearly reporting, and regular inspection.[12] Of course this might seem, if unchecked, to be a license for

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[6] *Thompson*, 535 U.S. at 364.

[7] *See* 21 U.S.C. § 353a.

[8] Pub. L. No. 113-54 (2013).

[9] FDA, Human Drug Compounding Progress Report 4, 7 (Jan. 2017), https://www.fda.gov/media/102493/download; *see also* Logan J. Eliason, *The Drug Quality and Security Act: Providing Quality, but Not Security, for Patients*, 103 IOWA L. REV. 1245, 1254–56 (2018).

[10] *See* 21 U.S.C. §§ 353a(a), 353b(a).

[11] *See* § 353b(a).

[12] *See* § 353b(b).

wholesale copying of FDA-approved drugs, at least after patent protection expires, without the statutory safeguards for generic drugs.[13] But it is not meant to be a new route for generics. The new scheme addresses the risk of creating an accidental new avenue for generics by creating an exclusion to the exception from FDA approval of compounded drugs that are "essentially a copy of one or more approved drugs."[14] Nexus argues that Central Admixture's ready-to-use ephedrine sulfate is "essentially a copy" of its Emerphed, so it is excluded from the exception from the requirement of FDA approval for "outsourcing facilities."

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[13] So-called "generic drugs," those drugs that are designed to copy a reference drug already approved by the FDA, *PLIVA, Inc. v. Mensing*, 564 U.S. 604, 612 n.2 (2011), go through an "abbreviated new drug application." *See* § 355(j).

[14] § 353b(a)(5). The statute defines "essentially a copy" as

> (A) a drug that is identical or nearly identical to an approved drug, or a marketed drug not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless, in the case of an approved drug, the drug appears on the drug shortage list in effect under section 506E at the time of compounding, distribution, and dispensing; or
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> (B) a drug, a component of which is a bulk drug substance that is a component of an approved drug or a marketed drug that is not subject to section 503(b) and not subject to approval in an application submitted under section 505, unless there is a change that produces for an individual patient a clinical difference, as determined by the prescribing practitioner, between the compounded drug and the comparable approved drug.

§ 353b(d)(2).

The FDA, in a "Guidance for Industry" publication, discusses the rationale for preventing compounders from copying. The FDA explains that the "essentially a copy" prohibition "protects the integrity and effectiveness of the new drug . . . approval process."[15] The Guidance points out that "[s]ponsors would be less likely to invest in and seek approval of innovative lifesaving medications if outsourcing facilities could compound copies that would be cheaper because they had not gone through the [FDA] approval process."[16] Focusing on copying allows desirable compounding, adapting drugs to patients who need something a little different from the FDA-approved version, while ensuring that new drugs go through the FDA's rigorous safety and efficacy testing.

Nexus does not base its claim on Central Admixture's alleged violation of section 353b, no doubt because the statute is part of the Federal Food, Drug, and Cosmetic Act ("FDCA"). This Act includes a prohibition on private enforcement: all proceedings to enforce or restrain violations of the FDCA must be "by and in the name of the United States," except for certain proceedings by state governments.[17]

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[15] FDA, *Compounded Drug Products That Are Essentially Copies of Approved Drug Products Under Section 503B of the Federal Food, Drug, and Cosmetic Act*, at 4 (Jan. 2018) [FDA Guidance]. This guidance "does not establish legally enforceable responsibilities." *Id.* at 1.

[16] *Id.* at 4.

[17] § 337(a); *see also Perez v. Nidek Co., Ltd.*, 711 F.3d 1109, 1119 (9th Cir. 2013).

To avoid that bar, Nexus's First Amended Complaint, the one before us, avers that Central Admixture is violating the laws of several states in which it sells Emerphed, all of which "prohibit the sale of drugs not approved by the FDA." The theory of the complaint involves a series of steps:

> (1) Nexus's Emerphed product is the only FDA-approved ready-to-use ephedrine sulfate product on the market in the United States;
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> (2) Central Admixture's ready-to-use ephedrine sulfate has neither independent FDA approval nor does it fall within the exception to the approval requirement for compounding, because it is "essentially a copy" of Nexus's drug;
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> (3) California, Florida, Connecticut, Pennsylvania, and Arizona prohibit the sale of drugs not approved by the FDA;
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> (4) Central Admixture is violating those states' laws and harming Nexus by illegally copying their FDA-approved drug.

Nexus seeks an injunction, declaratory relief, and damages. Nexus does not allege any claim that does not rest upon a violation of the FDCA.

The district court dismissed the claim under Rule 12(b)(6) for failure to state a claim upon which relief could be granted. It held that because Nexus's claims "exist only because of the FDCA's requirements," they are preempted under our

decision in *Perez v. Nidek*.[18] The district court noted that private enforcement of the FDCA is prohibited by express statutory language, and the district court adverted to a declaration by the FDA's Acting Director of the Division of Compounded Drugs saying that the FDA had taken no enforcement action as yet based on the "essentially a copy" exclusion in situations where outsourcing facilities "compound drug products using FDA-approved drug products—rather than bulk drug substances—as a starting point," pending an "upcoming revision to its guidance for outsourcing facilities." The district court cited this as further reason why the determination of whether Central Admixture's product was "essentially a copy" "must be left to the FDA."

ANALYSIS

This is our first occasion to interpret section 353b. Because we agree with the district court that Nexus's claims are barred, we do not reach the question of whether Central Admixture's ephedrine sulfate is "essentially a copy" of Nexus's Emerphed.

The district court and the briefs evaluate this case under "implied preemption." Preemption is an application of the Supremacy Clause:

> This Constitution, and the Laws of the United States which shall be made in Pursuance thereof; and all Treaties made, or which shall be made, under the Authority of the United States, shall be the supreme Law of the Land;

[18] 711 F.3d at 1111.

> and the Judges in every State shall be bound thereby, any Thing in the Constitution or Laws of any State to the Contrary notwithstanding.[19]

The Supremacy Clause is the source of preemption doctrine, which invalidates state laws that are contrary to federal statutes.[20]

Deciding just when a state law is "contrary" to a federal law is often difficult and important, with serious implications for federalism.[21] The difficulty has grown as Congress has promulgated more laws regulating conduct formerly regulated only by the states. As one treatise puts it, "there is no simplistic constitutional test that will predict the results in all the cases" and "there is an *adhoc* [sic] sense to many of the cases."[22] The Supreme Court agrees that no "rigid formula" is *a priori* determinative.[23] Though *Pennsylvania v. Nelson* enunciated a purported three-pronged inquiry,[24] that test does not clearly sort out the cases.

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[19] U.S. CONST. art. VI, cl. 2.

[20] *See Hillsborough Cnty. v. Automated Med. Lab'ys., Inc.*, 471 U.S. 707, 712 (1985) (citing *Gibbons v. Ogden*, 22 U.S. (9 Wheat.) 1, 211 (1824) (Marshall, C.J.)).

[21] *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 485 (1996).

[22] 2 R. ROTUNDA & J. NOWAK, CONSTITUTIONAL LAW § 12.1, p. 302 (5th ed. 2012).

[23] *Hines v. Davidowitz*, 312 U.S. 52, 67 (1941).

[24] *Pennsylvania v. Nelson*, 350 U.S. 497, 502–06 (1956).

The notion that preemption may be "implied" at all seems oxymoronic, in light of the well-established rule that a "clear expression" of congressional intent is required to overcome the "presumption" against implied preemption.[25] We have been instructed to "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."[26]

Several controlling cases address the statute governing FDA approval of medical devices, not drugs. These cases are easily distinguishable because the medical device statute has an express preemption clause that prohibits states from imposing any "safety or effectiveness" requirement which "is different from, or in addition to" those imposed by federal law.[27] Some of these medical device decisions nevertheless speak to implied preemption rather than merely construing the express preemption clause.

In *Medtronic v. Lohr*, an injured patient (pacemaker failure) sued the manufacturer of the pacemaker on a common-law negligence theory.[28] The Court interpreted the statutory preemption clause for medical devices and held that the statute did not bar the claims on behalf of an injured patient.[29]

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[25] *See Wyeth v. Levine*, 555 U.S. 555, 565 (2009).

[26] *Id.* (quoting *Lohr*, 518 U.S. at 485).

[27] 21 U.S.C. § 360k(a).

[28] *Lohr*, 518 U.S. at 474.

[29] *Id.* at 484–86, 503.

But *Buckman v. Plaintiffs' Legal Committee* held that another injured patient's fraud-on-the-FDA claim (defective bone screws) against a consulting company that helped the manufacturer obtain FDA approval for the device was impliedly preempted (rather than expressly preempted).[30] The Court explained that because "[p]olicing fraud against federal agencies is hardly 'a field which the States have traditionally occupied,'" the presumption against preemption did not apply.[31] The Court determined that "the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration" and that the "delicate balance of statutory objectives . . . can be skewed by allowing fraud-on-the-FDA claims under state tort law."[32] Instead of holding that the express preemption clause applied, the Court held that the state law claims were "impliedly preempted" because allowing the claims to go forward would "exert an extraneous pull on the scheme established by Congress."[33] *Buckman* distinguished *Lohr* because in *Buckman* "the fraud claims exist[ed] solely by virtue of" the FDCA and not on traditional state tort law fraud predating the federal statute.[34] Likewise, in the case before us, Nexus relies on a state statute which itself relies on the federal statute, not traditional state tort law theory.

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[30] *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 353 (2001).

[31] *Id.* at 347–48 (quoting *Rice v. Santa Fe Elevator Corp.*, 331 U.S. 218, 230 (1947)).

[32] *Id.* at 341, 348.

[33] *Id.* at 353.

[34] *Id.*

Riegel v. Medtronic held that an injured patient (defective balloon catheters) could not sue under state tort law, because state law in that case "require[d] a manufacturer's [devices] to be safer, but hence less effective," than the balance chosen by the FDA, and that would be disruptive of the federal scheme.[35] Unlike *Buckman*, *Riegel* analyzed the case in terms of the express statutory preemption, asking whether the state law requirement would be "different from, or in addition to," the federal requirements.[36] *Riegel* never mentions "implied" preemption, but the "implied" preemption analysis set out in *Buckman* was not repudiated.

While all three cases just discussed were subject to the express preemption provision for medical devices, and thus distinguishable from the case at hand, they have an additional and relevant feature that is distinguishable from our case. The claims not preempted were made by patients injured by defective medical devices, who pleaded traditional common law tort claims against the manufacturers of the medical devices. The claims allowed to go forward did not rely on noncompliance with FDA requirements, as Nexus's does, but rather on traditional tort law duties. *Buckman* and *Riegel* also teach that, despite the presumption against implied preemption and the requirement of a clear expression from Congress to preempt state law, there is nevertheless a live doctrine of "implied" preemption.

Wyeth v. Levine addressed preemption in the context of prescription drugs, not medical devices, so as in the case

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[35] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 325 (2008).

[36] *Id.* at 323–30.

before us, no applicable express preemption clause applied.[37] Levine, an injured patient, brought a state law failure-to-warn tort claim against Wyeth, the drug's manufacturer.[38] Levine's arm had to be amputated because the attending physician's assistant did not comply with the warning label on the anti-nausea drug he administered.[39] Levine claimed that the warning should have been stronger.[40] Her preemption problem was that the FDA regulated the warning language and required the manufacturer to use the precise language used on the label.[41] Thus, her claim that state negligence law required a stronger warning would, on its face, require violation of federal law.[42]

Nevertheless, *Wyeth* holds that the state law tort claims at issue were not preempted. Wyeth argued that Levine's state law claims were preempted because it was impossible for Wyeth to comply with both federal law (give the FDA-approved warning) and state law (give a stronger warning), and allowing the state law tort action would create an "obstacle to the accomplishment and execution of the full purpose and objectives of Congress."[43] The Court rejected

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[37] *Wyeth*, 555 U.S. at 558–59, 567.

[38] *Id.* at 558.

[39] *Id.* at 559.

[40] *Id.* at 559–60.

[41] *Id.* at 562.

[42] *Id.* at 561–62.

[43] *Id.* at 563–64 (quoting *Hines*, 312 U.S. at 67).

the impossibility argument, even though the drug manufacturer had done precisely what the FDA told it to do, because Wyeth could have asked the FDA to approve a stronger warning.[44] The Court also rejected the obstacle argument, reasoning that because there was no express preemption clause, Congress must have intended that injured consumers would seek a remedy through state tort law, and tort suits would contribute to drug safety.[45] Thus, tort law would aid the FDA's enforcement ability rather than be an obstacle. The Court also noted that the last time Congress had amended the FDCA with regard to drugs, it had included a savings clause,[46] saying that nothing in that amendment "shall be construed as invalidating any provision of State law which would be valid in the absence of such amendments unless there is a direct and positive conflict between such amendments and such provision of State law."[47]

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[44] *Id.* at 570; *cf. id.* at 613–621 (Alito, J., dissenting) (describing the process Wyeth undertook to get the drug's label approved by the FDA).

[45] *Id.* at 574–75.

[46] *Id.* at 567.

[47] Pub. L. 87-781, § 202, 76 Stat. 780, 793 (1962); *but see Wyeth*, 555 U.S. at 612 n.4 (Alito, J., dissenting) (the Amendment only recognized background principles of conflict preemption). The FDCA does not, however, have a general savings clause, as opposed to this savings clause for this amendment. *Wyeth*, 555 U.S. at 612 (Alito, J., dissenting). And in any event, a savings clause "does *not* bar the ordinary working of conflict pre-emption principles." *Grier v. Am. Honda Motor Co., Inc.*, 529 U.S. 861, 869 (2000).

Though some commentators have been critical of *Wyeth*,[48] and subsequent decisions have applied it narrowly,[49] it has not been overruled. It is distinguishable, though, from the case at hand. *Wyeth* involved a claim based on traditional tort law made by an injured patient against a drug manufacturer. Our case, by contrast, is based on state laws that incorporate federal law, rather than on traditional tort law. Because Levine did not allege a violation of the FDCA, no issue arose in *Wyeth* regarding the FDA's exclusive enforcement authority. In the case before us, by contrast, a necessary element of Nexus's claim is the alleged violation of the FDCA. Unlike *Wyeth*, no injured patient in our case asserts a traditional state law tort.

The statutory prohibition on private enforcement gives the FDA discretion to temper enforcement or not to enforce in circumstances it deems appropriate. If state law facilitates enforcement beyond what the FDA has deemed appropriate, then state law claims may indeed "stand as an obstacle" to FDA's enforcement discretion by enabling what the FDA regards as over-enforcement.

We have been protective of the FDA's statutory monopoly on enforcement authority. In *PhotoMedex v. Irwin*, a medical device manufacturer claimed that a competitor misrepresented in marketing materials the scope

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[48] *See, e.g.*, Richard A. Epstein, *The Case for Field Preemption of State Laws in Drug Cases*, 103 NW U. L. REV. 462, 470–72 (2009).

[49] *See PLIVA*, 564 U.S. at 609 (state tort law failure-to-warn claims against manufacturers of generic drugs preempted); *Mut. Pharm.*, 570 U.S. at 476 (state tort law design-defect claims against manufacturers of generic drugs preempted).

of its FDA approval for a laser used in dermatological treatments.[50] We held that the claims were "preempted," because of the statute reserving enforcement to the FDA.[51] The plaintiff argued that the statutory prohibition of private enforcement of the FDCA did not apply, because it was suing to enforce other laws, the Lanham Act and state unfair competition law, not the FDCA.[52] We held that to the extent the claim was based on an arguably false assertion of FDA approval, it "would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was a violation," so the action was barred by the FDCA's prohibition of private enforcement.[53] That claim could only be permissibly made by the government.[54] The other claims in the case did not implicate the FDA's exclusive enforcement authority and accordingly were not barred by the prohibition of private enforcement.[55] Like *Photomedex*, Nexus's claims would require litigation of whether Central Admixture's compounded drugs are "essentially a copy" of Emerphed where the FDA has not itself so concluded.

In another of our decisions, *Stengel v. Medtronic*, a medical device rendered Stengel quadriplegic, and he sued on

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[50] *PhotoMedex, Inc. v. Irwin*, 601 F.3d 919, 922 (9th Cir. 2010).

[51] *Id.*

[52] *See id.* at 924–25, 928–30.

[53] *Id.* at 924, 930–31.

[54] *Id.* at 926–28.

[55] *See id.* at 931–33.

a traditional negligence, failure-to-warn tort theory.[56] Stengel sought to make a claim that the manufacturer had failed to report risks it knew of to the FDA, thereby violating state tort law.[57] We held that this "you should have told the FDA" claim was not preempted, because it fell within traditional state tort "failure to warn" claims.[58] The statutory prohibition on private enforcement was not addressed in *Stengel*, just preemption. *Stengel* differs from the case before us, in that no traditional tort law duty at all is pleaded in our case, just a violation of the FDCA.

In another medical device case, *Perez v. Nidek* (using LASIK for far-sightedness, though FDA approval was then only for near-sightedness), we held that the claim was preempted.[59] The theory, in that class action, was fraud—the manufacturer did not warn the class members that FDA approval had been granted only for use on near-sightedness.[60] We held that the express preemption clause did apply.[61] But we added an alternative holding: even without express preemption, the claim was impliedly preempted.[62] This

[56] *Stengel v. Medtronic, Inc.*, 704 F.3d 1224, 1226 (9th Cir. 2013) (en banc).

[57] *Id.*

[58] *Id.* at 1232–33.

[59] *Perez*, 711 F.3d at 1111.

[60] *Id.* at 1112.

[61] *Id.* at 1117–19.

[62] *Id.* at 1117.

implied preemption holding rested on two propositions. First, we noted that "private enforcement of the [FDCA] statute is barred."[63] And second, the claim for fraud by omission "exist[s] solely by virtue of the FDCA."[64]

Though *Perez* did not construe or fall within the "outsourcing facilities" statute applicable to our case, the district court correctly applied that decision. The reasoning of *PhotoMedex* must likewise be extended to the "outsourcing facilities" statute. In *PhotoMedex*, the plaintiff tried to assert claims under other laws, but they were based on putative violation of the FDCA.[65] Rather than phrasing our decision in preemption terms, *PhotoMedex* treated the issue as an application of the bar on private enforcement of the FDCA:

> Because the FDCA forbids private rights of action under that statute, a private action brought under [other laws] may not be pursued when, as here, the claim would require litigation of the alleged underlying FDCA violation in a circumstance where the FDA has not itself concluded that there was such a violation.[66]

That holding construes section 337, the bar on private enforcement, not section 324(k), the express preemption

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[63] *Id.* at 1119.

[64] *Id.* (quoting *Buckman*, 531 U.S. at 353).

[65] *PhotoMedex*, 601 F.3d at 922.

[66] *Id.* at 924.

clause of medical devices, so it controls here and requires us to affirm. For Nexus to prevail in our case, it would likewise have to prove that Central Admixture's drug is "essentially a copy," which would amount to litigation of the alleged underlying FDCA violation even though the FDA has not itself concluded that there was a violation.

As in *PhotoMedex*, to permit Nexus "to proceed with a claim that Defendants violated this law when the FDA did not so determine would, in effect, permit [Nexus] to assume enforcement power which the statute does not allow and require the finder of fact to make a decision that the FDA itself did not make."[67] Proceedings to enforce or restrain violations of the FDCA, including the compounding statute, must be by and in the name of the United States, not a private party.[68] Nexus's claim is such a proceeding, so it is barred by the exclusive enforcement statute.

Allergan v. Athena Cosmetics,[69] a case from the Federal Circuit, misinterprets our case law regarding the bar on private enforcement. Allergan, a manufacturer of an FDA-approved eyelash growth product, claimed that Athena, a manufacturer of a competing product not approved by the FDA, violated California's unfair competition law and infringed on its patent.[70] The Federal Circuit held that the claims were not impliedly preempted, even though California

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[67] *Id.* at 930.

[68] 21 U.S.C. § 337.

[69] *Allergan, Inc. v. Athena Cosmetics, Inc.*, 738 F.3d 1350 (Fed. Cir. 2013).

[70] *Id.* at 1353.

law merely incorporated FDCA requirements. The court reasoned that the goals of the state and federal laws were consistent, so California law was not an obstacle to federal goals, and compliance with both laws was not impossible.[71] The court did not address the FDCA's prohibition of private enforcement. Had it done so, *Perez* and *PhotoMedex* would have required a contrary result.

These precedents do not say so in so many words, but a clear distinction reveals itself when one reads them all together. Nexus does not claim harm to a patient, where a traditional common law tort action might provide a remedy to the patient and escape preemption.[72] Instead, the claim is that a manufacturer is harmed economically because the defendant violated the FDCA. The purported state law violation is of a law that says in substance "comply with the FDCA," not a traditional common law tort. Nexus's theory is that Central Admixture's product is "essentially a copy" of Emerphed, so it falls outside the exception to the requirement of FDA approval for safety and effectiveness for compounded drugs.

The "Guidance for Industry" documents issued by the FDA do not have the force of law and we do not defer to them, but they do "describe the agency's current thinking on a topic."[73] They are helpful for that purpose, showing how and why the agency's enforcement policies operate as they do. The agency thinks compounded drugs "serve an

[71] *Id.* at 1354–56.

[72] *E.g., Wyeth*, 555 U.S. 555; *Stengel*, 704 F.3d 1224.

[73] FDA Guidance at 1.

important role for patients whose needs cannot be met by an FDA-approved product," but "they can also pose a higher risk."[74] The exclusion of compounded drugs that are "essentially a copy" of approved drugs ensures that "patients who could use an approved product" are not exposed to greater risk from drug products not shown to be safe and effective. And the exclusion protects drug manufacturers who go through the expensive approval process from competitors who produce "substitutes that may be less expensive because they have not gone through the approval process."[75] Thus, drug manufacturers would be less likely to invest and seek approval if copies could be sold more cheaply by evading FDA review.

The FDA says that it "does not intend to take action" against a facility that compounds drugs that are "essentially a copy" of drugs that have been discontinued and are no longer marketed, despite the statutory provision that entitles it to take action.[76] The FDA has indicated that it has plans to issue clarifying regulations on what "essentially a copy" means.

The issuance of this and other FDA documents shows that it has been attentive to the difficult issues of interpreting and enforcing the "essentially a copy" provision. All of Nexus's claims depend on a determination of whether Central Admixture's ephedrine sulphate is "essentially a copy" of Nexus's Emerphed. The plain text of the FDCA leaves that

[74] *Id.* at 3.

[75] *Id.* at 4.

[76] *Id.* at 5.

determination in the first instance to the FDA's balancing of risks and concerns in its enforcement process.

CONCLUSION

We affirm the district court's dismissal of this case. Nexus seeks to enforce its interpretation of the "essentially a copy" exclusion from the "outsourcing facilities" exception, a task reserved to the FDA. The prohibition of private enforcement applies squarely, as does "implied preemption."

AFFIRMED.