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CERTIFIED FOR PUBLICATION

IN THE COURT OF APPEAL OF THE STATE OF CALIFORNIA

SECOND APPELLATE DISTRICT

DIVISION FOUR

CHRISTOPHER TREJO, Plaintiff and Respondent, v. JOHNSON & JOHNSON et al., Defendants and Appellants.	B238339 (Los Angeles County Super. Ct. No. YC058023)

APPEAL from a judgment of the Superior Court of Los Angeles County, Robert H. O'Brien, Judge. Reversed and remanded.

Law Offices of Brian D. Witzer, Inc., Brian D. Witzer, Jeffrey E. Zinder and Michael P. Manapol for Plaintiff and Respondent.

Butler, Snow, O'Mara, Stevens & Cannada, Kari L. Sutherland; Drinker Biddle & Reath, Thomas W. Pulliam, Jr., Vernon I. Zvoleff, Alan J. Lazarus, Kenneth P. Conour, Benjamin J. Holl; O'Melveny & Myers, Catalina J. Vergara and Charles C. Lifland for Defendants and Appellants.

After taking Motrin, an over-the-counter ibuprofen medication manufactured and sold by McNeil Consumer Healthcare (McNeil), plaintiff Christopher Trejo suffered a reaction in the form of a rare skin disease, Stevens-Johnson Syndrome, and the more severe variant, Toxic Epidermal Necrolysis (collectively SJS/TEN).[1] He sued McNeil and its corporate parent, Johnson & Johnson, on various theories of products liability, four of which went to trial: strict liability failure to warn and negligent failure to warn, based on defendants' failure to include the symptoms of SJS/TEN (skin reddening, rash, and blisters) on Motrin's warning label, and strict liability design defect and negligent design defect, based on McNeil's failure to sell an allegedly safer product, dexibuprofen (an isomer or component of ibuprofen) rather than ibuoprofen.

Returning a special verdict, the jury found McNeil liable for negligent failure to warn (but not for strict liability failure to warn), negligent design defect, and strict liability design defect under the consumer expectation test (but not under the risk-benefit test). The jury found Johnson & Johnson

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[1] This is one of a number of SJS/TEN cases being brought against defendants, with varying results. (See, e.g., *Robinson v. McNeil Consumer Healthcare* (7th Cir. 2010) 615 F.3d 861 (*Robinson*) [affirming judgment in favor of defendants]; *Lofton v. McNeil Consumer & Specialty Pharmaceuticals* (5th Cir. 2012) 672 F.3d 372 [affirming summary judgment in favor of defendants because federal law preempted Texas tort law regarding failure to warn cases]; *Reckis v. Johnson & Johnson* (Mass. 2015) 28 N.E.3d 445 [affirming judgment in favor of plaintiff] (*Reckis*); *Batoh v. McNeil-PPC, Inc.* (D.Conn. 2016) 167 F.Supp.3d 296 (*Batoh*) [granting defendants' summary judgment motion]; *Wolfe v. McNeil-PPC, Inc.* (E.D.Pa. 2011) 773 F.Supp.2d 561 (*Wolfe*) [denying defendants' summary judgment motion on plaintiff's failure to warn claim and granting their motion on plaintiff's claims for negligent failure to test, negligent marketing, negligent defective design, and strict liability manufacturing, design defect and misrepresentation].)

liable for strict liability design defect on a consumer expectation theory (but not on a risk-benefit theory), and not liable on plaintiff's other claims.

In this appeal by defendants, we hold that the jury's verdict finding McNeil liable for negligent failure to warn must be reversed because it is fatally inconsistent with the verdict finding McNeil not liable for strict liability failure to warn. Accordingly, we reverse the negligent failure to warn verdict, and remand for a new trial on the claims against McNeil for negligent and strict liability failure to warn. We also conclude that the negligent failure to warn special verdict was defective on a second ground: the failure to include the necessary question whether a reasonable manufacturer under the same or similar circumstances would have warned of the danger (an issue we consider because there might be a retrial).

Further, we hold that the verdicts against McNeil for negligent and strict liability design defect, as well as against Johnson & Johnson for strict liability design defect, must be reversed, because the design defect claims were based on a theory—failure to sell dexibuprofen—that is impliedly preempted by the United States Supreme Court's decision in *Mutual Pharmaceutical Co., Inc. v. Bartlett* (2013) __ U.S. __, 133 S.Ct. 2466, 2473 (*Bartlett*). We also conclude that the strict liability design defect verdicts must be reversed on a second ground: the jury found McNeil and Johnson and Johnson liable solely under the consumer expectation test, but that test does not apply when, as here, the question of design defect involves complex questions of feasibility, practicality, risk, and benefit beyond the common knowledge of jurors. Accordingly, we reverse the verdicts finding McNeil liable for negligent and strict liability design defect, and finding Johnson and Johnson liable for strict liability design defect. Because plaintiff's negligent and strict liability design defect claims are preempted, and because the only

theory of strict liability design defect found by the jury (the consumer expectation test) does not apply, none of plaintiff's design defect claims can be retried.

Therefore, the ultimate disposition is that the judgment as to McNeil and Johnson and Johnson is reversed, and the case is remanded for retrial on the sole remaining claims in the case: those against McNeil for negligent and strict liability failure to warn.

FACTUAL AND PROCEDURAL BACKGROUND

I. *Factual Background*

A. *Ibuprofen*

Ibuprofen is a non-steroidal anti-inflammatory drug (NSAID). It was approved by the Food and Drug Administration (FDA or agency) for prescription use in the United States to treat arthritis and pain in 1974, and for over-the-counter (OTC) use in 1984. Both prescription and OTC ibuprofen are composed of the same ingredient, differing only in the dosage amounts. In 2006, the FDA estimated that approximately 29 million prescriptions for ibuprofen were dispensed per year, and that OTC ibuprofen had approximately 100 million users per year.

There are many different OTC ibuprofen products, both generic and brand name, sold by various companies. They all have the same labeling, regardless of the manufacturer. Motrin is a brand name ibuprofen product. McNeil acquired the right to produce Motrin from the Upjohn Manufacturing Company before the events giving rise to this action. In 1994, the FDA approved McNeil's application for OTC ibuprofen gelcaps, concluding "the drug is safe and effective for use as recommended in the submitted labeling."

Regarding the risk of SJS and TEN from taking ibuprofen, in 1989, the FDA provided McNeil with a medical officer review informing the company that, in 1982, 10 billion doses of ibuprofen were used worldwide, and that SJS was an adverse reaction reported with ibuprofen products at a rate of less than one percent. The labeling approved by the FDA in the 1980's for prescription ibuprofen contained a reference to SJS and TEN as possible adverse events. However, the FDA-approved label for OTC ibuprofen did not refer to SJS, TEN, skin reddening, rash or blisters. The labels differed because prescription labeling is intended for use by physicians, while OTC labeling is aimed at consumers.

The warning label on the bottle of OTC Motrin plaintiff took in October 2005 included the following FDA-approved warnings and instructions:

"**Warnings**

"**Allergy alert**: Ibuprofen may cause a severe allergic reaction which may include:

"• hives • facial swelling • asthma (wheezing) • shock . . .

"**Do not use** if you have ever had an allergic reaction to any other pain reliever/fever reducer. . . .

"**Stop use and ask a doctor if**

"• an allergic reaction occurs. Seek medical help right away.

"• pain gets worse or lasts more than 10 days

"• fever gets worse or lasts more than 3 days

"• stomach pain or upset gets worse or lasts

"• redness or swelling is present in the painful area

"• any new symptoms appear"

The label did not include specific warnings about skin reddening, rash, and blisters as possible allergic reactions. According to McNeil, the FDA did

not require such a specific warning for OTC products prior to 2005 because the warning to seek medical help if any new symptoms appeared was a broader warning that included these symptoms. McNeil did not seek permission from the FDA to add SJS or TEN to its OTC labels. On one occasion before 2005, it had asked the FDA for permission to change the allergy alert language, but the agency advised it not to do so.

In July 2005, the FDA made a "class label change," directing McNeil and other manufacturers of OTC ibuprofen products to change their labels within six months to add three additional symptoms—skin reddening, rash, and blisters. McNeil made the requested changes to its labels.

B. *Plaintiff's Use of Motrin*

Plaintiff was born in November 1988 and lived in Honduras with his grandmother, great-grandmother, and sister. His mother, Naara Silver, lived in the United States with her husband and other children and occasionally sent plaintiff care packages that included OTC medication. In 2005, Silver purchased OTC Motrin and sent it to plaintiff. She had never purchased Motrin before, but she wanted her grandmother to try it for her arthritis pain. Silver testified that she would not have bought Motrin had she known of the possibility of blisters because her grandmother was elderly and had delicate skin.

In October 2005, plaintiff experienced aches and soreness in his legs after a strenuous soccer practice. Plaintiff took half a tablet of aspirin and took a nap. Plaintiff took aspirin for two days because he continued to feel sore and very warm, but he stopped taking it after reading the label's warning about Reye's Syndrome.

Plaintiff continued to experience fever and muscle pain. He found Motrin in the medicine cabinet and read the label because he had never taken it before. After seeing that Motrin would treat pain and fever, plaintiff took one pill and felt better. However, his symptoms returned after a four-hour nap, so he took another Motrin and slept through the night. The following morning, he was warm and his legs hurt, so he took a third Motrin and continued to take it for two more days. When he awakened on the second day, he noticed blisters in his mouth. One of the blisters broke and started bleeding, so he asked his grandmother to take him to the doctor. He did not take any more Motrin.

Plaintiff testified that if there had been a warning about blisters on Motrin's label, he would not have taken it because he knew that blisters were painful and could lead to an infection. He also testified that a warning about skin reddening and rash would have convinced him not to take Motrin because he was a teenager and would not have wanted blisters or rash on his face. He acknowledged that he read the label, which included warnings about hives and facial swelling, and he took the Motrin even though he understood that facial swelling would affect his appearance.

Plaintiff was hospitalized in Honduras for about 10 days until November 4, 2005, when he was transferred to Shriners Hospital for Children in Galveston, Texas. When plaintiff arrived in Texas, he had blisters or open wounds over most of his body. He was treated for TEN and discharged on November 27, 2005.

C. *SJS/TEN*

The disease from which plaintiff suffered, SJS/TEN, is a rare disease, thought to be an allergic reaction to a drug. SJS and TEN are part of the

same disease spectrum, differing only in severity.[2] The initial signs of SJS/TEN include fever, malaise, redness of the skin, rash, and blisters, known as non-specific symptoms. The early symptoms last several days before the disease fully develops. Because various drugs may be taken to treat the early, non-specific symptoms, it is difficult to determine the cause of SJS and TEN.

At trial, one of plaintiff's experts, Roger Salisbury, opined that plaintiff's TEN was caused by the Motrin he consumed and not by any environmental factors. Another plaintiff's expert, Randall Tackett, testified that he did not believe the aspirin and Tylenol that plaintiff consumed contributed to his disease. He stated that TEN is referred to as an idiosyncratic side effect that can occur at a dosage even lower than the minimum recommended dosage. Tackett described the mechanism by which he believed ibuprofen caused plaintiff's TEN, explaining that NSAIDs affect a chemical in the body related to inflammation, leading to an immune system process and a reaction affecting a chemical compound known as tumor necrosis factor.

D. *FDA Safety Review and Citizen's Petition*

In early 2005, the FDA undertook a comprehensive safety review of NSAIDs, including ibuprofen. In February 2005, Salisbury, Tackett and several experts involved in other Motrin litigation, submitted a Citizen's Petition to the FDA and McNeil, asserting that the label on OTC Motrin should contain a warning about SJS and TEN. Salisbury asked the FDA to

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[2] Generally, the diagnosis is SJS when less than 10 percent of the body surface area is affected, SJS/TEN when 10 to 30 percent is affected, and TEN when more than 30 percent of the body is affected.

conduct a risk assessment of SJS/TEN, to investigate whether manufacturers had withheld "critical safety information regarding the risks of SJS and TEN associated with ibuprofen products," and to require manufacturers to add warnings of SJS/TEN to their labeling.

The FDA responded to the petition in a detailed letter dated June 22, 2006. The agency explained that in April 2005, it issued a press release, a public health advisory, and a decision memo explaining the risks of NSAID products but emphasizing the need for a wide variety of NSAID options. The agency decided to ask prescription NSAID manufacturers to change their labels to include additional warnings about SJS/TEN. As to OTC NSAIDs, the FDA decided to warn consumers about the risks of severe skin reactions but did not believe it was useful to use the terms "SJS" and "TEN" because most consumers are not familiar with those terms. The agency thus decided to add warnings about skin reddening, rash, and blisters to OTC NSAID labels.

The FDA disputed Salisbury's estimate that there are 49-60 per million cases of SJS per year, stating instead that there are 1.2 to 6 per million cases of SJS per year and 0.4 to 1.2 per million of TEN per year. The agency's estimate was based on its review of the Adverse Event Report System database, which revealed 88 cases from 1975 through March 2005, of which 49 were possibly related to the use of ibuprofen. Given that "there are approximately 29 million prescriptions dispensed per year in the U.S. retail setting for prescription single-ingredient ibuprofen . . . and probably more than 100 million users of OTC ibuprofen per year," the FDA concluded that the risk of SJS/TEN was much lower than Salisbury had asserted.

The FDA further disputed Salisbury's assertion that the mortality rate for SJS was 5 to 30 percent and 80 percent for TEN. Instead, the agency

asserted that SJS was fatal in 5 percent of cases and TEN in 30 percent of cases. Salisbury acknowledged at trial that the mortality rate for TEN patients at his burn center was actually 30 percent or lower, not 80 percent.

In response to the petition's assertion that manufacturers withheld safety information about SJS/TEN, the FDA stated that Salisbury provided no evidence, and the FDA had no evidence of undisclosed safety information. Salisbury acknowledged at trial that he was not aware of any adverse event report received by McNeil that it failed to report to the FDA.

The FDA disagreed with Salisbury's statement that the agency should "reconsider the OTC status of the pediatric formulation of ibuprofen" because "the incidence of SJS or TEN is not as great as cited." The agency further explained that "the overall benefit versus risk profile for ibuprofen products remains very favorable when they are used according to the labeled instructions. It is in the interest of the public health to maintain in the pediatric OTC market a range of therapeutic options for the short-term relief of pain."

E. *Dexibuprofen as an Alternative to Ibuprofen*

Tackett testified that dexibuprofen, an isomer or component of ibuprofen, "appears to be a safer product" with fewer side effects than ibuprofen. He believed that defendants should have withdrawn ibuprofen and marketed dexibuprofen instead, even though the FDA has not approved dexibuprofen for sale in the United States. Tackett testified that when the FDA denied an application to market dexibuprofen, it was not due to a safety issue but because it "had not been put forward as a prescription drug first, which is the usual way things . . . go from prescription to over the counter."

Tackett opined that, unlike dexibuprofen, Motrin contained a component called racemic ibuprofen that contributed to SJS/TEN, and that dexibuprofen was not associated with SJS/TEN. However, a prescription label for dexibuprofen, which was sold outside the United States, contained a warning for SJS/TEN. Tackett acknowledged that dexibuprofen use was much lower than ibuprofen, which had been used several billion times.

II. *Procedural History*

A jury trial commenced in August 2011 on plaintiff's claim that he developed SJS/TEN as a result of taking Motrin. He alleged claims for strict liability failure to warn, negligent failure to warn, negligent design defect, and strict liability design defect based on the consumer expectation test and the risk-benefit test.[3]

The jury found McNeil liable for negligent failure to warn, strict liability design defect under the consumer expectation test, and negligent design defect. As to Johnson & Johnson, the jury found in favor of plaintiff only on his strict liability design defect claim under the consumer expectation test. The jury awarded plaintiff $11,401,220 in economic damages, $21,166,660 in non-economic damages, $6,833,330 in punitive damages against McNeil, and $8,791,670 in punitive damages against Johnson & Johnson.

After polling the jurors on their verdicts, the trial court asked if there was any reason why the jury should not be discharged. Defense counsel

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[3] In January 2011, we denied defendants' petition for writ of mandate challenging the trial court's order denying their motion for summary adjudication of issues regarding punitive damages. (See *Johnson & Johnson v. Superior Court* (2011) 192 Cal.App.4th 757.)

stated, "Other than about the verdict being fatally inconsistent." The court replied, "Anything else. Other than that." Defense counsel said no, and the court discharged the jury. The court subsequently asked counsel to put their objections on the record, which they did, arguing that the verdicts on negligent and strict liability failure to warn were fatally inconsistent. As later explained in the trial court's order denying defendants' motion for new trial, defendants raised the issue of inconsistent verdicts in an unreported chambers discussion before the jury was discharged, but the court did not find the verdicts to be inconsistent. Defendants timely appealed from the judgment.

DISCUSSION

I. *Inconsistent Verdicts on Negligent and Strict Liability Failure to Warn*

By special verdict, the jury found McNeil liable on plaintiff's claim for negligent failure to warn, but not liable on plaintiff's claim for strict liability failure to warn. McNeil contends that the verdicts are inconsistent, and that therefore the verdict of liability on the negligence theory must be set aside. For the reasons explained below, we agree.[4]

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[4] Plaintiff contends that McNeil forfeited this contention by failing to object before the jury was discharged and ask the court to have the jury reconvene under Code of Civil Procedure section 619 to correct the inconsistency. We disagree. First, no objection was required to preserve the claim. (*Lambert v. General Motors* (1998) 67 Cal.App.4th 1179, 1182 (*Lambert*) [no objection to preserve the issue of inconsistent verdicts for review]; see *Morris v. McCauley's Quality Transmission Service* (1976) 60 Cal.App.3d 964, 972 [inconsistent verdict defect "is not waived by failure to call it to the attention of the trial court prior to discharging the jury"].) Second, in any event, McNeil raised the issue in the trial court. According to the trial court's denial of the motion for new trial, defense counsel raised the issue in an unreported conference in chambers before the jury was discharged, but the court found no inconsistency in the verdicts. Then, on the

A. *Inconsistency in Special Verdicts*

"'"The inconsistent verdict rule is based upon the fundamental proposition that a factfinder may not make inconsistent determinations of fact based on the same evidence. . . ." [Citations.] An inconsistent verdict may arise from an inconsistency between or among answers within a special verdict [citation] or irreconcilable findings. [Citation.] Where there is an inconsistency between or among answers within a special verdict, both or all the questions are equally against the law. [Citation.] The appellate court is not permitted to choose between inconsistent answers.' [Citation.]" (*Oxford v. Foster Wheeler LLC* (2009) 177 Cal.App.4th 700, 716 (*Oxford*).)

"The proper remedy for an inconsistent special verdict is a new trial. [Citation.]" (*Singh v. Southland Stone, U.S.A., Inc.* (2010) 186 Cal.App.4th 338, 358 (*Singh*).) "A court reviewing a special verdict does not infer findings in favor of the prevailing party [citation], and there is no presumption in favor of upholding a special verdict when the inconsistency is between two questions in a special verdict. [Citation.]" (*Zagami, Inc. v. James A. Crone, Inc.* (2008) 160 Cal.App.4th 1083, 1092 (*Zagami*).) The standard of review for inconsistency in a special verdict is de novo.[5] (*Cumbre, Inc. v. State Comp. Ins. Fund* (2010) 189 Cal.App.4th 1381, 1388.)

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record, after polling the jury, the trial court asked if there was any reason why the jury should not be discharged. Defense counsel stated, "Other than about the verdict being fatally inconsistent." Finally, after the jury was discharged, the court asked counsel to put their objections to the verdict on the record, which they did. In short, the issue was not forfeited.

[5] Plaintiff asserts that "A jury's 'verdict will stand unless the facts found by the jury in answer to special interrogatories are so clearly antagonistic to it as to be absolutely irreconcilable, the conflict being such as to be beyond the possibility of being removed by any evidence admissible under the

B. *Products Liability Failure to Warn*

Products liability may be premised upon a theory of design defect, manufacturing defect, or failure to warn. (*Anderson v. Owens–Corning Fiberglas Corp.* (1991) 53 Cal.3d 987, 995 (*Anderson*).) "[A] plaintiff may seek recovery in a 'products liability case' either 'on the theory of strict liability in tort or on the theory of negligence.' [Citations.] The rules of products liability 'focus responsibility for defects, whether negligently or nonnegligently caused, on the manufacturer of the completed product.' [Citation.] Thus, under either a negligence or a strict liability theory of products liability, to recover from a manufacturer, a plaintiff must prove that a defect caused injury. [Citations.] Under a negligence theory, a plaintiff must also prove 'an additional element, namely, that the defect in the product was due to negligence of the defendant.' [Citations.]" (*Merrill v. Navegar, Inc.* (2001) 26 Cal.4th 465, 478-479 (*Merrill*); *Brown v. Superior Court* (1988) 44 Cal.3d 1049, 1056 (*Brown*) ["Strict liability differs from negligence in that it eliminates the necessity for the injured party to prove that the

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issues,'" quoting *Lowen v. Finnila* (1940) 15 Cal.2d 502, 504. However, this standard applies when a special finding is alleged to be inconsistent with a general verdict, not when special verdict findings are inconsistent with other special verdict findings—a fact made obvious in portions of the quoted sentence plaintiff omits. The rule that "a verdict should not be modified 'if there is any "possibility of reconciliation under any possible application of the evidence and instructions"' . . . [¶] applies only to inconsistencies between general and special verdicts, and inconsistencies between special findings rendered in support of a general verdict." (*Mendoza v. Club Car, Inc.* (2000) 81 Cal.App.4th 287, 302-303.) "With a special verdict, unlike a general verdict or a general verdict with special findings, a reviewing court will not infer findings to support the verdict." (*Singh*, *supra*, 186 Cal.App.4th at p. 358.)

manufacturer of the product which caused injury was negligent."].)
"'Ordinarily, strict liability, which was developed to ease a claimant's burden of proof, requires proof of fewer elements than negligence, making a positive verdict on the latter difficult to explain if strict liability cannot be found.'" (1 Owen & Davis on Prod. Liab. (4th ed. 2016) § 5:29, fn. 25.)

The failure to warn theory of products liability is based on the premise that "'a product, although faultlessly made, may nevertheless be deemed "defective" under the rule and subject the supplier thereof to strict liability if it is unreasonably dangerous to place the product in the hands of a user without a suitable warning and the product is supplied and no warning is given.' [Citation.]" (*Anderson*, *supra*, 53 Cal.3d at pp. 995-996.) "Whether the absence of a warning makes a product defective involves several factors, including a consumer's normal expectations of how a product will perform; degrees of simplicity or complication in its operation or use; the nature and magnitude of the danger to which the user is exposed; the likelihood of injury; and the feasibility and beneficial effect of including such a warning. [Citation.]" (*Oxford*, *supra*, 177 Cal.App.4th at p. 717.)

C. *The Jury's Verdicts*

In the present case, the evidentiary basis of plaintiff's failure to warn theory for both strict liability and negligence was that OTC Motrin was defective because its warning label did not include the potential side effects of skin reddening, rash and blisters. In returning a special verdict finding McNeil not liable on a theory of strict liability failure to warn, the jury found that OTC Motrin had "potential risks, side effects and/or allergic reactions that were known or knowable through the use of scientific knowledge available at the time of manufacture, distribution or use by Christopher

Trejo," that "ordinary consumers [would not] have recognized the potential risks, side effects and/or allergic reactions," and that "McNeil fail[ed] to adequately warn or instruct of [*sic*] the potential risks, side effects and/or allergic reactions." But in response to question 6 on verdict form, the jury answered "no" to the query: "Did the potential risks, side effects, and/or allergic reactions present a substantial danger when the OTC Motrin is used or misused in an intended or reasonably foreseeable way?"[6] This "no"

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[6] The jury's full findings on strict liability and negligent failure to warn were as follows:

"(Strict Liability—Failure to Warn)

"1. Did Defendant McNeil manufacture, distribute and/or sell over-the-counter ('OTC') Motrin? [¶] Yes 12 No 0 . . .

"2a. Did Defendant Johnson & Johnson receive a direct financial benefit from the sale of OTC Motrin? [¶] Yes 12 No 0 . . .

"2b. Was Defendant Johnson & Johnson an integral part of the marketing enterprise such that its conduct was a necessary factor in bringing OTC Motrin to the consumer market? [¶] Yes 12 No 0 . . .

"2c. Did Defendant Johnson & Johnson have control over, or a substantial ability to influence, the marketing of OTC Motrin? [¶] Yes 12 No 0 . . .

"3. Did OTC Motrin have potential risks, side effects and/or allergic reactions that were known or knowable through the use of scientific knowledge available at the time of manufacture, distribution or use by Christopher Trejo? [¶] Yes 12 No 0 . . .

"4. Would ordinary consumers have recognized the potential risks, side effects and/or allergic reactions? [¶] Yes 1 No 11. . .

"5(a) Did McNeil fail to adequately warn or instruct of the potential risks, side effects and/or allergic reactions? [¶] Yes 10 No 2 . . .

"5(b) Did Johnson & Johnson fail to adequately warn or instruct of the potential risks, side effects and/or allergic reactions associated with OTC Motrin? [¶] Yes 2 No 10 . . .

"6. Did the potential risks, side effects, and/or allergic reactions present a substantial danger when the OTC Motrin is used or misused in an intended or reasonably foreseeable way? [¶] Yes 2 No 10

"If you answered 'Yes' to Question 6, please answer Question 7. If you answered 'No,' please skip to Question 8.

response—i.e., that OTC had no potential risks that caused a substantial danger when used in a foreseeable way—compelled a verdict in McNeil's favor, because under the jury instructions for strict liability, OTC Motrin lacked adequate warnings only if it "had potential risks/side effects/allergic reactions that were known or knowable by the use of scientific knowledge available at the time of manufacture/distribution/sale," and if those reactions "*presented a substantial danger* when the Motrin is used or misused in an intended or reasonably foreseeable way."[7] (Italics added.)

"7. Was the lack of sufficient warnings or instructions a substantial factor in causing harm to Plaintiff? [¶] Yes __ No __ . . .

"(Negligence—Failure to Warn)

"8. Did Defendant know or should it reasonably have known that OTC Motrin was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner?

Defendant McNeil Yes 10 No 2 . . .

Defendant Johnson & Johnson Yes 10 No 2

"If you answered 'Yes' to either part of Question 8, please answer Question 9 as to that Defendant or Defendants. Otherwise, please proceed to Question 11.

"9. Did Defendant know or should it reasonably have known that users would not realize the danger?

Defendant McNeil Yes 10 No 2 . . .

Defendant Johnson & Johnson Yes 10 No 2

"If you answered 'Yes' to either part of Question 9, please answer Question 10 as to that Defendant or Defendants. Otherwise, please skip to Question 11.

"10. Was Defendant's failure to warn a substantial factor in causing harm to Christopher Trejo?

Defendant McNeil Yes 9 No 3 . . .

Defendant Johnson & Johnson Yes 1 No 11."

[7] We note that the verdict form for strict liability failure to warn presented the elements of the claim in a different order than the strict liability jury instruction, CACI No. 1205, and the sample verdict form for CACI No. 1205 provided by the Judicial Council. CACI No. 1205 and VF-1205, as well as the verdict form proposed by defendants, ask whether the potential risks present a substantial danger *before* asking whether the

By contrast, the jury found McNeil liable on plaintiff's cause of action for negligent failure to warn. In returning that special verdict, the jury found (in response to question 8) that McNeil knew or "should . . . reasonably have known that OTC Motrin was dangerous or was likely to be dangerous when used in a reasonably foreseeable manner." The jury also concluded that McNeil knew or "should . . . reasonably have known that users would not realize the danger," and McNeil's "failure to warn [was] a substantial factor in causing harm to [plaintiff]." These findings compelled a verdict for plaintiff on the negligent failure to warn claim, because under the jury instructions for that claim, McNeil was liable if it "knew or reasonably should have known that the Motrin was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner," but failed to warn of the danger under circumstances in which a reasonable manufacturer would have warned.

Considering that both the strict liability and negligence theories were premised on a single alleged defect—failure to warn of potential skin reddening, rash and blisters—the jury's findings meant, in substance, that McNeil was not strictly liable for failure to warn of those possible reactions because they created no substantial danger, but was liable for negligent failure to warn because those possible reactions were, or were likely to be, dangerous. As we next explain, we conclude that these verdicts are fatally inconsistent. (See *Oxford*, *supra*, 177 Cal.App.4th at p. 720 ["a finding of negligent failure to warn is logically and legally inconsistent with the jury's

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defendant failed to adequately warn of the potential risks. Placing the special verdict questions in that order is more logical than the verdict form here, because if the potential risks do not present a substantial danger, there is no need to warn under strict liability principles.

finding [in favor of defendants] on plaintiffs' strict products liability failure to warn"]; *Valentine v. Baxter Healthcare Corp.* (1999) 68 Cal.App.4th 1467, 1483 (*Valentine*) ["the manufacturer's strict liability duty to warn is greater than its duty under negligence, and thus negligence requires a greater showing by plaintiffs"]; *Lambert*, *supra*, 67 Cal.App.4th at pp. 1185-1186 [jury's finding of negligent design inconsistent with its finding of no strict liability design defect].)

D. *The Verdicts are Inconsistent*

The decision in *Valentine*, *supra*, 68 Cal.App.4th 1467 is particularly instructive, and virtually indistinguishable in all pertinent aspects from the present case. As here relevant, the plaintiff in *Valentine* sued a manufacturer of silicone gel breast implants for strict liability and negligent failure to warn, based on the manufacturer's failure to warn her physician (and through him, her) that the migration or bleeding of silicone from implants might cause disease. The case was tried twice. The first jury returned a special verdict for the defense on the plaintiff's strict liability failure to warn claim, but deadlocked on negligent failure to warn. After the declaration of a mistrial, the negligent failure to warn claim was tried to a second jury. That jury deadlocked as well, and the trial court directed a defense verdict on that claim.

On appeal, the appellate court considered whether "the defense verdict in the first trial on strict liability failure to warn subsume[d] the cause of action for negligent failure to warn so that the court presiding over the second trial was within its authority to direct a defense judgment on that

negligence count."[8] (*Valentine*, *supra*, 68 Cal.App.4th at p. 1471.) The court concluded that the defense verdict on strict liability failure to warn mandated a defense verdict on negligent failure to warn as well.

For strict liability failure to warn, the jury in *Valentine* was instructed in part that "'[a] product is defective if the use of the product in a manner that is reasonably foreseeable by the defendant involves a substantial danger that would not be readily recognized by the ordinary user of the product and the manufacturer knows or should have known of the danger but fails to give adequate warning of such danger. . . . A manufacturer has a duty to provide an adequate warning to the user on how to use the product if a reasonably foreseeable use of the product involves a substantial danger of which the manufacturer is either aware or should be aware, and that would not be recognized by the ordinary user." (*Valentine*, *supra*, 68 Cal.App.4th at p. 1481.)

For negligent failure to warn, the jury was instructed that a supplier who "'knows or has reason to know [the product] is dangerous or is likely to be dangerous for the use for which it is supplied, has a duty to use reasonable care to give warning of the dangerous condition of the product or of facts which make it likely to be dangerous to those who the supplier would expect to use the product or to be endangered by its probable use, if the supplier has reason to believe that they will not realize its dangerous condition.'" (*Valentine*, *supra*, 68 Cal.App.4th at pp. 1481-1482.)

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[8] Plaintiff contends that *Valentine* is inapplicable because the court there was not deciding whether two special verdicts were inconsistent. However, the different procedural posture is immaterial. The issue decided by *Valentine* was the same as that raised here: whether a jury's finding of no strict liability failure to warn foreclosed a finding of negligent failure to warn. (*Valentine*, *supra*, 68 Cal.App.4th at pp. 1480-1481.)

Under these instructions (as pertinent here),[9] the appellate court held that the defense verdict in the first trial on plaintiff's strict liability failure to warn claim "disposed of *any* liability for failure to warn," because "the strict liability definition of defective product, coupled with instructions on the strict liability duty to warn physicians of the potential risks or side effects of silicone breast implants that were 'known or knowable,' more than subsumed the elements of duty to warn set forth in the negligence instructions." (*Valentine*, *supra*, 68 Cal.App.4th at p. 1482.)

The court explained: "The [trial] court defined a product as defective if its use involved a substantial danger that would not be readily recognized by the ordinary user and the manufacturer knows/should have known of the danger but fails to warn. Under the negligence warning instructions, the manufacturer was charged with knowing/having reason to know that the product is dangerous or likely to be dangerous for its intended use." (*Valentine*, *supra*, 68 Cal.App.4th at p. 1482.) The appellate court found no "real difference between a warning to ordinary users about a product *use* that involves a substantial danger, and a warning about a *product* that is dangerous or likely to be dangerous for its intended use. The former warning [applicable for strict liability] centers on the term 'use.' A product whose use *involves* a substantial danger may or may not harm any particular user. The latter warning [applicable for negligence] centers on (1) the dangerous condition of the *product*, or (2) facts likely to make *the product* dangerous.

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[9] The court also considered claims that the strict liability instructions did not adequately convey that the duty to warn was a continuing duty (*Valentine*, *supra*, 68 Cal.App.4th at p. 1482) and that the instructions failed to convey that an ordinary user included someone highly susceptible to autoimmune disease (*id.* at p. 1483). As these issues are not relevant here, we do not discuss them.

Again, under the 'likely' prong, the product may or may not harm any particular user. As a practical matter then, the difference in the two concepts is so small as to make no difference." (*Id.* at pp. 1482-1483.)

Similarly, the court reasoned that "the finding of the [first] jury [for strict liability purposes] that the implants were not defective due to Baxter's [the manufacturer's] failure to warn included the finding that Baxter discharged its duty to warn of potential risks or side effects which were 'known or knowable . . . .' The manufacturer's duty, per strict liability instructions, to warn of *potential* risks and side effects envelopes a *broader* set of risk factors than the duty, per negligence instructions, to warn of facts which make the product '*likely to be* dangerous' for its intended use. A 'potential' risk is one 'existing in possibility' or 'capable of development into actuality,' while a product 'likely' to be dangerous will 'in all probability' or 'probably' be dangerous. Stated differently, if Baxter adequately warned of potential risks and side effects [a necessary conclusion of the verdict finding it not liable on a strict liability theory], it of necessity warned of facts likely to render the product dangerous to the user [for negligence purposes]. But conversely, one could discharge the duty to warn of likely risks [for negligence purposes] without discharging the duty to warn of potential risks [for strict liability purposes]. In sum, the manufacturer's strict liability duty to warn is greater than its duty under negligence, and thus negligence requires a greater showing by plaintiffs." (*Valentine*, *supra*, 68 Cal.App.4th at p. 1483, fns. omitted.)

The court also concluded "the 'known or knowable in light of' language in the strict liability instruction at a minimum encompasses the 'knows or has reason to know' language in the negligence instruction. Under a negligence standard, a reasonable manufacturer would not be charged with

knowing more than what would come to light from the prevailing scientific and medical knowledge. . . . 'Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about. Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. The rules of strict liability require a plaintiff to prove only that the defendant did not adequately warn of a particular risk that was known or knowable in light of the generally recognized and prevailing best scientific and medical knowledge available at the time of manufacture and distribution. Thus, in strict liability, as opposed to negligence, the reasonableness of the defendant's failure to warn is immaterial.'" (*Valentine*, *supra*, 68 Cal.App.4th at pp. 1483-1484.) In short, the court concluded that "a jury finding of no strict liability for failure to warn . . . cannot admit a companion finding for negligent failure to warn." (*Id.* at p. 1484.)

In the present case, the jury was instructed on substantially the same principles as in *Valentine.*[10] In *Valentine,* the jury instructions required a finding of negligent failure to warn if the defendant manufacturer knew or had reason to know that the product "'is dangerous or is likely to be dangerous for the use for which it is supplied,'" and failed to meet the "'duty

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[10] Plaintiff contends that *Valentine* does not apply because the jury instructions in *Valentine* differ from the jury findings here. However, plaintiff compares the jury instructions in *Valentine* with the jury's *findings* here, rather than the instructions given here, which is not an apt comparison. We compare the jury instructions to the instructions here. The jury instructions are similar and are, in fact, identical as to the salient requisite elements.

to use reasonable care to give warning of the dangerous condition of the product or of facts which make it likely to be dangerous . . . if the supplier has reason to believe that [expected users] will not realize its dangerous condition.'" (*Valentine*, *supra*, 68 Cal.App.4th at p. 1482.) Similarly, in the present case, to return a verdict for plaintiff on the negligent failure to warn, the jury was instructed in relevant part it had to find that "McNeil knew or reasonably should have known that the Motrin was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner," that "McNeil knew or reasonably should have known that users would not realize the danger," that "McNeil failed to adequately warn of the danger or instruct on the safe use of Motrin," and that "a reasonable manufacturer . . . under the same or similar circumstances would have warned of the danger or instructed on the safe use of Motrin."[11] These instructions track the principles of the negligent failure to warn instructions in *Valentine*—in both

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[11] The instruction on negligent failure to warn was CACI No. 1222, modified to address plaintiff's claim, as follows: "[P]laintiff claims that Johnson & Johnson and/or McNeil was negligent by not using reasonable care to warn or instruct about the Motrin's dangerous condition or about facts that make Motrin likely to be dangerous. To establish this claim, [plaintiff] must prove all of the following: [¶] 1. That Johnson & Johnson and/or McNeil manufactured, distributed, or sold Motrin; [¶] 2. That Johnson & Johnson and/or McNeil knew or reasonably should have known that the Motrin was dangerous or was likely to be dangerous when used or misused in a reasonably foreseeable manner; [¶] 3. That Johnson & Johnson and/or McNeil knew or reasonably should have known that users would not realize the danger; [¶] 4. That Johnson & Johnson and/or McNeil failed to adequately warn of the danger or instruct on the safe use of Motrin; [¶] 5. That a reasonable manufacturer, distributor, or seller under the same or similar circumstances would have warned of the danger or instructed on the safe use of Motrin; [¶] 6. That plaintiff was harmed by Motrin; and [¶] 7. That Johnson & Johnson and/or McNeil's failure to warn or instruct was a substantial factor in causing [plaintiff]'s harm."

cases, "the manufacturer was charged with knowing/having reason to know that the product is dangerous or likely to be dangerous for its intended use," and required to warn of that actual or likely danger. (*Ibid.*)

On the other hand, for strict liability in *Valentine,* the jury instructions permitted a finding of liability if "use [of the product] involved a substantial danger that would not be readily recognized by the ordinary user and the manufacturer knows/should have known of the danger but fails to warn." (*Valentine*, *supra*, 68 Cal.App.4th at p. 1482.) The same concept was conveyed to the jury in the present case: the jury was instructed OTC Motrin lacked adequate warnings if it "had potential risks/side effects/allergic reactions that were known or knowable by the use of scientific knowledge available at the time of manufacture/distribution/sale," "the potential risks/side effects/allergic reactions presented a substantial danger when the Motrin is used or misused in an intended or reasonably foreseeable way," "ordinary consumers would not have recognized the potential risks/side effects/allergic reactions," and "McNeil failed to adequately warn or instruct of [*sic*] the potential risks/side effects/allergic reactions.[12] Thus, the instructions in the present case, as in *Valentine,* conveyed that strict liability

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[12] The instruction on strict liability failure to warn was CACI No. 1205, modified to address plaintiff's claim, as follows: "Plaintiff claims that the Motrin [product] lacked sufficient [instructions] [or] [warning of potential [risks/side effects/allergic reactions]]. To establish this claim, [plaintiff] must prove all of the following: [¶] That [Johnson & Johnson] and/or McNeil [manufactured/distributed/sold] the [product]; [¶] That the [product] had potential [risks/side effects/allergic reactions] that were [known] [or] [knowable by the use of scientific knowledge available] at the time of [manufacture/distribution/sale]; [¶] 3. That the potential [risks/side effects/allergic reactions] presented a substantial danger when the Motrin is used or misused in an intended or reasonably foreseeable way; [¶] 4. That ordinary consumers would not have recognized the potential [risks/side effects/allergic reactions]; [¶] 5. That [Johnson & Johnson] and/or McNeil

depends on finding that the manufacturer failed to warn of potential risks from an intended use of the product that creates substantial danger.

Given that the jury here was instructed on the same principles as in *Valentine,* the same conclusions necessarily flow from the jury's finding in its strict liability verdict that "the potential risks, side effects, and/or allergic reactions" of OTC Motrin—skin reddening, rash and blisters—did not "present a substantial danger when the OTC Motrin is used or misused in an intended or reasonably foreseeable way." As in *Valentine*: (1) the strict liability instructions "more than subsumed the elements of duty to warn set forth in the negligence instructions" (*Valentine*, *supra*, 68 Cal.App.4th at p. 1482); (2) under the instructions, there is no "real difference between a warning to ordinary users about a product *use* that involves a substantial danger, and a warning about a *product* that is dangerous or likely to be dangerous for its intended use" (*ibid.*); (3) McNeil's duty under the strict liability instructions "to warn of *potential* risks and side effects envelope[d] a *broader* set of risk factors than the duty, [under the] negligence instructions, to warn of facts which make the product '*likely to be* dangerous' for its intended use" (*id.* at p. 1483); (4) the reference in the strict liability instructions here to "potential risks . . . that were known or knowable by the use of scientific knowledge" encompasses the concept in the negligence instructions of risks McNeil "knew or reasonably should have known"; and (5) for all these reasons, the jury's finding that McNeil was not liable under a

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failed to adequately warn [or instruct] of the potential [risks/side effects/allergic reactions]; [¶] 6. That [plaintiff] was harmed; and [¶] 7. That the lack of sufficient [instructions] [or] [warnings] was a substantial factor in causing [plaintiff]'s harm."

strict liability theory "disposed of *any* liability for failure to warn" on a negligence theory. (*Id.* at p. 1482.)

If there were any doubt that the verdicts are inconsistent, that doubt is put to rest by the decision in *Oxford, supra,* 177 Cal.App.4th 700. There, the plaintiffs sued the manufacturer of ship boilers that contained asbestos, alleging products liability causes of action for strict liability failure to warn and design defect, as well as a general negligence claim. (*Id.* at p. 704.) The jury returned a special verdict that found the defendant not liable for strict liability failure to warn and design defect, but a general verdict for plaintiff on the negligence claim, without any specification of the factual basis of negligence. (*Id.* at p. 706.) The Court of Appeal reversed the general negligence verdict as being irreconcilable on the evidence and instructions with the special verdict on strict liability failure to warn.[13] (*Id.* at pp. 721-722.)

The court reasoned that in finding no strict liability for failure to warn, the jury "found explicitly that under California products liability law the boilers were not defective with respect to warnings. Consequently the finding

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[13] Because the inconsistency was between a general and special verdict, the court did not apply the standard applicable to inconsistency between special verdicts (the situation in the present case), but the more lenient rule applicable to inconsistencies between the special and general verdicts. "General and special verdicts are deemed inconsistent when they are 'beyond possibility of reconciliation under any possible application of the evidence and instructions.' [Citations.] 'If any conclusions could be drawn thereunder which would explain the apparent conflict, the jury will be deemed to have drawn them.' [Citation.] Where the jury's findings are so inconsistent that they are incapable of being reconciled and it is impossible to tell how a material issue is determined, the decision is '"against law"' within the meaning of Code of Civil Procedure section 657. [Citation.]"] (*Oxford, supra*, 177 Cal.App.4th at p. 716.)

of negligence can be reconciled [with the finding of no liability for strict liability failure to warn] only if the record reveals some other basis on which the jury, under the court's instructions, could have found defendant to have been negligent." (*Oxford*, *supra*, 177 Cal.App.4th at p. 719.) The court thus examined "the precise instructions that were given and the particular evidence that was before the jury" to determine whether the jury's finding of negligence was supportable under a theory other than negligent failure to warn. (*Id.* at p. 718.) The court concluded that the only other possible theory of negligence supported by the evidence (negligent testing) was inconsistent with the jury's verdict for the defendant on the design defect claim, and thus could not support a negligence verdict. Ruling out that and any other potential basis for negligence, the court concluded that "a finding of negligent failure to warn is logically and legally inconsistent with the jury's finding on plaintiffs' strict products liability failure to warn." (*Id.* at p. 720; see *id.* at p. 721 ["the jury necessarily found that defendant did not fail to provide adequate warnings when it found against plaintiffs on the products liability failure to warn claim"].) Because the jury's verdicts were inconsistent, the court reversed and remanded for a new trial. (*Id.* at p. 722.)

In the present case, unlike *Oxford*, plaintiff did not pursue a general negligence claim based on different factual bases, but rather a specific claim of negligent failure to warn based on a single factual basis—the failure to include warnings of skin reddening, rash, and blisters. Further, the jury returned a special verdict, not a general verdict. Thus, we need not ask whether the jury's finding of negligence can be supported on some factual basis other than failure to warn; we know it cannot. Under these circumstances, as in *Oxford,* the jury's finding of negligent failure to warn was "logically and legally inconsistent" with the finding of no strict products

liability failure to warn. (*Oxford*, *supra*, 177 Cal.App.4th at p. 720; accord *Werner v. Upjohn Co., Inc.* (4th Cir. 1980) 628 F.2d 848, 860 [jury verdicts "obviously inconsistent" where "[t]he effect of the jury verdict on negligence was to find that Upjohn failed to use due care to give an adequate warning of the propensities of the drug marketed, and, in the same breath, the verdict on strict liability found that the drug marketed with such an inadequate warning was not unreasonably dangerous"].)[14]

Plaintiff argues that the verdicts should stand, because "negligence and strict products liability are not identical doctrines." (*Oxford*, *supra*, 177 Cal.App.4th at p. 718.) True enough—the two theories of products liability are not identical. In *Carlin v. Superior Court* (1996) 13 Cal.4th 1104 (*Carlin*), the California Supreme Court explained the difference between strict liability failure to warn and negligent failure to warn, stating that, unlike negligent failure to warn, "'[s]trict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct. . . .'

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[14] Though it did not involve failure to warn, the decision in *Lambert, supra*, 67 Cal.App.4th 1179, is to the same effect regarding the preclusive effect of a defense verdict on strict liability. In *Lambert*, the plaintiff, who was injured in an accident in which the Chevrolet Blazer he was driving rolled over, sued General Motors, alleging that the design of the Blazer was defective on both a strict liability and negligence theory. In answer to the first question in the special verdict, which related to the theory of strict liability, the jury found no "defect in the design" of the Blazer. (*Id.* at p. 1182.) But in response to the fifth question, which related to the negligence claim, the jury found that "General Motors [was] negligent in the design of" the Blazer. (*Ibid.*) The Court of Appeal set aside the negligence finding as inconsistent with the finding of no design defect on the strict liability claim. The court noted that the only evidence of negligence presented by plaintiff was of negligent design. In that context, the court held that "[i]f the design of the [vehicle] was not defective, [the defendant] could not be deemed negligent." (*Id.* at p. 1186.) Because the special verdict was "fatally inconsistent," the court reversed and remanded for a new trial. (*Ibid.*)

[Citation.]" (*Id.* at p. 1112.) The court gave examples illustrating that a manufacturer could be held liable under strict liability principles even if its failure to warn conformed to industry-wide practices and thus was not negligent. (*Id.* at pp. 1112-1113.) The court did not, however, indicate that a manufacturer could be held liable *for negligent failure* to warn despite being found not liable *for strict liability failure to warn*. Indeed, as illustrated by *Valentine* and *Oxford*, this cannot be so where, as here, only one viable factual basis supports both theories.

Plaintiff also argues that the verdicts are not inconsistent because the term "danger" in the negligence instructions and in question 8 of the negligence special verdict referred to a different type of danger than "substantial danger" as referred to in the strict liability instructions and in question 6 of the strict liability verdict. According to plaintiff, "substantial danger" for strict liability is a quantitative danger and refers to how rare the disease is, while "danger" for negligence purposes is a qualitative danger and refers to how severe the disease is. Thus, in plaintiff's view, the jury could have concluded for strict liability that the risk of skin reddening, rash and blisters from SJS/TEN was not a substantial danger because it was such a rare reaction, but at the same time concluded for negligence that such a reaction was a danger because of its severity. To support this supposed dichotomy, plaintiff relies on *Cavers v. Cushman Motor Sales, Inc.* (1979) 95 Cal.App.3d 338 (*Cavers*).

In *Cavers,* the court rejected the plaintiff's challenge to a jury instruction on strict liability failure to warn, which gave guidance on the concept of substantial danger: "'Whether a danger is substantial or insubstantial must be determined from the evidence and measured in the light of several criteria none of which is totally controlling including the

potential injurious consequences of such danger, the likelihood that injury might result, the quality and extent of danger to which the user is exposed, and whether a danger is latent or patent (patent means apparent and latent is its antonym).'" (*Cavers*, *supra*, 95 Cal.App.3d at p. 349.) Plaintiff quotes *Cavers* for the proposition that "the term 'substantial danger' embraces several criteria, 'none of which is totally controlling.'"

For several reasons, plaintiff's attempt to draw a quantitative-qualitative distinction between "substantial danger" and "danger" fails. First, the jury instruction on negligence itself defeats the claim that "danger" for negligence purposes referred to a qualitative danger, that is, the severity of the potential reaction. Under the instructions, liability was premised on McNeil's failure to warn of reactions that were "dangerous or . . . likely to be dangerous," not reactions based on their severity. Second, in the present case, *defendants* requested a jury instruction modeled on *Cavers* to aid in defining substantial danger for strict liability: "In determining whether a danger is substantial, you may consider several factors, including the likelihood that harm will occur and the nature of that harm." However, the trial court declined to give the instruction, instead relying on CACI No. 1205, which does not include an explanation of the term "substantial danger." Thus, the jury was never instructed on factors to weigh in determining whether the potential risks of OTC Motrin posed a substantial danger.

Third, plaintiff relies on *Cavers* for the proposition that "the term 'substantial danger' embraces several criteria, 'none of which is totally controlling.'" But even if this concept had been explained to the jury, it directly contradicts plaintiff's argument on appeal that "substantial danger" in the strict liability failure to warn instructions and verdict refers only to a singular type of danger—a quantitative danger, meaning how rare SJS/TEN

is. Fourth, as we have noted, under the reasoning of *Valentine,* there is no "real difference between a warning to ordinary users about a product *use* that involves a substantial danger, and a warning about a *product* that is dangerous or likely to be dangerous for its intended use." (*Valentine*, *supra*, 68 Cal.App.4th at p. 1482.) Indeed, in the instant case, the jury was not instructed that there was any such quantitative-qualitative distinction between "substantial danger" and "danger." In short, plaintiff's portrayal of the findings on strict liability and negligence as consistent based on distinguishing types of danger is unsupportable. The jury's special verdict on negligent failure to warn is fatally inconsistent with its verdict on strict liability failure to warn and must be reversed.[15]

II. *Failure to Include Question on Duty to Warn*

Although we reverse the verdict on negligent failure to warn as inconsistent with the verdict on strict liability failure to warn, in the event of a retrial, we also consider defendants' contention that the special verdict for negligent failure to warn was defective for failing to include an essential element: whether a reasonable manufacturer under the same or similar circumstances would have warned of the danger. We agree that the verdict form was defective.

"'[A] special verdict is that by which the jury find the facts only, leaving the judgment to the Court. The special verdict must present the conclusions of fact as established by the evidence, and not the evidence to prove them; and those conclusions of fact must be so presented as that nothing shall

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[15] Because we reverse the negligent failure to warn verdict, we do not address defendants' argument that the failure to warn of skin reddening, rash, and blisters did not cause plaintiff's injuries.

remain to the Court but to draw from them conclusions of law.' (Code Civ. Proc., § 624.) [¶] . . . 'A special verdict is "fatally defective" if it does not allow the jury to resolve every controverted issue. [Citations.]' [Citation.]" (*Taylor v. Nabors Drilling USA, LP* (2014) 222 Cal.App.4th 1228, 1240.)

Defendants' proposed verdict form for negligent failure to warn included the following question: "Would a reasonable manufacturer, distributor or seller under the same or similar circumstances have warned of the danger of or instructed on the safe use of OTC Motrin."[16] The trial court believed that the question was unnecessary because the instruction on negligent failure to warn included this element. Plaintiff opposed the proposed question, and the court did not include the question on the verdict form. We conclude that because this question resolves a necessary element of a negligent failure to warn claim, it was error to exclude it from the special verdict.

On appeal, plaintiff contends that the special verdict form did require the jury to consider appellants' duty to warn, despite the omission of the question. He cites question 5(a), under the Strict Liability - Failure to Warn portion of the special verdict form: "Did McNeil fail to adequately warn or instruct of the potential risks, side effects and/or allergic reactions?" He also cites question 10, under the Negligence—Failure to Warn portion of the form: "Was [McNeil's] failure to warn a substantial factor in causing harm to [plaintiff]?" He contends that the jury's findings on these questions sufficiently answer whether a reasonable manufacturer would have provided the warning. Plaintiff further argues that the jury instruction on a

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[16] This question is taken from the standard CACI verdict form of negligent failure to warn, VF-1205.

reasonable manufacturer's duty to warn rendered it unnecessary to include the question on the verdict form. None of these contentions is meritorious.

First, question 5(a), regarding strict liability failure to warn, is irrelevant to whether the special verdict form omitted an element as to negligent failure to warn. "'Negligence law in a failure-to-warn case requires a plaintiff to prove that a manufacturer or distributor did not warn of a particular risk for reasons which fell below the acceptable standard of care, i.e., what a reasonably prudent manufacturer would have known and warned about. Strict liability is not concerned with the standard of due care or the reasonableness of a manufacturer's conduct.'" (*Carlin*, *supra*, 13 Cal.4th at p. 1112.) Thus, the question defendants wanted included in the special verdict form—whether a reasonable manufacturer under the same or similar circumstances would have given a warning—is an essential inquiry in the negligent failure to warn claim. (See CACI No. 1222.) The question regarding strict liability failure to warn does not address this element of negligent failure to warn.

Second, question 10, asking whether McNeil's failure to warn was a substantial factor in causing plaintiff harm, deals with causation and does not address whether a reasonable manufacturer would have included a warning about skin reddening, rash, and blisters. The question defendants contend was erroneously omitted from the verdict form is not whether their failure to warn caused plaintiff harm, but whether a reasonable manufacturer would have provided the warning, because that is a necessary element to prove liability for negligent failure to warn.

Third, that the jury instruction on negligent failure to warn defined a reasonable manufacturer's duty to warn did not obviate the necessity of including that required element in the special verdict. "A jury instruction

alone does not constitute a finding. Nor does the fact that the evidence might support such a finding constitute a finding." (*Myers Building Industries, Ltd. v. Interface Technology, Inc.* (1993) 13 Cal.App.4th 949, 961; see also *Fuller-Austin Insulation Co. v. Highlands Ins. Co.* (2006) 135 Cal.App.4th 958, 1005 (*Fuller-Austin*) ["despite instructions asking the jury to consider the issue of the settlement's reasonableness, the special verdict did not require the jury to make any finding on the issue of reasonableness"].) """The jury must resolve all of the ultimate facts presented to it in the special verdict, so that 'nothing shall remain to the court but to draw from them conclusions of law.' [Citation.]""" (*Vanderpol v. Starr* (2011) 194 Cal.App.4th 385, 396.) Because the essential basis of a negligence failure to warn claim is that the manufacturer did not warn of a particular risk that "'a reasonably prudent manufacturer would have known and warned about,'" (*Carlin*, *supra*, 13 Cal.4th at p. 1112) the verdict form should have included this question.

Plaintiff relies on *Amerigraphics, Inc. v. Mercury Casualty Co.* (2010) 182 Cal.App.4th 1538 (*Amerigraphics*), disapproved on another ground in *Nickerson v. Stonebridge Life Ins. Co.* (2016) 63 Cal.4th 363, 377, fn. 2, to argue that the omission of this element was immaterial. There, the court rejected the defendant's argument that the punitive damages were not supported by the special verdict because the jury did not separately award damages for bad faith, which were "an absolute predicate" for a punitive damages award. (*Id.* at p. 1557.) The court reasoned that the jury's special finding that the defendant breached its obligation of good faith and fair dealing "necessarily included the finding that [the plaintiff] had been damaged by [the defendant's] conduct." (*Id.* at p. 1558.)

Amerigraphics is distinguishable. Unlike *Amerigraphics*, the jury's findings here regarding strict liability to warn and causation do not

"necessarily include[]" a finding regarding whether a reasonable manufacturer would have added a warning about skin reddening, rash, and blisters to an ibuprofen product. (*Amerigraphics*, *supra*, 182 Cal.App.4th at p. 1558.) As discussed above, the questions relied on by plaintiff (questions 5(a) and 10) do not address the duty to warn.

Instead, the situation here is similar to *Fuller-Austin* and *Saxena v. Goffney* (2008) 159 Cal.App.4th 316 (*Saxena*). In *Fuller-Austin*, insurance companies that were not parties to the insured's bankruptcy proceedings sought to show that the bankruptcy settlement was not reasonable. Although the jury was instructed to consider the settlement's reasonableness, the special verdict form did not include a question concerning reasonableness. The jury found that the insured was not guilty of inequitable misconduct in entering into the settlement. (*Fuller-Austin*, *supra*, 135 Cal.App.4th at p. 1005.) However, "the jury's finding that [the insured] was not guilty of inequitable misconduct did not answer the distinctly different question of whether the [settlement] was unreasonable. [Citation.]" (*Id.* at p. 1006.) Because the special verdict did not ask the jury to resolve the controverted issue of reasonableness, the court found the verdict to be "fatally defective" and reversed and remanded for retrial. (*Id.* at pp. 1006-1007.)

Similarly, in *Saxena*, the court reversed a special verdict that did not require the jury to make a finding on the plaintiff's battery claim. (*Saxena*, *supra*, 159 Cal.App.4th at p. 326.) The special verdict form asked the jury whether the defendant doctor performed a procedure without "informed consent," but "did not require the jury to answer the separate and distinct question of whether [the defendant] performed the procedure with 'no consent' at all." (*Ibid.*)

Similar to *Fuller-Austin* and *Saxena*, whether a reasonable ibuprofen manufacturer would have added a warning about skin reddening, rash, and blisters was a controverted issue not addressed by the special verdict form. As in *Fuller-Austin*, the defective verdict "affords an additional basis for reversal" of the jury's negligent failure to warn findings. (*Fuller-Austin, supra*, 135 Cal.App.4th at p. 1006.)

At oral argument, plaintiff argued that under *Babcock v. Omansky* (1973) 31 Cal.App.3d 625 (*Babcock*), disapproved on another point in *Canal-Randolph Anaheim, Inc. v. Wilkoski* (1978) 78 Cal.App.3d 477, 485-486, the failure to include a question in the special verdict form asking whether a reasonable manufacturer of ibuprofen under the same or similar circumstances would have given a warning was not fatal to the special verdict. *Babcock* is inapposite.

In *Babcock,* as here relevant, the plaintiffs sued defendant Leon for recovery on four promissory notes and sought to void Leon's conveyances of certain property to his wife as fraudulent. In turn, Leon cross-complained, contending that he was induced to enter the promissory notes by fraud and seeking damages. (*Babcock, supra,* 31 Cal.App.3d at p. 628.) After the jury found Leon liable on the promissory notes, and found the property conveyances to be fraudulent, he appealed. (*Ibid.*)

According to the appellate opinion, the jury was presented with "special verdicts (in response to pertinent interrogatories)." (*Babcock, supra*, 31 Cal.App.3d at p. 628.) However, regarding Leon's cross-complaint, the verdict form did not ask questions relating to each element of fraud, but rather simply whether Leon was induced to enter the loan agreement resulting in the promissory note "'by reason of any fraud on the part'" of the plaintiffs. To that question, the jury responded no. (*Id.* at p. 630.) Similarly,

regarding plaintiffs' claim challenging Leon's property conveyances, the jury was asked simply whether the conveyances were "'fraudulent'" as to plaintiffs. To that question, the jury answered yes. (*Ibid.*)

On appeal, Leon contended that the judgment was void because in these two findings, the jury made conclusions of law, not fact. As to the first finding, Leon argued that the verdict should have asked the jury to make findings on each element of fraud. The court disagreed: "Although, as pointed out by Leon, the court in its own motion instructed the jury on all such elements . . . , we do not believe that a cumbersome interrogatory embracing each of the several elements was necessarily required. Said the court in *McCloud v. Roy Riegels Chemicals*, 20 Cal.App.3d 928, 936-937, 'Parties should have one chance (by request for special verdict forms) to have a jury's fact finding pinpointed.' Leon was apparently satisfied with the pinpointing form of this first interrogatory at the trial of the cause—the record is devoid of any showing that he objected thereto; having failed to do so below, any error inherent therein is waived. [Citations.] Furthermore, as noted by Witkin, 'The questions submitted in special issues must call for *ultimate facts*, not for evidentiary facts or conclusions of law.' [Citation.] As applied to the point here under discussion such view is consistent with decisional law commencing with *Hick v. Thomas*, 90 Cal. 289, that a finding as to fraud may be couched in general terms. [Citations.]" (*Babcock, supra,* 31 Cal.App.3d at p. 630.) On the same reasoning, the court upheld the jury's second finding. (*Id.* at p. 631.)

For several reasons, *Babcock* is of no aid to plaintiff. First, despite the appellate court's description of the verdict as a special verdict, the jury's findings at issue were in the nature of a general verdict (one in which findings on all issues are implied) rather than a special verdict (in which

express findings are made on each ultimate fact essential to the claim). (See *Markow v. Rosner* (2016) 3 Cal.App.5th 1027, 1047.) Thus, we question its precedential value in judging the sufficiency of a true special verdict. Second, assuming *Babcock's* reasoning can apply to a special verdict, unlike defendant Leon in *Babcock,* McNeil specifically objected to omitting from the special verdict a question regarding whether a reasonable manufacturer in the same or similar circumstances would have given a warning. Thus, the argument was not forfeited.

Third, to the extent *Babcock*'s reasoning may apply to a special verdict, it does not apply here. In *Babcock,* the jury was asked to find in general terms the "ultimate fact" whether fraud occurred. Because the question was so phrased, the appellate court could conclude that the verdict form permitted the jury to resolve every controverted issue regarding fraud under the jury instructions. But in the present case, the jury was not asked generally to find whether McNeil was negligent. The jury was asked to make findings on specific elements of the negligence cause of action—all elements except the fundamental question, which was contested at trial, whether a reasonable manufacturer in the same or similar circumstances would have warned of the danger. In that circumstance, the verdict was clearly defective, because it cannot be inferred from the findings made by the jury that it resolved that controverted issue. """"The requirement that the jury must resolve every controverted issue is one of the recognized pitfalls of special verdicts. "[T]he possibility of a defective or incomplete special verdict, or possibly no verdict at all, is much greater than with a general verdict that is tested by special findings . . . ." [Citation.]' [Citation.]"' 'A special verdict is "fatally defective" if it does not allow the jury to resolve every controverted issue.'" (*J.P. v. Carlsbad Unified School Dist.* (2014) 232 Cal.App.4th 323,

338.) In short, whereas in *Babcock,* "a cumbersome interrogatory embracing each of the several elements [of fraud] was [not] necessarily required" (31 Cal.App.3d at p. 630), questions regarding each element of negligence were required here.

On remand, therefore, any special verdict form for negligent failure to warn must include a question regarding whether a reasonable manufacturer under the same or similar circumstances would have given a warning.

III. *Design Defect Claims*

In addition to his strict liability and negligent failure to warn theories at trial, plaintiff also sought recovery for design defect on strict liability and negligence theories. The alleged design defect for both claims was that defendants should have withdrawn Motrin from the market and sold dexibuprofen, an isomer or component of ibuprofen, instead.[17] On the negligent design defect claim, the jury found McNeil liable, and Johnson & Johnson not liable. On the strict liability design defect claim, the jury found both McNeil and Johnson and Johnson liable under the consumer expectation test, but not under the risk-benefit test.

On appeal, defendants contend that under *Ramirez v. Plough, Inc.* (1993) 6 Cal.4th 539 (*Ramirez*), plaintiff's design defect claim is preempted as a matter of law because the FDA approved OTC Motrin as safe and effective and approved the warning label. They also contend that under *Brown*, *supra*, 44 Cal.3d 1049, a nonprescription drug manufacturer cannot be held strictly

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[17] Plaintiff contends that this design defect claim also relied on the theory that Motrin's design was defective for its failure to warn of skin reddening, rash, and blisters. However, as we explain, *infra*, the jury was not instructed on that theory of design defect, plaintiff did not argue it, and the verdict form did not refer to it.

liable for a design defect. We disagree with defendants' interpretation of *Ramirez* and *Brown*. However, we conclude that plaintiff's design defect claim—that defendants should have withdrawn OTC Motrin and sold dexibuprofen instead—is preempted by the analysis of the United States Supreme Court in *Bartlett*, *supra*, 133 S.Ct. 2466. We also agree with defendants that the trial court erred in instructing the jury on the consumer expectation test.

A. *Design Defect Defined*

"A design defect exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective. [Citation.]" (*Chavez v. Glock, Inc.* (2012) 207 Cal.App.4th 1283, 1303 (*Chavez*).) "'A product . . . is defective in design when the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the seller or other distributor.'" (*Morson v. Superior Court* (2001) 90 Cal.App.4th 775, 786 (*Morson*), quoting Restatement Third of Torts, Products Liability, § 2.)

"'[T]he Supreme Court [has] recognized two tests for proving design defect. The "consumer expectation test" permits a plaintiff to prove design defect by demonstrating that "the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." [Citation.] . . . [¶] 'The second test for design defect is known as the "risk-benefit test." Under this test, products that meet ordinary consumer expectations nevertheless may be defective if the design embodies an "'excessive preventable danger.'" [Citations.]'" (*Chavez*, *supra*, 207 Cal.App.4th at p. 1303.)

B. *Ramirez*

In *Ramirez, supra,* the plaintiff alleged that he suffered Reye's syndrome as a reaction to OTC children's aspirin, and sued the manufacturer for products liability based (as here relevant) on the manufacturer's failure to withdraw the aspirin from the market.[18] (6 Cal.4th at p. 555; see *O'Neill v. Novartis Consumer Health, Inc.* (2007) 147 Cal.App.4th 1388, 1393 (*O'Neill*) [describing the plaintiff's theories of liability].) Affirming the trial court's grant of summary adjudication of this claim (as part of the trial court's grant of summary judgment), the California Supreme Court held, "as a matter of law, . . . defendant may not be held liable for failing to withdraw its product from the market in early 1986, when plaintiff's mother purchased and used it. . . . Although devastating, Reye's syndrome was then and remains now a rare and poorly understood illness. A few scientific studies had shown an association between aspirin and Reye's syndrome, but the methodology of those studies had been questioned and the FDA had determined that further studies were needed to confirm or disprove the association. Pending completion of those studies, the FDA concluded that product warnings were an adequate public safety measure. Although the FDA's conclusion is not binding on us, we think it deserves serious consideration. Plaintiff has submitted nothing that causes us to doubt the FDA's judgment in this matter that in early 1986 aspirin could be considered a reasonably safe product for

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[18] *Ramirez* is better known for its rejection of the plaintiff's claim that the manufacturer should have used an additional Spanish-language warning, instead of "adopt[ing] the legislative/regulatory standard of care that mandates nonprescription drug package warnings in English only." (*Ramirez*, *supra*, 6 Cal.4th at p. 555.) That issue is not relevant to the instant case.

administration to children, when distributed with appropriate warnings." (*Ramirez*, *supra*, 6 Cal.4th at p. 556.)

Defendants argue that *Ramirez* bars plaintiff's design defect claim because ibuprofen is approved by the FDA. However, *Ramirez* did not hold that the FDA's approval preempts all state law claims, but only that the FDA's judgment "deserves serious consideration." (*Ramirez*, *supra*, 6 Cal.4th at p. 556; see also *O'Neill*, *supra*, 147 Cal.App.4th at p. 1396 ["the government agency in our case, the FDA, is the regulatory body charged with protecting the public health by ensuring that drugs are safe and effective. [Citations.] While the FDA's standards and decisions do not immunize a drug manufacturer from liability, they are nevertheless entitled to 'serious consideration' on the issue of the safety of [the drug] at the time of appellants' injuries."].) The Supreme Court upheld the summary adjudication rejecting the claim that the manufacturer should have stopped selling children's aspirin, because the plaintiff had "submitted nothing"—in context, meaning no evidence sufficient to raise a triable issue of material fact—that caused the court to doubt the FDA's conclusion that children's aspirin was safe with appropriate warnings. (*Ramirez*, *supra*, 6 Cal.4th at p. 556.)

Here, defendant's appeal is not from a grant of summary judgment, but rather from a jury verdict. Unlike the standard of review in *Ramirez,* therefore, which was de novo, our review is circumscribed by the rules governing an appeal from a judgment following a jury verdict, including the substantial evidence rule. In the present case, plaintiff *did* present to the jury evidence tending to contradict the FDA's conclusion concerning the safety of OTC Motrin. Much of plaintiff's case was directed to proving that OTC Motrin was unsafe without a label warning of skin reddening, rash and blisters. Moreover, Tackett testified that dexibuprofen is an isomer or

component of ibuprofen, and "appears to be a safer product" with fewer side effects than ibuprofen. Although the FDA denied an application to market dexibuprofen, that denial was not due to a safety issue, but rather to the failure to "put [the drug] forward as a prescription drug first, which is the usual way things . . . go from prescription to over the counter." Tackett further testified that, unlike dexibuprofen, Motrin contained a component called racemic ibuprofen that contributed to SJS/TEN, and that dexibuprofen was not associated with SJS/TEN.

On this record, it is not for this court to declare, as a matter of law, that a jury could not disagree with the FDA's conclusions. The reasoning of *Ramirez* simply does not govern this case.

C. *Brown*

We likewise disagree that *Brown, supra*, 44 Cal.3d 1049, immunized defendants, who manufacture and distribute a nonprescription medication, from plaintiff's design defect claim. *Brown* held that "a manufacturer is not strictly liable for injuries caused by a prescription drug so long as the drug was properly prepared and accompanied by warnings of its dangerous propensities that were either known or reasonably scientifically knowable at the time of distribution." (*Id.* at p. 1069.) The court noted that prescription drug manufacturers could still be liable for "for manufacturing defects, as well as under general principles of negligence, and for failure to warn of known or reasonably knowable side effects." (*Id.* at p. 1069, fn. 12; see *Garrett v. Howmedica Osteonics Corp.* (2013) 214 Cal. App. 4th 173, 182-183 (*Garrett*) [explaining *Brown*].)

The court's decision was based on the determination that neither of the two tests for strict liability design defect—consumer expectation and risk-

benefit—should be applied to a prescription drug manufacturer. As for the consumer expectation test, the court reasoned that, assuming the manufacturer provided sufficient warnings to the prescribing physician, the manufacturer should have no strict liability for the physician's failure to convey them: "While the 'ordinary consumer' may have a reasonable expectation that a product such as a machine he purchases will operate safely when used as intended, a patient's expectations regarding the effects of such a drug are those related to him by his physician, to whom the manufacturer directs the warnings regarding the drug's properties. The manufacturer cannot be held liable if it has provided appropriate warnings and the doctor fails in his duty to transmit these warnings to the patient or if the patient relies on inaccurate information from others regarding side effects of the drug." (*Brown, supra,* 44 Cal.3d at pp. 1061-1062, fn. omitted.)

As for the risk benefit analysis, the court conceded that the rationale of strict liability (to deter manufacturers from marketing unsafe products and to pass the cost of injury to all consumers, who will pay a higher price for the product because of a manufacturer's increased insurance burden) "could justify application of the doctrine to the manufacturers of prescription drugs. It is indisputable, as plaintiff contends, that the risk of injury from such drugs is unavoidable, that a consumer may be helpless to protect himself from serious harm caused by them, and that, like other products, the cost of insuring against strict liability can be passed on by the producer to the consumer who buys the item. Moreover, . . . in some cases additional testing of drugs before they are marketed might reveal dangerous side effects, resulting in a safer product." (*Brown, supra,* 44 Cal.3d at p. 1063.)

Nonetheless, the court concluded that public policy weighed in favor of precluding imposition of strict liability on manufacturers of prescription

drugs. The court observed that unlike non-medical products for which manufacturers had been held strictly liable in the past, which were "product[s] used to make work easier or to provide pleasure," prescription drugs "may be necessary to alleviate pain and suffering or to sustain life. Moreover, unlike other important medical products (wheelchairs, for example), harm to some users from prescription drugs is unavoidable. Because of these distinctions, the broader public interest in the availability of drugs at an affordable price must be considered in deciding the appropriate standard of liability for injuries resulting from their use. [¶] Perhaps a drug might be made safer if it was withheld from the market until scientific skill and knowledge advanced to the point at which additional dangerous side effects would be revealed. But in most cases such a delay in marketing new drugs—added to the delay required to obtain approval for release of the product from the Food and Drug Administration—would not serve the public welfare. Public policy favors the development and marketing of beneficial new drugs, even though some risks, perhaps serious ones, might accompany their introduction, because drugs can save lives and reduce pain and suffering. [¶] If drug manufacturers were subject to strict liability, they might be reluctant to undertake research programs to develop some pharmaceuticals that would prove beneficial or to distribute others that are available to be marketed, because of the fear of large adverse monetary judgments. Further, the additional expense of insuring against such liability—assuming insurance would be available—and of research programs to reveal possible dangers not detectable by available scientific methods could place the cost of medication beyond the reach of those who need it most." (*Brown, supra,* 44 Cal.3d at p. 1063.)

Relying on the public policy concerns expressed by *Brown*, courts have applied its exemption from strict liability design defect claims to manufacturers of a limited range of other products, including implanted prescription medical products (*Hufft v. Horowitz* (1992) 4 Cal.App.4th 8, 11 [a penile prosthesis]; *Plenger v. Alza Corp.* (1992) 11 Cal.App.4th 349, 357-361 [intrauterine device]), and implanted medical devices that, although not prescription devices, are available only through the services of a physician (*Artiglio v. Superior Court* (1994) 22 Cal.App.4th 1388, 1395-1397 (*Artiglio*) [breast implants]; *Garrett*, *supra*, 214 Cal.App.4th at pp. 183-185 [implanted prosthetic device]). Relying on *Artiglio* and *Garrett,* which extended *Brown* to nonprescription devices, defendants contend that *Brown* should apply to OTC drugs as well.

We disagree that the rationale of *Brown* extends that far. A necessary predicate of *Brown's* public policy analysis, and that of *Artiglio* and *Garrett*, is intervention of a physician between the manufacturer and the patient. As recognized in *Artiglio*, "all of the drugs considered in *Brown* and following cases were stipulated, or assumed to be, available only by 'prescription.' The conclusion is that the imposition of the condition of 'prescription' provides insulation between the manufacturer and the user such as to warrant elimination of the consumer protections afforded by strict liability. We find the same to be true of medical prostheses, at least as to those in the category of devices available only through the services of a physician." (*Artiglio*, *supra*, 22 Cal.App.4th at p. 1397.) Similarly, *Garrett* held that "[t]he public interest in the development, availability and affordability of implanted medical devices justifies an exemption from design defect strict products liability for all implanted medical devices *that are available only through the services of a physician.* [Citations.]" (*Garrett*, *supra*, 214 Cal.App.4th at p.

184, italics added.) By contrast, OTC Motrin is meant to be taken orally by the typical consumer, without the services of a physician. Thus, OTC Motrin is distinguishable from prescription drugs as discussed in *Brown*, and from the nonprescription medical devices as discussed in *Artiglio* and *Garrett.* We have found no cases, and defendants have provided none, that extend *Brown* to OTC drugs as a class, and we decline to do so.[19] (See *Rodriguez v. Superior Court* (1990) 221 Cal.App.3d 1371, 1373 [declining plaintiff's request to conclude that *Brown's* holding "abolishing strict liability for the manufacture of a prescription drug, should not be extended to cases of certain nonprescription medications"].)

D. *Federal Preemption*

Although neither *Ramirez* nor *Brown* preempts plaintiff's claim, we conclude that plaintiff's design defect claim that defendants should have withdrawn Motrin from the market is preempted by the impossibility preemption analysis of the United States Supreme Court in *Bartlett, supra*, ___ U.S. ___, 133 S.Ct. 2466, which held, in pertinent part, that a manufacturer may not be required to stop selling a product in order to avoid a state products liability claim. (*Id.* at p. 2477.)

In his supplemental brief, plaintiff concedes that his "risk/benefit design-defect claim premised on the defendants' failure to use an

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[19] (See Michael M. Walsh, *Testing Liability: While Brown v. Superior Court Remains A Foundational Case in Medical Products Litigation, Attempts to Expand Its Reach Have Not Always Been Successful*, L.A. Law., September 2014, at p. 26 [explaining that "there remain efforts to expand *Brown*'s protection against design defect claims to a widening scope of medical products. The most likely candidates for this include nonprescription drugs and medical products that, while not implanted, interact with the human body."].)

alternative active ingredient in Motrin is preempted" under *Bartlett*.[20] He argues, however, that his design defect claim was based not only on defendants' failure to sell dexibuprofen, but also on their failure to warn of the symptoms of SJS/TEN, and he concludes that his consumer expectation design defect claim and his negligent design defect claim are not preempted under *Bartlett*.

For reasons we explain below, we conclude that the record does not support plaintiff's contention that the jury based its design defect finding on a failure to warn theory. We agree with plaintiff that his claim that defendants should have sold dexibuprofen instead of ibuprofen is preempted under *Bartlett*. We further conclude that the consumer expectation test was not properly applied in these circumstances.

1. *Plaintiff's Design Defect Claim*

Plaintiff's contention that his design defect claim was based in part on the theory of failure to warn is not supported by the record. He did not argue his design defect claim to the jury under a failure to warn theory, but under the theory that dexibuprofen was a safer product that defendants should have sold. Nor was the jury instructed to find design defect by the failure to

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[20] Plaintiff concedes, on the one hand, that his design defect claim is barred to the extent that it relied on defendants' failure to use dexibuprofen instead of ibuprofen in Motrin. On the other hand, he asserts that he did not argue that defendants "should have withdrawn Motrin from the marketplace, or should have never sold it in the first place." This argument is merely a matter of semantics. No matter how plaintiff words his argument, the claim that defendants failed to sell dexibuprofen instead of ibuprofen requires the claim that defendants should have withdrawn Motrin from the market because defendants could not have changed the active ingredient of Motrin without undergoing an entirely new FDA drug application process. (21 U.S.C. § 355(a); 21 C.F.R. § 314.70(b)(2)(i).)

warn. Rather, the jury was instructed separately on the design defect and failure to warn claims, and the design defect instructions did not refer to the warning label as a consideration.

Plaintiff relies on the negligence instruction on design defect, which instructed the jury to "balance what Johnson & Johnson and/or McNeil knew or should have known about the likelihood and severity of potential harm from the product against the burden of taking safety measures to reduce or avoid the harm." However, this instruction does not refer to the warning label as a consideration in the balancing test, and we cannot infer that the jury understood the instruction in this manner, in particular because the instructions distinguished between design defect and failure to warn.

Plaintiff also relies on the jury's finding of negligent failure to warn to support his contention that the negligent design defect verdict was based on the failure to warn. However, the jury's special verdict on negligent design defect did not refer to the warning label at all, and we cannot infer such a finding. (See *Zagami*, *supra*, 160 Cal.App.4th at p. 1092 ["A court reviewing a special verdict does not infer findings in favor of the prevailing party."].) Moreover, even if we could infer that the jury relied on the negligent failure to warn finding in considering the design defect claim, we already have determined that the negligent failure to warn verdict is fatally inconsistent with the strict liability failure to warn verdict, and that inconsistency would vitiate a finding of negligent design defect on a failure to warn theory. The jury's negligent failure to warn finding accordingly cannot be relied upon to support the negligent design defect verdict.[21]

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[21] After oral argument, plaintiff filed a letter brief reiterating his argument that he did rely on the failure to warn theory to support his design defect claim. As discussed above, we disagree. Even if the record supported plaintiff's contention, the negligent failure to warn verdict is fatally

2. *General Principles of Federal Preemption*

Having concluded that plaintiff's design defect claim was based on the theory that defendants should have sold dexibuprofen instead of ibuprofen, we conclude that this claim is preempted under *Bartlett*. We begin with an overview of federal preemption principles in the pharmaceuticals context.

"Under the supremacy clause of the United States Constitution, '[w]hen a state statute, administrative rule, or common-law cause of action conflicts with a federal statute, it is axiomatic that the state law is without effect. [Citations.]' [Citation.] 'In determining whether federal law preempts state law, a court's task is to discern congressional intent. [Citation.] Congress's express intent in this regard will be found when Congress explicitly states that it is preempting state authority. [Citation.] Congress's implied intent to preempt is found (i) when it is clear that Congress intended, by comprehensive legislation, to occupy the entire field of regulation, leaving no room for the states to supplement federal law [citation]; (ii) when compliance with both federal and state regulations is an impossibility [citation]; or (iii) when state law "stands as an obstacle to the accomplishment and execution of the full purposes and objectives of Congress." [Citations.]' [Citations.] In addition, federal agency regulation with the force of law can preempt conflicting state requirements. [Citations.]" (*Eckler v. Neutrogena Corp.* (2015) 238 Cal.App.4th 433, 447-448 (*Eckler*).) "Even in the absence of an express pre-emption provision, the Court has found state law to be impliedly

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inconsistent with the strict liability failure to warn verdict. The failure to warn accordingly cannot be relied upon to support the design defect claim. Moreover, plaintiff's contention is that the warning label is relevant to the consumer expectation test. As explained below, we conclude that the consumer expectation test does not apply in these circumstances.

pre-empted where it is 'impossible for a private party to comply with both state and federal requirements.' [Citations.]" (*Bartlett*, *supra*, 133 S.Ct. at p. 2473; see also *PLIVA, Inc. v. Mensing* (2011) 564 U.S. 604, 618 (*Mensing*) ["[S]tate and federal law conflict where it is 'impossible for a private party to comply with both state and federal requirements.'"].)

Preemption of state product liability suits regarding OTC drugs is addressed by 21 United States Code section (U.S.C. §) 379r, which is entitled, "National Uniformity for Nonprescription Drugs and Preemption for Labeling or Packing of Cosmetics." The statute "authorizes the FDA to regulate, among other things, the ingredients and labeling of nonprescription, over-the-counter (OTC) drugs . . . . Section 751 of the FDCA [Federal Food, Drug, and Cosmetic Act], codified at 21 United States Code section 379r(a), specifically prohibits state requirements that are *not identical* with federal requirements: 'no State . . . may establish or continue in effect any requirement—[¶] (1) that relates to the regulation of a drug . . . and [¶] (2) that is different from or in addition to, or that is otherwise not identical with, a requirement under this chapter . . . .'" (*Eckler*, *supra*, 238 Cal.App.4th at p. 439, fn. omitted.) However, a savings clause in the statute provides that "Nothing *in this section* shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State." (21 U.S.C. § 379r(e), italics added.) Courts are divided about the scope of this savings clause.

In *Hunt v. McNeil Consumer Healthcare* (E.D.La. 2014) 6 F.Supp.3d 694 (*Hunt*), the federal district court concluded that federal law did not preempt a state inadequate warning claim involving a nonprescription drug, Children's Motrin. The court quoted the savings clause in 21 U.S.C. § 379r(e) and concluded that this subdivision showed "Congress' intent to preserve

state-law product liability actions with respect to non-prescription drugs . . . ." (*Id.* at p. 699.)

The Supreme Judicial Court of Massachusetts came to the opposite conclusion in *Reckis*, *supra*, 471 Mass. 272 [28 N.E.3d 445, 456], which addressed a failure to warn claim by a plaintiff who contracted TEN after ingesting Children's Motrin. The court rejected the plaintiff's argument that conflict preemption was "irrelevant" because of the savings clause in 21 U.S.C. § 379r. (*Id.* at p. 284 [28 N.E.3d at p. 455].) The court explained that, "by its terms, the § 379r(e) savings clause frames its exemption from preemption with a reference to § 379r itself and, as a result, must be read in the context of § 379r as a whole and specifically the express preemption provision set out in § 379r(a). The savings or exemption from preemption provided by § 379r(e), however, does not extend beyond the provisions of § 379r, and in particular does not preclude 'the ordinary working of conflict pre-emption principles.' [Citation.] That is, even if the savings clause in § 379r(e) 'removes tort actions from the scope of [an] express pre-emption clause' such as § 379r(a), the savings clause 'does not foreclose . . . the possibility that a federal [law] will pre-empt a state common-law tort action with which it conflicts' [citation] . . . ." (*Ibid.* [28 N.E.3d at p. 456, fn. omitted].)

The federal district court in *Batoh*, *supra*, 167 F.Supp.3d 296, relied on *Reckis* in holding that 21 U.S.C. § 379r(e) did not save the plaintiff's failure to warn claim regarding OTC Motrin. (*Id.* at p. 316, fn. 15.) The court reasoned that "the statute at issue, which states that '*[n]othing in this section* shall be construed to modify or otherwise affect any action or the liability of any person under the product liability law of any State,' 21 U.S.C. § 379r(e) (italics added), does not foreclose the possibility that conflict preemption may

arise from other sources of federal law." (*Ibid.*; see also *National Federation of the Blind v. United Airlines, Inc.* (9th Cir. 2012) 813 F.3d 718, 731 ["the inclusion of either a saving clause or an express preemption clause within a statutory scheme does not foreclose the application of ordinary implied preemption principles"].)

Our colleagues in Division Seven similarly stated regarding the FDCA that, "'even where the express preemption provision in [21 U.S.C. § 379r] is not applicable, implied preemption may arise [citation].' [Citation.]" (*Eckler*, *supra*, 238 Cal.App.4th at p. 443.) Because the savings clause expressly refers to "this section"—that is, 21 U.S.C. § 379r(e)—we disagree with *Hunt* and instead agree with *Eckler*, *Reckis*, and *Batoh* that the savings clause does not foreclose the possibility that conflict preemption may arise from federal sources other than 21 U.S.C. § 379r. We therefore examine whether impossibility preemption applies. We conclude that it does under *Bartlett*.

3. *Bartlett's Holding*

The plaintiff in *Bartlett* asserted a New Hampshire design defect claim against the manufacturer of a generic prescription NSAID (sulindac) after she contracted SJS/TEN. New Hampshire design defect law relied on the risk-utility test, under which "'a product is defective as designed if the magnitude of the danger outweighs the utility of the product.' [Citation.]" (*Bartlett*, *supra*, 133 S.Ct. at p. 2474.) The Supreme Court reasoned that "[i]n the drug context, either increasing the 'usefulness' of a product or reducing its 'risk of danger' would require redesigning the drug: A drug's usefulness and its risk of danger are both direct results of its chemical design and, most saliently, its active ingredients. [Citation.]" (*Id.* at p. 2475.) The Court concluded that it was impossible to redesign the drug at issue because if the

manufacturer were to change the composition of the drug, it would be required to file a new drug application with the FDA, and the drug was "chemically incapable of being redesigned" because it was essentially "'a one-molecule drug.'" (*Ibid.*)

Pertinent to the case before us, *Bartlett* rejected the appellate court's reasoning that the manufacturer "could escape the impossibility of complying with both its federal- and state-law duties by 'choos[ing] not to make [the drug] at all.' [Citation.]" (*Bartlett*, *supra*, 133 S.Ct. at p. 2477.) The Court explained: "We reject this 'stop-selling' rationale as incompatible with our pre-emption jurisprudence. Our pre-emption cases presume that an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability. Indeed, if the option of ceasing to act defeated a claim of impossibility, impossibility pre-emption would be 'all but meaningless.' [Citation.] [¶] The incoherence of the stop-selling theory becomes plain when viewed through the lens of our previous cases. In every instance in which the Court has found impossibility pre-emption, the 'direct conflict' between federal- and state-law duties could easily have been avoided if the regulated actor had simply ceased acting." (*Ibid.*)

"Given the impossibility of redesigning sulindac, the only way for [the manufacturer] to ameliorate the drug's 'risk-utility' profile—and thus to escape liability—was to strengthen 'the presence and efficacy of [sulindac's] warning' in such a way that the warning 'avoid[ed] an unreasonable risk of harm from hidden dangers or from foreseeable uses.' [Citations.]" (*Bartlett*, *supra*, 133 S.Ct. at p. 2475.) Because the manufacturer was prevented by federal law from changing the warning label, "federal law prohibited [the manufacturer] from taking the remedial action required to avoid liability

under New Hampshire law."[22] (*Id.* at p. 2476.) The plaintiff's design defect claim accordingly was preempted by federal law. (*Id.* at p. 2470.)

4. *Bartlett's Application to OTC Drugs*

Bartlett concerned generic prescription drugs, not OTC drugs, and the Court noted the difference, stating that "the FDCA's treatment of prescription drugs includes neither an express pre-emption clause (as in the vaccine context, 42 U.S.C. § 300aa–22(b)(1)), nor an express non-pre-emption clause (as in the over-the-counter drug context, 21 U.S.C. §§ 379r(e), 379s(d)). In the absence of that sort of 'explicit' expression of congressional intent, we are left to divine Congress' will from the duties the statute imposes." (*Bartlett*, *supra*, 133 S.Ct. at p. 2480.) Because *Bartlett* drew a distinction between prescription drugs and OTC drugs, lower courts are divided about whether *Bartlett*'s preemption analysis applies to OTC drugs. (See *Brown v. Johnson & Johnson* (E.D.Pa. 2014) 64 F.Supp.3d 717, 721 ["The Supreme Court has not addressed whether federal law can preempt state law design defect claims brought against manufacturers of brand-name or non-prescription drugs."]; *Hunt*, *supra*, 6 F.Supp.3d at p. 703 ["The scope of the *Bartlett* holding has been the subject of much debate among lower courts."].) We conclude that *Bartlett*'s reasoning is not limited to prescription drugs.

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[22] Generic drug manufacturers are not free to strengthen drug label warnings under 21 C.F.R. § 314.70, the FDA's "changes being effected" (CBE) regulation, which permits a brand name prescription drug manufacturer to strengthen a warning label while waiting for FDA approval of the change. (*Wyeth v. Levine* (2009) 555 U.S. 555, 558-559; *Mensing*, *supra*, 564 U.S. at pp. 613-615.) The CBE regulations do not apply to generic prescription drug labels, which are required by federal law to be identical to brand name labels. (*Mensing*, *supra*, 564 U.S. at pp. 613-615.)

In *Brown v. Johnson & Johnson*, *supra*, the federal district court concluded that *Bartlett*'s holding did not extend to manufacturers of non-prescription drugs and therefore rejected the defendants' argument that federal law preempted the plaintiffs' claim that Children's Motrin was defectively designed. (*Brown v. Johnson & Johnson*, *supra*, 64 F.Supp.3d at p. 721; see also *Hunt*, *supra*, 6 F.Supp.3d at p. 704 [concluding the plaintiff's design defect claim regarding a non-prescription drug was not preempted under *Bartlett*].)

Batoh disagreed with the conclusions of *Brown v. Johnson & Johnson, supra*, 64 F.Supp.3d at page 721, and *Hunt, supra,* 6 F.Supp.3d at page 704, that *Bartlett* is limited to manufacturers of generic prescription drugs. (*Batoh*, *supra*, 167 F.Supp.3d at p. 321, fn. 19.) The court reasoned that the "non-preemption clause" in 21 U.S.C. § 379r(e) "only limits the scope of the express preemption clause in § 379r(a). It does not purport to limit the preemptive effect of other sources of federal law, including FDA regulations, that conflict with state law requirements." (*Ibid.*) The court thus relied on *Bartlett* to hold that federal law preempted the plaintiff's "claim that Defendants could have altered the chemical composition of Motrin" by selling dexibuprofen instead of ibuprofen. (*Id.* at p. 322.)

Consistent with our conclusion that the savings clause in 21 U.S.C. § 379r(e) does not prevent the applicability of ordinary preemption principles in the nonprescription drug context, we agree with *Batoh* that *Bartlett*'s holding is not limited to prescription drugs.

5. *Impossibility Preemption Analysis*

In determining whether impossibility preemption applies, we begin with the manufacturer's duties under state law. (See *Bartlett*, *supra*, 133

S.Ct. at p. 2473 ["We begin by identifying [the manufacturers'] duties under state law."].) As stated above, "A design defect exists when the product is built in accordance with its intended specifications, but the design itself is inherently defective. [Citation.]" (*Chavez, supra*, 207 Cal.App.4th at p. 1303.) "[A] product may be found defective in design if the plaintiff demonstrates that the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." (*Barker v. Lull Engineering Co.* (1978) 20 Cal.3d 413, 429.) A product also "'may be found defective in design, even if it satisfies ordinary consumer expectations, if through hindsight the jury determines that the product's design embodies "excessive preventable danger," or, in other words, if the jury finds that the risk of danger inherent in the challenged design outweighs the benefits of such design. [Citations.]' [Citation.]" (*Soule v. General Motors Corp.* (1994) 8 Cal.4th 548, 562 (*Soule*).)

Under plaintiff's theory, the design of Motrin was inherently defective because defendants used ibuprofen instead of dexibuprofen. However, federal law prohibited defendants from changing the design of Motrin by selling dexibuprofen without prior FDA approval.[23] Defendants accordingly could not have avoided design defect liability without violating federal law.

"FDA regulations provide that once a drug, whether generic or brand-name, is approved, the manufacturer is prohibited from making any major changes to the 'qualitative or quantitative formulation of the drug product . . . .' [Citation.]" (*Yates v. Ortho-McNeil-Janssen Pharmaceuticals, Inc.* (6th Cir. 2015) 808 F.3d 281, 298 (*Yates*); see also 21 U.S.C. § 355(a) ["No person shall introduce or deliver for introduction into interstate commerce any new

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[23] It is undisputed that dexibuprofen has not been approved by the FDA.

drug, unless an approval of an application filed pursuant to subsection (b) or (j) of this section is effective with respect to such drug."]; *Bartlett*, *supra*, 133 S.Ct. at p. 2470 ["Under the [FDCA], drug manufacturers must gain approval from the [FDA] before marketing any drug in interstate commerce. [21 U.S.C.] § 355(a)."].)

According to Tackett's testimony in the present case, dexibuprofen is an isomer or component of ibuprofen. 21 C.F.R. section 310.3(h)(1) provides that "The newness of a drug may arise by reason (among other reasons) of: [¶] (1) The newness for drug use of any substance which composes such drug, in whole or in part, whether it be an active substance or a menstruum, excipient, carrier, coating, or other component." Dexibuprofen therefore would be a new drug, requiring a new drug application. (See *Kanter v. Warner-Lambert Co.* (2002) 99 Cal.App.4th 780, 784-785 ["Under the [FDCA] (21 U.S.C. § 301 et seq.), a drug manufacturer is prohibited from marketing a new drug unless the FDA has approved the drug as both safe and effective for its intended use. [Fn. omitted.] [Citations.] [¶] A manufacturer seeking approval of a new drug must submit a detailed new drug application in accordance with the requirements of the FDCA and related regulations promulgated by the FDA. [Citations.]"]; *Upjohn Mfg. Co. v. Schweiker* (6th Cir. 1982) 681 F.2d 480, 481–482 [describing the new drug application process Upjohn complied with in order to market ibuprofen as Motrin].)

In light of the statutes and regulations regarding new drug applications and preventing changes to drugs already approved by the FDA, defendants could not have "unilaterally changed the active ingredient of Motrin from ibuprofen to dexibuprofen to satisfy their state law duty" without violating federal law. (*Batoh*, *supra*, 167 F.Supp.3d at p. 322.) "Because it would have been impossible for Defendants to comply both with any state law duty to

substitute dexibuprofen for ibuprofen and with federal requirements, federal law preempts [the] claim that Defendants should have altered the chemical composition of Motrin." (*Ibid.*; see also *Wolfe*, *supra*, 773 F.Supp.2d at p. 572 [granting the manufacturers' summary judgment motion as to a strict liability defective design claim regarding Children's Motrin because "[t]here exists no FDA-approved alternative form of ibuprofen, meaning there is no available alternative design of the drug for defendants to adopt"]; *Yates*, *supra*, 808 F.3d at p. 298 ["to the extent [the plaintiff] argues that defendants should have altered the formulation of ORTHO EVRA® after the FDA had approved the patch, we find this claim clearly preempted"]; *Rheinfrank v. Abbott Laboratories, Inc.* (S.D. Ohio 2015) 137 F.Supp.3d 1035, 1040–1041 [concluding that the plaintiffs' argument that the defendants could sell a different drug or "tweak the [drug's] molecule to make it safer" was preempted, reasoning that "[c]reating an alternative design would require changing the composition of an FDA-approved drug, which is prohibited by federal law"]; *Booker v. Johnson & Johnson* (N.D. Ohio 2014) 54 F.Supp.3d 868, 875 [relying on *Bartlett* to conclude the plaintiff's design defect claim regarding a birth control patch under the risk-utility test was preempted because "it was impossible for the Defendants to comply with both its state-law duty to alter the composition of the drug, and its federal-law duty not to alter an FDA-approved design"].)

Thus, under federal law—including 21 U.S.C. § 355, 21 C.F.R. §§ 310.3 and 314.70, and *Bartlett*—defendants could not unilaterally change the chemical composition of Motrin from ibuprofen to dexibuprofen in order to satisfy consumer expectations or to increase the benefits or decrease the risks of Motrin. Nor could they be required to stop selling Motrin in order to avoid

state liability. (*Bartlett*, *supra*, 133 S.Ct. at p. 2477.) Plaintiff's design defect claim accordingly is preempted.

In his supplemental brief, plaintiff argues that *Bartlett* does not preempt his design defect claims because defendants could have strengthened the warning label without FDA approval. He cites the following language in *Bartlett*: "In cases where it is impossible—in fact or by law—to alter a product's design (and thus to increase the product's 'usefulness' or decrease its 'risk of danger'), the duty to render a product 'reasonably safe' boils down to a duty to ensure 'the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.' [Citation.]" (*Bartlett*, *supra*, 133 S.Ct. at p. 2480.) *Bartlett*, however, was applying New Hampshire law and thus was quoting from a New Hampshire state court case.[24]

Plaintiff's argument fails for several reasons. Most importantly, as discussed above, there is no indication in the record that the jury was instructed to or did consider the warning label in determining plaintiff's design defect claim. To the contrary, plaintiff's design defect claim was based

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[24] The risk-utility inquiry under New Hampshire law was based on three factors: "'the usefulness and desirability of the product to the public as a whole, whether the risk of danger could have been reduced without significantly affecting either the product's effectiveness or manufacturing cost, and the presence and efficacy of a warning to avoid an unreasonable risk of harm from hidden dangers or from foreseeable uses.' [Citations.]" (*Bartlett*, *supra*, 133 S.Ct. at p. 2475.) Under California's risk-benefit test, the considerations include "'the gravity of the danger posed by the challenged design, the likelihood that such danger would occur, the mechanical feasibility of a safer alternative design, the financial cost of an improved design, and the adverse consequences to the product and to the consumer that would result from an alternative design. [Citations.]' [Citation.]" (*Soule*, *supra*, 8 Cal.4th at p. 562.)

on his dexibuprofen argument. Furthermore, the language plaintiff relies on deals with New Hampshire's risk-utility test, which focused on three factors, including "'the presence and efficacy of a warning.'" (*Bartlett*, *supra*, 133 S.Ct. at p. 2475.) Here, not only are we applying California law, but the jury found in favor of defendants under the risk-benefit test.[25]

For the foregoing reasons, we conclude that plaintiff's design defect claim is preempted under *Bartlett*.

E. *Consumer Expectation Test*

Defendants argue that the trial court erred in instructing the jury on the consumer expectation test for design defect. We agree. "We review de novo claims of instructional error. [Citation.]" (*Romine v. Johnson Controls, Inc.* (2014) 224 Cal.App.4th 990, 1000 (*Romine*).)

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[25] Plaintiff relies on language in *Fraser v. Wyeth, Inc.* (D. Conn. 2014) 992 F.Supp.2d 68, 88 (*Fraser*) stating that "evidence of Wyeth's marketing, advertising, and ghost-writing efforts was relevant to Plaintiffs' strict liability claim under the modified consumer expectation test." However, *Fraser* applied a modified consumer expectation test, which "'incorporat[ed] risk-utility factors into the ordinary consumer expectation analysis.'" (*Id.* at p. 83.) Because the jury here found in favor of defendants under the risk-benefit test, *Fraser* does not support plaintiff's contention. Similarly, *Hansen v. Sunnyside Products, Inc.* (1997) 55 Cal.App.4th 1497 (*Hansen*) does not help plaintiff because that case held "that product label warnings are relevant in determining whether a product has a design defect *under the risk/benefit test*," not the consumer expectation test. (*Id.* at p. 1501, italics added.) Also unlike here, in *Hansen*, "defense counsel argued to the jurors that in determining whether there was a design defect under the risk/benefit test (inquiring whether the risk of harm outweighed the benefits of the product), they could consider the warning label as part of the product." (*Id.* at p. 1504.) Here, the failure to warn was presented to the jury as a separate cause of action, and the jury was instructed separately on the claims and made findings separately.

"[T]he consumer expectations test is reserved for cases in which the *everyday experience* of the product's users permits a conclusion that the product's design violated *minimum* safety assumptions, and is thus defective *regardless of expert opinion about the merits of the design*." (*Soule*, *supra*, 8 Cal.4th at p. 567.) "'The critical question, in assessing the applicability of the consumer expectation test, is not whether the product, when considered in isolation, is beyond the ordinary knowledge of the consumer, but whether the product, *in the context of the facts and circumstances of its failure*, is one about which the ordinary consumers can form minimum safety expectations.'" (*Pannu v. Land Rover North America, Inc.* (2011) 191 Cal.App.4th 1298, 1311–1312.) "[W]hen the ultimate issue of design defect calls for a careful assessment of feasibility, practicality, risk, and benefit, the case should not be resolved simply on the basis of ordinary consumer expectations [because] '. . . in many instances it is simply impossible to eliminate the balancing or weighing of competing considerations in determining whether a product is defectively designed or not. . . .' [Citation.]" (*Soule*, *supra*, 8 Cal.4th at pp. 562–563.)

In order to establish a design defect under the consumer expectation test when a """product is one within the common experience of ordinary consumers,""" the plaintiff must """provide[] evidence concerning (1) his or her use of the product; (2) the circumstances surrounding the injury; and (3) the objective features of the product which are relevant to an evaluation of its safety." [Citation.] The test is that of a hypothetical reasonable consumer, not the expectation of the particular plaintiff in the case.'" (*Mansur v. Ford Motor Co.* (2011) 197 Cal.App.4th 1365, 1375 (*Mansur*).)

In *Mansur*, the court affirmed the trial court's decision not to instruct the jury on the consumer expectation test in the plaintiffs' design defect

action following the rollover of their vehicle. (*Mansur*, *supra*, 197 Cal.App.4th at p. 1368.) The plaintiffs satisfied their burden of presenting evidence of their use of the product and the circumstances surrounding the injury. (*Id.* at pp. 1375-1376.) However, as to the objective features, they presented evidence only of the vehicle's marketing and handling, as well as of the lack of warning about rollovers. The court concluded that this evidence failed to "show the vehicle's objective features in such a way that a jury could understand why the roof crushed in . . . . Since Plaintiffs did not present sufficient evidence about the objective features of the product, which are relevant to an evaluation of its safety, we conclude the trial court correctly denied the consumer expectations instruction." (*Id.* at p. 1378.)

In *Soule*, the plaintiff sued the manufacturer of her car after she was injured in an accident, alleging that the defective design of the car caused her injuries. The California Supreme Court held that the jury should not have been instructed on the consumer expectation test because the plaintiff's "theory of design defect was one of technical and mechanical detail. It sought to examine the precise behavior of several obscure components of her car under the complex circumstances of a particular accident." (*Soule*, *supra*, 8 Cal.4th at p. 570.) The court further reasoned that "ordinary experience and understanding [would not] inform such a consumer how safely an automobile's design should perform under the esoteric circumstances of the collision at issue here," pointing out that expert testimony was required to explain the "complicated design considerations" at issue.[26] (*Ibid.*)

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[26] The court subsequently held that the instructional error was harmless because it was "not reasonably probable defendant would have obtained a more favorable result in its absence. [Citations.]" (*Soule*, *supra*, 8 Cal.4th at p. 570.)

Similarly, in *Morson*, *supra*, the court held that the consumer expectation test did not apply to the plaintiffs' design defect claim against manufacturers of latex gloves. (*Morson*, *supra*, 90 Cal.App.4th at p. 779.) The plaintiffs contended that they had sensitivities to latex that worsened from their usage of the gloves. *Morson* recognized the difficulty of "reconciling products liability law that has developed in the context of merchandise, such as soda bottles and automobiles, with the body of knowledge that deals with medical and allergic conditions and their genesis." (*Id.* at p. 791.) Because "the alleged circumstances of the product's failure involve technical and mechanical details about the operation of the manufacturing process, and then the effect of the product upon an individual plaintiff's health," the consumer expectation test did not apply. (*Id.* at p. 792.)

Morson explained that "[t]he clear trend of authority allows for the application of scientific understanding and analysis in the products liability context, and this is particularly so where there are allegations of allergic and/or idiosyncratic reactions to the product that is allegedly defective in design. The complex nature of the design defects alleged here requires such scientific resources to achieve a just resolution of the controversy by the finder of fact." (*Morson*, *supra*, 90 Cal.App.4th at p. 795.) Because expert testimony was "essential to assist the finder of fact in understanding the pros and cons of" the design defect claim, *Morson* concluded that the alleged design defects of the latex gloves could not correctly be evaluated under the consumer expectation test. (*Id.* at pp. 793, 795.)

The court in *Pruitt v. General Motors Corp.* (1999) 72 Cal.App.4th 1480 (*Pruitt*) held the consumer expectation test did not apply despite the plaintiff's testimony that she did not expect the air bag to injure her during a

low-speed collision. The court explained that "[m]inimum safety standards for air bags are not within the common knowledge of lay jurors. Jurors are in need of expert testimony to evaluate the risks and benefits of the challenged design. Even [plaintiff's] own expert testified that in designing air bags there are tradeoffs involving complex technical issues." (*Id.* at pp. 1483-1484.)

Plaintiff here contends that the consumer expectation test applies because the ordinary consumer does not expect to contract SJS/TEN from taking OTC Motrin. However, it could be said that any injury from the intended or foreseeable use of a product is not expected by the ordinary consumer. If this were the end of the inquiry, the consumer expectation test always would apply and every product would be found to have a design defect. (See *Soule*, *supra*, 8 Cal.4th at p. 568, fn. 5 ["we have consistently held that manufacturers are not insurers of their products; they are liable in tort only when 'defects' in their products cause injury."].)

As the court in *Morson* explained, "Plaintiffs view the product as a simple one that can give rise to simple consumer expectations of safety that have nothing to do with the chemical composition of the material from which the product is manufactured, or any other design characteristics for which specialized knowledge is required for understanding or taking appropriate precautions. [¶] However, the protective or barrier function of the latex gloves, on which the Plaintiffs' safety argument is mainly premised, is not their only characteristic. These gloves are made of a particular material through a particular manufacturing process. The effect of this material and these processes may well be to create in their users many degrees of allergic reactions. Understanding and assessing responsibility for such allergic reactions is a matter that is driven by the science of the manufacturing and preparation procedures, as well as the medical aspects of an individual's

allergic reactions to various substances." (*Morson*, *supra*, 90 Cal.App.4th at p. 793.)

Soule, *Morson*, *Mansur* and *Pruitt* indicate that the consumer expectation test does not apply merely because the consumer states that he or she did not expect to be injured by the product. As in those cases, the design defect claim here involves "technical and mechanical detail" (*Soule*, *supra*, 8 Cal.4th at p. 570) and testimony regarding the "medical aspects of an individual's . . . reactions to various substances." (*Morson*, *supra*, 90 Cal.App.4th at p. 793.) Because "the ultimate issue of design defect calls for a careful assessment of feasibility, practicality, risk, and benefit," the consumer expectation test does not apply here. (*Soule*, *supra*, 8 Cal.4th at p. 562.)

The need in this case for expert testimony about the risks and benefits of Motrin's design is highlighted by the fact that the trial court repeatedly sustained objections and admonished plaintiff's counsel not to allow expert testimony related to the consumer expectation test. "'[E]xpert witnesses may not be used to demonstrate what an ordinary consumer would or should expect,' because the idea behind the consumer expectations test is that the lay jurors have common knowledge about the product's basic safety. [Citation.] Using expert testimony to demonstrate common knowledge would be inappropriate (Evid. Code, § 801, subd. (a)), 'and would invite circumvention of the rule that the risks and benefits of a challenged design must be carefully balanced whenever the issue of design defect goes beyond the common experience of the product's users.'" (*Mansur, supra*, 197 Cal.App.4th at p. 1375; see *Stephen v. Ford Motor Co.* (2005) 134 Cal.App.4th 1363, 1370, fn. 6 ["The consumer expectation test applies only when the defect can be determined by common knowledge regarding minimum safety

expectations, not where (as here) an expert must balance the benefits of design against the risk of danger."].) Instead, the plaintiff should "present pertinent nonexpert testimony related to the features of the [product], which would allow a trier of fact to evaluate the safety of the [product's features]." (*Mansur*, *supra*, 197 Cal.App.4th at p. 1379.)

It cannot reasonably be disputed that contracting SJS/TEN after taking OTC Motrin is an "idiosyncratic reaction[]" to the drug, which the FDA estimated is used approximately 100 million times per year in the United States. (*Morson*, *supra*, 90 Cal.App.4th at p. 795.) Indeed, when Tackett was explaining the physiological mechanism by which he believed ibuprofen caused plaintiff's TEN, he stated that TEN is referred to as an "idiosyncratic" side effect. (See *Robinson*, *supra*, 615 F.3d at p. 868 ["The prevalence of TEN from *all* causes is estimated to be only between .4 and 1.2 cases per million users of the drug, and what fraction of that slight probability is due to ibuprofen is unknown and may be zero"].) Because SJS/TEN is an unusual reaction, expert testimony was required to explain plaintiff's theory of how Motrin caused his injury.

"That causation for a plaintiff's injuries was proved through expert testimony does not mean that an ordinary consumer would be unable to form assumptions about the product's safety. [Citations.]" (*Romine*, *supra*, 224 Cal.App.4th at p. 1004.) Nonetheless, "'in many instances it is simply impossible to eliminate the balancing or weighing of competing considerations in determining whether a product is defectively designed or not. . . .' [Citation.]" (*Soule*, *supra*, 8 Cal.4th at pp. 562–563.) The circumstances of Motrin's failure involve technical details and expert testimony regarding "the effect of the product upon an individual plaintiff's health" (*Morson*, *supra*, 90 Cal.App.4th at p. 792), and the ultimate question

of whether Motrin was defectively designed "calls for a careful assessment of feasibility, practicality, risk, and benefit" (*Soule*, *supra*, 8 Cal.4th at p. 562). Accordingly, we conclude that the consumer expectation test should not have been applied here.[27]

DISPOSITION

We summarize our holdings as follows:

(1) The jury's finding that McNeil was not liable for strict liability failure to warn is fatally inconsistent with its finding that McNeil was liable for negligent failure to warn.

(2) The special verdict form for negligent failure to warn was defective for failing to include the element of whether a reasonable manufacturer under the same or similar circumstances would have warned of the danger.

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[27] Because we conclude the case must be retried, we do not address defendants' argument that the negligent design defect finding against McNeil is inconsistent with the finding in favor of defendants on the risk-benefit test. We note, however, that our Supreme Court has stated that, "in a products liability action based on negligence in the design of a product 'placed on the market,' the test of negligent design 'involves a balancing of the likelihood of harm to be expected from a machine with a given design and the gravity of harm if it happens against the burden of the precaution which would be effective to avoid the harm.' [Citation.] . . . Thus, 'most of the evidentiary matters' relevant to applying the risk/benefit test in strict liability cases 'are similar to the issues typically presented in a negligent design case.'" (*Merrill*, *supra*, 26 Cal.4th at pp. 479–480.) Nor do we need to address Johnson & Johnson's argument that the finding in plaintiff's favor on his strict liability design defect claim is not supported by the evidence. We also do not address defendants' arguments regarding punitive damages and plaintiff's counsel's alleged misconduct. (See *Lambert*, *supra*, 67 Cal.App.4th at p. 1186 ["Having determined that the verdict is fatally inconsistent and must be reversed, we do not need to address the multitude of evidentiary and misconduct issues raised by General Motors. The proper disposition, in our view, is to remand for a new trial."].)

(3) Plaintiff's negligent and strict liability design defect claims, which were based on defendants' failure to sell dexibuprofen instead of ibuprofen, are preempted under federal law.

(4) The consumer expectation test of design defect does not apply when, as here, the question of design defect involves complex questions of feasibility, practicality, risk, and benefit beyond the common knowledge of jurors.

As to both McNeil and Johnson and Johnson, the judgment is reversed. As to McNeil alone, the case is remanded for retrial on plaintiff's claims for negligent and strict liability failure to warn. The parties shall bear their own costs on appeal.

CERTIFIED FOR PUBLICATION

WILLHITE, J.

We concur:

EPSTEIN, P. J.

COLLINS, J.