FILED
United States Court of Appeals
Tenth Circuit

August 9, 2019

Elisabeth A. Shumaker
Clerk of Court

UNITED STATES COURT OF APPEALS

FOR THE TENTH CIRCUIT

VICTORIA CERVENY; CHARLES CERVENY; ALEXANDER CERVENY,

Plaintiffs - Appellants,

v.

AVENTIS, INC.,

Defendant - Appellee.

No. 17-4204
(D.C. No. 2:14-CV-00545-DB)
(D. Utah)

ORDER AND JUDGMENT*

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

This case comes to us a second time. Previously, we affirmed the district court's dismissal of the Cervenys' primary claim that Aventis had violated Utah law by failing to warn of alleged risks from *pre*-pregnancy ingestion of Clomid (a fertility drug). We ruled that federal law preempted this claim. But we reversed and remanded the district court's dismissal of the Cervenys' four remaining Utah state-law claims—for failure to warn of the risk of ingesting of Clomid *during* pregnancy, fraud, negligent misrepresentation, and breach of implied warranty—because the district court had not explained how federal law preempted those claims. In our remand, we expressed no view on the ultimate viability of

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* This order and judgment is not binding precedent, except under the doctrines of law of the case, res judicata, and collateral estoppel. It may be cited, however, for its persuasive value consistent with Fed. R. App. P. 32.1 and 10th Cir. R. 32.1.

these claims. After reviewing the district court's grant of summary judgment against the remanded claims, and exercising jurisdiction under 28 U.S.C. § 1291, we affirm.

BACKGROUND

In September and October 1992, Mrs. Victoria Cerveny's physician prescribed her Clomid, a drug that helps women conceive by stimulating ovulation.[1] Sometime after Mrs. Cerveny's October round of Clomid, she became pregnant (importantly, the parties agree that Mrs. Cerveny ingested Clomid *before*, not *after*, becoming pregnant). In late July 1993, she gave birth to Alexander, who arrived with serious birth defects: his left hand lacked the thumb and small finger, and his left elbow was beset with a flexion deformity that has required multiple surgeries and interventions.[2]

Twenty-one years after Alexander's birth, the Cervenys sued Aventis in the United States District Court for the District of Utah, alleging that pre-pregnancy ingestion of Clomid had caused Alexander's birth defects. In their Amended Complaint, the Cervenys allege that the 1992 version of the Clomid label had inadequately warned Clomid users of the risks to the fetus from ingesting the drug.

To track the Cervenys' claims, we must first summarize Clomid's regulatory history. The FDA approved Clomid in 1967, making it one of the first fertility drugs marketed. To obtain FDA approval for a brand-name drug like Clomid, manufacturers

[1] As we understand the briefs, the Cervenys attribute both Alexander's birth and birth defects to Clomid.

[2] The Cervenys assert that their families have no history of birth defects, and that Mrs. Cerveny later conceived, without fertility drugs, a second child, who had no birth defects.

submit an application, which includes a proposed label. 21 U.S.C. § 355(a), (b)(1); 21 C.F.R. § 314.50(c)(2)(i). Subject to limited exceptions, a manufacturer generally may not change the label for an approved brand-name drug without the FDA's permission. 21 U.S.C. §§ 331(a), (c), 352; 21 C.F.R. § 314.70. Clomid's original label reads, in relevant part:

> **CONTRAINDICATIONS**
> *Pregnancy*
> Although no causative evidence of a deleterious effect of Clomid (clomiphene citrate) therapy on the human fetus has been seen, such evidence in regard to the rat and the rabbit has been presented (see Animal Pharmacology and Toxicology). Therefore, Clomid should not be administered during pregnancy. *To avoid inadvertent Clomid administration during early pregnancy, the basal body temperature*[3] *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.

Cervenys' App. vol. 3 at 590 (emphasis in original).[4] Notably, this warning appears under "Contraindications," which "describe[s] those situations in which the drug should not be used because the risk of use clearly outweighs any possible benefit." 21 C.F.R. § 201.80(d). Under the heading "**ADVERSE REACTIONS**," the label contains the subheading "*Birth Defects.*" Cervenys' App. vol. 3 at 590–92. Here, the label advises that

[3] "Basal body temperature" is the body's temperature when fully at rest. Ovulation slightly increases basal body temperature. *See* Mayo Clinic, *Basal body temperature for natural family planning*, available at https://www.mayoclinic.org/tests-procedures/basal-body-temperature/about/pac-20393026.

[4] The 1992 version of this label contains identical language.

"[f]rom 2369 delivered and reported pregnancies associated with Clomid administration, 58 infants with birth defects were reported." *Id.* at 592. The label was revised in 1980, but the revised label retained the same pregnancy-contraindication language.

In 1981, Aventis's predecessor (Merrell Dow) proposed an amended label, which among other things would have deleted the language stating that "no causative evidence of a deleterious effect of Clomid therapy on the human fetus has been seen." Among the new language, the label would have included this:

> 4. Pregnancy Wastage and Birth Anomalies
>
> The overall incidence of reported birth anomalies from pregnancies associated with maternal Clomid ingestion during the investigational studies was within the range of that reported in published references for the general population. Among the birth anomalies spontaneously reported as individual cases since commercial availability of Clomid, the proportion of neural tube defects has been high among pregnancies associated with ovulation induced by Clomid, but this has not been supported by data from population-based studies.

Cervenys' App. vol. 9 at 1684, 1694. In a separate chart, the proposed label restated the findings of 58 births with birth defects from 2369 pregnancies. The FDA approved the proposed revision, asking Aventis to submit printed labeling identical to the draft copy, but Aventis did not ultimately incorporate these proposed revisions into the label.[5]

In 1986, the FDA directed Aventis to add a "Pregnancy category X" designation to Clomid's label. *Id.* vol. 3 at 584. The FDA used this designation when

[5] Before 2007, the FDA did not have the statutory authority to order a drug manufacturer to change a drug label "based on safety information that becomes available after a drug's initial approval." *See Wyeth v. Levine*, 555 U.S. 555, 567–68 (2009); 21 U.S.C. § 355(o)(4)(E).

> studies in animals or humans have demonstrated fetal abnormalities or if there is positive evidence of fetal risk based on adverse reaction reports from investigational or marketing experience, or both, and the risk of the use of the drug in a pregnant woman clearly outweighs any possible benefit (for example, safer drugs or other forms of therapy are available).

Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37434, 37464 (June 26, 1979). Aventis objected to this change. It protested that women already pregnant would have no reason to take Clomid, making the designation unnecessary and confusing.[6] Acknowledging this, in 1987 the FDA "suggest[ed]" the following label:

> 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.

Id. vol. 3 at 596. Aventis ultimately declined to use this label.[7]

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[6] Aventis proposed using "Pregnancy category B" instead. Such a designation was appropriate "[i]f animal reproduction studies ha[d] failed to demonstrate a risk to the fetus and there [we]re no adequate and well-controlled studies in pregnant women." Labeling and Prescription Drug Advertising; Content and Format for Labeling for Human Prescription Drugs, 44 Fed. Reg. 37434, 37464 (June 26, 1979). The FDA recently finalized a rule eliminating the pregnancy category system because "the pregnancy categories were confusing and did not accurately and consistently communicate difference in degrees of fetal risk." *See* Content and Format of Labeling for Human Prescription Drug and Biological Products; Requirements for Pregnancy and Lactation Labeling, 79 Fed. Reg. 72064, 72065 (Dec. 4, 2014).

[7] In December 1993, five months after Alexander's birth, Aventis changed the relevant language in Clomid's label. In September 1994, Aventis amended the relevant language again. The relevant portion of the 1994 label reads:

Based on this regulatory history, Aventis moved to dismiss the Cervenys' Amended Complaint. The district court granted the motion for several claims,[8] but it denied it for four others: failure to warn, fraud, negligent misrepresentation, and breach of implied warranty. About a year later, the district court granted summary judgment on those four claims, concluding that federal preemption applied. *Cerveny v. Aventis, Inc.*, 155 F. Supp. 3d 1203 (D. Utah 2016). The Cervenys appealed.

On appeal, we agreed with the district court that federal preemption defeated the Cervenys' claim for failure to warn of risks from ingesting Clomid *before* pregnancy. *Cerveny v. Aventis, Inc.*, 855 F.3d 1091, 1095, 1110 (10th Cir. 2017) ("*Cerveny I*"). In

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> **CONTRAINDICATIONS**
> * * *
> **Pregnancy**
> CLOMID should not be administered during pregnancy. CLOMID may cause fetal harm in animals (see Animal Fetotoxicity). Although no causative evidence of a deleterious effect of CLOMID therapy on the human fetus has been established, there have been reports of birth anomalies which, during clinical studies, occurred at an incidence within the range reported for the general population (see Fetal/Neonatal Anomalies and Mortality; ADVERSE REACTIONS).
> To avoid inadvertent CLOMID administration during early pregnancy, appropriate tests should be utilized during each treatment cycle to determine whether ovulation occurs. The patient should be evaluated carefully to exclude pregnancy, ovarian enlargement [sic], or ovarian cyst formation between each treatment cycle. The next course of CLOMID therapy should be delayed until these conditions have been excluded.

Id. vol. 3 at 599; vol. 2 at 443.

[8] The dismissed state claims were for design defect, manufacturing defect, strict liability for failure to warn, punitive damages, breach of express warranty, negligent design, negligence per se, and unjust enrichment.

support, we concluded that Aventis had shown "clear evidence" that in 1992 the FDA would have rejected this warning.[9] *Id.* at 1105–06. As support, we relied on the FDA's 2012 denial of a citizen petition requesting that the FDA order Aventis to add such a warning to Clomid's label. *Id*. at 1101–03, 1106.

But we remanded for the district court to reconsider the Cervenys' other claims. *Id.* at 1108. Though not taking a position on whether the remanded claims would

[9] The Cervenys have filed a Rule 28(j) letter advising us of *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S. Ct. 1668 (2019). They contend that *Albrecht* runs counter to our decision in *Cerveny I*, in which we preempted their pre-pregnancy-usage failure-to-warn claim. Specifically, the Cervenys contend that *Albrecht* "dictates that only labeling changes sought by the manufacturer can lead to preemption," and that "Aventis never sought the changes proposed by the Cervenys." Cervenys' Rule 28(j) letter at 1. But we note that *Albrecht* prefaced its requirement that "[the drug manufacturer] fully informed the FDA of the justifications for the warning required by state law" as applying "[i]n a case like *Wyeth* [*v. Levine*, 555 U.S. 555 (2009)]" and noted that "in *Wyeth*, [the Court] confronted [the impossibility-preemption question] in the context of a particular set of circumstances." *Albrecht*, 139 S. Ct. at 1678. And here, the Cervenys' case involves a particular set of circumstances with a key difference from those in *Wyeth*. In *Wyeth*, the Court needed to decide whether Wyeth was entitled to impossibility preemption based on the FDA's having earlier approved a drug label not warning of the specific dangers posed by the IV-push method of administering the drug. 555 U.S. at 558, 563. In *Wyeth*'s particular set of circumstances, the Court evaluated whether Wyeth had shown "clear evidence" that the FDA would have rejected the plaintiff's proposed label change warning of a risk from using the IV-push method of administering Phenergan. *Id.* at 571–72. The Court concluded that Wyeth had failed to make this showing, noting in part that Wyeth had not shown that it had "supplied the FDA with an evaluation or analysis concerning the specific dangers posed by the IV-push method." *Id.* at 572–73. Here, Aventis argues a different ground to show that the FDA would have rejected the Cervenys' proposed warning. Unlike Wyeth, Aventis is not left to show clear evidence that the FDA would have rejected any unilateral label change under the CBE regulation, 21 C.F.R. § 314.70(c)(6)(iii), *see Wyeth*, 555 U.S. at 572–73, but Aventis has a separate avenue—the FDA's unequivocally having rejected Terry Mix's citizen petition advocating for the warning that the Cervenys now assert. We see nothing in *Wyeth* or *Albrecht* excluding Aventis from justifying preemption on this basis.

ultimately be viable, we required the district court to explain its reasoning that federal preemption would defeat those claims, and if it would not, whether they could proceed under Utah law. *Id.* at 1106. We expressed doubts about whether federal preemption would apply against the remaining claims, noting that those claims rested on the FDA's own proposed 1987 label language. *Id.* at 1095. And we declared that Aventis could unquestionably have used the FDA's proposed language. *Id*. at 1108.

But all this left the Cervenys in a tight spot on remand. First, as noted, they had agreed that Mrs. Cerveny ingested Clomid *before*, and not *after*, becoming pregnant with Alexander. Second, we had ruled that federal law preempted their claim that Aventis had failed to warn of alleged risks from *pre*-pregnancy Clomid use. Third, their remaining failure-to-warn claim was for failure to adequately warn about *during*-pregnancy ingestion of Clomid—even though Mrs. Cerveny had not ingested Clomid during her pregnancy. And fourth, even if the Cervenys were able to surmount those difficulties, they would still need to prove that *pre*-pregnancy ingestion of Clomid had indeed caused Alexander's birth defects—a causation argument that the FDA has obviously not adopted in Clomid's 52-year run.

As for the Cervenys' fraud, negligent-misrepresentation, and breach-of-implied warranty claims,[10] we remanded on grounds that the district court had implicitly treated them as preempted failure-to-warn claims. *Id.* at 1108. We noted the Cervenys' allegation "that Clomid's label falsely represented that no one had seen any evidence of causation

[10] On remand, the Cervenys abandoned their breach-of-implied-warranty claim.

between the use of Clomid and fetal harm." *Id.* at 1109. And we further noted that just because "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." *Id.* (emphasis in original).

In considering Aventis's post-remand motion for summary judgment, the district court accurately characterized the Cervenys' failure-to-warn theory as being "that Victoria Cerveny would not have taken Clomid *before* she was pregnant if she had known that taking it *after* she was pregnant could cause birth defects[.]"[11] *Cerveny v. Aventis, Inc.*, No. CIV 0545-DB, 2017 WL 5897406, at *4 (D. Utah Nov. 29, 2017) (emphasis in original). Against this, the court weighed Aventis's argument that the Cervenys could not premise a *pre*-pregnancy-ingestion failure-to-warn claim on the alleged inadequacy of the 1992 label's warning about *during*-pregnancy-ingestion risk. *Id.* at *3–4.

The district court ruled in favor of Aventis, stressing the undisputed fact that "Alexander Cerveny was not harmed by Victoria Cerveny ingesting Clomid *while* she was pregnant with him because she did not ingest Clomid *while* she was pregnant." *Id.* at *5. Applying Utah law, the district court concluded that the Cervenys "cannot prevail on their failure to warn cause of action based on [Aventis's] alleged failure to warn about the risk of taking Clomid *during* pregnancy." *Id.* In addition, the district court ruled that the

[11] In *Cerveny I*, we accepted the Cervenys' argument that they had alleged this additional failure-to-warn theory in their Amended Complaint, rejecting Aventis's argument to the contrary. 855 F.3d at 1107.

relevant portion of the 1992 version of the Clomid label (using identical language to the original label) "specifically discussed the potential for fetal harm," and "as a matter of Utah law" adequately warned of the risk of birth defects from ingesting Clomid during pregnancy. *Id.*[12]

DISCUSSION

The Cervenys appeal the district court's summary-judgment order, arguing that a jury must decide their claims for failure to adequately warn of the risk of fetal harm from ingesting Clomid during pregnancy, negligent misrepresentation, and fraud. We review de novo a district court's summary-judgment ruling. *Amro v. Boeing Co.*, 232 F.3d 790, 796 (10th Cir. 2000). Summary judgment is appropriate only if "the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." Fed. R. Civ. P. 56(a); *Celotex Corp. v. Catrett*, 477 U.S. 317, 322 (1986).

I. Failure to Warn

The Cervenys set forth the following elements of a failure-to-warn claim in Utah: "(1) the defendant 'knew or should have known of the risks involved, (2) the risk was not disclosed or adequately disclosed rendering the product unreasonably dangerous, and (3)

[12] At least in part, the district court ruled that the Cervenys lacked standing to pursue a claim for harm allegedly caused by pre-pregnancy ingestion of Clomid by relying on a supposedly inadequate warning of the risk of harm from during-pregnancy ingestion of Clomid. *Id.* (citing *Rivera v. Wyeth–Ayerst Labs*, 283 F.3d 315, 321 (5th Cir. 2002)).

the failure to provide an adequate warning caused the injury.'" Appellant's Br. at 18 (quoting *Herrod v. Metal Powder Prod.*, 413 Fed. App'x 7, 18–19 (10th Cir. 2010)).[13]

The Cervenys' remaining failure-to-adequately-warn claim—the warning about ingesting Clomid *during* pregnancy—fails on the first prong. As the district court noted, Mrs. Cerveny never encountered that risk (meaning it is not the risk involved)—she did not ingest Clomid during her pregnancy. *See Cerveny*, 2017 WL 5897406, at *2–3. And as Aventis points out, the Cervenys have cited no Utah law authorizing a failure-to-adequately-warn claim on their unusual theory. The Cervenys highlight two Utah cases they assert are instructive and analogous to their own case. But those two cases, in addition to others they cite, differ from the Cervenys' case in a dispositive way—they involve a precise symmetry between a risk actually encountered and the injury. *See House*, 886 P.2d at 342, 345 (deputy sheriff shot and killed by rifle fire when his body armor had no warning that it would not stop rifle fire); *Shipley v. Forest Labs, Inc.*, No. CIV 06-0048-TC, 2015 WL 4199739, at *1, 3–4 (D. Utah July 13, 2015) (man commits suicide while taking the drug Lexapro when the drug's label did not warn that it could increase or induce suicidal thoughts and behavior.).

Nor is this a case where we could confidently expand Utah law to include the Cervenys' claims on grounds that the Utah Supreme Court likely would do so. "As a federal court, we are generally reticent to expand state law without clear guidance from [the state's] highest court . . . ." *Taylor v. Phelan*, 9 F.3d 882, 887 (10th Cir. 1993). We

[13] Aventis lists the same elements. Appellee's Br. at 29.

see no basis to expand Utah's failure-to-warn law to a place so far outside the mainstream. *See Proctor & Gamble Co. v. Haugen*, 222 F.3d 1262, 1280 (10th Cir. 2000) ("[I]t is not our place to expand Utah state law beyond the bounds set by the Utah Supreme Court or, in the absence of Utah Supreme Court precedent, by the lower Utah courts.").

Further, we agree with the district court that the 1992 version of the Clomid label adequately warned of risk from Clomid use during pregnancy. *See Cerveny*, 2017 WL 5897406, at *5 (citing *House*, 929 P.2d at 343; *House v. Armour of Am., Inc.*, 886 P.2d 542, 547 (Utah Ct. App. 1994)). The pregnancy contraindication advised that "Clomid should not be administered during pregnancy," and in italicized text it gave a method to ensure that it was not so administered—monitoring basal body temperature throughout treatment cycles. Cervenys' App. vol. 3 at 590. And the adequacy of this warning breaks a link in the Cervenys' failure-to-warn theory and claim. Simply put, the warning about the risk of ingesting Clomid during pregnancy sufficed even if it did not frighten Mrs. Cerveny from using Clomid before pregnancy.

II. Negligent Misrepresentation and Fraud

The Cervenys also allege claims for fraud and negligent misrepresentation. Utah law recognizes negligent misrepresentation as "a form of fraud." *Smith v. Frandsen*, 94 P.3d 919, 923 (Utah 2004). They note that the two claims each rely on an affirmative false statement—for fraud, a statement made with knowledge of falsity; and for negligent misrepresentation, a statement "made due to carelessness, without knowledge of falsity." Appellant's Br. at 39–40 (citing *Schwartz v. Celestial Seasonings, Inc.*, 124 F.3d 1246,

1252 (10th Cir. 1997) (requiring specific allegations about the false representation to support a fraud claim)); and *Christenson v. Commonwealth Land Title Ins. Co.*, 666 P.2d 302, 305 (Utah 1983) (including carelessly or negligently making a false representation as an element of a negligent-misrepresentation claim).

The Cervenys claim that Aventis provided a false statement in the introductory sentence from the 1992 version of Clomid label:

> **CONTRAINDICATIONS**
>
> *Pregnancy*
>
> Although no causative evidence of a deleterious effect of Clomid (clomiphene citrate) therapy on the human fetus has been seen, such evidence in regard to the rat and rabbit has been presented (see Animal Pharmacology and Toxicology). 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.

Cervenys' App. vol. 3 at 590 (emphasis in original).

The first sentence must be read as part of the entire paragraph. The paragraph speaks to the risk of fetal harm if Clomid is ingested *during* pregnancy. The Cervenys cannot isolate the first sentence from the rest of the paragraph. And even if Aventis had deleted the first sentence, the warning would not suddenly sound an alarm about risk to a fetus from the mother's ingesting Clomid before pregnancy. By speaking of a possible risk of fetal harm if Clomid is used during pregnancy, while silent about any harm if used

before pregnancy, the warning would implicitly assure women they risked no harm from pre-pregnancy ingestion.

The same is true even had Aventis adopted the FDA's proposed 1987 label change. That proposed language read as follows:

> 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.

Id. vol. 3 at 596. Here again, the message is that using Clomid during pregnancy risks fetal harm, but, implicitly, that pre-pregnancy ingestion does not.

Even so, the Cervenys contend that the first sentence is false, pointing to Aventis's reported studies showing 58 total birth defects involving patients using Clomid. But this number needs context. The Clomid label in effect when Mrs. Cerveny took the drug stated under a "Birth Defects" subheading that "[f]rom 2369 delivered and reported pregnancies associated with Clomid administration, 58 infants with birth defects were reported." Cervenys' App. vol. 3 at 592. This would indicate a 2.45% rate of birth defects, which is *lower* than the prevalence of birth defects among the general population.[14]

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[14] *See* Centers for Disease Control and Prevention, *Updated National Birth Prevalence Estimates for Selected Birth Defects in the United States, 2004–2006*, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5701a2.htm, ("Birth defects occur in about 3% of all live births."); Centers for Disease Control and Prevention, *Update on Overall Prevalence of Major Birth Defects—Atlanta, Georgia, 1978–*

Further, in assessing the truth or falsity of the first sentence, we cannot ignore the FDA's own findings on this point. As Aventis notes, the FDA independently reviewed the medical evidence in 2007 and 2009 and concluded "that the data is insufficient to demonstrate reasonable evidence of an association between clomiphene citrate and congenital abnormalities." Appellee's Br. at 16 (citing Cervenys' App. vol. 2 at 389). And the FDA's present warning continues along this line.[15]

In addition, the district court dismissed these claims because "the pregnancy contraindication was not directed to women like Victoria Cerveny who were prescribed the medication specifically for use *before* becoming pregnant." *Cerveny*, 2017 WL 5897406, at *6. In one sense, Aventis directed the warning to any woman considering using Clomid at all. But we agree with the district court that the warned risk exclusively concerned the use of Clomid *during* pregnancy. And in that sense, the warning never

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2005, https://www.cdc.gov/mmwr/preview/mmwrhtml/mm5701a2.htm ("Major structural or genetic birth defects affect approximately 3% of births in the United States.").

[15] The current version of the Clomid label continues to contraindicate the drug for pregnant women and further advises:

> Available human data do not suggest an increased risk for congenital anomalies above the background population risk when used as indicated. However, animal reproductive toxicology studies showed increased embryo-fetal loss and structural malformations in offspring. If this drug is used during pregnancy, or if the patient becomes pregnant while taking this drug, the patient should be apprised of the potential risks to the fetus. (See PRECAUTIONS: Pregnancy.).

United States Food & Drug Administration, https://www.accessdata.fda.gov/drugsatfda_docs/label/2012/016131s026lbl.pdf.

applied to (or was directed to) Mrs. Cerveny. The warning cautions against using Clomid at one certain time—during pregnancy. So, we also agree with the district court that "Clomid's warning label, including its pregnancy contraindication, were not intended to induce women to take the drug." *Id*.

CONCLUSION

Consistent with this opinion, we affirm the judgment of the district court.

Entered for the Court

Gregory A. Phillips
Circuit Judge