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United States Court of Appeals
Tenth Circuit

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PUBLISH

UNITED STATES COURT OF APPEALS

FOR THE TENTH CIRCUIT

VICTORIA CERVENY; CHARLES CERVENY; ALEXANDER CERVENY,

Plaintiffs - Appellants,

v.

AVENTIS, INC.,

Defendant - Appellee.

PRODUCT LIABILITY ADVISORY COUNCIL, INC.; AMERICAN TORT REFORM ASSOCIATION; PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA; BIOTECHNOLOGY INNOVATION ORGANIZATION; CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; NATIONAL ASSOCIATION OF MANUFACTURERS,

Amici Curiae.

No. 16-4050

Appeal from the United States District Court
for the District of Utah
(D.C. No. 2:14-CV-00545-DB)

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Eric A. Swan, Shook, Hardy & Bacon L.L.P., Kansas City, Missouri (William F. Northrip, Shook, Hardy & Bacon, L.L.P., Chicago, Illinois; Shawn McGarry, and Gary T. Wight, Kipp and Christian, P.C., Salt Lake City, Utah, with him on the brief), for Defendant-Appellee.

Kate Comerford Todd, U.S. Chamber Litigation Center, Washington, D.C., Linda E. Kelly and Leland P. Frost, Manufacturers' Center for Legal Action, Washington, D.C., Jeffrey S. Bucholtz and Sheldon Bradshaw, King & Spalding LLP, Washington, D.C., and Andrew T. Bayman and Heather M. Howard, King & Spalding LLP, Atlanta, Georgia, filed an amicus curiae brief for Chamber of Commerce of the United States of America, American Tort Reform Association, and National Association of Manufacturers, on behalf of Defendant-Appellee.

Michael X. Imbroscio, Paul W. Schmidt, and Gregory L. Halperin, Covington & Burling, Washington, D.C., filed an amici curiae brief for Pharmaceutical Research and Manufacturers of America and Biotechnology Innovation Organization, on behalf of Defendant-Appellee.

Hugh F. Young, Jr., Product Liability Advisory Council, Inc., Reston, Virginia, Andrew E. Tauber, Mayer Brown LLP, Washington, D.C., and Charles M. Woodworth, Mayer Brown LLP, Chicago, Illinois, filed an amicus curiae brief for Product Liability Advisory Council, Inc., on behalf of Defendant-Appellee.

Before **BACHARACH**, **PHILLIPS**, and **McHUGH**, Circuit Judges.

BACHARACH, Circuit Judge.

Mr. Alexander Cerveny was born over twenty years ago with birth defects.[1] Alexander and his parents attribute these birth defects to Mrs. Cerveny's use of Clomid (a fertility drug) in 1992, before she became pregnant with Alexander. The Cervenys sued the manufacturer of Clomid (Aventis, Inc.), asserting various tort claims under Utah law: failure to warn under theories of strict liability and negligence, breach of implied warranty, negligent misrepresentation, and fraud.[2]

The district court granted summary judgment to Aventis based on federal preemption, reasoning that the U.S. Food and Drug Administration ("FDA") would not have approved the drug warnings that the Cervenys allege are required under Utah law. This reasoning led the district court to conclude that Aventis could not have complied with both federal law and Utah law. Based on this conclusion, the district court granted summary judgment to Aventis on all of the Cervenys' claims.

On appeal, the Cervenys note that they "did not advocate for a specific warning in laying out their failure-to-warn claims." Appellants' Opening Br. at 9. Instead, the Cervenys present two theories, pointing to two types of warning labels that Aventis had allegedly failed to provide:

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[1] Alexander was born with a left elbow flexion deformity and only three digits on his left hand.

[2] The Cervenys also brought additional state-law tort claims that were dismissed for failure to state a claim. *See* Fed. R. Civ. P. 12(b)(6). These dismissals have not been appealed.

(1) a label that warned of risks to the fetus when a woman takes Clomid before becoming pregnant and (2) a label that unmistakably warned about harm to the fetus when Clomid is taken during pregnancy.

For both theories, the Cervenys point to a warning that the FDA proposed in 1987, which stated that "Clomid may cause fetal harm when administered to pregnant women." Appellants' App'x vol. 3, at 596. For their first theory, the Cervenys argue that this proposed warning demonstrates the FDA's willingness to approve warnings for women taking Clomid prior to pregnancy. For their second theory, the Cervenys argue that (1) the warning clearly informed women of risks to the fetus if taken during pregnancy and (2) Mrs. Cerveny would not have taken Clomid if Aventis had used the FDA's proposed wording.

The district court rejected the Cervenys' claims based on preemption. The ruling was correct on the Cervenys' first theory, for the undisputed evidence shows that the FDA would not have approved a warning about taking Clomid before pregnancy. But on the second theory, the district court did not explain why a state claim based on the FDA's own proposed language would be preempted by federal law.

The district court also erred in failing to distinguish the remaining claims (breach of implied warranty, negligent misrepresentation, and fraud) from the failure-to-warn claims. These claims are based at least partly on affirmative misrepresentations rather than on a failure to provide

a warning. The district court failed to explain why claims involving affirmative misrepresentations would have been preempted.

I. Standard of Review

On the award of summary judgment, we engage in de novo review, drawing all reasonable inferences and resolving all factual disputes in favor of the Cervenys. *Birch v. Polaris Indus., Inc.*, 812 F.3d 1238, 1251 (10th Cir. 2015). Summary judgment was required if Aventis had shown that no genuine issue existed on a material fact and that Aventis was entitled to judgment as a matter of law. Fed. R. Civ. P. 56(a).

In determining whether Aventis had satisfied this burden, we engage in de novo review of all the district court's legal conclusions. *Auraria Student Hous. at the Regency, LLC v. Campus Vill. Apartments, LLC*, 843 F.3d 1225, 1244 (10th Cir. 2016) ("[W]e review the district court's conclusions of law de novo . . . ."). Thus, we ordinarily consider preemption as a legal issue subject to de novo review. *See Mount Olivet Cemetery Ass'n v. Salt Lake City*, 164 F.3d 480, 486 (10th Cir. 1998) (stating that we review preemption rulings de novo); *see also GTE Mobilnet of Ohio v. Johnson*, 111 F.3d 469, 475 (6th Cir. 1997) ("Questions of federal preemption of state law generally are considered questions of law subject to de novo review.").

II. Preemption of the Failure-to-Warn Claims

Mrs. Cerveny had taken Clomid in September and October 1992, before she became pregnant with Alexander. When Mrs. Cerveny took Clomid, its label warned women[3] against use during pregnancy, stating that Clomid had been shown to cause harm in fetuses for rats and rabbits.

The Cervenys contend that this warning was insufficient under Utah law. As mentioned above, the Cervenys support their failure-to-warn claims under two separate theories: (1) Aventis should have warned women of the risks of taking Clomid prior to pregnancy and (2) Aventis should have better warned women of the risks to the fetus when Clomid is taken during pregnancy. The district court correctly held that federal law preempted the first theory, which involved a failure to warn of risks prior to pregnancy. But the district court failed to explain the applicability of preemption to the second theory, which was based on the FDA's own proposed wording.

A. FDA Approval Process and Clomid's Regulatory History

The Federal Food, Drug, and Cosmetic Act has long required a manufacturer to obtain approval from the FDA before the manufacturer can introduce a new drug in the market. 21 U.S.C. § 355(a). For brand-name

[3] The district court noted that a drug manufacturer bears a duty to provide a warning to a patient's prescribing physician. For convenience, we omit reference to the prescribing physician in this opinion.

drugs, a manufacturer must submit an application. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466, 2470-71 (2013). The application must include the proposed label, "full reports of investigations which have been made to show whether such drug is [safe and effective]," comprehensive information of the drug's composition and the "manufacture, processing, and packing of such drug," relevant nonclinical studies, and "any other data or information relevant to an evaluation of the safety and effectiveness of the drug product obtained or otherwise received by the applicant from any source." 21 U.S.C. § 355(b)(1); 21 C.F.R. § 314.50(c)(2)(i), (d)(1), (2), (5)(iv).

If the FDA approves the application, the manufacturer generally is restricted from changing the label without advance permission from the FDA. 21 U.S.C. §§ 331(a), (c), 352; 21 C.F.R. § 314.70(a), (b). But an exception exists, allowing a manufacturer under certain circumstances to change the label before obtaining FDA approval. 21 C.F.R. § 314.70(c).[4] But even when this exception applies, the FDA will ultimately approve the label change only if it is based on reasonable evidence of an association

[4] The text of the regulation in 1992 (when Mrs. Cerveny took the Clomid) differs from today's version. The 1992 regulation required the applicant to notify the FDA of the change "at the time the applicant makes any kind of [labeling] change." 21 C.F.R. § 314.70(c) (1992). The current version requires notification at least 30 days before distribution of the drug. 21 C.F.R. § 314.70(c) (2016).

between the drug and a serious hazard. 21 C.F.R. §§ 201.80(e), 314.70(c)(6)(iii).

Against this regulatory backdrop, we consider the FDA's historical consideration of Clomid's labels. Clomid entered the market in 1967 upon approval by the FDA. Since 1967, Clomid's labels have consistently warned about the risk of fetal harm if the mother takes Clomid while she is pregnant. For example, the 1967 warning stated:

> CONTRAINDICATIONS
>
> *Pregnancy*
>
> Although no causative evidence of a deleterious effect of Clomid . . . therapy on the human fetus has been seen, such evidence in regard to the rat and the rabbit has been presented . . . . Therefore, Clomid should not be administered during pregnancy. *To avoid inadvertent Clomid administration during early pregnancy, the basal body temperature should be recorded throughout all treatment cycles, and the patient should be carefully observed to determine whether ovulation occurs*. If the basal body temperature following Clomid is biphasic and is not followed by menses, the patient should be examined carefully for the presence of an ovarian cyst and should have a pregnancy test. The next course of therapy should be delayed until the correct diagnosis has been determined.

Appellants' App'x vol. 3, at 590. This warning addressed the risk of continuing to take Clomid after a woman has become pregnant, noting that the woman may be unaware of her pregnancy. The label was revised in both 1980 and 1991, but the revised labels contained the same pregnancy warning. *Id.* at 579; Appellants' App'x vol. 1, at 239.

In 1986, the FDA ordered Aventis to add a "Pregnancy Category X" designation to Clomid's label. This designation would indicate that "the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit." 21 C.F.R. § 201.57(f)(6)(i)(*e*) (1986).[5] The FDA recommended this designation on the ground that Clomid does not benefit pregnant women and that any risk to pregnant women would be unjustified. Appellants' App'x vol. 3, at 586.

Aventis resisted this change, and the FDA acknowledged a dilemma: Aventis needed to warn about taking Clomid during pregnancy, but no woman who was already pregnant would have any reason to take Clomid. In light of this dilemma, the FDA suggested in 1987 that Aventis change the label to add a clear warning about the risk of fetal harm when Clomid is taken during pregnancy:

> PREGNANCY CATEGORY X. See Contraindications and Information for Patients.
>
> CONTRAINDICATIONS: Clomid is contraindicated in pregnant women. Clomid may cause fetal harm when administered to pregnant women. Since there is a reasonable likelihood of the patient becoming pregnant while receiving Clomid, the patient should be apprised of the potential hazard to the fetus.

[5] Until recently, the FDA used a five-letter system to categorize the risks of taking a drug or biological product during pregnancy. In 2015, the FDA replaced the five-letter system with different labeling requirements. *See* 21 C.F.R. § 201.80(f)(6) (2016).

Appellants' App'x vol. 3, at 596. Aventis eventually added a similar warning, but only after Alexander had been born.

B. Conflict Preemption and the Clear-Evidence Standard

There are three types of preemption: "(1) express preemption, which occurs when the language of the federal statute reveals an express congressional intent to preempt state law . . . ; (2) field preemption, which occurs when the federal scheme of regulation is so pervasive that Congress must have intended to leave no room for a State to supplement it; and (3) conflict preemption, which occurs either when compliance with both the federal and state laws is a physical impossibility, or when the state law stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." *Mount Olivet Cemetery Ass'n v. Salt Lake City*, 164 F.3d 480, 486 (10th Cir. 1998).

Aventis asserts a form of conflict preemption known as impossibility preemption. Under impossibility preemption, state law is preempted "when compliance with both the federal and state laws is a physical impossibility." *Id.*

For conflict preemption, the Supreme Court set forth the governing framework in *Wyeth v. Levine*, 555 U.S. 555 (2009). In *Levine*, the plaintiff was severely injured when she was administered an antinausea drug using the "IV-push" method of injection, which resulted in the drug accidentally entering her arteries. *Levine*, 555 U.S. at 559. The plaintiff sued Wyeth,

the manufacturer of the drug, for failing to adequately warn of the risks of the IV-push method. *Id.* at 560. Wyeth responded that the failure-to-warn claim was preempted because the desired warning would have been disallowed by the FDA. *Id.* at 563.

The Supreme Court rejected Wyeth's preemption argument, but the Court noted that the claim would have been preempted upon "clear evidence" that the FDA would have rejected the desired label change. *Id.* at 571 ("But absent clear evidence that the FDA would not have approved a change to Phenergan's label, we will not conclude that it was impossible for Wyeth to comply with both federal and state requirements."). The Court reasoned that Wyeth had not (1) alleged an attempt to provide the kind of warning allegedly required under state law or (2) supplied the FDA with any analysis about the dangers from the IV-push method. *Id.* at 572-73.

The Cervenys emphasize that in *Levine*, the Supreme Court held that the state tort claim was not preempted, downplaying the discussion of the "clear evidence" standard as dicta. But our court has relied on *Levine* in holding that a state tort claim is preempted if a pharmaceutical company presents clear evidence that the FDA would have rejected an effort to strengthen the label's warnings. *Dobbs v. Wyeth Pharm.*, 606 F.3d 1269,

1269 (10th Cir. 2010). Thus, we must apply the "clear evidence" test set forth in *Levine*.[6]

The resulting issue is whether this test involves a question of fact or law. On this issue, the Cervenys and Aventis debate the potential impact of a recent Third Circuit opinion: *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 2017 WL 1075047 (3d Cir. Mar. 22, 2017).[7] *Fosamax* interpreted the "clear evidence" language from *Wyeth* to refer to the "standard of proof" for the manufacturer to "convince the factfinder that the FDA would have rejected a proposed label change." *In re Fosamax*, 2017 WL 1075047, at *11. As a result, the court concluded that satisfaction of this standard involves a question of fact: "A state-law failure-to-warn claim will only be preempted if a jury concludes it is highly probable that the FDA would not have approved a label change." *Id.* at *18.

The Cervenys did not argue in their briefing that the "clear evidence" standard involves a question of fact, and Aventis did not argue that the "clear evidence" standard raises a question of law. Nonetheless, the Cervenys insist that we should adopt the Third Circuit's approach and deny

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[6] The Cervenys question our prior application of *Levine*, but we are bound by our published opinions. *United States v. Spedalieri*, 910 F.2d 707, 710 n.3 (10th Cir. 1990).

[7] The parties debated the issue after oral argument in dual letters to the Court regarding supplemental authority.

summary judgment if "no reasonable juror could conclude that it is anything less than highly probable that the FDA would have rejected" the proposed label. *Id.* at *19. We are reticent to take this approach, for the parties' appeal briefs do not address this issue.

Nonetheless, we may assume for the sake of argument that the Cervenys are correct, for their characterization of the issue is nondispositive because all of the material facts are undisputed. In applying these undisputed facts, we consider (1) whether Aventis presented clear evidence that the FDA would have disapproved of the warnings suggested by the Cervenys and (2) whether a reasonable juror could conclude that the FDA would have approved those warnings.

C. Preemption of the Failure-to-Warm Claims: The Risks of Pre-Pregnancy Use of Clomid

The parties agree that Mrs. Cerveny took Clomid before she became pregnant, but not afterward. The Cervenys contend that even pre-pregnancy use of Clomid may harm the fetus because (1) Clomid has a long half-life and can accumulate in the body with multiple courses of treatment, remaining active in the body after pregnancy, and (2) Clomid inhibits cholesterol, which may harm the fetus's development. For both reasons, the Cervenys allege in part that Aventis should have warned women about the risks when taking Clomid prior to pregnancy.

Aventis argues that even if the Cervenys are correct, the FDA would not have allowed addition of a warning in 1992 about the risks when taking Clomid prior to pregnancy. Thus, Aventis contends that it would have been impossible to comply with both federal and Utah law. If Aventis is right, federal law would preempt the Utah tort claims. We agree with Aventis that the FDA would have prohibited Aventis from warning about the risk when taking Clomid prior to pregnancy.

Aventis bears the burden to present clear evidence that the FDA would not have approved the desired warning. *See Emerson v. Kan. City S. Ry. Co.*, 503 F.3d 1126, 1133-34 (10th Cir. 2007). To meet this burden, Aventis points to (1) the FDA's history of approving Clomid for use by women before becoming pregnant and (2) the FDA's rejection of a citizen petition by Mr. Terence Mix,[8] which had alleged a risk of fetal harm when Clomid is taken prior to pregnancy. In response, the Cervenys rely on the FDA's recommendation in 1987 for Aventis to warn of potential harm to the fetus. We conclude that clear evidence is not established by Clomid's regulatory history, but is established by the FDA's rejection of Mr. Mix's citizen petition. In the face of that clear evidence, we reject the Cervenys' argument based on the FDA's 1987 recommendation.

[8] Mr. Mix is an attorney who was involved in litigation relating to birth defects allegedly caused by Clomid. He has authored a book on the subject. Terence Mix, *The Price of Ovulation: The Truth About Fertility Drugs and Birth Defects and a Solution to the Problem* (2009).

1. Aventis's Argument Involving Clomid's Regulatory History

Aventis argues that Clomid's regulatory history provides clear evidence that the FDA would have rejected the label changes desired by the Cervenys. According to Aventis, the FDA has long approved of Aventis's labels and has never suggested that Aventis include warnings regarding when Clomid is taken prior to pregnancy.

As Aventis points out, its label has continuously denied a link between Clomid and fetal harm. *See* Appellants' App'x vol. 2, at 443 (1994 label) (stating that "no causative evidence of a deleterious effect of CLOMID therapy on the human fetus has been established"); *id.* at 528 (2013 label) (stating that the "[a]vailable human data do not suggest an increased risk for congenital anomalies above the background population risk when used as indicated"). In our view, however, Aventis's regulatory history alone does not constitute clear evidence that the FDA would have rejected the warnings desired by the Cervenys.

Levine involved the drug Phenergan. Thus, it is helpful to compare the regulatory histories of Phenergan (in *Levine*) and Clomid (in our case). *See Mason v. SmithKline Beecham Corp.*, 596 F.3d 387, 392 (7th Cir. 2010).

The *Levine* majority described Phenergan's regulatory history.[9] The FDA initially approved Phenergan in 1955, decades before the *Levine* plaintiff was injured. *Wyeth v. Levine*, 555 U.S. 555, 561 (2009). The drug manufacturer, Wyeth, submitted supplemental new drug applications in 1973 and 1976, which the FDA approved after proposing label changes. *Id.* A third supplemental application was submitted in 1981 in response to a new FDA rule. *Id.* Then, Wyeth and the FDA spent seventeen years intermittently corresponding about Phenergan's label. *Id.* "The most notable activity occurred in 1987, when the FDA suggested different [but not stronger] warnings about the risk of arterial exposure, and in 1988, when Wyeth submitted revised labeling incorporating the proposed changes." *Id.* at 561-62. The FDA never responded and ultimately instructed Wyeth in 1996 to retain its current label, which omitted the 1987 proposed label change regarding arterial exposure. *Id.* at 562. Based on this regulatory history, the Supreme Court concluded that the manufacturer

[9] The *Levine* dissent paints a different picture of Phenergan's regulatory history, one in which the FDA carefully "considered and reconsidered" whether IV-push administration of Phenergan is safe when performed in accordance with Phenergan's label. *Wyeth v. Levine*, 555 U.S. 555, 612-16 (2009) (Alito, J., dissenting). We follow the majority's view of the facts but also note that the majority would have rejected preemption even under the dissent's version of Phenergan's regulatory history. *Id.* at 573 n.6 (majority opinion) ("[E]ven the dissent's account does not support the conclusion that the FDA would have prohibited Wyeth from adding a stronger warning pursuant to the CBE regulation.").

had not presented clear evidence that the FDA would have disallowed a stronger warning about the IV-push method. *Id.* at 573.

Clomid's regulatory history is similar to Phenergan's. Like Phenergan, Clomid had appeared on the market for decades before Mrs. Cerveny took Clomid. And Aventis has intermittently corresponded with the FDA about Clomid's labels.

Aventis argues that this case differs because Clomid's FDA-approved labels stated that there was no definitive evidence linking Clomid to birth defects. But in *Levine*, the label suggested "extreme care" when someone uses the IV-push method to administer Phenergan. *Levine*, 555 U.S. at 560 n.1. Thus, the regulatory history in *Levine* showed that the FDA had known of the dangers of the IV-push method, but had not required a stronger warning. This was not enough in *Levine* to trigger preemption.

Likewise, the FDA's approval of Clomid's labels suggests only that the FDA knew about potential issues involving pre-pregnancy use of Clomid—not that the FDA would have rejected a stronger warning if one had been proposed. As a result, Clomid's regulatory history alone does not meet the clear-evidence standard.

2. Consideration of Mr. Mix's Citizen Petition as Clear Evidence

To meet the clear-evidence standard, Aventis also relies on the FDA's rejection of Mr. Mix's citizen petition,[10] which had alleged risks when taking Clomid prior to pregnancy.

a. Mr. Mix's Prior Claims to the FDA

In his citizen petition, Mr. Mix presented arguments virtually identical to the Cervenys'. For example, Mr. Mix alleged that taking Clomid prior to pregnancy risks fetal harm because (1) Clomid "has a long half-life and is still biologically active well into the second month of pregnancy when most organs are being formed . . . and can accumulate with multiple courses of treatment" and (2) Clomid inhibits cholesterol, which may endanger the developing fetus. Appellants' App'x vol. 1, at 248-49. Accordingly, Mr. Mix urged stronger warnings to (1) "set[] forth reasonable and effective warnings of the teratogenic risks" for Clomid, (2) "order risk evaluation and mitigation strategies . . . in order to determine whether the benefits of [Clomid] outweigh the risks," and (3) order studies to determine whether dietary supplements of cholesterol or a high

[10] Under the FDA's regulations, citizens may petition the FDA to "issue, amend, or revoke a regulation or order, or to take or refrain from taking any other form of administrative action." 21 C.F.R. § 10.25(a). Accordingly, any citizen may ask the FDA to change or strengthen drug labels. *See id.* §§ 10.25, 10.30.

cholesterol diet "can mitigate or eliminate the increased risk of birth defects" from using Clomid. *Id*. at 248.

In 2009, the FDA denied Mr. Mix's petition, stating that the FDA had "reviewed the references submitted with the Petition," "evaluated the scientific merit of each reference . . . submitted," and "independently surveyed the literature regarding [Clomid]." Appellants' App'x vol. 2, at 383. The FDA concluded that (1) "the scientific literature [did] not justify ordering changes to the labeling that warn of such risks beyond those presently included in labeling" and (2) there was "insufficient evidence" to support Mr. Mix's other requests. *Id.*

Mr. Mix sought reconsideration, which he twice supplemented with more information. The FDA declined to reconsider, explaining that the original denial had "appropriately applied the standards in the [Federal Food, Drug, and Cosmetic Act] and FDA regulations regarding drug safety, warnings, and potential safety hazards." *Id.* at 422. The FDA added that the new information was not enough to alter the outcome. *Id.*

Aventis argues that the denial of Mr. Mix's petition constitutes clear evidence that the FDA would not have approved a warning in 1992 about the risks when taking Clomid prior to pregnancy. The Cervenys admit that their failure-to-warn claims are based on the same theories and scientific evidence presented in Mr. Mix's citizen petition. Oral Arg. at 5:09-6:11.

Nonetheless, the Cervenys present two challenges to Aventis's reliance on the FDA's denial of Mr. Mix's petition. First, the Cervenys argue that the FDA affords greater deference to label changes proposed by manufacturers than by citizens. Second, the Cervenys urge a bright-line rule that the denial of a citizen petition, standing alone, can never constitute clear evidence. We reject both arguments.

b. Manufacturer-Submitted Label Changes Versus Citizen Petitions

The Cervenys contend that when the FDA considers proposed label changes, manufacturers are treated more favorably than others. According to the Cervenys, this favoritism leads the FDA to accord greater deference to changes proposed by manufacturers than to changes proposed in citizen petitions. For this alleged favoritism, the Cervenys rely on expert testimony and statistics.

The Cervenys' contention is based on an understandable, but mistaken, premise: that a manufacturer's willingness to strengthen its warning is something always to be encouraged. Many would agree with that proposition, but the FDA doesn't. Instead, the FDA views overwarnings as problematic because they can render the warnings useless and discourage use of beneficial medications. Supplemental Applications Proposing Labeling Changes for Approved Drugs, Biologics, and Medical Devices, 73 Fed. Reg. 2848, 2851 (proposed Jan. 16, 2008) (codified at 21

C.F.R. pts. 314, 601, 814); Requirement on Content and Format of Labeling for Human Prescription Drug and Biologic Products, 71 Fed. Reg. 3922, 3927, 3935 (Jan. 24, 2006); Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37434, 37447 (June 26, 1979).

In addition, the FDA standard for revising a warning label does not discriminate between proposals submitted by manufacturers and proposals submitted by citizens. *See* 21 C.F.R. § 201.80(e) ("The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a serious hazard with a drug; a causal relationship need not have been proved."). The Cervenys admit that the standard is the same regardless of who proposes to revise the label. Appellants' Opening Br. at 38. Indeed, in denying Mr. Mix's citizen petition, the FDA stated nine times that it was applying the "reasonable evidence" standard for label changes. Appellants' App'x vol. 2, at 387, 389-90, 392-94. This is the same standard that would have applied if Aventis had proposed to strengthen its warnings. *See* Part II(A), above.

The Cervenys suggest that the FDA disobeys its own regulations to apply different standards depending on the source of the proposed change. But we do not presume that the FDA deviates from regulatory requirements. *Yuk v. Ashcroft*, 355 F.3d 1222, 1232 (10th Cir. 2004). Even if the FDA rejects more citizen petitions than manufacturer requests, the disparity would be easily explainable.

One explanation is that proposals by manufacturers are more informed and better supported than proposals in citizen petitions. *See* Brian K. Chen et al., *Petitioning the FDA to Improve Pharmaceutical, Device and Public Health Safety by Ordinary Citizens: A Descriptive Analysis*, PLoS ONE, May 12, 2016, at 2, 6, http://journals.plos.org/plosone/article/file?id=10.1371/journal.pone.0155259&type=printable (finding that "the majority of petitions [filed by 'ordinary' citizens] are denied because petitioners fail to present sufficient and/or convincing evidence" and that "[f]or these denials, the FDA provided detailed, point-by-point rebuttals to the petitioner's scientific basis for the requested actions").

Another explanation is that brand-name drug manufacturers often file frivolous citizen petitions, asking the FDA to disallow a generic drug's entry into the market. Michael A. Carrier & Daryl Wander, *Citizen Petitions: An Empirical Study*, 34 Cardozo L. Rev. 249, 260, 282 (2012). An empirical study of citizen petitions over a 9-year period found that 68% of citizen petitions had been filed by brand-name drug manufacturers. *Id.* at 270. Of those petitions, 78% targeted generic drugs. *Id.* at 271. The study's authors hypothesized that citizen petitions are frequently denied because they involve unsupported efforts to stall entry of generic medications into the marketplace. *Id.* at 253, 279.

Rejecting these explanations, the Cervenys hypothesize that the FDA would be more receptive to a manufacturer's request to strengthen a warning than to a citizen's effort to compel a stronger warning. But a factual dispute cannot be based on speculation that the FDA would jettison its legal requirements and rubber-stamp Aventis's hypothetical proposal notwithstanding the risk of overwarning.

* * *

Under the same standard for manufacturer-initiated changes, the FDA rejected a citizen petition containing arguments virtually identical to the Cervenys'. We will not assume that the FDA would have scuttled its own regulatory standard if Aventis had requested the new warning.[11] Thus, we reject the Cervenys' challenge to Aventis's reliance on Mr. Mix's citizen petition.

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[11] This conclusion would remain the same regardless of whether the "clear evidence" standard entails a question of law or a question of fact. The Third Circuit's *Fosamax* opinion noted that district courts considering summary judgment should "compare the evidence presented with the evidence in *Wyeth [v. Levine]*, to determine whether it is more or less compelling" and that a jury trial would only be necessary "in those cases where the evidence presented is more compelling than that in *Wyeth* but no 'smoking gun' rejection letter from the FDA is available." *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 2017 WL 1075047, at *18 (3d Cir. Mar. 22, 2017)). No jury trial is needed here because the multiple rejections of Mr. Mix's citizen petition constitute "smoking guns" that would foreclose any reasonable juror from finding that the FDA would have approved warnings about the risks when Clomid is taken prior to pregnancy.

c. Bright-Line Rule

The Cervenys argue that the denial of a citizen petition, by itself, cannot constitute clear evidence. For this argument, the Cervenys rely on opinions by one federal appellate court, one state supreme court, and five federal district courts. We reject the Cervenys' argument.

The Cervenys rely partly on *Mason v. SmithKline Beecham Corp.*, where the Seventh Circuit concluded that the FDA's rejection of a citizen petition on three separate occasions did not constitute clear evidence. 596 F.3d 387, 396 (7th Cir. 2010). But *Mason* is distinguishable in two ways.

First, the citizen petitions in *Mason* pertained to a drug (Prozac) that was similar, but not identical, to the drug (Paxil) that had injured the plaintiff. *See id.* at 395 ("[W]e give little weight to the administrative history of Prozac when we are concerned with whether there is clear evidence that the FDA would have rejected a labeling change in Paxil.").

Second, unlike in the present case, the citizen petitions in *Mason* had been rejected *before* the plaintiff's injury. *Id.* The court considered this temporal gap as "especially important" because the FDA's analysis of drugs "constantly evolves as new data emerges." *Id.* Thus, when the injury took place, the FDA might have permitted the labeling change despite the FDA's earlier rejection of the citizen petition.

The Seventh Circuit's subsequent approach in *Robinson v. McNeil Consumer Healthcare* crystallizes the significance of the difference

between our facts and those in *Mason*. In *Robinson*, the Seventh Circuit found preemption because the FDA had "refus[ed] to require" a warning label "when [the FDA] had been asked to do so in the submission to which the agency was responding." 615 F.3d 861, 873 (7th Cir. 2010). The fact that *Robinson* came to a different result than *Mason* suggests that the two distinguishing characteristics in *Mason* drove the result there.

The Cervenys also rely on *Reckis v. Johnson & Johnson*, 28 N.E.3d 445 (Mass. 2015). There the Supreme Judicial Court of Massachusetts concluded that the denial of a citizen petition constituted clear evidence that the FDA would have rejected some of the plaintiff's requested warnings. 28 N.E.3d at 457-58 ("[T]he FDA's explicit rejection of the 2005 citizen petition's proposed inclusion . . . provides the necessary 'clear evidence' that the FDA would have rejected the addition of [that same inclusion] . . . ."). But the court reached the opposite conclusion for another warning by distinguishing the proposal in the citizen petition from the newly proposed warning. *Id.* at 458-59. In discussing this distinction, the court suggested a difference between label changes requested by a manufacturer and changes requested by others. *Id.* at 459 ("[E]ven assuming for sake of argument that we could predict the FDA would have rejected a citizen petition proposal to add only this warning, that would not answer whether the FDA would have rejected the warning had it been sought by the defendants themselves.").

Reckis does not foreclose consideration of a citizen petition as clear evidence. As noted, the court expressly concluded that rejection of the citizen petition constituted clear evidence on some warnings. The Cervenys point out that *Reckis* treats the "clear evidence" standard as fact-specific. *See id.* at 457 ("*Wyeth* did not 'define clear evidence,' so 'application of the clear evidence standard is necessarily fact specific.'" (quoting *Dobbs v. Wyeth Pharm.*, 797 F. Supp. 2d 1264, 1270 (W.D. Okla. 2011))). That's true, but the facts here involve the FDA's prior rejection of a virtually identical allegation based on virtually identical evidence and an identical legal standard.

The Cervenys also point to five district court opinions in arguing that the FDA's rejection of a citizen petition cannot constitute clear evidence. These opinions have little persuasive value. Only one of the opinions (*Schedin v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.*) unambiguously supports the Cervenys' argument that rejection of a citizen petition, without more, can never constitute clear evidence. 808 F. Supp. 2d 1125, 1133 (D. Minn. 2011), *rev'd in part on other grounds sub nom. In re Levaquin Prods. Liab. Litig.*, 700 F.3d 1161 (8th Cir. 2012). Another district court opinion (*Forst v. Smithkline Beecham Corp.*) arguably supports the Cervenys' argument, though this opinion involved the FDA's handling of a manufacturer's voluntary labeling supplement. 639 F. Supp. 2d 948, 954 (E.D. Wis. 2009). Neither *Schedin* nor *Forst* is persuasive on

our facts because the FDA here had rejected virtually identical arguments about the need for stronger warnings about Clomid.

The remaining three district court opinions are distinguishable. In two, the citizen petitions had been submitted and rejected years before the plaintiffs suffered their respective injuries. *See Koho v. Forest Labs., Inc.*, 17 F. Supp. 3d 1109, 1117 (W.D. Wash. 2014) ("In light of the evolving nature of the data regarding the effects of prescription drugs, the temporal gap between the latest rejection of a citizen petition in 1997 and Ilich's death in 2002 is significant."); *Dorsett v. Sandoz, Inc.*, 699 F. Supp. 2d 1142, 1158-59 (C.D. Cal. 2010) (similar reasoning). In our case, the sequence was opposite: The FDA denied Mr. Mix's citizen petition after obtaining scientific data for over 20 years after Mrs. Cerveny had taken the Clomid.

In the third case, *Hunt v. McNeil Consumer Healthcare*, the court held that rejection of a citizen petition did not constitute clear evidence because (1) the rejection had occurred years before the plaintiff's injury and (2) the warnings proposed by the plaintiffs had gone "much further" than the citizen petition. 6 F. Supp. 3d 694, 700-01 (E.D. La. 2014). These factors are absent in our case.

In our view, there is no persuasive authority for a bright-line rule that the denial of a citizen petition cannot constitute clear evidence under *Levine*.

* * *

We conclude that the rejection of a citizen petition may constitute clear evidence that the FDA would have rejected a manufacturer-initiated change to a drug label. Our case provides a perfect example. In rejecting Mr. Mix's citizen petition, the FDA analyzed claims and data virtually identical to those submitted by the Cervenys. Under the standard that would have applied to a change proposed by Aventis, the FDA concluded that warnings were unjustified for risks in taking Clomid prior to pregnancy. That conclusion controls here, and the FDA's denial constitutes clear evidence that the FDA would not have approved the Cervenys' desired warning of the risks of taking Clomid prior to pregnancy.

3. The Cervenys' Argument About the FDA's Proposed Warning in 1987 Regarding the Risks When Taking Clomid Prior to Pregnancy

The Cervenys argue that Clomid's regulatory history shows that the FDA would have approved a warning about taking Clomid prior to pregnancy. For this argument, the Cervenys point to the FDA's 1987 proposal to add the following Pregnancy Category X warning to Clomid:

> PREGNANCY CATEGORY X. See Contraindications and Information for Patients.
>
> CONTRAINDICATIONS: Clomid is contraindicated in pregnant women. Clomid may cause fetal harm when administered to pregnant women. Since there is a reasonable likelihood of the patient becoming pregnant while receiving Clomid, the patient should be apprised of the potential hazard to the fetus.

Appellants' App'x vol. 3, at 596. The FDA's 1987 proposal does not support the Cervenys' argument for a warning of the risks when Clomid is taken prior to pregnancy.

We presume that the FDA would have allowed Aventis to include a proposed warning that the FDA itself had proposed. The problem, however, is that the 1987 proposed warning addresses only the risk of taking Clomid after a woman has become pregnant. For instance, the warning's "Pregnancy Category X" notation indicated to the user that "the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit." 21 C.F.R. § 201.57(f)(6)(i)(*e*) (1987). And the warning itself referred to the risk of fetal harm when Clomid is "administered to pregnant women." Appellants' App'x vol. 3, at 596. Thus, the FDA's 1987 proposal does not suggest that the FDA would have approved a warning about taking Clomid prior to pregnancy.

The Cervenys argue that the FDA's 1987 proposal must refer to the risks of pre-pregnancy Clomid use because women take Clomid only if they are trying to become pregnant; no one would reasonably need to take Clomid after pregnancy had begun. It is true that the 1987 warning is directed to women who are trying to become pregnant. But the FDA was addressing a risk for women who might take Clomid before realizing that they had become pregnant. *See* Appellants' App'x vol. 3, at 596 (1987

proposed warning) ("Since there is a reasonable likelihood of the patient becoming pregnant while receiving Clomid, the patient should be apprised of the potential hazard to the fetus."). Mrs. Cerveny is not in this group, for she did not take Clomid after becoming pregnant.

The Cervenys also argue that we should examine the FDA's 1987 proposal alongside other known evidence of the risks of taking Clomid before becoming pregnant. But, as explained above, the FDA considered such evidence when rejecting Mr. Mix's citizen petition.[12] *See* Part

[12] In responding to Mr. Mix's citizen petition, the FDA specifically addressed his argument that the shelf-life of Clomid could remain in a woman's system after she became pregnant:

> Radioactive tracer studies presented in the original NDA document that clomiphene has a half-life of about 5 days. En-clomiphene . . . and zu-clomiphene . . . are the racemic isomers of clomiphene citrate [Clomid],. [sic] The long half-life of clomiphene citrate is attributable to zu-clomiphene. En-clomiphene disappears rapidly from the circulation, whereas zu-clomiphene is cleared slowly and may accumulate across consecutive cycles of treatment. Zu-clomiphene has been found in feces up to 6 weeks after administration. Accordingly, it is possible that there is some fetal exposure to zu-clomiphene in mothers who have been treated with clomiphene prior to pregnancy. Zu-clomiphene, however, had little effect on sterol metabolism in an animal model. Currently available clinical data support our conclusion that the level of zu-clomiphene present at the time of organogenesis is insufficient to cause significant inhibition of cholesterol synthesis even after multiple cycles of treatment.

Appellants' App'x vol. 2, at 386-87 (footnote omitted).

II(C)(2), above. Therefore, this evidence does not bolster the Cervenys' argument regarding the proposed 1987 warning.

* * *

For the reasons above, we conclude that the FDA would not have permitted Aventis to warn users about the risks of taking Clomid prior to pregnancy.

D. Preemption of the Failure-to-Warn Claims: The Potential for Fetal Harm Caused by Taking Clomid During Pregnancy

The Cervenys argue not only that the FDA's proposal in 1987 suggests the opportunity for Aventis to warn about risks prior to pregnancy, but also that the injury could have been averted if Aventis had used the same wording that the FDA had proposed in 1987, warning of the risks of taking Clomid during pregnancy. The district court rejected this argument, but did not say how the issue would have involved preemption. Thus, a remand is necessary on this issue.

1. The 1987 Warning and the Potential Harm to the Fetus if Clomid Is Taken During Pregnancy

When Mrs. Cerveny took Clomid, the label did not directly say that Clomid could harm the fetus if Clomid is taken during pregnancy. Appellants' App'x vol. 1, at 239 ("Although no causative evidence of a deleterious effect of Clomid therapy on the human fetus has been seen, such evidence in regard to the rat and the rabbit has been presented."). The FDA's 1987 proposal would have warned women more directly about

potential harm to the fetus when Clomid is taken during pregnancy. Appellants' App'x vol. 3, at 596 ("Clomid may cause fetal harm when administered to pregnant women.").

The Cervenys assert that "Aventis should have added [the 1987] warning that was *expressly proposed* by the FDA." Appellants' Opening Br. at 41. Mrs. Cerveny insists that she would not have taken Clomid, even pre-pregnancy, if Aventis had used the FDA's proposed wording. *Id.* at 42.[13]

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[13] In district court, the Cervenys also presented the same argument. *See* Opp. to Defendant's Mot. for Summary Judgment at 15-19, Appellants' App'x vol. 2, at 486-490:

- "[T]here is clear evidence that the FDA proposed a [warning] in 1987 that would have warned of a 'potential hazard to the fetus.'" *Id.* at 15, Appellants' App'x vol. 2, at 486.
- "Not only are Plaintiffs advocating a warning different from what was rejected in response to the citizen petition, Plaintiffs are also proposing a warning that was *expressly suggested* by the FDA . . . ." *Id.* at 17, Appellants' App'x vol. 2, at 488.
- "Mrs. Cerveny's affidavit establishes a question of fact as to whether the warning proposed by the FDA in 1987—describing a 'potential hazard to the fetus'—would have altered Mrs. Cerveny's decision to use Clomid." *Id.* at 18, Appellants' App'x vol. 2, at 489.
- "In a nutshell, the FDA's 1987 proposed label change shows that it was possible to warn about a potential hazard to the fetus, and to alert women attempting to become pregnant that they, too, should be concerned about this hazard. This fact alone defeats preemption, because it establishes that it was possible for Defendant to change the label to warn about a

2. Inclusion in the Complaint

Aventis implies that the Cervenys did not present this theory in the complaint. Appellee's Resp. Br. at 48. We disagree. It is true that the complaint focused primarily on Aventis's failure to warn of the risks when Clomid is taken prior to pregnancy. But in the complaint, the Cervenys also alleged that Aventis had "failed to adequately warn . . . consumers . . . of the known effects in Clomid that can lead to . . . birth defects [and] fraudulently concealed these effects . . . . [by] represent[ing] . . . that 'no causative evidence of a deleterious effect of Clomid therapy on the human fetus has been seen.'" First Amended Complaint at 12, ¶¶ 56-57, Appellants' App'x vol. 1, at 22; *see also id.* at 5, ¶ 21, Appellants' App'x vol. 1, at 15 (alleging that Aventis had failed to warn "of the dangers of taking the fertility drug"). We conclude that the Cervenys adequately presented this theory in the complaint.

3. The Need for Remand

Aventis does not deny that it could have used the wording that the FDA had proposed in 1987. Rather, Aventis points out that (1) the proposed warning addresses the risks from taking Clomid during pregnancy and (2) Mrs. Cerveny took Clomid prior to her pregnancy. Appellee's Resp. Br. at 48 ("A plaintiff cannot allege as a defect in a label a warning that

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potential hazard to the fetus." *Id.* at 19, Appellants' App'x vol. 2, at 490 (citation omitted).

would not have applied to them."). Aventis acknowledges that this contention focuses on a deficiency under Utah law rather than federal preemption. *See* Defendant's Mot. for Summary Judgment at 18, Appellants' App'x vol. 1, at 235 (arguing that the 1987 warning is "irrelevant to the question of preemption" because the Cervenys' claim would fail under Utah law); *see also* Appellants' Opening Br. at 42 ("[T]he issue . . . is one of [Utah law], not an issue of impossibility preemption.").[14]

But Aventis moved for summary judgment based solely on preemption. For this reason, the Cervenys urged the district court to ignore Aventis's state-law argument. Opp. to Defendant's Mot. for Summary Judgment at 17, Appellants' App'x vol. 2, at 488. But the district court entertained Aventis's state-law argument and relied on it, reasoning that it "would be a nonsensical result if a plaintiff could avoid a preemption defense by arguing that a drug label could have been strengthened in any form, regardless of its relevance to the plaintiff's case." Appellants' App'x vol. 3, at 731.

[14] Aventis also argues that adoption of the FDA's 1987 warning "would not have substantively altered the information that was contained on the 1992 Clomid label" because the drug was already "contraindicated for use in pregnant women." Appellee's Resp. Br. at 47 n.10. Though rooted in federal law, this argument does not support preemption.

But the Cervenys' failure-to-warn claims are based on Utah law. If the FDA's proposed warning would have been irrelevant under Utah law, Aventis could have

- moved for summary judgment under Utah law or
- moved to strike the portions of the Cervenys' complaint that had raised this issue.

But Aventis did not make either kind of motion; instead, Aventis relied solely on federal preemption.

The district court did not explain why the defect here fell within the scope of Aventis's summary judgment motion. To be sure, a preemption analysis requires the reviewing court to consider state law. *See PLIVA, Inc. v. Mensing*, 564 U.S. 604, 611 (2011) ("Pre-emption analysis requires us to compare federal and state law. We therefore begin by identifying the [applicable] state tort duties and federal labeling requirements . . . ."). But "[i]n pre-emption cases, the question is whether state law is pre-empted by a federal statute, or in some instances, a federal agency action." *POM Wonderful LLC v. Coca-Cola Co.*, 134 S. Ct. 2228, 2236 (2014). Here there is no question that Aventis could have added the proposed warning; after all, the warning had been proposed by the FDA. The Cervenys contend that Mrs. Cerveny would not have taken Clomid if Aventis had added the 1987 warning. Aventis's argument that the 1987 warning is "irrelevant" to the Cervenys' case is based on Utah law, not preemption.

In sum, the district court did not consider whether it could rest on Utah law when deciding a summary judgment motion that had relied solely on federal preemption. Because the district court did not consider this question and it has not been fully briefed on appeal, we leave this question for the district court to address on remand.[15] *See Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1096 (8th Cir. 2013) (remanding for the district court to decide whether state claims were sufficient under state law when the claims had been mistakenly rejected on preemption grounds).

III. Claims of Fraud, Negligent Misrepresentation, and Breach of Implied Warranty

On the basis of federal preemption, the district court granted summary judgment to Aventis not only on the failure-to-warn claims but also on the claims of fraud, negligent misrepresentation, and breach of implied warranty. In doing so, the district court did not distinguish between the claims.

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[15] Even if the district court could consider whether the 1987 proposed warning was relevant to the Cervenys' state-law claim, the district court did not adequately address Utah law. The court said simply that the 1987 warning was "irrelevant" because Mrs. Cerveny had taken Clomid before she became pregnant. Appellants' App'x vol. 3, at 731. But the Cervenys argued that the 1987 proposed warning had stated that (1) the fetus could be harmed if Clomid is taken during pregnancy and (2) Mrs. Cerveny would not have taken Clomid if Aventis had used the FDA's proposed language. The district court did not explain why these arguments would render the 1987 proposed warning irrelevant under Utah law.

The Cervenys urge remand for further consideration of the claims involving fraud, negligent misrepresentation, and breach of implied warranty, even if the failure-to-warn claims are preempted. We agree that remand is required.

The district court implicitly characterized all of the Cervenys' claims as failure-to-warn claims that had been preempted. Aventis defends this implicit characterization, stating that all of the claims were based on a failure to warn rather than on affirmative misrepresentations. But this characterization of the claims is too restrictive. For instance, on the claims of fraud (Count VIII) and negligent misrepresentation (Count IX), the Cervenys allege that Clomid's label falsely represented that no one had seen any evidence of causation between the use of Clomid and fetal harm. In contrast, the preemption discussion focuses on whether the FDA would have allowed Aventis to *add* a warning about fetal harm when Clomid is taken prior to pregnancy. The fact that the FDA would have rejected the *addition* of a warning does not mean that the FDA would have disallowed the *removal* of language that was false or misleading.

Aventis essentially responds that the Clomid label is accurate because there was no evidence of a causal relationship between Clomid and birth defects. But this argument goes to the merits rather than to Aventis's ability to delete false or misleading information.

Similarly, the warranty claim (Count IV) alleges in part that "[c]ontrary to the implied warranty . . . Clomid was not of merchantable quality, and [was] not safe or fit for its intended uses and purposes." Appellants' App'x vol. 1, at 30. The Cervenys argue that Clomid causes birth defects, making Clomid unfit for its ordinary purpose (having a baby). Appellants' Reply Br. at 26-27. That claim is not necessarily related to Clomid's labeling and is therefore not automatically preempted.

In sum, we reverse and remand the award of summary judgment on the claims of fraud, negligent misrepresentation, and breach of an implied warranty. *See Bell v. Pfizer, Inc.*, 716 F.3d 1087, 1095-96 (8th Cir. 2013) (remanding because the district court mistakenly treated claims for design defect and breach of an implied warranty as claims involving a failure to warn). We do not foreclose the possibility that these claims might be preempted. But on remand, the district court should explain the effect of preemption on the claims of fraud, negligent misrepresentation, and breach of an implied warranty. We reverse the entry of summary judgment on these claims.

IV. Additional Discovery

The Cervenys alternatively urge reversal and remand on the ground that the district court should have allowed more time for discovery. In district court, the Cervenys' attorney filed an affidavit seeking more time

for discovery under Federal Rule of Civil Procedure 56(d).[16] Nonetheless, the district court awarded summary judgment to Aventis without allowing the additional time.[17]

In reviewing the district court's refusal to allow further discovery, we apply the abuse-of-discretion standard. *Ellis v. J.R.'s Country Stores*,

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[16] Federal Rule of Civil Procedure 56(d) provides:

> **When Facts Are Unavailable to the Nonmovant.** If a nonmovant shows by affidavit or declaration that, for specified reasons, it cannot present facts essential to justify its opposition, the court may:
>
> (1) defer considering the motion or deny it;
>
> (2) allow time to obtain affidavits or declarations or to take discovery; or
>
> (3) issue any other appropriate order.

[17] The district court did not expressly rule on the Rule 56(d) affidavit. Ordinarily, remand to the district court may be appropriate. *See Patty Precision v. Brown & Sharpe Mfg. Co.*, 742 F.2d 1260, 1264 (10th Cir.1984) (remanding for the trial court to "specifically rule" on the plaintiff's Rule 56(d) affidavit "before making any ruling on the defendants' summary judgment motion"); *see also Greystone Constr., Inc. v. Nat'l Fire & Marine Ins. Co.*, 661 F.3d 1272, 1290 (10th Cir. 2011) ("[T]he better practice on issues raised [below] but not ruled on by the district court is to leave the matter to the district court in the first instance." (alteration in original) (internal quotation marks omitted)). But we have declined to remand when the district court did not explicitly rule on a Rule 56(d) issue. *See Comm. for First Amendment v. Campbell*, 962 F.2d 1517, 1522 (10th Cir. 1992) (holding that the district court did not abuse its discretion by implicitly denying a Rule 56(d) motion through the grant of summary judgment). The Cervenys do not complain that the district court failed to rule on the issue, and we conclude that a remand on this issue is unnecessary here.

Inc., 779 F.3d 1184, 1206 (10th Cir. 2015). Thus, we "defer to the district court's judgment so long as it falls within the realm of [the] rationally available choices." *Id.* (alteration in original) (internal quotation marks omitted). The district court did not abuse its discretion.

"[S]ummary judgment [should] be refused where the nonmoving party has not had the opportunity to discover information that is essential to his opposition." *Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 250 n.5 (1986). Requests for further discovery should ordinarily be treated liberally. *Comm. for First Amendment v. Campbell*, 962 F.2d 1517, 1522 (10th Cir. 1992). But relief under Rule 56(d) is not automatic. *Burke v. Utah Transit Auth. & Local 382*, 462 F.3d 1253, 1264 (10th Cir. 2006).

To obtain relief under Rule 56(d), the movant must submit an affidavit (1) identifying the probable facts that are unavailable, (2) stating why these facts cannot be presented without additional time, (3) identifying past steps to obtain evidence of these facts, and (4) stating how additional time would allow for rebuttal of the adversary's argument for summary judgment. *Valley Forge Ins. Co. v. Health Care Mgmt. Partners, Ltd.*, 616 F.3d 1086, 1096 (10th Cir. 2010); *Burke*, 462 F.3d at 1264.

The Cervenys' Rule 56(d) affidavit did not satisfy requirements (3) and (4). For example, the affidavit did not identify the discovery steps that had been taken or explain how additional discovery would rebut Aventis's preemption defense. Rather, the affidavit merely stated that additional

discovery would "outline the facts of the case" and provide "expert foundation." Appellants' App'x vol. III, at 618-19.

The Cervenys' summary judgment response arguably contains the information required in Rule 56(d). But we may not look beyond the affidavit in considering a Rule 56(d) request. *See Campbell*, 962 F.2d at 1522 ("[C]ounsel's unverified assertion in a memorandum opposing summary judgment does not comply with Rule [56(d)] and results in a waiver."). As a result, the district court did not abuse its discretion in declining to postpone its summary judgment ruling under Rule 56(d). *See Valley Forge*, 616 F.3d at 1096 (holding that an affidavit did not meet Rule 56(d)'s requirements when the affiant listed additional materials sought by the defendants, but made "no attempt to explain" why the defendants had lacked the evidence or how they had attempted to obtain it).

V. Disposition

We reverse the grant of summary judgment to Aventis on the failure-to-warn claims. We uphold the ruling on the Cervenys' theory that Aventis had a duty to warn of the risks of using Clomid prior to pregnancy, for claims based on this theory are preempted by federal law. But on remand, the district court should further address the claim based on the failure to use the FDA's own wording on the risk of harm to the fetus when Clomid is taken during pregnancy.

We affirm the district court's implicit denial of the Cervenys' request for additional time to conduct discovery.

Finally, we remand to the district court to address anew the Cervenys' claims involving fraud, negligent misrepresentation, and breach of an implied warranty.