IN THE COURT OF APPEALS
STATE OF ARIZONA
DIVISION ONE

KRISTEN-MARIE LYNETTE MYERS, by and through her Guardian Ad Litem, HEIDI MYERS, Plaintiff/Appellant, v. HOFFMAN-LA ROCHE, INC.; ROCHE LABORATORIES, INC.; MARY F. FREDENBURG, M.D., Defendants/Appellees.	1 CA-CV 06-0137 DEPARTMENT A **OPINION** **(Amended by Order filed 10-5-08)**

Appeal from the Superior Court in Maricopa County

Cause No. CV 2005-006573

The Honorable Paul J. McMurdie, Judge

REVERSED AND REMANDED

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J O H N S E N, Judge

¶1 Through her mother, Kristen-Marie Lynette Myers sued Hoffman-La Roche, Inc. and Roche Laboratories, Inc. (together "Roche") and Mary F. Fredenberg, M.D., seeking damages for personal injuries she sustained after her mother took Accutane, a drug manufactured by Roche, while she was pregnant with Kristen-Marie. The complaint alleged claims of negligence, strict products liability and breach of express and implied warranty against Roche and a claim of medical negligence against Fredenberg, who prescribed Accutane to Kristen-Marie's mother. Each defendant moved to dismiss, asserting that Kristen-Marie's complaint constituted a claim for "wrongful life," for which Arizona permits no relief. *See Walker v. Mart*, 164 Ariz. 37, 790 P.2d 735 (1990). Roche also asserted that its warnings about the dangers of Accutane were adequate as a matter of law pursuant to the "learned intermediary" doctrine. After the superior court granted defendants' motions to dismiss, Kristen-Marie brought this appeal.

¶2 We hold the claims Kristen-Marie alleges are not barred by the "wrongful life" doctrine because she sues not for a "wrongful life" but rather for the damages she sustained *in utero*, allegedly as a result of defendants' tortious acts. We also hold that her allegations were sufficient to state claims against Roche, notwithstanding the "learned intermediary" doctrine. Accordingly, we reverse the superior court's entry of judgment in favor of defendants and remand for further proceedings.

I. THE ALLEGATIONS OF THE COMPLAINT

A. Allegations About Accutane and Roche's Purported Failure to Properly Instruct Prescribing Physicians.

¶3 Kristen-Marie filed her complaint on April 19, 2005, and an amended complaint on August 16, 2005. According to the amended complaint, Roche manufactured Accutane for treatment of severe cystic acne.[1] The amended complaint alleged that the drug is a teratogen in that it can cause catastrophic physical and cognitive birth defects and abnormalities in children who are exposed to it during gestation. Fetal exposure to Accutane has been linked to significantly decreased cognitive abilities, premature births and stillbirths. Ingestion of Accutane during gestation is known also to cause abnormalities in the fetus's central nervous system, cardiovascular system and in the skull, external ear and eye.

¶4 According to the amended complaint, as it brought Accutane to market in the United States in the early 1980s, Roche was aware the drug was associated with birth defects in children whose mothers took Accutane during pregnancy. According to the amended complaint, Roche at the time advocated abortion in all Accutane-affected pregnancies. As Kristen-Marie further alleged, Roche "chose to emphasize abortion over a comprehensive and adequate pregnancy prevention program because Roche feared that such a

[1] "In reviewing the grant of a motion to dismiss a complaint, we assume the facts alleged in the complaint to be true and give plaintiffs the benefit of all inferences arising from those facts." *Capitol Indem. Corp. v. Fleming*, 203 Ariz. 589, 590, ¶ 2, 58 P.3d 965, 966 (App. 2002).

such a program would substantially reduce sales" of the drug. Ultimately, according to the amended complaint, the United States Food and Drug Administration ("FDA") disproved the notion that each exposure of Accutane to a pregnant woman would result in birth defects. According to the amended complaint, the "current judgment" is that 25 percent of women who take Accutane while pregnant bear children impaired by catastrophic birth defects.

¶5 In 1988, in the face of recommendations from senior FDA officials that Accutane be removed from the market, Roche implemented a "Pregnancy Prevention Program," by which, according to the amended complaint, it purported to give "family planning and contraceptive counseling to female Accutane users of child-bearing potential." Roche's Pregnancy Prevention Program included instructions to the prescribing physician and the patient that were printed in a Patient Information/Consent and Enrollment Form ("Patient Information Form"), package inserts, other labeling, and scripts to be read by treating physicians to patients.

¶6 According to the amended complaint, Roche's Pregnancy Prevention Program "failed in its essential purpose." Roche gathered "substantial evidence of incomplete use and understanding of the program, causing Roche to conclude that the program contained serious weaknesses." According to a study conducted in the 1990s, "unacceptably high percentages of physicians and patients were not complying with core components of the pregnancy-prevention program." By 2000, according to the amended complaint, Roche was aware of

Roche was aware of 1,995 cases of Accutane-exposed pregnancies, of which 70 percent occurred after Roche implemented its Pregnancy Prevention Program. The amended complaint alleged that in hearings before an FDA committee in September 2000, Roche admitted that its Pregnancy Prevention Program was flawed because "patients were often not able to comprehend its instructions and follow the core concepts" of the program.

¶7 According to the amended complaint, Accutane also has been linked to "depression, psychosis and other psychiatric and psychological disturbances" in women who take the drug. Depression affects one's "capacity to consider, appreciate and follow instructions and warnings in general." According to the amended complaint, depression "also affects a person's attitudes relating to complicated social issues like sex" and Roche knew throughout the 1990s "that depression caused by Accutane had a substantial likelihood to undermine a patient's ability to comprehend its pregnancy-prevention instructions." The amended complaint alleged that "Roche was negligent in failing to warn, instruct and educate dermatologists regarding depression and its effects on patients' ability to comply with pregnancy prevention procedures."

¶8 Because of the substantial risk of birth defects linked to Accutane, Roche required dermatologists to question and counsel patients with respect to any potential pregnancy. For example, according to a FDA briefing document (as quoted in the amended complaint), Roche directed that prescribing physicians must:

1. question the patient thoroughly relative to sexual activity and contraceptive use[.]

2. carefully assess the patient's responses.

3. effectively guide, counsel and motivate them in sound contraceptive practice and continue to monitor and reinforce this throughout treatment.

4. assure that patients are not pregnant before they start their Accutane treatment.

¶9 The amended complaint alleged that Roche had a duty not only to warn of the danger of birth defects posed by Accutane "but also to provide adequate instructions and information essential to make the use of Accutane as safe as possible." The amended complaint continued, "In this case, safe use requires adequate, safe and competent instructions and advice concerning regular pregnancy testing to ensure that a child, once conceived, is not regularly exposed to Accutane over a number of days in an amount sufficient to cause severe and debilitating birth defects." The amended complaint alleged that Roche's instructional program was "defective and inadequate [and] fails to prevent fetal exposure to Accutane and resulting birth defects." "It is specifically contrary to reasonably prudent practice and to the standard of care," the amended complaint alleged, "not to have an instructional regime in place that ensures that female Accutane patients do not expose unborn children to this dangerous drug."

¶10 It was not until 2001 and 2002, the amended complaint alleged, that Roche implemented a "Targeted Pregnancy Prevention Program," which "emphasized contraceptive counseling by increasing

pregnancy prevention education for likely treating physicians, including dermatologists." The same program also included "additional efforts to educate patients regarding compliance strategies and the consequences of failure."

¶11 The amended complaint asserted that due to the severe risks posed by Accutane and the flaws in its Pregnancy Prevention Program, Roche should have instituted a "national registry" that would have permitted "only those treating physicians and pharmacists who have completed extensive instruction and training programs in pregnancy prevention to prescribe and distribute the drug." According to the amended complaint, under the registry program that Roche eventually did put in place, a pharmacy may not fill a prescription for a woman unless she presents a record of a negative pregnancy test within the previous seven days. If the registry system had been in place in 1996, the amended complaint alleged, the pharmacy could not have given Accutane to Kristen-Marie's mother.

B. The Accutane Prescriptions Given to Kristen-Marie's Mother, and Kristen-Marie's Condition Upon Her Birth.

¶12 According to the amended complaint, Fredenberg prescribed Accutane for Kristen-Marie's mother beginning in late May 1996. Her mother underwent pregnancy tests, each of which was negative, on May 31, July 2 and August 7. No pregnancy test was performed in September. On September 3, Fredenberg prescribed four more weeks of

more weeks of Accutane, and Kristen-Marie's mother continued on the drug through September and October.

¶13 Kristen-Marie was born on May 11, 1997. Based on her birthdate, it was estimated that her mother took Accutane during the first eight weeks of her pregnancy. According to the amended complaint, Kristen-Marie was born with "severe cognitive and physical birth defects that will require intensive care for the rest of her life."

C. The Claims Alleged Against Roche and Fredenberg.

¶14 The amended complaint alleged that Roche acted negligently by manufacturing an unsafe product and distributing it with "substandard instructions and warnings." Specifically as it pertains to this appeal, the amended complaint alleged that Roche failed "to give adequate warnings of the hazards associated with" Accutane, failed "to act on reports of undetected pregnancies prior to Accutane treatment," failed "to adequately warn the public in general, and the Plaintiff['s mother] in particular, that despite reasonable efforts at methods of birth control[,] Accutane maternal fetal exposures will occur," and marketed "the drug to the public in a manner which created the impression that birth control methods were sufficient to eliminate fetal exposure to Accutane."

¶15 Additionally, the amended complaint alleged that Roche acted negligently by "failing to train physicians in the appropriate uses and indications of [Accutane] to prevent known side effects" and by "failing to institute appropriate policies and procedures to

procedures to prevent the type of injury suffered by" Kristen-Marie.

¶16 In her second cause of action, which alleged a claim for strict products liability, Kristen-Marie alleged that Accutane was a defective product, unreasonably dangerous in its design and/or manufacture, "including inadequate instructions and labeling and the defective 1988 safety program which was known to have an unacceptable failure rate."[2]

¶17 The amended complaint alleged that Fredenberg acted negligently by failing "to consider [Kristen-Marie's mother's] emotional and physical history prior to prescribing Accutane" and by failing to perform "all required pregnancy blood tests."

¶18 Kristen-Marie sought damages against all defendants for pain and suffering, emotional distress, hospital and other medical expenses, loss of earnings and punitive damages.

II. LEGAL ANALYSIS

A. Basic Principles and Standard of Review.

¶19 "A [defendant's] motion to dismiss for failure to state a claim admits the truth of all material allegations of the nonmoving party." *Carrillo v. State*, 169 Ariz. 126, 129, 817 P.2d 493, 496 (App. 1991). Motions to dismiss are not favored because they test the legal sufficiency of the complaint without the benefit of a

[2] The complaint also alleged claims against Roche for breach of express and implied warranties. Kristen-Marie does not appeal the superior court's dismissal of those claims.

benefit of a fully developed factual record. *See Newman v. Maricopa County*, 167 Ariz. 501, 504, 808 P.2d 1253, 1256 (App. 1991).

¶20 Thus, a trial court should grant a motion brought pursuant to Arizona Rule of Civil Procedure 12(b)(6) only when it appears certain that the plaintiff would not be entitled to relief under any theory given the facts and claims alleged. *See Forum Dev., L.C. v. Ariz. Dep't of Revenue,* 192 Ariz. 90, 93, 961 P.2d 1038, 1041 (App. 1997). Although we review the superior court's dismissal of the complaint for an abuse of its discretion, we review questions of law *de novo*. *Dressler v. Morrison*, 212 Ariz. 279, 281, ¶ 11, 130 P.3d 978, 980 (2006).

B. "Wrongful Life" Rule.

¶21 In their separate motions to dismiss the amended complaint,[3] Roche and Fredenberg argued that Kristen-Marie's claims were based on their alleged failure to ensure that her mother did not become pregnant while taking Accutane and thus constituted claims for "wrongful life." Citing *Walker*, 164 Ariz. 37, 790 P.2d 735 (1990), they argued that the amended complaint should be dismissed because Arizona law permits no such claim to be stated.

¶22 Although the superior court did not explain its ruling, we presume the court concluded that the amended complaint failed to

[3] After Roche moved to dismiss the original complaint, Kristen-Marie filed an amended complaint. Roche then withdrew its original motion and filed a revised motion to dismiss the amended complaint. Fredenberg's motion to dismiss followed.

state a claim against any defendant pursuant to *Walker*. That case was brought by a child born with severe birth defects and her mother, both of whom sued a physician and his assistant, alleging they negligently failed to detect that the mother had contracted rubella during the first trimester of her pregnancy. *Id.* at 38, 790 P.2d at 736. The mother alleged that had she been told she had contracted rubella and been warned of the significant risks the disease posed to her fetus, she would have aborted the fetus. *Id*.

¶23 Responding to a question certified to it by the United States District Court, our supreme court explained that the premise of both sets of claims was that the "defendants wrongfully deprived [the mother] of relevant information pertaining to the fetal risk, thereby preventing her from invoking her legal right to terminate the pregnancy." *Id*. at 39, 790 P.2d at 737. Specifically addressing the claims brought by the daughter, the court said she alleged "she was damaged by defendants' negligence because [her mother], ignorant of the fetal risk, allowed the pregnancy to go to term. As a result, [daughter] was born and must now live in an impaired condition." *Id.*

¶24 In a detailed analysis, the *Walker* court described a category of lawsuits brought by children who allege what it called claims for "wrongful life." Some such actions are brought by "normal but unwanted children who seek damages either from parents, doctors, or institutions negligently responsible for their

conception or birth." *Id.*[4] Other such claims are brought by "impaired children" who "allege that because of defendants' negligence, their parents either decided to conceive them ignorant of the risk of impairment or were deprived of information that would have impelled them to terminate the pregnancy." *Id.* at 40, 790 P.2d at 738.[5]

¶25 To determine whether such allegations may state a claim under Arizona law, the court began with the proposition that a mother's physician owes both the mother and her fetus a duty to inform the mother about fetal problems and risks, such that "if defendants' negligence injured [the daughter], she could bring a tort action against them." 164 Ariz. at 41, 790 P.2d at 739. But the daughter in *Walker* did not allege "that defendants injured her *in utero* nor [did] she allege defendants could have done anything to prevent or mitigate the unfortunate conditions with which she is afflicted." *Id.* Put differently, the defendants in that case

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[4] The court cited as an example a case alleging failure of a contraceptive method. *Id.* at 40, 790 P.2d at 738 (citing *Coleman v. Garrison*, 349 A.2d 8 (Del. 1975), *overruled on other grounds by Garrison v. Med. Ctr. of Del.*, 571 A.2d 786 (Del. 1989)). It distinguished such claims from similar claims brought by a child's parents. *E.g. University of Arizona Health Sciences Center v. Superior Court*, 136 Ariz. 579, 667 P.2d 1294 (1983) (failed vasectomy).

[5] Suits of this nature are "based on the premise that being born, and having to live, with the affliction is a disadvantage and thus a cognizable injury, when compared with the alternative of not having been born at all – that an impaired existence is worse than nonexistence – and that, if that injury results from the defendant's negligence, a cause of action exists." *Kassama v. Magat*, 792 A.2d 1102, 1104 (Md. 2002).

"caused none of the impairments" the daughter suffered; the only "damage" arguably resulting from their negligence was that she was born. *Id.* at 42, 790 P.2d at 740. Concluding that children have "neither the ability nor the right to determine questions of conception, termination of gestation, or carrying to term," the court held that the daughter had no cause of action against defendants for failing to enable her mother to prevent her birth. *Id*.[6]

¶26 Kristen-Marie's claim is different than that asserted by the daughter in *Walker*. There was no contention in *Walker* that defendants' negligence caused the injuries with which the daughter was born. Instead, the daughter there alleged that the defendants effectively *caused her life* by preventing her mother from terminating the pregnancy. By contrast to the claim asserted in *Walker*, Kristen-Marie asserted that defendants negligently *caused her injuries*. Specifically, she alleged that Roche and Fredenberg negligently adopted and carried out an inadequate safety program and that absent their negligence, she would not have received sufficient exposure to Accutane to inflict the very serious defects with which she was born.

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[6] In reaching its conclusion, the court noted that by contrast, if a parent proves that a physician's negligence prevented her from choosing to terminate a pregnancy, that parent may bring a "wrongful birth claim" against the physician. *Id.* at 39, 790 P.2d at 737; *see id.* at 42, 790 P.2d at 740 (if defendants negligently failed to provide information to mother that would have prompted her to terminate pregnancy, "any wrong that was done was a wrong to the

¶27 The central premise of Kristen-Marie's claims -- bearing in mind that on appeal we assume the truth of the facts alleged in the amended complaint, *see Capitol Indem. Corp. v. Fleming*, 203 Ariz. 589, 590, ¶ 2, 58 P.3d 965, 966 (App. 2002) -- is that absent defendants' negligence, she would have been born without the severe impairments that Accutane allegedly inflicted on her during gestation. Kristen-Marie explicitly alleged that Roche knew that its Pregnancy Prevention Program was not effective, and that young women such as her mother were becoming pregnant while taking Accutane despite Roche's warnings to avoid pregnancy. According to the amended complaint, Roche knew from a study conducted in the 1990s that its Pregnancy Prevention Program "contained serious weaknesses" because "unacceptably high percentages of physicians and patients were not complying with core components" of the program.

¶28 By contrast to the complaint in *Walker*, nowhere did the amended complaint in this case allege that Kristen-Marie's mother would have terminated her pregnancy if she had known she had become pregnant while taking Accutane. Instead, fairly read, the amended complaint alleged that Roche's Pregnancy Prevention Program negligently permitted and encouraged Fredenberg to prescribe Accutane for Kristen-Marie's mother despite a substantial risk that she would become pregnant while taking the drug and permitted Fredenberg to continue to prescribe the drug (and a pharmacy to fill

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the parents, not to the fetus").

fill that prescription) even after she became pregnant with Kristen-Marie. Construed in such a manner, the amended complaint does not state a claim by Kristen-Marie for a "wrongful life" but instead states a claim for the damages caused by defendants' negligence in permitting her mother to take Accutane despite the risk that she would become pregnant or the fact that she had become pregnant.[7]

¶29 According to the amended complaint, despite the warnings contained in the packaging materials and in the Patient Information Form, Roche's Pregnancy Prevention Program was flawed, in part because "patients were often not able to comprehend its instructions and follow the core concepts" of the program. The amended complaint also alleged that Roche negligently relied on dermatologists such as Fredenberg to act as birth-control counselors even though they were not properly trained to do so. For example, Kristen-Marie alleged that Fredenberg gave her mother another prescription for Accutane in early September 1996 without requiring that she first undergo a pregnancy test. A fair reading of the amended complaint is that had a pregnancy test been conducted, the pregnancy would have been discovered and the use of Accutane would have been discontinued, perhaps before significant damage was done to the fetus. Thus, the

[7] The claim against Fredenberg was that the physician negligently prescribed Accutane for Kristen-Marie's mother despite a substantial risk that the mother would become pregnant and that Fredenberg negligently wrote a prescription for Kristen-Marie's mother after the mother had become pregnant.

damage was done to the fetus. Thus, the amended complaint alleged that Roche was required to provide "adequate, safe and competent instructions and advice concerning regular pregnancy testing to ensure that a child, once conceived, is not regularly exposed to Accutane over a number of days in an amount sufficient to cause severe and debilitating birth defects."

¶30 More generally, the amended complaint also can be read to allege that Roche's instructional program was fundamentally flawed in that it permitted physicians such as Fredenberg, who allegedly lacked training in gynecological and family planning matters, to prescribe Accutane without careful and effective inquiry into whether a patient was capable of following the warnings about the need to practice birth control while taking the drug.[8] It also

drug.[8] It also alleged that Accutane commonly causes depression in persons taking the drug, and that patients suffering from depression are even less likely to follow warnings about birth control.[9] These allegations, read together, can be taken to mean that patients such as Kristen-Marie's mother should not have been prescribed Accutane

[8] Kristen-Marie's original complaint alleged that her mother represented to Fredenberg that she would practice abstinence while taking the drug; thus, according to the Roche printed materials, she could receive Accutane even though she was not using any birth control methods. Roche argued in the superior court and on appeal that "[a]bstinence simply cannot fail as a method of pregnancy prevention." The original complaint alleged that the fact that Kristen-Marie's mother became pregnant after telling her physician that she intended to abstain from intercourse showed the unreasonableness of Roche's assurances to prescribing physicians that they could believe that patients who declared at the beginning of a several-month course of treatment that they intended to abstain from sexual intercourse would in fact do so. Even though the allegations in the original complaint concerning abstinence were omitted from the amended complaint, they are the subject of argument by both sides on appeal. Because the original complaint was superseded by the amended complaint, however, *see Collins v. Streitz*, 47 Ariz. 146, 152, 54 P.2d 264, 267 (1936); *Campbell v. Deddens*, 21 Ariz. App. 295, 297, 518 P.2d 1012, 1014 (1974), in this appeal we will not consider allegations contained in the former but not in the latter.

[9] On appeal, Kristen-Marie argues in vague terms that her mother would have struggled to understand and follow the Roche birth-control warnings because she was mentally impaired to some unspecified degree. Because no such allegation is found in the amended complaint, however, we do not consider it. *See supra* note 8.

prescribed Accutane to begin with, and that she was prescribed Accutane and took the drug only as a result of defendants' negligence.[10]

¶31 In sum, the amended complaint alleged that Roche's negligence and other tortious wrongdoing proximately caused Kristen-Marie to be injured *in utero.* This is by contrast to the complaint in *Walker*, which did not allege that defendants there injured the child *in utero*, 164 Ariz. at 41, 790 P.2d at 739, but instead alleged that defendants failed to alert the child's mother to facts that would have caused her to terminate the pregnancy, *id.* at 38, 790 P.2d at 736. Because the amended complaint seeks damages for *in utero* damages allegedly caused by Roche, it does not state a claim for a "wrongful life" as described in *Walker*. *See generally Kassama v. Magat*, 792 A.2d 1102, 1116 (Md. 2002) (distinguishing child's claim for damages caused by defendants and incurred *in utero* from a claim for "the injury of life itself").

¶32 The amended complaint likewise alleged Fredenberg acted negligently in prescribing Accutane for Kristen-Marie's mother, thereby causing her injuries. In support of Fredenberg's contention that the claims against her are barred because they are based on her failure to have prevented Kristen-Marie's conception, Fredenberg cites the preliminary expert witness affidavit Kristen-Marie

[10] As the amended complaint alleged, "It is specifically contrary to reasonably prudent practice and to the standard of care not to have an instructional regime in place that ensures that female

Marie provided as required by A.R.S. § 12-2603(A) (Supp. 2006). In that affidavit, the expert opined that Fredenberg fell below the standard of care in part by failing to order monthly pregnancy tests and that otherwise, the pregnancy would have been discovered "in October 1996 *allowing for termination of the pregnancy*." (Emphasis added.) This preliminary opinion, however, did not change the amended complaint's allegations, which failed to allege that Kristen-Marie's mother would have terminated the pregnancy had it been revealed by a pregnancy test performed before the September prescription was written.[11]

¶33 We conclude that unlike the child in *Walker*, Kristen-Marie does not allege that she should not have been born; instead, she alleges that defendants' negligence caused her to incur the defects with which she was born. Accordingly, her amended complaint is not barred by *Walker's* holding that a child may not state a claim for "wrongful life."

C. Adequacy of Roche's Warnings.

¶34 We next consider whether the alternative ground urged by Roche in support of its motion to dismiss supports the superior court's dismissal of the amended complaint against Roche. Although the adequacy of a manufacturer's warning of hidden dangers associated with a product usually presents a question of fact, Roche

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Accutane patients do not expose unborn children to this dangerous drug."

[11] Neither defendant argues that the complaint should have been dismissed for failure to comply with A.R.S. § 12-2603(A).

Roche argues that it was entitled to dismissal of the claims against it because other courts have found its warnings of birth defects, the very injuries suffered by Kristen-Marie, to be clear, unambiguous and "adequate as a matter of law." Roche asserts that because its warnings were adequate and were conveyed to a prescribing physician, pursuant to the "learned intermediary doctrine," it met its duty to warn of any known defects and the amended complaint failed to state a claim for relief against Roche.[12]

¶35 Roche's packaging for Accutane in 1996 contained a fine-print insert with a black-box warning labeled: "Avoid Pregnancy."[13] The insert stated:

> Accutane must not be used by females who are pregnant or who may become pregnant while undergoing treatment. Although not every fetus exposed to Accutane has resulted

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[12] *See generally* Diane Schmauder Kane, Annotation, *Construction and Application of the Learned-intermediary Doctrine*, 57 A.L.R. 5th 1 (1998).

[13] Roche attached a copy of its packaging material to its initial motion to dismiss, and relied on the same warning in its motion to dismiss the amended complaint. Without objection from Kristen-Marie, Roche argued that the superior court could consider the package warning because the warning was an undisputedly authentic document referenced in (but not attached to) the complaint. *See Greenberg v. The Life Ins. Co. of Virginia*, 177 F.3d 507, 514 (6th Cir. 1999) (court may consider document referenced in complaint without converting motion to dismiss into a motion for summary judgment). Roche also attached a copy of a Patient Information Form to its motion to dismiss the amended complaint. The record does not disclose whether Roche provided other warning/instructional materials to Fredenberg. Neither Kriten-Marie nor Roche takes the position on appeal that we should review the superior court's order as if it were a motion for summary judgment.

> in a deformed child, there is an extremely high risk that a deformed infant can result if pregnancy occurs while taking Accutane in any amount even for short periods of time. . . .
>
> It is recommended that a prescription for Accutane should not be issued by the physician until a report of a negative pregnancy test has been obtained . . . .
>
> Effective contraception must be used for at least 1 month before beginning Accutane therapy, during therapy and for 1 month following discontinuation of therapy . . . . It is recommended that two reliable forms of contraception be used simultaneously unless abstinence is the chosen method.

Similar language was contained in the Patient Information Form that Kristen-Marie's mother completed and signed in Fredenberg's office before receiving her Accutane prescription. That form contained several paragraphs, each of which was initialed by the patient. The fourth such paragraph stated:

> I have been told by my doctor that effective birth control (contraception) must be used for at least 1 month before starting Accutane, all during Accutane therapy and for at least 1 month after Accutane treatment has stopped. My doctor has recommended that I either abstain from sexual intercourse or use two reliable kinds of birth control at the same time.

¶36 "The learned-intermediary doctrine provides that the manufacturer or supplier of a prescription drug has no legal duty to warn a consumer of the dangerous propensities of its drug, as long as adequate warnings are provided to the prescribing physician." Diane Schmauder Kane, Annotation, *Construction and Application of the Learned-intermediary Doctrine*, 57 A.L.R. 5th 1 (1998); *see Dole Food Co. v. N. C. Foam Indus., Inc.*, 188 Ariz. 298, 302-03, 935 P.2d 876, 880-81 (App. 1996) (citing Restatement (Second) of Torts § 388

(Second) of Torts § 388 cmt. n); *Piper v. Bear Med. Sys., Inc.*, 180 Ariz. 170, 178 n.3, 883 P.2d 407, 415 n.3 (App. 1993) ("'Learned intermediary doctrine' means the manufacturer's duty to warn is ordinarily satisfied if a proper warning is given to the specialized class of people that may prescribe or administer the product."); *Gaston v. Hunter*, 121 Ariz. 33, 47, 588 P.2d 326, 340 (App. 1978) ("In the case of prescription drugs . . . the manufacturer's duty to warn is ordinarily satisfied if a proper warning is given to the prescribing physician."); *Shell Oil Co. v. Gutierrez*, 119 Ariz. 426, 433, 581 P.2d 271, 278 (App. 1978) (citing Restatement (Second) of Torts § 388 cmt. n (1965)); *Dyer v. Best Pharmacal*, 118 Ariz. 465, 468, 577 P.2d 1084, 1087 (App. 1978) ("A drug manufacturer has discharged his duty to the public if he has properly warned the administering physician of the contraindications and possible side effects of the drug.").

¶37 The learned intermediary rule as applied in the pharmaceutical context is stated in Restatement (Third) of Torts: Products Liability ("Restatement") § 6 (1998). The Restatement provides as follows:

> (d) A prescription drug or medical device is not reasonably safe due to inadequate instructions or warnings if reasonable instructions or warnings regarding foreseeable risks of harm are not provided to:
>
> (1) prescribing and other health-care providers who are in a position to reduce the risks of harm in accordance with the instructions or warnings . . . .

Restatement § 6(d).[14]

¶38 Under this rule, warnings given by prescription drug manufacturers generally are "legally adequate to apprise the learned intermediary of the known or knowable risk of harm associated with its product . . . where [the warnings are] reasonable under the circumstances." Kane, *supra* ¶ 36, at § 2[a]. Specifically, warnings must "(1) indicate the scope of the danger; (2) communicate the extent or seriousness of the potential danger; (3) alert a reasonably prudent practitioner to the danger; and (4) be conveyed in a satisfactory manner." *Id.*; *see also Salmon v. Parke, Davis & Co.*, 520 F.2d 1359, 1362 (4th Cir. 1975) ("A manufacturer of an ethical drug must exercise reasonable care, commensurate with the risk, to warn physicians effectively of the drug's inherent dangers.").

¶39 In a case such as this, the Restatement requires the manufacturer to give "reasonable instructions or warnings" to the prescribing physician. The Restatement's requirement that the manufacturer's instructions and warnings be "reasonable" is

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[14] "[T]he learned-intermediary doctrine is based upon the premise that, as a medical expert, a patient's prescribing or treating physician is in the best position to evaluate the often complex information provided by the manufacturer concerning the risks and benefits of its drug or product and to make an individualized medical judgment, based on the patient's particular needs and susceptibilities, as to whether the patient should use the product." Kane, *supra* ¶ 36, at § 2[a]. *See generally* Restatement, *supra* ¶ 37, at § 6 Reporters' Note cmt. b (collecting reasons advanced for reliance on the learned intermediary rule, including lower drug prices, prevention of interference with doctor-patient relationship and detailed federal regulations).

consistent with the authorities, in Arizona and elsewhere, that specify that the adequacy of those instructions and warnings ordinarily is a question of fact. *Dole Food*, 188 Ariz. at 303, 935 P.2d at 881 (citing *Shell Oil*, 119 Ariz. at 434, 581 P.2d at 279); *Piper*, 180 Ariz. at 177, 883 P.2d at 414 ("Determining whether a warning is adequate to apprise users of dangers in the product is ordinarily a question for the trier of fact."); *Brown v. Sears, Roebuck & Co.*, 136 Ariz. 556, 563, 667 P.2d 750, 757 (App. 1983) (same); *Shell Oil*, 119 Ariz. at 434, 581 P.2d at 279 ("determination as to whether the supplier's duty . . . has been reasonably discharge[d] comes within the function of the trier of fact.").[15]

¶40 Roche asserts that cases from other jurisdictions hold that manufacturers' warnings under the learned intermediary doctrine may be found to be sufficient "as a matter of law."[16] But the

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[15] Expert testimony may be needed to assist in determining whether a particular warning or set of instructions is adequate. *See Williams v. Lederle Labs.*, 591 F. Supp. 381, 385 (S.D. Ohio 1984) (expert affidavit created question of fact on adequacy of warning); Kane, *supra* ¶ 36, at § 24 (collecting cases).

[16] Roche cites *Ziliak v. AstraZeneca LP*, 324 F.3d 518 (7th Cir. 2003); *Ralston v. Smith & Nephew Richards, Inc.*, 275 F.3d 965 (10th Cir. 2001); *In re Meridia Prods. Liab. Litig.*, 328 F. Supp. 2d 791 (N.D. Ohio 2004); *In re Norplant Contraceptive Prods. Liab. Litig.*, 215 F. Supp. 2d 795 (E.D. Tex. 2002); *Brumley v. Pfizer, Inc.*, 149 F. Supp. 2d 305 (S.D. Tex. 2001); *Caveny v. CIBA-GEIGY Corp.*, 818 F. Supp. 1404 (D. Colo. 1992); *Cather v. Catheter Tech. Corp.*, 753 F. Supp. 634 (S.D. Miss. 1991); *Jacobs v. Dista Prods. Co.*, 693 F. Supp. 1029 (D. Wyo. 1988); *Percival v. Am. Cyanamid Co.*, 689 F. Supp. 1060 (W.D. Okla. 1987); *Upjohn Co. v. MacMurdo*, 562 So. 2d 680 (Fla. 1990); *Mikell v. Hoffman-LaRoche, Inc.*, 649 So. 2d 75 (La. Ct.

the several cases Roche cites for this proposition were decided on summary judgment, not, as this case, on a motion to dismiss. The issue in those cases was whether the plaintiff offered admissible evidence sufficient to create a material issue of fact. In reviewing the order granting the motions to dismiss in this case, we are concerned instead with whether the facts alleged in the complaint, if believed, would support a claim for relief. *See*, *e.g.*, *Carrillo*, 169 Ariz. at 129, 817 P.2d at 496.

¶41 Roche also cites a number of Accutane cases in which it argues that the very warnings it provided Fredenberg were held to be adequate for purposes of the learned intermediary doctrine.[17] Roche contends that those cases held that its warnings were "adequate as a matter of law," but again, all but one of those cases arose in connection with a motion for summary judgment, after full discovery. The one exception is *Banner v. Hoffmann-La Roche, Inc.*, 891 A.2d 1229 (N.J. Super. Ct. App. Div. 2006), a case in which a New Jersey court granted Roche's motion to dismiss a complaint brought by an Accutane patient who alleged that she became pregnant after telling

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(La. Ct. App. 1994); *Mowery v. Crittenton Hosp.*, 400 N.W.2d 633 (Mich. Ct. App. 1986); and *Rolen v. Burroughs Wellcome Co.*, 856 S.W.2d 607 (Tex. App. 1993). (Roche's papers in this case correctly represent the company's name as Hoffman-La Roche, Inc. We state the names of the cases we cite involving the company as they are spelled in the reporter.)

[17] Roche cites *Gerber v. Hoffmann-LaRoche, Inc.*, 392 F. Supp. 2d 907 (S.D. Tex. 2005); *Hunt v. Hoffmann-LaRoche, Inc.*, 785 F. Supp. 547 (D. Md. 1992); *Carter v. Hoffman-LaRoche Inc.*, No. CV 590-285, 1991 U.S. Dis. LEXIS 19304 (S.D. Ga. Dec. 12, 1991); *Bealer v. Hoffmann-LaRoche, Inc.*, 729 F. Supp. 43 (E.D. La. 1990); and *Felix v. Hoffmann-LaRoche, Inc.*, 540 So. 2d 102 (Fla. 1989).

became pregnant after telling her treating physician that for religious reasons she would not practice artificial birth control but instead would abstain from intercourse. *Id*. at 1230, 1233. In the face of the several Arizona cases instructing that the adequacy of a manufacturer's warning is a question of fact, we decline to follow the New Jersey authority proffered by Roche. Given the lack of a full record in this case, and that a motion to dismiss may be granted only when it appears certain that the plaintiff would not be entitled to relief under any theory given the facts and claims alleged, *see Forum Dev.*, 192 Ariz. at 93, 961 P.2d at 1041, we cannot at this time conclude as a matter of law that Roche satisfied its duty to Kristen-Marie under the learned intermediary doctrine.

¶42 Moreover, by relying on authorities pertaining to label or packaging warnings, Roche fails to address a primary theory of the amended complaint: That even if Roche plainly *warned* Fredenberg of adverse side effects, it did not meet its duty to provide adequate *instructions* to the dermatologist about pregnancy prevention counseling. Roche argues that "[i]t is absurd to suggest that dermatologists are not medically qualified to administer pregnancy tests." Roche provides no authority, however, for its assertion that a dermatologist such as Fredenberg is in fact always qualified to administer pregnancy tests. More to point, Roche's contention does not address the amended complaint's allegation that Roche unreasonably relied on dermatologists untrained in providing

untrained in providing pregnancy counseling to adequately instruct patients with regard to pregnancy prevention and to discern, under all the circumstances, whether a patient could be relied upon to practice effective birth control.

¶43 The amended complaint also alleged that Roche's Pregnancy Prevention Program was defective because it failed to include a mandatory registry that would have prevented pharmacies from dispensing Accutane to women who could not show a record of a negative pregnancy test performed within the previous seven days.[18] Therefore, cases Roche cites concerning the adequacy of mere warnings of Accutane's side effects are inapposite.

¶44 Warnings of a product's possible harmful effects are not equivalent to adequate directions on how to safely use the product in order to avoid the identified harm. *See Piper*, 180 Ariz. at 178, 883 P.2d at 415 (distinguishing between a general warning of danger and a failure to properly instruct user how to avoid the danger); *Brown,* 136 Ariz. at 564, 667 P.2d at 758 (noting distinction between manufacturer's warnings and instructions for safe use); *Ontai v. Straub Clinic & Hosp. Inc.*, 659 P.2d 734, 743 (Haw. 1983)

[18] Roche insists that it had no duty to implement a monitoring program to ensure that prescribers or patients followed its safety recommendations, but Kristen-Marie alleges that several years after her mother's Accutane treatment was complete, Roche adopted a mandatory registry to ensure compliance with pregnancy testing and other safety measures. Although we do not intend to suggest that we agree that Roche had such a duty, we cannot disregard the amended complaint's allegations that under the circumstances, such a duty should have been imposed on Roche.

(Haw. 1983) (manufacturer has dual duty to warn of hidden dangers and to inform/instruct on how to avoid dangers through safe product use); David G. Owen, *Products Liability Law* § 9.1 (2005).

¶45 Roche's failure to advise of the effect of depression on patient compliance with safety measures might be regarded, for example, as a failure to properly instruct physicians in how to counsel patients about Accutane. *See Wagner v. Roche Labs.,* 671 N.E.2d 252, 255-56 (Ohio 1996) (Roche failed to advise against taking Accutane in combination with certain other drugs; what Roche knew or should have known was fact question for jury). Moreover, the adequacy of a manufacturer's instructions about how to safely use a product must be evaluated in light of the user's expertise. *See Piper,* 180 Ariz. at 177, 883 P.2d at 414 (evidence that manufacturer could foresee that untrained nurses as well as respiratory therapists would have access to ventilator may show design was defective); *Thom v. Bristol-Myers Squibb Co.*, 353 F.3d 848, 853 (10th Cir. 2003) ("Physicians become learned intermediaries only when they have received adequate warnings from the drug manufacturer."). Here, for example, whether dermatologists have sufficient training or information to act as learned intermediaries may be a question of fact.

¶46 In summary, a complaint may state a claim for relief if it alleges that a drug manufacturer failed to fully inform the prescribing physician of necessary safety precautions required to prevent risks anticipated in connection with the drug. Therefore,

even if it might be concluded that the *warnings* that Roche gave Fredenberg were adequate, that would not dispose of the allegations in the amended complaint that Roche failed to meet its duty to provide adequate *instructions* concerning how to avoid the known risks its drug posed. We conclude that because the amended complaint presented facts and theories that may support claims for relief against Roche, it should not have been dismissed pursuant to the learned intermediary doctrine.

III. CONCLUSION

¶47 For the reasons set forth above, we hold that the amended complaint set forth claims against Roche and Fredenberg that are not barred by the wrongful life rule. In addition, the amended complaint sufficiently alleged that the instructions that Roche provided to prescribing physicians at the relevant time may not be entitled to the protection of the learned intermediary rule. Accordingly, we reverse the judgment entered in favor of defendants and remand for further proceedings.

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DIANE M. JOHNSEN, Judge

CONCURRING:

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PATRICIA A. OROZCO, Presiding Judge

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SUSAN A. EHRLICH, Judge