SUPREME COURT OF WISCONSIN

Case No.: 98–2162

Complete Title of Case:

Linda M. Green,

Plaintiff-Respondent,

v.

Smith & Nephew AHP, Inc., a/k/a Smith &

Nephew Perry,

Defendant-Appellant-Petitioner.

REVIEW OF A DECISION OF THE COURT OF APPEALS

2000 WI App 192

Reported at: 238 Wis. 2d 477, 617 N.W.2d 881

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Source of APPEAL

COURT: Circuit
COUNTY: Milwaukee

JUDGE: Charles F. Kahn, Jr.

JUSTICES:

Concurred: ABRAHAMSON, C.J., concurs (opinion filed).

BRADLEY, J., joins Part I of concurrence.

CROOKS, J., concurs (opinion filed).

WILCOX, J., joins concurrence.

Dissented: SYKES, J., dissents (opinion filed).

PROSSER, J., joins dissent.

Not Participating:

ATTORNEYS: For the defendant-appellant-petitioner there were

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Sherry A. Knutson and Peterson Johnson & Murray, S.C., Milwaukee;

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For the plaintiff-respondent there was a brief by Robert L. Habush, Mary S. Young, Virginia M. Antoine and Habush, Habush, Davis & Rottier, S.C., Milwaukee, and oral argument by Robert L. Habush.

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NOTICE

This opinion is subject to further editing and modification. The final version will appear in the bound volume of the official reports.

No. 98-2162

STATE OF WISCONSIN

IN SUPREME COURT

Linda M. Green,

FILED

Plaintiff-Respondent,

JUL 12, 2001

v.

Cornelia G. Clark Clerk of Supreme Court Madison, WI

Smith & Nephew AHP, Inc., a/k/a Smith & Nephew Perry,

Defendant-Appellant-Petitioner.

REVIEW of a decision of the Court of Appeals. Affirmed.

¶1 JON P. WILCOX, J. This case arises from a products liability claim brought by Linda M. Green (Green) against Smith & Nephew AHP, Inc. (S&N). Green alleged that S&N manufactured defective and unreasonably dangerous latex medical gloves, which caused her to suffer injuries arising from allergic reactions to the proteins in those gloves. Accordingly, Green claimed, S&N should be held strictly liable for these injuries.

¶2 At the close of the trial on Green's claim, the jury returned a verdict in favor of Green and against S&N. The Milwaukee County Circuit Court, Judge Charles F. Kahn, Jr., entered judgment on the verdict. S&N subsequently appealed, but

the court of appeals affirmed the circuit court judgment in its entirety. Green v. Smith & Nephew AHP, Inc., 2000 WI App 192, 238 Wis. 2d 477, 617 N.W.2d 881.

ΨЗ S&N now argues to this court that the jury verdict and, consequently, the circuit court judgment and court of appeals decision affirming that verdict were the result of four distinct legal errors. S&N thus presents four issues for review: (1) Did the circuit court err in instructing the jury that a product can be deemed defective and unreasonably dangerous based solely on consumer expectations about that product? (2) Did the circuit court err in instructing the jury a product can be deemed defective and unreasonably dangerous regardless of whether the manufacturer of that product knew or could have known of the risk of harm the product presented to consumers? (3) Could the jury properly find that S&N's gloves were defective and unreasonably dangerous where the evidence introduced at trial showed that the gloves contained a substance that causes an allergic reaction in 5 to 17 percent of their consumers? (4) Did the circuit court err in admitting certain opinion evidence regarding the safety of S&N's gloves?

¶4 Upon review of the issues presented by S&N, we conclude as follows. First, the circuit court did not err in instructing the jury that a product can be deemed defective and unreasonably dangerous based solely on consumer expectations about that product. Second, the circuit court did not err in instructing the jury that a product can be deemed defective and unreasonably dangerous regardless of whether the manufacturer of

that product knew or could have known of the risk of harm the product presented to consumers. Third, the jury could properly find that because the evidence introduced at trial showed that S&N's gloves contained a substance which causes an allergic reaction in 5 to 17 percent of their consumers, those gloves were defective and unreasonably dangerous. And fourth, although the circuit court erred in admitting the opinion evidence at issue, this error was harmless and, therefore, does not warrant a new trial.

¶5 In light of these conclusions, we hold that the jury verdict in this case was not the result of reversible error. Thus, we hold that the court of appeals correctly affirmed the circuit court's entry of judgment on the verdict.

Ι

Thompson v. Village of Hales Corners, 115 Wis. 2d 289, 314, 340 N.W.2d 704 (1983). "This is especially true where, as here, the verdict has the approval of the [circuit] court." Id. In the case at hand, the jury returned a verdict in favor of Green. Hence, we review the evidence adduced at trial in the present case in the light most favorable to Green.

Α

¶7 Green is a health care worker. She began employment at St. Joseph's Hospital in Milwaukee in 1978 where, prior to the commencement of this action, she worked as a radiology technologist and, beginning in 1986, as a CT scan technologist.

During the course of this employment, hospital rules required Green to wear protective gloves while attending patients. To comply with these rules, Green wore powdered latex gloves manufactured by S&N. Initially, Green used one or two pairs of gloves per shift. However, upon her promotion to the CT department, this use began increasing and, by about 1987 or 1988, Green's job required her to don up to approximately forty pairs of gloves per shift.

¶8 Prior to 1989, Green never had experienced allergies; however, in 1989 Green began suffering various health problems. Early that year, Green's hands became red, cracked, and sore, and began peeling. In response to this condition, she applied hand lotion, changed the soap she used, changed the type of hand towels she used, and tried various other remedies. Nevertheless, the rash continued.

Her rash spread to her upper trunk and neck, and she began experiencing chronic cold-like symptoms such as a runny nose and watery eyes. Green's symptoms grew increasingly severe, eventually culminating in an acute shortness of breath, coughing, and tightening of the throat. As a result, Green spent significant time in the hospital: approximately one day in September 1989; approximately five days beginning in late

¹ S&N "powdered" some brands of its gloves with cornstarch in order to facilitate donning and removal of the gloves.

March 1990; approximately five days in February 1991; and approximately three days beginning in late April 1991.

¶10 After undergoing various treatments and tests, Green was diagnosed in May 1991 with latex allergy. This allergy has compelled Green to avoid contact with latex, thus causing her to change jobs and limit the items she purchases, things she eats, and activities in which she participates. Moreover, Green's latex allergy caused her to develop asthma, thereby further limiting her lifestyle.

В

In 1994 Green commenced the present products liability action against S&N. Green alleged that the S&N gloves which she St. Joseph's Hospital were defective in two had used at (1) the gloves contained excessive levels of allergyrespects: causing latex proteins; and (2) the cornstarch with which S&N powdered its gloves increased the likelihood that persons would inhale the latex proteins. Green conceded that the proteins in S&N's gloves naturally occur in the rubber-tree latex from which they are produced. Green also conceded that S&N did not add any proteins to its gloves. However, Green argued that although S&N could have significantly reduced the protein levels in and discontinued powdering its gloves by adjusting its production process, S&N nonetheless utilized a production process that maintained these defects in the gloves. These defects, Green alleged, created the unreasonable danger that S&N's gloves would cause consumers to develop latex allergy and suffer allergyrelated conditions. Moreover, Green alleged that as a result of

these unreasonably dangerous defects, S&N's gloves caused her to develop latex allergy and allergy-related conditions and, therefore, suffer injuries. Consequently, Green claimed, S&N should be held strictly liable for these injuries.

¶12 At the subsequent trial on Green's claim, the parties presented in pertinent part the following evidence to the jury. Latex allergy is caused by exposure to latex proteins. exposure to latex proteins, some persons' immune systems produce antibodies to expel those proteins. The likelihood that such a person's immune system will produce antibodies in response to latex proteins increases in relation to the person's exposure to the proteins. Once a person's immune system produces these antibodies, he or she is "sensitized" to latex. Subsequent exposure to latex then may cause that person to progressively worse allergic reactions including irreversible asthma and even anaphylaxis, a hypersensitivity which, upon exposure to even a small amount of latex proteins, may trigger a life-threatening allergic reaction—anaphylactic However, at the time Green began experiencing her injuries, the health care community generally was unaware that persons could develop latex allergy.

¶13 The primary cause of latex allergy is latex gloves and, for this reason, latex allergy disproportionately affects members of the health care profession. According to Green's

² Green suffered anaphylactic shock during the May 1991 allergy test at which she was diagnosed with latex allergy.

medical experts, the vast majority of people with latex allergy—up to 90 percent—are health care workers. And while latex allergy is not common among the general population, Green's medical experts testified that it affects between 5 and 17 percent of all health care workers in the United States.³

¶14 Green further presented evidence that high-protein, powdered latex gloves are more dangerous than low-protein, powderless gloves. For example, one of Green's medical experts cited a study in which researchers tested how latex-sensitive persons reacted to various protein levels in latex gloves. In this study, the researchers found that while 75 percent of the tested individuals reacted to high-protein gloves, only 7 percent reacted to low-protein gloves. Similarly, another of Green's medical experts read to the jury a statement developed by a joint subcommittee of the American Academy of Allergy, Asthma and Immunology and the American College of Allergy, Asthma and Immunology (ACAAI Statement), which provides in part:

[L]atex allergy is the result of the exposure of susceptible individuals to latex rubber proteins. Medical devices, principally latex gloves, are the largest single source of exposure to these potent allergens. Exposure to [latex proteins] may be by direct contact with an offending device or by inhalation of allergen carried by cornstarch powder with which most powdered gloves are coated. . . .

Allergic sensitization to constituent latex rubber proteins is linked to exposure to latex allergens in the vast majority of cases. Direct

³ Although Green's experts did not agree on a single figure, their figures all fell within the 5 to 17 percent range.

exposure to latex allergens results from either contact exposures to medical devices and latex gloves or from respiratory exposure to latex aeroallergen [i.e., aerosolized latex proteins] carried by donning glove powders.

. . .

[The] risks of acute allergic reactions and of occupational asthma can be reduced only by curtailing exposure to latex rubber proteins. We recommend that the following steps, which utilize currently available devices, be taken to reduce these risks:

. . .

Only low-allergen latex gloves should be purchased and used. This will reduce the occurrence of reactions among sensitized personnel and should reduce the rate of sensitization.

Only powder-free latex gloves should be purchased and used. This will reduce latex rubber aeroallergen levels and exposure.

American College of Allergy, Asthma and Immunology, ACAAI Statement Concerning the Use of Powdered and Non-powdered Natural Rubber Latex Gloves (1997) (citations omitted), available at http://allergy.mcg.edu/physicians/joint.html; see also Green, 2000 WI App 192, ¶25 (quoting ACAAI Statement in part). Based on such evidence, both of these experts opined that high-protein gloves are much more likely than low-protein gloves to cause latex sensitization and allergic reactions. In addition, citing similar supporting evidence, these medical experts stated that powdered latex gloves, unlike powderless

⁴ Even two of S&N's experts agreed that low-protein gloves generally are safer than high-protein gloves.

gloves, pose a substantial risk insofar as they allow latex proteins to become aerosolized and, thus, easily inhaled.⁵ For these reasons, one of the experts specifically concluded that high-protein, powdered latex gloves are defective and unreasonably dangerous.

#15 Green's experts also testified that the S&N gloves which Green had used at St. Joseph's Hospital were high-protein, powdered latex gloves. One of Green's experts discussed a study conducted at Mayo Clinic in which researchers tested 30 brands of latex gloves. Of the 30 brands, only 3 had protein levels greater than the S&N gloves at issue. That witness similarly discussed another Mayo Clinic study in which researchers tested 13 brands of latex gloves. Of those brands, S&N's gloves contained more than 100 times the level of latex proteins than 10 of the 12 other brands. Further, several witnesses noted—and S&N did not dispute—that the S&N gloves which Green had used were powdered with cornstarch.

¶16 Green also presented evidence that the powder and high protein levels in S&N's gloves caused her latex allergy and allergy-related conditions. In the opinion of one testifying doctor, Green's exposure to S&N's gloves caused her to become sensitized to latex in 1989 and subsequently caused her to

⁵ As explained at trial, latex proteins tend to adhere to the cornstarch powders in powdered latex gloves. Hence, when a person dons or removes his or her gloves and the powder consequently is released into the air, the latex proteins adhering to that powder become aerosolized. These aerosolized proteins may be inhaled.

develop asthma and other allergy-related conditions. As the doctor further opined, the likelihood of Green having developed a latex allergy had she been exposed only to low-protein, powderless gloves would have been "very remote."

¶17 Finally, Green presented evidence that S&N could have eliminated the alleged unreasonably dangerous defects in its latex gloves by altering its glove production process. S&N did not dispute that different production processes in use during the 1980s could have been used to manufacture lower-protein, powderless latex gloves.

¶18 At the close of the case, the circuit court instructed the jury on the law surrounding Green's claim for strict liability. The court explained:

A manufacturer of a product who sells or places on the market a defective product which is unreasonably dangerous to the ordinary user or consumer and which expected and does reach the consumer without substantial change in the condition in which it is sold is regarded by law as responsible for harm caused by the product even though he or she has exercised all possible care in the preparation and sale of the product provided the product was being used for the purposes for which it was designed and intended to be used. A product is said to be defective when it is in a condition not contemplated by the ordinary user or is unreasonably dangerous to the consumer which ordinary user or consumer, and the defect arose out of design, manufacture or inspection while the article was in the control of the manufacturer. A defective product is unreasonably dangerous to the ordinary user or consumer when it is dangerous to an extent beyond that which would be contemplated by the ordinary user or consumer possessing the knowledge of the product's characteristics which were common to the community. A product is not defective if it is safe for normal use.

A manufacturer is not under a duty to manufacture a product which is absolutely free from all possible harm to every individual. It is the duty of the manufacturer not to place upon the market a defective product which is unreasonably dangerous to the ordinary user or consumer.

The court then put this law into the context of Green's case:

Question No. 1 on the verdict form is "Were the latex gloves manufactured or sold by defendants [S&N] to which Linda Green was exposed, defective and unreasonably dangerous to a prospective user"? . . .

Now, ladies and gentlemen, before you can answer the first question yes . . ., you must be satisfied by the greater weight of the credible evidence to a reasonable certainty that 1. the product was in a defective condition; 2. the defective condition made the product unreasonably dangerous to people; 3. the defective condition of the product existed when the product was under the control of the manufacturer; and 4. the product reached the user or consumer without substantial change in the condition in which it was sold.

There is no claim in this case that [S&N's] latex gloves failed to perform their intended purpose of protecting against the transmission of bloodborne pathogens. You may find the latex gloves were dangerous beyond the reasonable contemplation by an ordinary user or consumer, even if they served their intended purpose.

Lack of knowledge on the part of [S&N] that proteins in natural rubber latex may sensitize and cause allergic reactions to some individuals is not a defense to the claims made by the plaintiff [Green] in this action. A manufacturer is responsible for harm caused by a defective and unreasonably dangerous product even if the manufacturer had no knowledge or

could [not] have known of the risk of harm presented by the condition of the product.

A manufacturer of a product who sells (places on the market) a defective product which is unreasonably dangerous to the user or consumer, or to his or her property, and which is expected to and does reach the user or consumer without substantial change in the condition in which it is sold, is regarded by law as negligent even though he or she has exercised all possible care in the preparation and sale of the product, provided the product was being used for the purpose for which it was designed and intended to be used.

A product is said to be defective when it does not reasonably fit for the ordinary purposes for which such product was sold and intended to be used, and the defect arose out of design, manufacture, or inspection while the article was in the control of the manufacturer. A defective product is unreasonably dangerous to the user or consumer when it is dangerous to an extent beyond which would be contemplated by the ordinary user (consumer) possessing the knowledge of the product's characteristics which were common to the community.

A manufacturer is not under a duty to manufacture a product which is absolutely free from all possible harm to every individual. . . .

It is the duty of the manufacturer not to place upon the market a defective product which is unreasonably dangerous to the user (consumer).

Before you can answer the first question [on the special verdict form] yes, that (name of product) was defective so as to be unreasonably dangerous, you must be satisfied by the greater weight of the credible evidence to a reasonable certainty that: (1) the product was in a defective condition; (2) the defective condition made the product unreasonably

⁶ As we discuss in Part II of this opinion, these jury instructions differ in some respects from the pattern strict products liability jury instruction, Wis JI—Civil 3260. The pattern instruction provides:

¶19 After receiving these instructions, the jury returned a verdict in favor of Green. The jury found that S&N's gloves were defective and unreasonably dangerous. It additionally found that this defective and unreasonably dangerous condition caused Green's injuries. Based on these findings, the jury awarded Green \$1,000,000 in damages.

 $\P20$ S&N subsequently moved for judgment notwithstanding the verdict, a new trial, or remittitur. The circuit court denied S&N's motions and entered judgment on the jury's verdict.

¶21 S&N appealed, arguing that the jury verdict and, thus, the circuit court judgment entered on that verdict resulted from several legal errors. However, the court of appeals rejected S&N's arguments and, in a unanimous opinion, affirmed the circuit court judgment.

 $\mbox{$\mathbb{I}$22}$ S&N then petitioned this court to review the court of appeals decision. We granted review. 7

ΙI

 $\P 23$ Strict products liability holds manufacturers and other sellers of products accountable for selling defective and

dangerous to persons or property; (3) the defective condition of the product existed when the product was under the control of the manufacturer; and (4) the product reached the user (consumer) without substantial change in the condition in which it was sold.

Wis JI--Civil 3260.

 $^{^{7}}$ Parts II(B)(1) and IV(A) of this opinion contain additional facts.

unreasonably dangerous products that cause injuries to consumers. Since 1967, Wisconsin has adhered to the rule of strict products liability set forth in the Restatement (Second) of Torts § 402A (1965):

Special Liability of Seller of Product for Physical Harm to User or Consumer

- (1) One who sells any product in a defective condition unreasonably dangerous to the user or consumer or to his [or her] property is subject to liability for physical harm thereby caused to the ultimate user or consumer, or to his [or her] property, if
- (a) the seller is engaged in the business of selling such a product, and
- (b) it is expected to and does reach the user or consumer without substantial change in the condition in which it is sold.
- (2) The rule stated in Subsection (1) applies although
- (a) the seller has exercised all possible care in the preparation and sale of his [or her] product, and
- (b) the user or consumer has not bought the product from or entered into any contractual relation with the seller.

See Dippel v. Sciano, 37 Wis. 2d 443, 460, 155 N.W.2d 55 (1967).
To prevail on a claim under this rule, a plaintiff must prove
all of the following five elements:

(1) that the product was in defective condition when it left the possession or control of the seller, (2) that it was unreasonably dangerous to the user or consumer, (3) that the defect was a cause . . . of the plaintiff's injuries or damages, (4) that the seller engaged in the business of selling such product or, put negatively, that this is not an isolated or infrequent transaction not related to the principal business of the seller, and (5) that the product was one which the seller expected to and did reach the

user or consumer without substantial change in the condition it was when he [or she] sold it.

Id.

¶24 In the case at hand, S&N initially contends that the circuit court incorrectly instructed the jury regarding the first two elements of this standard. Specifically, S&N argues that the circuit court erroneously instructed the jury that:
(1) a product can be deemed defective and unreasonably dangerous based solely on consumer expectations about that product; and (2) a product can be deemed defective and unreasonably dangerous regardless of whether the manufacturer of that product knew or could have known of the risk of harm the product presented to consumers. Accordingly, S&N asks us to review the circuit court's jury instructions.

¶25 On review, this court will affirm a circuit court's choice of jury instructions so long as the selected instructions fully and fairly inform the jury of the relevant law. Nowatske v. Osterloh, 198 Wis. 2d 419, 428-29, 543 N.W.2d 265 (1996). The issue of whether the jury instructions fully and fairly explained the relevant law is a question of law, which this court reviews de novo. County of Kenosha v. C&S Mgmt., Inc., 223 Wis. 2d 373, 395, 588 N.W.2d 236 (1999).

Α

¶26 We first review whether the circuit court erred in instructing the jury that a product can be deemed defective and unreasonably dangerous based solely on consumer expectations about that product. As S&N indicates, the circuit court

deviated from the pattern products liability jury instruction, Wis JI—Civil 3260, which provides in pertinent part that "[a] product is said to be defective when it does not reasonably fit for the ordinary purposes for which such product was sold and intended to be used, " and instead instructed the jury that "[a] product is said to be defective when it is in a condition not contemplated by the ordinary user or consumer unreasonably dangerous to the ordinary user or consumer." (Emphasis added.) This "consumer-contemplation" instruction, S&N contends, defined "defect" by the same terms that the circuit court, in accordance with Wis JI-Civil 3260, defined "unreasonable danger": "[a] defective product is unreasonably dangerous to the user or consumer when it is dangerous to an extent beyond that which would be contemplated by the ordinary user or consumer possessing the knowledge of the product's characteristics which were common to the community." (Emphasis added.) S&N asserts that the circuit court's jury instruction thus erroneously merged the elements of "defect" and "unreasonable danger" into a single element based solely on consumer contemplation.

1

¶27 S&N maintains that the consumer-contemplation standard enunciated in the jury instructions is at odds with current Wisconsin law. According to S&N, this court has recognized that the consumer-contemplation test is not appropriate in all strict products liability cases. S&N observes that in Sumnicht v. Toyota Motor Sales, U.S.A., Inc., 121 Wis. 2d 338, 360 N.W.2d 2

(1984), we cited a list of five permissive factors that "may be beneficial to plaintiffs in proving their case[s]":

1) [C] onformity of defendant's design to the practices of other manufacturers in its industry at the time of manufacture; 2) the open and obvious nature of the alleged danger; . . . 3) the extent of the claimant's use of the very product alleged to have caused the injury and the period of time involved in such use by the claimant and others prior to the injury without any harmful incident . .; 4) the ability of the manufacturer to eliminate danger without impairing the product's usefulness or making it unduly expensive; and 5) the relative likelihood of injury resulting from the product's present design.

Id. at 372 (quoting Collins v. Ridge Tool Co., 520 F.2d 591, 594 (7th Cir. 1975)). By approving of this list, S&N asserts, this court indicated that factors other than consumer expectations may be important to determining whether a product is defective and unreasonably dangerous. Accordingly, S&N concludes, pursuant to Sumnicht, Wisconsin applies a "hybrid consumer expectation risk-benefit test."

¶28 Based on its reading of <u>Sumnicht</u>, S&N argues that the court of appeals erred in affirming the circuit court's deviation from the pattern jury instruction. S&N contends that had the circuit court instructed the jury about the defect element of Green's claim according to the pattern jury instruction (<u>i.e.</u>, in terms of whether the gloves were reasonably fit for their intended purpose), the jury could have considered the <u>Sumnicht</u> factors set out above. This, S&N

 $^{^{8}}$ S&N borrows this term from John S. Allee et. al, <u>Product</u> Liability, § 2.05[2][c], at 2-41 n.23 (2000).

asserts, would have allowed the jury to consider not only consumer expectations about S&N's gloves, but also facts such as: the gloves' effectiveness in preventing the spread of disease; the gloves' potential danger to only 5 to 17 percent of consumers; and S&N's inability to know of and, therefore, to eliminate the danger presented by the gloves' alleged design defects. But by instructing the jury solely in terms of consumer contemplation, S&N argues, the circuit court prevented the jury from considering the <u>Sumnicht</u> factors, including the risks and benefits of its gloves. S&N thus concludes that the circuit court's jury instruction erroneously incorporated a products liability standard that conflicts with Sumnicht.

In Vincer v. Esther Williams All-¶29 We disagree. Aluminum Swimming Pool Co., 69 Wis. 2d 326, 230 N.W.2d 794 (1975), this court adopted Comment g to § 402A, which provides that a product is defective "where the product is, at the time it leaves the seller's hands, in a condition not contemplated by the ultimate consumer, which will be unreasonably dangerous to him [or her]." Id. at 330 (quoting Restatement (Second) of Torts § 402A (1965)) (emphasis added). Similarly, in the same case, this court adopted Comment i to § 402A, which provides in pertinent part that a defective product is unreasonably dangerous where it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchases it, with the ordinary knowledge common to the community as to its characteristics." Id. at 331 (quoting Restatement (Second) of Torts § 402A (1965)) (emphasis added). These Comments provide that although defect and unreasonable danger are distinct elements to a claim in strict products liability, both elements are based on consumer expectations. See Sumnicht, 121 Wis. 2d at 367-70. Accordingly, based on our adoption of the definitions set out in these Comments, we concluded in Vincer:

[T]he test in Wisconsin of whether a product contains an unreasonably dangerous defect depends upon the reasonable expectations of the ordinary consumer concerning the characteristics of this type of product. If the average consumer would reasonably anticipate the dangerous condition of the product and fully appreciate the attendant risk of injury, it would not be unreasonably dangerous and defective. This is an objective test and is not dependent upon the knowledge of the particular injured consumer.

Vincer, 69 Wis. 2d at 332 (emphasis added). Indeed, since Vincer, we frequently have reiterated that Wisconsin applies a consumer-contemplation test in strict products liability cases.

See, e.g., Beacon Bowl, Inc. v. Wisconsin Elec. Power Co., 176 Wis. 2d 740, 792, 501 N.W.2d 788 (1993) ("Put another way, [a product] is defective and unreasonably dangerous when it is in a condition not contemplated by the ultimate consumer and unreasonably dangerous to that consumer."); Sumnicht, 121 Wis. 2d at 369-70 (noting that the Vincer test is the law in Wisconsin); Ransome v. Wisconsin Elec. Power Co., 87 Wis. 2d 605, 620-21, 275 N.W.2d 641 (1979) (quoting Vincer); Kozlowski v. John E. Smith's Sons Co., 87 Wis. 2d 882, 893, 275 N.W.2d 915 (1979) (noting the Vincer court's adoption of Comments g and i); accord Netzel v. State Sand & Gravel Co., 51 Wis. 2d 1, 10-11,

186 N.W.2d 258 (1971) (approving a jury instruction based on the consumer-contemplation standard).

¶30 <u>Sumnicht</u> is consistent with this precedent. In <u>Sumnicht</u>, 121 Wis. 2d at 346, 348-49, we reviewed a strict products liability claim in which the plaintiff, Sumnicht, alleged that a design defect in the defendants' automobiles exacerbated the injuries that he sustained during a traffic accident. In examining this claim, we acknowledged that states differ regarding their approaches to products liability standards. As we explained:

Two separate approaches have emerged to evaluate design defect—a consumer-contemplation test and a danger-utility [i.e., risk-benefit] test. . . .

Under the consumer-contemplation test, . . . a product is defectively dangerous if it is dangerous to an extent beyond that which would be contemplated by the ordinary consumer who purchased it with the ordinary knowledge common to the community as to the product's characteristics.

Under [the danger-utility test] approach, a product is defective as designed if, but only if, the magnitude of the danger outweighs the utility of the product. The theory underlying this approach is that virtually all products have both risks and benefits and that there is no way to go about evaluating design hazards intelligently without weighing danger against utility. There have been somewhat different ways of articulating this . . . test. But in essence, the danger-utility test directs attention of attorneys, trial judges, and juries to the necessity for weighing the danger-in-fact of a particular feature of a product against its utility.

Id. at 367-68 (quoting Prosser & Keeton on the Law of Torts § 99 at 698-99 (W. Page Keeton et al. eds., 5th ed. 1984)) (footnotes

and quotations omitted)). We then unequivocally held that "Wisconsin is committed to the consumer-contemplation test for determining whether a product is defective." Id. at 368.

¶31 After reaffirming Wisconsin's legal standard for products liability, we examined what evidence was necessary to support Sumnicht's claim. The defendants argued that we could not sustain the jury verdict that their automobiles were defective and unreasonably dangerous because there was no proof of "an alternative, safer design, practicable under the circumstances." Id. at 370 (quotation omitted). In rejecting this argument, we explained that we have "refrained from adopting mandatory factors that must be weighed when determining if a product is defective and unreasonably dangerous." Id. at 371. We did, however, suggest that the set of five permissive factors cited by S&N "may be beneficial to plaintiffs in proving their case[s]." Id. at 372.

¶32 But contrary to S&N's contentions, the <u>Sumnicht</u> factors did not change the nature of Wisconsin's consumer-contemplation test. In listing the <u>Sumnicht</u> factors, this court merely recognized that consumer expectations about products may vary depending on the nature of and consumer familiarity with those products. These factors are not supplements to the consumer-contemplation test, to be considered in addition to consumer expectations. Nor are these factors independent legal tests.

 $\P 33$ Rather, the <u>Sumnicht</u> factors are considerations that may be relevant to determining whether the ordinary consumer

could anticipate and, hence, contemplate an alleged unreasonably dangerous defect. For example, one of the Sumnicht factors is "[c]onformity of the defendant's design to the practices of other manufacturers in the industry at the time of manufacture." This factor does not allow a plaintiff to prove Id. at 372. that a manufacturer's design is defective simply by proving that the design did not conform with other manufacturers' designs for similar products. Id. at 371 ("The question is not whether any other manufacturer has produced a safer design, but whether the specific product in question is defective and unreasonably dangerous."). Instead, this factor may allow a plaintiff to show that because the defendant manufacturer's design differed from other contemporary manufacturers' designs, an ordinary consumer familiar with the other manufacturers' designs may not be able to contemplate the potential danger presented by the relevant aspect of the defendant manufacturer's design. Τo further illustrate, another Sumnicht factor is "the ability of the manufacturer to eliminate danger without impairing the product's usefulness or making it unduly expensive." This factor does not imply that in determining a manufacturer's liability, a trier of fact must balance the danger that the manufacturer's product presents to consumers with the benefits or cost-value of the product; Sumnicht expressly rejected such a risk-benefit analysis. Id. at 368; id. at 371 ("A product may be defective and see also unreasonably dangerous even though there are no alternative, safer designs available."). To the contrary, this factor allows

parties to show that due to the inherent nature or cost of a particular product, the ordinary consumer may expect, for example, the product to include more or less safety devices.

¶34 In sum, the <u>Sumnicht</u> factors must be understood and applied in light of the consumer-contemplation test. Instead of abrogating or redefining Wisconsin's products liability standard, <u>Sumnicht</u> reiterated this state's devotion to the consumer-contemplation test: Wisconsin strict products liability law applies the consumer-contemplation test and only the consumer-contemplation test in all strict products liability cases.

¶35 In the present case, the circuit court properly instructed the jury on this standard. As the court of appeals aptly noted, the circuit court's instruction was "essentially a clone of Comment g to \$ 402A, which was adopted by Vincer."

Green, 2000 WI App 192, ¶16. And as explained above, in products liability cases, this state adheres solely to the consumer-contemplation test delineated in \$ 402A, adopted in Dippel, and further defined in Vincer. Therefore, we hold that based on our prior products liability caselaw, the circuit court did not erroneously exercise its discretion in instructing the jury that it could find S&N's gloves to be defective and unreasonably dangerous based solely on consumer expectations about those gloves.

2

¶36 S&N further contends that a number of policy considerations gravitate against this court's continued use of

the consumer-contemplation test. S&N thus argues that this state should abandon its exclusive reliance on the consumer-contemplation test.

¶37 According to S&N, consumers do not always have expectations regarding the relevant design aspects of a product. S&N suggests that while most consumers likely have expectations about how safely a product will perform its basic functions or serve its intended use, they generally do not have expectations about—or, oftentimes, even know of—technical or mechanical design aspects of the product. Thus, in cases involving technical or mechanical matters, consumer contemplation may be an inappropriate measure for liability.

¶38 In addition, S&N posits that in many circumstances, the consumer-contemplation test may bar manufacturer liability and, therefore, contravene public safety. S&N suggests that in cases where a consumer sustains injuries caused by a product containing a patent defect, the consumer-contemplation test may prevent recovery because, due to the obvious nature of the defect, the defect—i.e., the condition of the product—would not be beyond the contemplation of the ordinary consumer. Consequently, S&N argues, for manufacturers to avoid liability under a pure consumer-contemplation standard, they simply need

to ensure that any unreasonably dangerous defects in their products are patent and, thus, obvious to the ordinary consumer. 9

¶39 Finally, S&N claims that a pure consumer-contemplation test, without consideration of the risks and benefits of a product, will unnecessarily cause many useful products to be taken off the market. S&N contends that by finding a particular product to be defective and unreasonably dangerous, a trier of fact effectively is condemning the entire product line. Thus, S&N argues, a finding that a particular product is defective and unreasonably dangerous will cause the product's manufacturer or other sellers to remove the product from the market. S&N postulates that, under the consumer-contemplation test, this may eliminate entire lines of beneficial products without any consideration of the good that the products generate.

¶40 We fail to see that any of these policy considerations advanced by S&N warrant this court to overrule <u>Sumnicht</u>, <u>Vincer</u>, <u>Dippel</u>, and the rest of Wisconsin products liability law. First, we do not agree with S&N that the consumer-contemplation test is inappropriate in cases involving complex products. The consumer-contemplation test imposes liability where a product is: (1) "in a condition not contemplated by the ultimate consumer"; and (2) "dangerous to an extent beyond that which would be contemplated by the ordinary consumer." Vincer, 69

This argument suggests that S&N recognizes that at least one of the <u>Sumnicht</u> factors, "the open and obvious nature of the alleged danger," must be understood in light of the consumer-contemplation test. <u>Sumnicht v. Toyota Motor Sales, U.S.A., Inc.</u>, 121 Wis. 2d 338, 372, 360 N.W.2d 2 (1984).

Wis. 2d at 330-31 (quoting Restatement (Second) of Torts § 402A cmts. g and i). Neither of these elements necessarily require proof that at the time of injury, the plaintiff pursuing a claim in products liability knew of or understood the defective or unreasonably dangerous condition of the product that caused his or her injury.

¶41 We agree with S&N that in many instances, ordinary consumers may not know of or fully understand the technical or mechanical design aspects of the product at issue. In such instances, the technical or mechanical product design features of the product will comprise "condition[s] not contemplated by the ultimate consumer." 10 Id. at 330 (quotation omitted). Thus, the inquiry in those cases must focus on whether the design features present an unreasonable danger to the ordinary consumer.

¶42 A determination of "unreasonable danger," like a determination that a product is in a condition not contemplated by the ordinary consumer, does not inevitably require any degree of scientific understanding about the product itself. Rather, it requires understanding of how safely the ordinary consumer would expect the product to serve its intended purpose. If the

Indeed, if an injured consumer knows of and understands— $\underline{i.e.}$, contemplates—at the time of his or her injury the condition of the design feature that caused that injury, the consumer likely would be unable to prove that the injury-causing product was defective and/or unreasonably dangerous. See Vincer v. Esther Williams All-Aluminum Swimming Pool Co., 69 Wis. 2d 326, 332, 230 N.W.2d 794 (1975).

product falls below such minimum consumer expectations, the product is unreasonably dangerous.

 $\P43$ These standards are straightforward and may be applied even in "complex" cases. This court frequently has upheld use of the consumer-contemplation test in cases involving complex Beacon Bowl, e.g., 176 Wis. 2d See, (electricity); Sumnicht, 121 Wis. 2d 338 (automobile design); Ransome, 87 Wis. 2d 605 (electricity). Additionally, this court has rejected the argument that the average jury cannot properly evaluate the often complex economic and engineering data presented at products liability trials. Arbet v. Gussarson, 66 Wis. 2d 551, 561-62, 225 N.W.2d 431 (1975), overruled in part on other grounds by Greiten v. LaDow, 70 Wis. 2d 589, 600 n.1, 235 N.W.2d 677 (1975). As we have explained, "juries are always called upon to make decisions based upon complex facts in many different kinds of litigation. . . . The problems presented in products liability jury trials would appear no more insurmountable than similar problems in other areas of the law." For these reasons, we reject the notion that the consumercontemplation test cannot be applied in cases technical or mechanical matters.

¶44 Second, we acknowledge that in some cases, the open and obvious nature of a design defect may defeat claims for strict products liability. This does not mean, however, that manufacturers can avoid all liability by making unreasonably dangerous design defects open and obvious to the ordinary consumer. Wisconsin recognizes several other causes of action

which may be applicable against manufacturers that produce products with open and obvious dangers. The open and obvious nature of a defective and unreasonably dangerous condition does not inherently bar claims based on, for example, negligence, breach of implied warranty, or breach of express warranty. We do not believe, as S&N suggests, that simply because strict products liability may not allow recovery in all circumstances involving defective and unreasonably dangerous products, we should abandon our current products liability standard.

¶45 And third, this court does not agree with S&N that the consumer-contemplation test unnecessarily eliminates products from the marketplace. An otherwise defective and unreasonably dangerous product may in many cases be made safe for consumer use by means of adequate warnings or instructions. Arbet, 66 Wis. 2d at 556-57; see also Restatement (Second) of Torts § 402A cmts. h, j (1965). If, even in light of warnings or instructions, a product remains defective and unreasonably dangerous to the ordinary consumer, we see no reason that the product should remain on the market.

¶46 For these reasons, we decline S&N's invitation to abandon or qualify this state's exclusive reliance on the consumer-contemplation test. We reaffirm that Wisconsin is

committed to the consumer-contemplation test in all strict products liability cases. 11

В

¶47 We next review whether the circuit court erred in instructing the jury that a product can be deemed defective and unreasonably dangerous regardless of whether the manufacturer of that product knew or could have known of the risk of harm the product presented to consumers. S&N contends that the circuit court erroneously instructed the jury that "[a] manufacturer is responsible for the harm caused by a defective and unreasonably dangerous product even if the manufacturer had no knowledge or could [not] have known of the risk of harm presented by the condition of the product." As S&N points out, one of the primary policies underlying products liability law is encourage manufacturers to produce safer products. To advance this policy, S&N further indicates, the law imposes liability on manufacturers who fail to eliminate from their products unreasonably dangerous defects, which present a risk of harm to S&N asserts that manufacturers cannot However, consumers. consciously eliminate potentially harmful defects from their

 $^{^{11}}$ We note that other than changing gender references in 1994, the Wisconsin Civil Jury Instructions Committee (the Committee) has not substantively amended Wis JI—Civil 3260 since it initially published the instruction in 1971. That is, the Committee in effect has not updated this instruction since approximately four years before Vincer, 69 Wis. 2d at 330-31, in which this court adopted Comments g and i to § 402A. In light of Vincer and our present holding, we suggest that the Committee consider revisiting Wis JI—Civil 3260.

products when the manufacturers do not and cannot know that those defects exist. Consequently, S&N argues, imposing liability on manufacturers that do not and cannot know of the risk of harm that their products present to consumers does not encourage manufacturers to produce safer products. Rather, S&N claims, imposing liability in such circumstances transforms strict products liability into absolute liability, a legal standard that this court specifically disavowed in Dippel v.Sciano, 37 Wis. 2d 443, 459-60, 155 N.W.2d 55 (1967).

¶48 S&N contends that in order to avoid imposing absolute liability, current Wisconsin products liability law necessarily includes an element of foreseeability. Alternatively, S&N and amicus curiae, Product Liability Advisory Council, Inc., 12 suggest that if this court concludes that current Wisconsin law does not recognize that foreseeability of the risk of harm is an element of strict products liability, "it would be time to change Wisconsin law" by adopting the Restatement (Third) of Torts § 2(b) (1998), which does include an element of foreseeability.

1

¶49 As a preliminary matter, we note that Green contends S&N not only failed to properly preserve this issue in the circuit court, but specifically conceded to the circuit court

 $^{^{12}}$ Product Liability Advisory Council, Inc. is an association representing 132 manufacturers, including S&N. It joins S&N in urging this court to reverse the court of appeals decision.

that foreseeability of the risk of harm presented by a product is irrelevant to a strict products liability claim. Prior to trial, Green moved in limine to exclude any reference or evidence pertaining to S&N's "lack of knowledge as to latex allergy, its possible causes, or its connection with latex gloves at any time, on the grounds that such [knowledge] is irrelevant to [Green's] claim based upon strict products liability." S&N responded to Green's motion that it "agree[d] with [Green] that lack of knowledge regarding latex allergy is irrelevant and therefore inadmissible in this case." The circuit court, however, denied Green's motion.

¶50 Similarly, S&N conceded at the jury instruction conference that its inability to foresee the risk of harm presented by its gloves should not be a factor in assessing Green's claim. Green had requested that the circuit court instruct the jury that S&N's lack of knowledge about latex allergy was not a defense to Green's products liability claim. S&N objected to this proposed instruction not because the instruction misstated the law, but rather because it was "already covered in the [j]ury instructions." That is, S&N accepted that the instruction was correct, but objected merely because it believed the instruction was duplicative.

¶51 S&N did not raise the present issue until its motions after the verdict. As such and in light of S&N's concessions to the circuit court, Green argues that S&N waived this issue.

¶52 In general, this court will not address issues that have not been properly preserved in the lower courts. Apex

Elecs. Corp. v. Gee, 217 Wis. 2d 378, 384, 577 N.W.2d 23 (1998). However, when an issue involves a question of law, has been briefed by the opposing parties, and is of sufficient public interest to merit a decision, this court has discretion to address the issue. Id.

¶53 When we accepted review in the present case, we exercised our discretion in part to address the issue of whether foreseeability of the risk of harm is an element in strict products liability claims. This issue is a question of law, has been briefed by Green and S&N pursuant to an order of this court, and is of sufficient public interest to warrant a decision. Therefore, we address S&N's arguments regarding this issue on their merits.

2

¶54 As explained above, S&N contends that this court's existing caselaw provides that foreseeability of the risk of harm is an element of strict products liability. According to S&N, in order to avoid transforming strict liability into absolute liability, this court previously recognized that when considering whether a particular product is defective and unreasonably dangerous, the trier of fact must consider whether the manufacturer could have foreseen the risk of harm presented by its product. Relying on three Wisconsin Supreme Court cases—(1) Summicht v. Toyota Motor Sales, U.S.A., Inc., 121 Wis. 2d 338, 360 N.W.2d 2 (1984); (2) Sharp v. Case Corp., 227 Wis. 2d 1, 595 N.W.2d 380 (1999); and (3) Glassey v. Continental Ins. Co., 176 Wis. 2d 587, 500 N.W.2d 295 (1993); —in support of its

contention, S&N argues that where, as in the present case, a manufacturer does not and cannot foresee the risk of harm presented by its product, strict products liability does not apply.

¶55 We reject this argument. Foreseeability of harm is an element of negligence. As this court explained just last term:

"A negligence action requires the proof of four elements: (1)

A duty of care on the part of the defendant; (2) a breach of that duty; (3) a causal connection between the conduct and the injury; and (4) an actual loss or damage as a result of the injury." Morden v. Continental AG, 2000 WI 51, ¶45, 235 Wis. 2d 325, 611 N.W.2d 659 (quotation omitted). With regard to the first of these elements, duty of care, the court further explained:

The duty of any person is the obligation of due care to refrain from any act which will cause foreseeable harm to others... The duty of care of a defendant is established when we can state that it was foreseeable that the defendant's acts or omission could harm or injure another person.

Id. at $\P46$ (quotation and citations omitted). Negligence liability thus hinges in large part on the defendant's conduct under circumstances involving a foreseeable risk of harm. D.L. v. Huebner, 110 Wis. 2d 581, 610, 329 N.W.2d 890 (1983).

¶56 By contrast, unlike negligence liability, strict products liability focuses not on the defendant's conduct, but on the nature of the defendant's product. D.L., 110 Wis. 2d at 610; see also Greiten v. LaDow, 70 Wis. 2d 589, 603 n.2, 235 N.W.2d 677 (1975) ("[I]n a sec. 402A case the focus is upon the

condition of the product[;] in an ordinary negligence case the focus is upon the conduct creating a particular condition of a product."); Howes v. Hansen, 56 Wis. 2d 247, 259, 201 N.W.2d 825 (1972) ("Dippel makes it absolutely clear that the doctrine of foreseeability, although a recognized doctrine where ordinary negligence in tort is involved, has no part in the concept of strict liability in tort."); cf. Krueger v. Tappan Co., 104 Wis. 2d 199, 206-08, 311 N.W.2d 219 (Ct. App. 1981) (suggesting that because "duty to warn" claims are not based on § 402A and focus on the manufacturer's conduct rather than the product's condition, such claims are more akin to negligence than to strict products liability). As explained in Comment m to § 402A, strict products liability

does not rest upon negligence. . . . The basis of liability is purely one of tort.

. . .

The rule [of strict products liability] does not require any reliance on the part of the consumer upon the reputation, skill, or judgment of the seller who is to be held liable, nor any representation or undertaking on the part of that seller.

Restatement (Second) of Torts § 402A cmt. m (1965). In other words, strict products liability imposes liability without regard to negligence and its attendant factors of duty of care and foreseeability. Dippel, 37 Wis. 2d at 461; see also id. at 460 ("From the plaintiff's point of view the most beneficial aspect of the rule [of strict products liability] is that it relieves [the plaintiff] of proving specific acts of

negligence."); Fuchsgruber v. Custom Accessories, Inc., 2001 WI 81, ¶18, ___ Wis. 2d ___, __ N.W.2d ___ (explaining that strict products liability "is not based upon negligence"). Strict products liability "applies although . . . the seller has exercised all possible care in the preparation and sale of his product." Restatement (Second) of Torts § 402A(2)(a) (1965). Thus, regardless of whether a manufacturer could foresee potential risks of harm inherent in its defective and unreasonably dangerous product, strict products liability holds that manufacturer responsible for injuries caused by that product.

¶57 This is not to say that strict products liability is tantamount to absolute liability. Dippel, 37 Wis. 2d at 459-60. Strict products liability does not impose liability in every instance that a consumer is injured while using a product. Ransome v. Wisconsin Elec. Power Co., 87 Wis. 2d 605, 617, 275 N.W.2d 641 (1979). Rather, to prevail under a strict products liability theory,

the plaintiff is required to prove that the product was in a defective condition when it left the possession or control of the seller; that it was unreasonably dangerous to the [ordinary] user or consumer; that the defect was a cause . . of the plaintiff's injuries or damages; that the seller was engaged in the business of selling the product . .; and that the product was expected to and did reach the user or consumer without substantial change in the condition in which it was sold.

Kemp v. Miller, 154 Wis. 2d 538, 551, 453 N.W.2d 872 (1990)
(citing Dippel, 37 Wis. 2d at 460). Additionally, the plaintiff

must overcome the potential defense of contributory negligence.

Id. But under no circumstance must the plaintiff prove that the risk of harm presented by the product that caused his or her injury was foreseeable. Fuchsgruber, 2001 WI 81, ¶21 ("It is not necessary [in a products liability case] to show duty in terms of foreseeability." (quoting Greiten, 70 Wis. 2d at 603)).

¶58 None of the cases cited by S&N—Sumnicht, Sharp, and Glassey—support a contrary position. As noted above, Sumnicht involved a claim that automobiles sold by the defendants were defective and unreasonably dangerous because certain design aspects of those vehicles enhanced the plaintiff's injuries during a collision. 121 Wis. 2d at 346, 348-49. Before this court analyzed the issues in that case, we explained:

[W]e must first note that the risk that a car may be in an accident is reasonably foreseeable by the [defendants], and, therefore, the [defendants] have a duty to anticipate that risk. Arbet [v. Gussarson, 66 Wis. 2d 551, 558, 225 N.W.2d 431 (1975)]. We reemphasize the following from the Larsen decision:

We perceive no sound reason, either in logic or experience, nor any command in precedent, why the manufacturer should not be held to a reasonable duty of care in the design of its vehicle consonant with the state of the art to minimize the effect of accidents. manufacturers are not insurers but should be held to a standard of reasonable care in design to provide a reasonably safe vehicle in which to travel... The duty of reasonable care in design should be viewed in light of that risk. While all risks cannot be eliminated nor can a crash-proof vehicle be designed under the present state of the art, there are many common-sense factors in design, which are or should be well known to the manufacturer that will minimize or lessen the injurious effects of a collision. The standard of reasonable care is applied in many other negligence situations and should be applied here.

Larsen [v. General Motors Corp., 391 F.2d 495, 503 (8th Cir. 1968)], cited with approval in Arbet, 66 Wis. 2d at 560.

 $\overline{\text{Id.}}$ at 374-75. S&N contends that this language injected an element of foreseeability into Wisconsin products liability law.¹³

¶59 S&N misreads <u>Sumnicht</u>. This language in <u>Sumnicht</u> addressed the issue of "intended use," a concept interwoven with the defense of contributory negligence. <u>See Arbet</u>, 66 Wis. 2d at 559 (citation omitted). As explained above, contributory negligence is a defense to strict products liability claims. <u>See Dippel</u>, 37 Wis. 2d at 460. A consumer may be found to be contributorily negligent if he or she sustains injuries from a product while abusing or misusing, or after altering that product. <u>Id.</u>; <u>accord Restatement (Second) of Torts</u> § 402A cmt. h (1965) (explaining that a seller of a product is not responsible for injuries arising out of abnormal handling, abnormal preparation, or abnormal consumption of the product).

¹³ S&N also argues that the fourth <u>Sumnicht</u> factor—"the ability of the manufacturer to eliminate danger without impairing the product's usefulness or making it unduly expensive"—relates to the concept of foreseeable risk of harm. 121 Wis. 2d at 372 (quotation omitted). But as we explain above, this factor must be examined in light of the consumer-contemplation test: it relates to the ordinary consumer's reasonable expectations, not to the manufacturer's conduct. Thus, we find this argument to be without merit.

Thus, intended use, or "foreseeable use," is at issue in many products liability cases.

¶60 However, foreseeable use must not be confused with foreseeable risk of harm. As explained above, in tort law, the former concept relates to the consumer's conduct and the defense of contributory negligence; the latter concept relates the manufacturer's conduct and, hence, solely to negligence liability.

¶61 In Arbet, the decision from which Sumnicht quoted the language at issue, this court held that collisions are a "foreseeable use" of vehicles. 66 Wis. 2d at 560. Approximately ten years later, in Sumnicht, this court quoted Arbet for this holding. 121 Wis. 2d at 374-75. Sumnicht, however, did not expand the meaning of the Arbet quotation to hold that foreseeability of the risk of harm is an element of

strict products liability. 14 Therefore, <u>Sumnicht</u> fails to support S&N's argument.

¶62 S&N also cites as support for its argument this court's decision in Sharp, 227 Wis. 2d 1. In Sharp, the plaintiff brought claims for, among other things, strict products liability and failure to warn. Id. at 9. The jury rejected the strict products liability claim, but found in favor of the plaintiff on the failure to warn claims. Id.

 $\P63$ On review, the defendant in Sharp argued that:

the jury's finding [on the strict products liability claim] that the product was not unreasonably dangerous is inconsistent with the jury's finding that after manufacture and sale of the product, [the defendant] learned of a defect posing a serious hazard that originated at and was unforeseeable at the time of

acknowledge that in Arbet, while explaining foreseeable use as relating to the defense of contributory negligence, this court referred to the negligence concept of foreseeable risk of harm. See Arbet v. Gussarson, 66 Wis. 2d 551, 558-60, 225 N.W.2d 431 (1975). Indeed, Larsen v. General Motors Corp., 391 F.2d 495, 503 (8th Cir. 1968), the case that provided the language quoted in Arbet, which in turn provided the language quoted above from Sumnicht, was a negligence casenot a products liability case. However, in the term following our Arbet decision, this court clarified the difference between negligence and strict products liability and, in doing so, overruled Arbet to the extent that it "revived the issue of the exercise of ordinary care by the manufacturer in products liability cases." Greiten v. LaDow, 70 Wis. 2d 589, 600 n.1, 235 N.W.2d 677 (1975); see generally id. at 599-604. In quoting Arbet in Sumnicht, we did not overrule our partial overruling of Arbet. As this court reemphasized in Glassey v. Continental Ins. Co., 176 Wis. 2d 587, 604, 500 N.W.2d 295 (1993), more than eight years after Sumnicht: "Foreseeability is not an element considered in strict products liability claims, but instead is an element of negligence."

manufacture and that [the defendant] did not use due care in warning about the danger.

<u>Id.</u> at 20. In dismissing this argument, we explained:

We do not see any inconsistency between the two findings complained of in this case. A defect imposing a serious hazard may not be unreasonably dangerous. We agree with the circuit court that "the jury could have found that... the defects... were not foreseeable at the point of sale, but became apparent later." Accordingly, we hold that the special verdict findings are not fatally inconsistent.

Id.

¶64 In the present case, S&N contends that the Sharp court's explanation that "the jury could have found that . . . the defects . . . were not foreseeable at the point of sale, but became apparent later" leaves no doubt that a jury may reject a strict products liability claim simply because the defendant manufacturer could not have foreseen the risk of harm presented by its product. Id. That is, S&N contends that in this sentence, this court recognized foreseeability as an element of strict products liability.

T65 S&N misinterprets this sentence. In Sharp, we explained that although the jury may have found that the defendant's product posed a "serious hazard," thus giving rise to a duty to warn consumers of that hazard, it did not necessarily follow that the jury must have found that the defendant's product was unreasonably dangerous and, therefore, could give rise to strict products liability. Our explanation that "[a] defect imposing a serious hazard may not be unreasonably dangerous" explained why the jury rejected the

strict products liability claim. <u>Id.</u> By contrast, our following sentence, "the jury could have found that . . . the defects . . . were not foreseeable at the point of sale, but became apparent later," explained why the jury found the defendant liable for negligently breaching its post-sale duty to warn consumers of the risk of harm presented by its product. <u>Id.</u> (quotations omitted). Contrary to S&N's argument, this latter sentence did not provide that foreseeability is an element of Wisconsin products liability law.¹⁵

Glassey supports the position that foreseeability must be considered in strict products liability claims. In Glassey, 176 Wis. 2d at 597, we examined in part whether a plaintiff can recover under strict products liability when he or she has substantially changed the product at issue. We concluded that a plaintiff cannot recover under such circumstances because his or her claim fails as a matter of law to satisfy the fifth element of strict products liability: "'that the product was one which the seller expected to and did reach the user or consumer without substantial change in the condition it was when [the

 $^{^{15}}$ Even assuming arguendo that foreseeability is an element of strict products liability, we question whether it would have barred the plaintiff's recovery in Sharp v. Case Corp., 227 Wis. 2d 1, 595 N.W.2d 380 (1999). By finding that the defendant manufacturer in Sharp breached its post-sale duty to warn the plaintiff about the hazardous defects in the product at issue, the jury must have concluded that at least at the time of the plaintiff's injury, the product presented a foreseeable risk of harm.

seller] sold it.'" <u>Id.</u> at 599 (quoting <u>Dippel</u>, 37 Wis. 2d at 460).

¶67 In addition, however, we examined how our holding accorded with the public policy behind products liability law. As we explained, when this court recognized the cause of action for strict liability in tort, we identified several policy considerations supporting our decision to make manufacturers and other sellers of products responsible for placing defective and unreasonably dangerous products into the stream of commerce: (1) the seller of a product is "'in the paramount position to distribute the costs of the risks'" presented by the products by passing along costs to consumers or by purchasing insurance; (2) consumers have "'the right to rely on the apparent safety of the product and . . . it is the seller in the first instance who creates the risk by placing the defective product on the market'"; and (3) "'the manufacturer has the greatest ability to control the risk created by [its] product since [it] may initiate or adopt inspection and quality control measures thereby preventing defective products from reaching the consumer.'" Id. at 602-03 (quoting Dippel, 37 Wis. 2d at 450-51). Applying these policies to the issue that was before us in Glassey, we concluded that where "[t]he manufacturer or seller is not the one who creates the risk," imposing liability on the manufacturer or seller would not "achieve any significant reduction of risk" or serve the equitable purpose of imposing the cost of the risk on the party that created the dangerously defective product. Id. at 603. Accordingly, we held in Glassey that imposing liability on a manufacturer when the product at issue has undergone a substantial change since it left the manufacturer's control would not advance the policies undergirding Wisconsin products liability law. Id.

¶69 Second, S&N's argument focuses solely on one public policy underlying strict products liability while ignoring a second, more important policy consideration. Although products liability law is intended in part to make products safer for consumers, the primary "rationale underlying the imposition of strict liability on manufacturers and sellers is that the risk of the loss associated with the use of defective products should be borne by those who have created the risk and who have reaped the profit by placing a defective product in the stream of commerce." Kemp, 154 Wis. 2d at 556; see also D.L., 110 Wis. 2d at 646 ("The concept of strict [products] liability rests on the

public policy of allocating the costs of the risks associated with putting goods into the stream of commerce."); Ransome, 87 Wis. 2d at 619 ("'public policy demands that the burden of accidental injuries caused by products intended for consumption be placed upon those who market them, and be treated as a cost of production'" (quoting Restatement (Second) of Torts § 402A cmt. c (1965))); Greiten, 70 Wis. 2d at 604 ("Dippel is based upon the public-policy premise that a seller is socially responsible for what [it] puts into the stream of commerce irrespective of his degree of care."); Howes, 56 Wis. 2d at 260 (holding that strict products liability rests on the policy "that a manufacturer should be strictly liable in tort when [it] places a defective article on the market that causes injury" (quotation omitted)). In a case where a manufacturer places an unforeseeably defective and unreasonably dangerous product on the market, the manufacturer both creates the risk of harm and reaps the profit from the defective and unreasonably dangerous product; this is distinguishable from a case where, as Glassey, the product is not defective and unreasonably dangerous until it is substantially altered by a consumer. In the former instance, the manufacturer creates the risk of harm, whereas in the latter circumstance, the consumer creates the risk of harm. To be certain, imposing liability on the manufacturer under either circumstance may not materially affect a reduction of future risk. However, holding the manufacturer accountable in the former circumstance—unlike the latter circumstance—will serve the equitable purpose of imposing the cost of the risk on the party that created the risk. Thus, contrary to S&N's position, our policy discussion in <u>Glassey</u> does not suggest that foreseeability is or should be an element in products liability cases.

¶70 For this reason and the reasons set forth above, we reemphasize the long-standing rule that foreseeability of the risk of harm plays no role in current Wisconsin products liability law. Accordingly, we hold that current Wisconsin law does not support S&N's contention that the circuit court erred in instructing the jury that it could find S&N's gloves to be defective and unreasonably dangerous regardless of whether S&N knew or could have known of the risk of harm its latex gloves presented to consumers.

3

¶71 S&N and amicus curiae suggest in the alternative, however, that if Wisconsin strict products liability law currently does not include an element of foreseeability, this

court should adopt the <u>Restatement (Third) of Torts</u> § 2(b) (1998). Section 2(b) provides that 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, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe.

¶72 Comment a to § 2 of the Restatement (Third) of Torts explains that § 2(b) incorporates an element of foreseeability of risk of harm and a risk-benefit test. As such, § 2(b) departs from the consumer-contemplation test set forth in the Restatement (Second) of Torts § 402A (1965), and blurs the distinction between strict products liability claims and negligence claims. See Morden v. Continental AG, 2000 WI 51, ¶46, 235 Wis. 2d 325, 611 N.W.2d 659 (explaining that under

¹⁶ We note that there has been considerable controversy over the Restatement (Third) of Torts § 2(b). See, e.g., Marshall S. Shapo, A New Legislation: Remarks on the Draft Restatement of Products Liability, 30 U. Mich. J.L. Reform 215, 218 (1997) (stating that the Restatement (Third) of Torts is not a description of the existing law, but rather is the creation of drafters who acted as "a sounding board for essentially political discussion"); Frank J. Vandall, Constructing a Roof Before the Foundation is Prepared: The Restatement (Third) of Torts: Products Liability Section 2(b) Design Defect, 30 U. Mich. J.L. Reform 261, 261-65 (1997) (characterizing § 2(b) as "a wish list from manufacturing America" in which "[m]essy and awkward concepts such as precedent, policy, and case accuracy have been brushed aside for the purpose of tort reform"); Symposium, A Critical Analysis of the Proposed Restatement (Third) of Torts: Products Liability, 21 Wm. Mitchell L. Rev. 411, 412-13, 419-20 (1995) (criticizing § 2(b) as being "a vehicle for social reform" rather than a restatement of the existing law, and citing numerous articles with similar observations).

Wisconsin law, foreseeability of the risk of harm is an element of negligence, not strict products liability); Meyer v. Val-Lo-Will Farms, Inc., 14 Wis. 2d 616, 622, 111 N.W.2d 500 (1961) (explaining that negligence claims require a risk-benefit analysis). In this sense, for the reasons explained above, § 2(b) is fundamentally at odds with current Wisconsin products liability law.

\$173 But we are more troubled by the fact that \$2(b) sets the bar higher for recovery in strict products liability design defect cases. Than in comparable negligence cases. Section 2(b) does not merely incorporate a negligence standard into strict products liability law. Instead, it adds to this standard the additional requirement that an injured consumer seeking to recover under strict products liability must prove that there was a "reasonable alternative design" available to the product's manufacturer. Thus, rather than serving the policies underlying strict products liability law by allowing consumers to recover for injuries caused by a defective and unreasonably dangerous product without proving negligence on the part of the product's manufacturer, 18 \$2(b) increases the burden for injured consumers not only by requiring proof of the manufacturer's negligence, but also by adding an additional—and considerable—element of

 $^{^{17}}$ Design defect cases are cases such as the one at hand, in which the product at issue conforms with its intended design, but the design itself allegedly is defective and unreasonably dangerous.

¹⁸ See Dippel v. Sciano, 37 Wis. 2d 443, 460, 155 N.W.2d 55
(1967).

proof to the negligence standard. This court will not impose such a burden on injured persons. Accord Sumnicht v. Toyota Motor Sales, U.S.A., Inc., 121 Wis. 2d 338, 371, 360 N.W.2d 2 (1984) (rejecting the argument that Wisconsin strict products liability requires proof of an alternative, safer design).

¶74 Where a manufacturer places a defective and unreasonably dangerous product into the stream of commerce, the manufacturer, not the injured consumer, should bear the costs of the risks posed by the product. Because § 2(b) unduly obstructs this equitable principle, we refuse to adopt § 2(b) into Wisconsin law. Accord Sharp v. Case Corp., 227 Wis. 2d 1, 19, 595 N.W.2d 380 (1999) (declining to adopt the Restatement (Third) of Torts (1998)).

III

¶75 We next examine whether the jury could properly find that S&N's gloves were defective and unreasonably dangerous where the evidence introduced at trial showed that the gloves contained a substance that causes an allergic reaction in 5 to 17 percent of their consumers. S&N contends that as a matter of law, a faultlessly manufactured product that rendered defective impurities cannot be and unreasonably dangerous simply because some persons suffer an allergic reaction to that product. In essence, S&N's argument is that where a consumer suffers an allergic reaction to a product that is safe to the majority of the population, that reaction is not the result of a defect in the product, but rather a "defect" in the consumer—a propensity for allergies. Thus, although S&N

accepts as fact the evidence Green adduced at trial to the effect that health care workers were the "ordinary consumers" of S&N's latex gloves and that those latex gloves could cause an allergic reaction in 5 to 17 percent of health care workers in the United States, S&N nonetheless contends that Green's case fails as a matter of law.

¶76 Because S&N does not dispute the evidence relevant to this issue, resolution of this issue requires us to apply the law to an undisputed set of facts. This presents a question of law, which we review de novo. Tomczak v. Bailey, 218 Wis. 2d 245, 274, 578 N.W.2d 166 (1998).

¶77 To reiterate, in order to prevail in a products liability case, a plaintiff has the burden to prove that the product at issue is defective and unreasonably dangerous. Vincer, 69 Wis. 2d at 330, 331. A product is defective if it is "in a condition not contemplated by the ultimate consumer." Id. at 330 (quotation omitted). A product is unreasonably dangerous where it is "dangerous to an extent beyond that which would be contemplated by the ordinary consumer." Id. at 331 (quotation omitted).

¶78 Applying this standard to the facts of the case at hand, we initially conclude that the issue here is not whether S&N's gloves were defective. The evidence at trial showed that S&N's gloves were flawed in two respects: (1) they contained excessive levels of allergy-causing proteins; and (2) they were powdered with cornstarch, which allowed the latex proteins to become aerosolized and, consequently, easily inhaled. The

evidence further showed that both of these flaws can cause some consumers to suffer injuries—i.e., allergic reactions. Finally, the parties do not dispute that at the time Green became sensitized to latex and consequently began suffering allergic reactions, the health care community was unaware that persons could be allergic to latex; hence, the consumer" of S&N's gloves-i.e., health care workers-could not have contemplated at the time of Green's sensitization that S&N's gloves contained flaws that could cause injuries. Based on this evidence, the jury reasonably found that S&N's gloves were in a condition not contemplated by the ordinary consumeri.e., that the gloves were defective. For this reason, the only issue at hand is whether a product that causes an allergic reaction in 5 to 17 percent of its consumers can be deemed unreasonably dangerous.

¶79 We acknowledge, as S&N emphasizes, that most jurisdictions hold that where a consumer suffers an unusually rare idiosyncratic reaction to a particular product, strict products liability does not allow the consumer to impose liability on the product's manufacturer. See, e.g., Adelman—Tremblay v. Jewel Cos., 859 F.2d 517 (7th Cir. 1988) (holding that under Wisconsin law, the plaintiff could not recover where her "extremely rare" allergic reaction to fingernail glue was the only reported instance of such a reaction out of over 1,000,000 products sold); Gordon v. Proctor & Gamble Distrib. Co., 789 F. Supp. 1384, 1385 (W.D. Ky. 1992) (noting "the general rule that a plaintiff's unusual or rare idiosyncratic

sensitivity does not provide a basis for recovery under any theory of product liability"); Mountain v. Proctor & Gamble Co., 312 F. Supp. 534 (E.D. Wis. 1970) (holding that under Wisconsin law, the plaintiff could not recover where her allergic reaction to shampoo was one of only three reported instances of such a reaction out of 225,000,000 products sold); Simeon v. Doe, 618 So. 2d 848 (La. 1993) (holding that the plaintiff could not recover for a reaction to bacteria in raw oysters where the reaction occurred in only .6 to 1.9 of 100,000 persons in the general population); Booker v. Revlon Realistic Prof'l Prods., Inc., 433 So. 2d 407 (La. Ct. App. 1983) (holding that the plaintiff could not recover where her possible allergic reaction to hair relaxer was one of only four reported complaints of such a reaction out of 7,000,000 applications of the product sold). This rule is not, however, an innate bar to recovery in cases involving injuries arising from an allergic reaction.

¶80 We perceive the "idiosyncratic reaction" rule not as a recognition that in cases of unusually rare idiosyncratic reactions, the injury-causing defect is in the consumer rather than the product at issue. Contra, e.g., Simeon, 618 So. 2d at 851 (explaining that in cases of idiosyncratic reaction, the "'defect' is really found in the person rather than the product"). Instead, we conclude that this rule, properly interpreted, reflects that in cases involving unusually rare idiosyncratic reactions, the injured party typically cannot show that his or her injury was sufficiently common to render the injury-causing product dangerous to an extent beyond that which

the ordinary consumer would contemplate. That is, the "idiosyncratic reaction" rule is not a legal prohibition, but a frequent evidentiary shortcoming.

¶81 Virtually no product is entirely safe for all consumers under all conditions, even when being used as intended. We presume that the ordinary consumer recognizes as much. Thus, when the ordinary consumer purchases or uses a product, we must assume that consumer contemplates there is at least some danger involved. But to impose liability on the manufacturer of the product, an injured consumer must prove more than that the product posed some danger; the consumer must prove that the product is dangerous beyond the extent contemplated by the ordinary consumer. Sharp, 227 Wis. 2d at 20.

¶82 This does not mean, however, that to prevail on a strict products liability claim, an injured consumer must prove that the product at issue is potentially dangerous to every consumer. Because product defects vary, the magnitude of danger necessary to render a product dangerous to an extent beyond that which would be contemplated by the ordinary consumer—<u>i.e.</u>, unreasonably dangerous—must be evaluated on a case-by-case basis.

 $\P 83$ With regard to how this standard applies to allergy-causing products, we find guidance in the Restatement (Second) of Torts $\S 402A$ cmt. j (1965). Comment j provides that a manufacturer can, in some circumstances, prevent a product from being rendered unreasonably dangerous by issuing appropriate warnings or directions for use. Id. The Comment then notes

that "[w]here . . . the product contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known . . . the seller is required to give warning against it." Id. negative implication, this means that where a product "contains an ingredient to which a substantial number of the population are allergic, and the ingredient is one whose danger is not generally known," the product, absent warning or directions, is unreasonably dangerous. Id.; see also Schuh v. Fox River Tractor Co., 63 Wis. 2d 728, 737, 218 N.W.2d 279 (1974) ("In the absence of a warning to the contrary, the jury could well conclude that the machine was unreasonably dangerous defective in its design."). Following this guidance, we conclude that in order to prove that an allergy-causing product is unreasonably dangerous, a plaintiff must prove the following elements: (1) the product contains an ingredient that can cause allergic reactions in a substantial number of consumers; and (2) the ordinary consumer does not know that the ingredient can cause allergic reactions in a substantial number of consumers. Upon the plaintiff making this showing, the burden then shifts to the manufacturer to prove that the product includes a warning or directions that effectively alert the ordinary consumer that the ingredient can cause allergic reactions in a substantial number of consumers; if the manufacturer fails to meet this burden, a trier of fact can properly conclude that the product is unreasonably dangerous.

¶84 Employing this test in the case at hand, we conclude that the jury could properly have found that S&N's gloves were unreasonably dangerous. First, Green met her initial burden. There was evidence that S&N's gloves contained an ingredient latex proteins—which can cause allergic reactions in 5 to 17 percent of their consumers. From this, the jury reasonably could conclude that S&N's gloves contained an ingredient that can cause an allergic reaction in a "significant number" of consumers. 19 Additionally, the evidence at trial indicated that at the time of Green's sensitization, the ordinary consumer did not know that latex proteins could cause allergic reactions in approximately one-in-twenty to one-in-six consumers. second, S&N failed to show that its gloves included warnings or directions alerting consumers of the gloves' potential to cause allergic reactions. Therefore, with regard to this issue, we affirm the jury finding. Accord Stinson v. E.I. DuPont De Nemours & Co., 904 S.W.2d 428, 431 (Mo. Ct. App. 1995) (holding that where evidence showed that isocyanates potentially can cause injury to 7 percent of exposed persons, the evidence was

Statistics reported that in 1989, the year during which S&N's gloves sensitized Green to latex, approximately 7,551,000 people in the United States worked in the health care industry. Bureau of the Census, United States Dept. of Commerce, Statistical Abstract of the United States 1991 410 (111th ed. 1991). Assuming pursuant to the evidence Green introduced at trial that latex allergy potentially can affect 5 to 17 percent of this class, this means that in 1989, latex allergy potentially could have affected between 377,550 and 1,283,670 persons in the health care industry alone. This suggests that latex allergy is a far cry from an unusually rare idiosyncratic reaction.

sufficient to submit to a jury the question of whether isocyanates are unreasonably dangerous); Ray v. Upjohn Co., 851 S.W.2d 646, 655 (Mo. Ct. App. 1993) (holding that evidence that isocyanates potentially can cause injury to 5 percent of exposed persons is sufficient to sustain a verdict that isocyanates are unreasonably dangerous).

¶85 In sum, we hold that a product can be deemed defective and unreasonably dangerous where that product contains a substance which, unbeknownst to the ordinary consumer, can cause an allergic reaction in 5 to 17 percent of its consumers. Moreover, we conclude that because the evidence introduced at trial in the present case indicated that, unbeknownst to the ordinary consumer, the latex proteins in S&N's gloves could cause allergic reactions in 5 to 17 percent of the gloves' users, and because S&N failed to show that their gloves included adequate warnings or instructions regarding this potential danger, there was sufficient evidence for the jury to find that S&N's gloves were defective and unreasonably dangerous.

IV

¶86 We last examine whether the circuit court erred in admitting certain opinion evidence regarding the safety of S&N's gloves. If we conclude that the circuit court did so err, we then must determine whether this error necessitates a new trial.

¶87 S&N maintains that the circuit court erred in reading to the jury a summary of testimony by Paul Cacioli (Cacioli), which included Cacioli's opinions that he considered the "high level of protein" in S&N's gloves to be "unsafe and

unacceptable" and that "a lower protein glove is a safer glove." S&N contends that Cacioli was not qualified pursuant to Wis. Stat. § 907.02 (1997-98)²⁰ to provide such opinions. Moreover, S&N argues that these opinions were the "primary evidence regarding the safety of S&N's gloves." S&N accordingly claims there is a reasonable possibility that the admission of Cacioli's opinions contributed to the jury's verdict. Thus, S&N concludes that the circuit court's admission of Cacioli's opinions was not harmless error and, therefore, this court must remand this case for a new trial.

¶88 Green argues in response that Cacioli was qualified to express the opinions at issue. In the alternative, Green contends that even if the circuit court erred in admitting Cacioli's opinions, in light of the substantial other evidence which Green presented at trial regarding the safety of S&N's gloves, this error did not affect a substantial right of S&N and, hence, was harmless. Accordingly, Green maintains that this court should affirm the court of appeals decision, which upheld the circuit court's entry of judgment on the jury verdict.

Α

¶89 Section 907.02 of the Wisconsin Statutes provides:

Testimony by experts. If scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a

²⁰ All subsequent references to the Wisconsin Statutes are to the 1997-98 version unless otherwise indicated.

fact in issue, a witness qualified as an expert by knowledge, skill, experience, training, or education, may testify thereto in the form of an opinion or otherwise.

(Emphasis added.) The determination of whether a witness is qualified to testify as an expert under \$ 907.02 is a matter within the discretion of the circuit court. Glassey v. Continental Ins. Co., 176 Wis. 2d 587, 608, 500 N.W.2d 295 (1993). On review, we will sustain the circuit court's discretionary determination so long as the circuit court "examined the facts of record, applied a proper legal standard and, using a rational process, reached a reasonable conclusion."

Id.

¶90 In the present case, we must apply this standard to determine whether the circuit court properly exercised its discretion in ruling that Cacioli was qualified to provide the opinions at issue and, hence, whether the circuit court properly admitted those opinions at trial. The record reflects that at the time of Green's trial, Cacioli held a bachelor of science degree and a Ph.D. in organic chemistry, and had pursued several postdoctoral fellowships at various institutions. After completing his formal education, Cacioli served as the business manager for a consulting firm's chemistry division. He then joined Ansell, Inc. (Ansell), a manufacturer of latex medical gloves, where he worked as the Director of Research and Development at the time of Green's trial.

²¹ Neither party contends that the focus of the research in Cacioli's fellowships or Cacioli's experience at the consulting firm is relevant to the present issue.

¶91 While at Ansell, Cacioli consulted with leading experts in the field of latex allergy and formed an informational program regarding latex allergy, in which he employed several medical experts. As a result, Cacioli observed latex allergy testing, learned some of the language and issues of the field, and became aware of the protein levels in competing companies' latex gloves. He further was familiar with and implemented processes that altered the protein levels in Ansell's latex gloves.

¶92 However, Cacioli specifically denied being an expert in the field of latex allergy. When Green's attorney questioned Cacioli during a deposition about whether a high protein level in a latex glove could be deemed unsafe, Cacioli replied:

Could I clarify one thing in this terminology of unsafe? . . .

It's basically this terminology of unsafe, we're very much in the dark about what is safe and what is unsafe. There has been no definition at this point in time to us as to what is considered to be safe, and there are conflicting opinions, as well, from the knowledgeable people in this area. I can only make that statement from what I believe is unsafe, and I'm not an expert in that area, so I'd just like to clarify that.

(Emphasis added.) Cacioli then explained that he was an expert only in manufacturing processes and quality control.²²

²² Green's attorney seemed to recognize as much. After Cacioli disclaimed any expertise in the safety of various protein levels, the following exchange occurred:

Q: [Green's attorney]: I am asking you, within the level of your competence and your experience...

Nonetheless, the circuit court ruled that based on his background, Cacioli was qualified to provide an expert opinion regarding the safety of various protein levels in latex gloves.

This ruling was in error. To be sure, Cacioli knew of and could manipulate protein levels in latex gloves, and had some knowledge of the language and issues of the community that studied latex allergy. However, Cacioli was not medical doctor, had no formal experience, training, education in latex allergy, and had no first-hand knowledge of or why various protein levels affected individuals. Instead, he culled his knowledge by associating with observing medical doctors and others who had devoted their careers to the study of allergy and immunology. We cannot conclude from the fact that Cacioli seems to have acquainted himself with people qualified to testify about the effects of

I want to make clear for you that I wasn't asking you to testify as Dr. Beezhold or someone like that.

You do think you're competent, do you not, to discuss manufacturing practices, don't you?

- A: [Cacioli]: That is my field of expertise, yes.
- Q: And safe manufacturing processes?
- A: Yes.
- Q: And quality control?
- A: Yes.

various protein levels in latex gloves that Cacioli was qualified to testify on this subject.

¶94 But more importantly, we accord great weight to the fact that Cacioli specifically disclaimed any expertise regarding the safety of different protein levels in latex As the court of appeals previously has observed, a witness called upon to provide expert testimony may establish his or her qualifications by means of his or her own testimony. James v. Heintz, 165 Wis. 2d 572, 579, 478 N.W.2d 31 (Ct. App. 1991); cf. Wis. Stat. § 906.02 ("Evidence to prove personal knowledge may . . . consist of the testimony of the witness."). The circuit court must accept this foundational testimony unless "it finds the testimony not credible or there is contrary credible evidence that undercuts the proffered foundation." Id. Like the court of appeals in the present case, we hold that if witness's own testimony can establish the witness's qualifications, the witness's testimony similarly might limit the witness's qualifications. Green v. Smith & Nephew AHP, Inc., 2000 WI App 192, ¶22, 238 Wis. 2d 477, 617 N.W.2d 881.

¶95 In the present case, as noted above, Cacioli specifically disavowed being qualified to testify regarding the safety of different protein levels in latex gloves. The circuit court made no findings to the contrary, nor do we find any

evidence to the contrary in the record.²³ For these reasons, we hold that Cacioli was not qualified to provide the opinions at issue and, accordingly, the circuit court erred in admitting those opinions.

В

¶96 Although we hold that the circuit court's admission of Cacioli's opinions was in error, we still must determine whether such error requires us to reverse the court of appeals decision and remand this case for a new trial. As provided by Wis. Stat. § 805.18(2):

No judgment shall be reversed or set aside or new trial granted in any action or proceeding on the ground of . . . improper admission of evidence . . . unless in the opinion of the court to which the application is made, after an examination of the entire action or proceeding, it shall appear that the error complained of has affected the substantial rights of the party seeking to reverse or set aside the judgment, or to secure a new trial.

(Emphasis added.) For an error to "affect the substantial rights" of a party, there must be a reasonable possibility that the error contributed to the outcome of the action or proceeding at issue. State v. Dyess, 124 Wis. 2d 525, 543, 547, 370 N.W.2d 222 (1985); see also Town of Geneva v. Tills, 129 Wis. 2d 167, 184-85, 384 N.W.2d 701 (1986) (noting that the standard set forth in Dyess applies in civil cases as well as criminal

 $^{^{23}}$ Ironically, in light of Cacioli's disclaimer regarding the limits of his expertise, by ruling that Cacioli was qualified to provide the opinions at issue, the circuit court in effect ruled that Cacioli—or at least his disclaimer—was not credible.

cases). A reasonable possibility of a different outcome is a possibility sufficient to "undermine confidence in the outcome." Dyess, 124 Wis. 2d at 544-45 (quotation omitted). Where the erroneously admitted evidence affects constitutional rights or where the outcome of the action or proceeding at issue is weakly supported by the record, a reviewing court's confidence in the outcome may be more easily undermined than where the erroneously admitted evidence was peripheral or the outcome was strongly supported by evidence untainted by error. Id. at 545.

¶97 With this standard in mind, we examine the facts surrounding the circuit court's admission of Cacioli's opinions. The primary issue in the case at hand was whether S&N's gloves were defective and unreasonably dangerous. Cacioli's opinions that a low-protein glove is safer than a high-protein glove and that the high levels of latex proteins in S&N's gloves rendered them unsafe and unacceptable directly addressed this issue.

198 However, the jury heard similar evidence from several other sources, which were not affected by error. For example, one of Green's experts told the jury of a study in which 75 percent of tested latex-sensitive individuals reacted to high-protein latex gloves, but only 7 percent reacted to low-protein gloves. Similarly, the jury learned of the ACAAI statement, which provided: "Only low allergen latex gloves should be purchased and used. This will reduce the occurrence of reactions among sensitized personnel and should reduce the rate of sensitization." In addition, two of Green's medical experts

testified that high-protein gloves are much more likely than low-protein gloves to cause sensitization and allergic reactions. Further, one of these doctors specifically testified that high-protein, powdered latex gloves are defective and unreasonably dangerous. And even two of S&N's experts agreed that low-protein gloves are safer than high-protein gloves. Finally, the jury heard evidence regarding the Mayo Clinic studies in which S&N's gloves were found to have considerably higher protein levels than almost all other tested brands of latex medical gloves.

¶99 Moreover, the jury learned that Cacioli did not consider himself to be an expert on how different protein levels affect glove users. One of S&N's experts read to the jury Cacioli's deposition testimony in which he specifically disclaimed such expertise. Thus, the credibility and foundation of Cacioli's opinions was thrown into doubt before the jury, and the jury could make an informed decision whether to attach any credence to those opinions.

¶100 In light of these facts, we cannot discern a reasonable possibility that, absent the circuit court's admission of Cacioli's opinions, the outcome of the trial would have been any different. Consequently, we conclude that the circuit court's error in admitting Cacioli's testimony was harmless and, therefore, does not warrant a new trial.

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 $\P 101$ In conclusion, we hold that S&N has failed to show that the jury verdict should not stand. Contrary to S&N's

contentions, the circuit court fully and fairly instructed the jury regarding the relevant law. As the circuit explained, a product can be deemed defective and unreasonably dangerous based solely upon consumer expectations about that product. Indeed, because the consumer-contemplation test is the exclusive standard in Wisconsin strict products liability law, if a trier of fact is to find a product to be defective and unreasonably dangerous, it must do so based solely upon consumer expectations about the product at issue. Additionally, the circuit court correctly instructed the jury that a product can be deemed defective and unreasonably dangerous regardless of whether the manufacturer of that product knew or could have known of the risk of harm the product presented. As this court repeatedly has emphasized, foreseeability is not an element of this state's strict products liability law.

¶102 We further reject S&N's argument that as a blanket rule, a product cannot be deemed defective and unreasonably dangerous based on the fact that it causes allergic reactions in a minority of its consumers. Where a product contains a substance that, unbeknownst to the ordinary consumer, can cause an allergic reaction in a substantial number of the product's users, the product may be deemed defective and unreasonably dangerous. In the present case, because the evidence introduced at trial indicated that the ordinary consumer was not aware at the time of Green's injuries that the protein levels and cornstarch powder in S&N's gloves could cause an allergic reaction in 5 to 17 percent of the gloves' consumers, we

conclude that the jury reasonably found S&N's gloves to be defective and unreasonably dangerous.

¶103 Finally, while we agree with S&N that the circuit court's admission of Cacioli's opinions was in error, we do not agree with S&N that this error necessitates a new trial. Due to the substantial amount of evidence that mirrored Cacioli's opinions and because the jury was informed that Cacioli did not consider himself qualified to provide such opinions, we determine that the circuit court's error was harmless.

¶104 For the foregoing reasons, we conclude that jury verdict in the case at hand is legally sound. Accordingly, we affirm the decision of the court of appeals, which upheld the circuit court's entry of judgment on the verdict.

By the Court.—The decision of the court of appeals is affirmed.

¶105 SHIRLEY S. ABRAHAMSON, CHIEF JUSTICE (concurring). I join all but Part IV of the majority opinion. I do not join Part IV because I do not agree with what the opinion identifies as the evidentiary error in the present case. The opinion concludes that the circuit court erroneously exercised its discretion in finding Dr. Cacioli qualified to give expert testimony regarding glove safety.

¶106 An appellate court will uphold a circuit court's discretionary decision that an expert witness is qualified to answer a particular question if the circuit court "examined the facts of record, applied a proper legal standard and, using a rational process, reached a reasonable conclusion."²⁴

¶107 The majority sets forth two grounds for concluding that the circuit court's discretionary decision to admit Dr. Cacioli's testimony regarding glove safety was an erroneous exercise of discretion. First, Dr. Cacioli did not have the requisite qualifications to testify regarding glove safety because he "was not a medical doctor, had no formal experience, training, or education in latex allergy, and had no first-hand knowledge of how or why various protein levels affected individuals."

Second, and "more importantly," Dr. Cacioli "specifically disclaimed any expertise" in glove safety by stating "I'm not an expert in that area" as part of his response to a question regarding the relative safety of high protein

 $^{^{24}}$ See majority op. at ¶89.

 $^{^{25}}$ <u>See</u> majority op. at ¶93.

levels.²⁶ Neither basis for concluding that the circuit court erroneously exercised its discretion in admitting Dr. Cacioli's testimony on glove safety follows from our case law.

Ι

¶108 As to the first basis offered by the majority opinion, ample authority exists for the proposition that an individual may be qualified to give expert testimony based on association with and observation of professionals in a particular field.²⁷ Additionally, I see no support in the case law for the majority's conclusion that Dr. Cacioli could not testify because he "was not a medical doctor"²⁸; lacked "formal" experience,

 $[\]frac{26}{\text{See}}$ majority op. at ¶94.

 $^{^{27}}$ Compare majority op. at ¶93 (Cacioli "culled his knowledge by associating with and observing medical doctors and others who had devoted their careers to the study of allergy and immunology") with Henning v. Ahearn, 230 Wis. 2d 149, 178-82, 601 N.W.2d 14 (Ct. App. 1999) (concluding that an attorney whose practice focused on business should not be precluded from testimony regarding the practice of business executives merely because he was not a business executive).

Wisconsin case law has repeatedly stressed that a witness's "label" is not relevant to the determination of whether a witness is qualified to testify as an expert on a given subject. See, e.g., Karl v. Employers Ins., 78 Wis. 2d 284, 297, 254 N.W.2d 255 (1977) ("law traditionally has permitted limited testimony of a medical nature by one not licensed as a medical doctor, if he is, in fact, qualified as an expert") (citation and quotation omitted); Wester v. Bruggink, 190 Wis. 2d 309, 319-20, 527 N.W.2d 373 (Ct. App. 1994) ("[W]hether a witness qualifies to testify as an expert depends on the witness's background, education, and experience rather than a particular label.") (citation omitted).

"first-hand knowledge" of how latex proteins affect allergic individuals. The experience, not licensure, is the key. Expertise may be derived from experience working in a field of endeavor rather than from studies or diplomas. And Dr. Cacioli's experience, training, and education in latex are extensive. I am concerned that the majority's conclusion regarding Dr. Cacioli's qualifications raises the bar in Wisconsin regarding who is qualified to testify as an expert witness.

 $\P 109$ As to the second basis offered by the majority opinion, I, unlike the majority opinion, would not give "great weight" 33 to Cacioli's statement that "I am not an expert in that

The rule of evidence regarding the admission of expert testimony and the cases applying it speak only of "experience, training, and education" and not of "formal experience, education, and training," as the majority opinion does. See majority op. at ¶93; Wis. Stat. § 907.02; 7 Dan Blinka, Wisconsin Practice: Wisconsin Evidence § 702.4, at 489 (2d ed. 2001) ("Expertise, then, is a function of knowledge; it may be evidenced by academic degrees and licensure, but is not limited to these trappings.").

See generally 7 Dan Blinka, Wisconsin Practice: Wisconsin Evidence § 702.601, at 500-01 (2d ed. 2001) (suggesting that the law liberally allows experts to testify regarding knowledge that comes from interactions with others, as opposed to first-hand experience; concluding that "what distinguishes experts from lay witnesses, in part, is their ability to rely on hearsay sources").

³¹ Black v. Gen. Elec. Co., 89 Wis. 2d 195, 212, 278 N.W.2d 224 (Ct. App. 1979).

 $[\]frac{32}{2}$ See majority op. at ¶¶90-91.

 $^{^{33}}$ See majority op. at ¶94.

area," any more than I would give great weight to a witness's statement that "I am an expert in that area." What matters is not the witness's view of self. Rather, what matters is whether the circuit court determines in the exercise of its discretion that the witness has the requisite experience, training, and education to qualify as an expert in a court of law.³⁴

¶110 I would conclude that the error in the present case lay in the circuit court's failure to submit to the jury Dr. Cacioli's statement that "I am not an expert in this area" and Dr. Cacioli's explanation about the state of knowledge on the safety issue, alongside his response to the questions regarding glove safety. Dr. Cacioli's statement and explanation go to the weight, not the admissibility, of his testimony. Like the majority opinion, however, I conclude that any error was harmless. 36

ΙI

 $\P 111 \text{ Finally,} \quad \text{I} \quad \text{wrote a concurrence on the issue of}$ harmless error in $\underline{\text{In re the Termination of Parental Rights to}}$

 $[\]frac{34}{2}$ Compare majority op. at ¶¶94-95 with Leahy v. Kenosha Memorial, 118 Wis. 2d 441, 453, 348 N.W.2d 607 (Ct. App. 1984) (noting that the witness had admitted that she was not an expert in a particular field but listing this factor as one of many for the circuit court to consider in evaluating her qualifications as an expert).

 $^{^{35}}$ <u>See</u> majority op. at ¶99.

 $^{^{36}}$ <u>See</u> majority op. at ¶¶96-100.

Jayton S.: Evelyn C.R. v. Tykila S., 2001 WI 110 ¶¶37-42, ____ Wis. 2d ___, ___ N.W.2d ___ (Abrahamson, C.J. concurring). My views on harmless error expressed in that concurrence apply to the present case as well. Rather than repeat the concurrence verbatim in the present case, I refer the reader to the Evelyn C.R. case.

¶112 For these reasons, I write separately.

 $\P 113$ I am authorized to state that Justice ANN WALSH BRADLEY joins Part I of this opinion.

¶114 N. PATRICK CROOKS, J. (concurring). I agree with the majority's decision today and write separately only to remark upon the harmless error test utilized by the majority. See majority op. at ¶96. The majority's standard is whether there is "a reasonable possibility that the error contributed to the outcome," and that a "reasonable possibility" is one "sufficient to 'undermine confidence in the outcome.'" Id. (quoting State v. Dyess, 124 Wis. 2d 525, 544-45, 370 N.W.2d 222 (1985)). Since the standard for harmless error is the same for civil, as well as criminal, cases (Town of Geneva v. Tills, 129 Wis. 2d 167, 184-85, 384 N.W.2d 701 (1986)), it is imperative that the standard be accurately conveyed.

Dyess, 124 Wis. 2d at 545.³⁷ The Strickland case referred to is Strickland v. Washington, 466 U.S. 668, 693 (1984), and the test is whether "there is a reasonable probability" that "but for" the error, "the result of the proceeding would have been different. A reasonable probability is a probability sufficient to undermine confidence in the outcome." 466 U.S. at 694 (emphasis added). Dyess obviously adopted that test, but incorrectly assumed that there was no real difference between using "reasonable possibility" instead of "reasonable probability." 124 Wis. 2d at 544. Granted, Dyess applied its test by stating that "[i]n the present case, the probability to be weighed is whether the defendant would have been acquitted."

Id. at 546 (emphasis added). However, as evident in the majority's opinion here today, 38 Wisconsin courts have frequently

been without controversy. State v. Dyess, 124 Wis. 2d 525, 370 N.W.2d 222 (1985). In addition to the majority opinion's discussion of Dyess' harmless error standard, authored by Justice Day, in State v. Grant, 139 Wis. 2d 45, 406 N.W.2d 744 (1987), Chief Justice Heffernan, Justice Day, Justice Abrahamson, and Justice Callow separately concurred on the Dyess issue. The controversy has continued. See State v. Dodson, 219 Wis. 2d 65, 92-98, 580 N.W.2d 181 (1998) (Crooks, J., concurring, joined by Justice Steinmetz and Justice Wilcox).

See also Koffman v. Leichtfuss, 2001 WI 111, ___ Wis. 2d ___, __ N.W.2d ___; Martindale v. Ripp, 2001 WI 113, ___ Wis. 2d ___, __ N.W.2d ___; Evelyn C.R. v. Tykila S., 2001 WI 110, ___ Wis. 2d ___, __ N.W.2d ___; and Nommensen v. American Cont'l Ins. Co., 2001 WI 112, ___ Wis. 2d ___, __ N.W.2d __. (I have written dissents or concurrences in these cases.) But see State v. Lindell, 2001 WI 108, ___ Wis. 2d ___, __ N.W.2d ___ (Strickland's probability sufficient to undermine the confidence in the outcome test used to determine ineffective assistance of counsel claim).

used the term "reasonable possibility," and have not indicated that, in the context of a harmless error standard, possibility means probability.³⁹

¶116 There can be no doubt that there is a significant difference between what is reasonably probable and what is reasonably possible. "A possibility test is the next thing to automatic reversal." Wold v. State, 57 Wis. 2d 344, 356-57, 204 N.W.2d 482 (1973). 40 While I agree that the focus should be "on whether the error 'undermine[s] confidence in the outcome,'" (Dyess, 124 Wis. 2d at 545 (quoting Strickland, 466 U.S. at 694)), if that error need only possibly undermine the confidence in the outcome, rather than probably, appellate courts, and circuit courts considering motions after verdict and post-convictions motions, will find themselves invading the purview of the jury. A cornerstone of the common law is deference to the jury, which is diluted by determining whether the alleged error possibly, and only possibly, may have affected the jury's decision.

has this court, in a majority opinion, noted that reasonable possibility means reasonable probability. See State v. Armstrong, 223 Wis. 2d 331, 372 n.40, 588 N.W.2d 606 (1999); see also State v. Huntington, 216 Wis. 2d 671, 695-96, 575 N.W.2d 268 (1998). However, several court of appeals opinions have applied the Dyess harmless error test using the correct "reasonable probability" standard. See, e.g., State v. A.H., 211 Wis. 2d 561, 569, 566 N.W.2d 858 (Ct. App. 1997); State v. Joseph P., 200 Wis. 2d 227, 237, 546 N.W.2d 494 (Ct. App. 1996).

 $^{^{40}}$ <u>Wold</u>'s "reasonable probability" test for harmless error was replaced by Dyess' "reasonable possibility" test.

¶117 I do not take issue with the term "reasonable possibility," so long as it is made clear that this term means reasonable probability, and probability is the standard to be applied. Accordingly, I offer the following test for harmless error, which makes clear that Dyess' use of the term "reasonable possibility" is intended to require "reasonable probability":

Wisconsin Stat. § 805.18(2) provides that an error requires reversal only where it has "affected the substantial rights of the party" claiming error. have long recognized that the focus of a court's analysis under this statute is whether, in light of applicable burden of proof, the error is significant enough to "undermine confidence in the outcome" of the trial. Dyess, 124 Wis. 2d at 544-45. is significant enough to undermine confidence in the outcome if there is a reasonable probability of a different outcome without the error. that "probability" is Dyess made it clear as "possibility" under substantially the same Wisconsin law. Id. at 544.

¶118 Even though the majority used a "reasonable possibility" test, the alleged error at issue here—the admission of Paul Cacioli's expert opinion regarding the safety of Smith & Nephew's gloves—would be harmless under the more stringent "reasonable probability" test. As the majority points out, the jury heard evidence similar to that offered by Cacioli from other sources. See majority op. at ¶98. Also, the jury heard that Cacioli did not consider himself an expert on the issue of how protein levels affect those who use the gloves. See id. at ¶99. Given Cacioli's proviso, the jury could have accepted or disregarded his opinion. However, there was other similar evidence that the jury could have relied upon.

Consequently, there is no reasonable probability that the admission of Cacioli's opinion, assuming <u>arguendo</u>, it was error to do so, affected the jury's verdict.

¶119 That Wisconsin courts have often used "reasonable possibility" rather than "reasonable probability" should not dissuade the court from correcting such missteps today. See, e.g., State v. Sullivan 216 Wis. 2d 768, 792, 576 N.W.2d 30 (1998); State v. Alexander, 214 Wis. 2d 628, 653, 571 N.W.2d 662 (1997). There is no time like the present—dum fervet opus 41—when the court has before it five cases wherein it discusses the harmless error standard, to clarify Dyess.

¶120 For the reasons stated herein, I respectfully concur.

 $\P 121 \ \mbox{I}$ am authorized to state that Justice JON P. WILCOX joins this opinion.

 $^{^{41}}$ "While the action is fresh; in the heat of action." Black's Law Dictionary 518 (7th ed. 1999).

¶122 DIANE S. SYKES, J. (dissenting). I respectfully dissent. The majority opinion is seriously out of step with product liability law as it has evolved since this court adopted the Restatement (Second) of Torts § 402A in Dippel v. Sciano, 37 Wis. 2d 443, 155 N.W.2d 55 (1967). The majority blurs the distinctions between design, manufacturing, and failure—to—warn product defects. The majority also keeps Wisconsin in the much-criticized and rapidly dwindling minority of jurisdictions that rely exclusively on a consumer contemplation test to determine liability in design defect cases. And finally, the majority opinion's language about the role of foreseeability in product liability law is misleading and overbroad.

¶123 Strict liability in tort is imposed upon sellers of defective products that are unreasonably dangerous. Dippel, 37 Wis. 2d at 459-60 (adopting the Restatement (Second) of Torts § 402A (1965)); see also Restatement (Third) of Torts: Products Liability §§ 1, 2 (1998). Products can be defective and unreasonably dangerous in different ways, and so product liability cases fall into three distinct categories depending upon the nature of the alleged defect: 1) manufacturing defects (arising from a mistake in the manufacturing process); 2) design defects (arising from an unsafe product design); and 3) defects arising from an inadequate or nonexistent warning of a known danger. See Wis JI—Civil 3200, 3260, 3262; see also Restatement (Third) of Torts: Products Liability § 1 cmt. a (1998) ("[a]bundant authority recognizes the division of product

defects into manufacturing defects, design defects, and defects based on inadequate instructions or warnings").

¶124 In 1997, the American Law Institute issued the Restatement (Third) of Torts: Products Liability. In the introduction to the Third Restatement, the ALI describes the evolution of product liability law in this way:

To understand its place in the law, products liability must be examined in historical context. In 1964 The American Law Institute adopted § 402A as part of the Restatement Second of Torts. Section entitled "Special Liability of Seller of Product for Physical Harm to User or Consumer." It marked the first recognition by the Institute of privity-free strict liability for sellers of defective products. The major thrust of § 402A was to eliminate privity user or consumer, without having to that establish negligence, could bring an action against a manufacturer, as well as against any other member of a distributive chain that had sold a product containing a manufacturing defect. Section 402A had little to say about liability for design defects or for products sold with inadequate warnings. In the early 1960s these areas of litigation were in their infancy.

In restating the law of products liability more than a quarter of a century later, the Institute had before it thousands of judicial decisions that had fine-tuned the law of products liability in a manner hardly imaginable when Restatement Second was written. Issues that had not occurred to those involved in drafting Restatement Second had become points of serious contention and debate in the courts. What should be the governing standard for design and warning liability? Is there a cause of action for defective prescription drug design? What rule should govern when a plaintiff establishes that enhanced harm was suffered as a result of a defect in a defendant's product, beyond that which would have resulted from other causes, but the plaintiff cannot quantify the amount of the enhancement?

On almost every page of Restatement Third, Torts: Products Liability, the Institute has had to respond to questions that were not part of the landscape 35 years ago. This Restatement is, therefore, an almost total overhaul of Restatement Second as it concerns the liability of commercial sellers of products.

Restatement (Third) of Torts: Products Liability, at 3 (1998) (emphasis added).

¶125 The Third Restatement sets forth the following general rule of strict product liability:

§ 1. Liability of Commercial Seller or Distributor for Harm Caused by Defective Products

One engaged in the business of selling or otherwise distributing products who sells or distributes a defective product is subject to liability for harm to persons or property caused by the defect.

Restatement (Third) of Torts: Products Liability § 1 (1998).

¶126 The Third Restatement also sets forth the separate standards of liability that have developed over time for manufacturing defects, design defects, and defects based upon inadequate instructions or warnings:

§ 2. Categories of Product Defect

A product is defective when, at the time of sale or distribution, it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product:

- (a) contains a manufacturing defect when the product departs from its intended design even though all possible care was exercised in the preparation and marketing of the product;
- (b) 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, or a predecessor in the commercial chain of distribution, and the omission of the alternative design renders the product not reasonably safe;

(c) is defective because of inadequate instructions or warnings when the foreseeable risks of harm posed by the product could have been reduced or avoided by the provision of reasonable instructions or warnings by the seller or other distributor, or a predecessor in the commercial chain of distribution, and the omission of the instructions or warnings renders the product not reasonably safe.

Restatement (Third) of Torts: Products Liability § 2 (1998).

¶127 I would adopt the Third Restatement's recapitulation of the law as it has developed since the Second Restatement and Dippel, especially in the areas of design and warning defects, which the Restatement's authors acknowledge were not addressed in § 402A.

¶128 Strict liability without fault makes sense in manufacturing defect cases because it is often impossible to prove what went wrong in the manufacturing process to cause the dangerous defect, and because, as between the seller and the consumer, the seller is in a better position to control or distribute the risk of loss through quality control, insurance, and higher prices. Dippel, 37 Wis. 2d at 450-51; Restatement (Third) of Torts: Products Liability § 2 cmt. a (1998).

¶129 However, product liability for design and warning defects has a different rationale:

In contrast to manufacturing defects, design defects and defects based on inadequate instructions or warnings are predicated on a different concept of responsibility. In the first place, such defects cannot be determined by reference to the

manufacturer's own design or marketing standards because those standards are the very ones that plaintiffs attack as unreasonable. Some sort of independent assessment of advantages and disadvantages, to which some attach the label "risk-utility balancing," is necessary. Products are not generically defective merely because they are dangerous.

. . . .

In general, the rationale for imposing strict liability on manufacturers for harm caused manufacturing defects does not apply in the context of imposing liability for defective design and defects based on inadequate instruction or warning. Consumer expectations as to proper product design or warning are typically more difficult to discern than in the case of a manufacturing defect. Moreover, the element deliberation in setting appropriate levels design safety is not directly analogous to the setting of levels of quality control by the manufacturer. When a manufacturer sets its quality control at a certain level, it is aware that a given number of products may leave the assembly line in a defective condition and cause injury to innocent victims who can generally do nothing to avoid injury. deliberately drawing lines with implications of respect to product design safety are different. . . .

Most courts agree that, for the liability system to be fair and efficient, the balancing of risks and benefits in judging product design and marketing must be done in light of the knowledge of risks and riskavoidance techniques reasonably attainable at the time of distribution. To hold a manufacturer liable for a risk that was not foreseeable when the product was marketed might foster increased manufacturer But investment in safety. such investment definition would be a matter of quesswork. Furthermore, manufacturers may persuasively ask to be judged by a normative behavior standard to which it is reasonably possible for manufacturers to conform. For these reasons, Subsections (b) and (c) speak defective only when risks products being are reasonably foreseeable.

Restatement (Third) of Torts: Products Liability § 2 cmt. a (1998).

¶130 Wisconsin law on product defects arising out of inadequate instructions or warnings approximates the Third Restatement, in that liability is not imposed unless the seller knew or should have known of the particular danger connected with the use of the product. Tanner v. Shoupe, 228 Wis. 2d 357, 368, 596 N.W.2d 805 (Ct. App. 1999); Westphal v. E.I. du Pont de Nemours & Co., 192 Wis. 2d 347, 363, 531 N.W.2d 386 (Ct. App. 1995); Krueger v. Tappan Co., 104 Wis. 2d 199, 206, 311 N.W.2d 219 (Ct. App. 1981); Wis JI—Civil 3262. Wisconsin law on design defects and defects arising out of inadequate warnings should be brought into conformity with the Third Restatement.

¶131 Our leading design defect case, Sumnicht v. Toyota Motor Sales, U.S.A., Inc., 121 Wis. 2d 338, 360 N.W.2d 2 (1984), which declared allegiance to the consumer contemplation test for determining product design defectiveness, represents the minority rule. "In a minority of jurisdictions the failure of a product to meet consumer expectations suffices, in and of

Allergy cases fit most readily into the failure-to-warn category of product liability cases, because by definition, a product that is dangerous only to those who have allergic sensitivity to it cannot be considered dangerous when put to ordinary use by an ordinary consumer without such sensitivity. See Adelman-Tremblay v. Jewel Cos., 859 F.2d 517, 523-24 (7th Cir. 1988). Even then, the unusual susceptibility or idiosyncratic reaction of a consumer will not give rise to product liability for failure-to-warn unless the seller knew or had reason to know of the allergy-causing propensity of the product. Id. This case was not litigated on a failure-to-warn theory.

itself, to establish liability in cases predicated on design defect. These jurisdictions represent a distinct minority, and there are reasons to believe their numbers may diminish over time." Restatement (Third) of Torts: Products Liability § 2 cmt. d at 73. The authors of the Third Restatement note that decisions relying exclusively on a consumer expectations test for determining liability in design defect cases have been "roundly criticized." Id. at 76.

¶132 Just as there is little justification for imposing liability for lack of a warning absent proof that foreseeable risks could have been reduced by a warning, there is little justification for imposing liability for a product design defect absent proof that foreseeable risks could have been reduced by an alternate design. This is not to say that strict product liability is synonymous with negligence; it is not. See Fuchsgruber v. Custom Accessories, Inc., 2001 WI 81, ¶2, ____ Wis. 2d ___, ___ N.W.2d ___ (strict product liability "is liability in tort, not liability for negligence"). The focus remains on the defectiveness of the product rather than the conduct of the seller. 43 Id. at ¶24. But we must have some principled standards by which to evaluate product defectiveness

⁴³ Our failure-to-warn product liability cases tend to rely upon the language of negligence, which is misleading inasmuch as strict product liability is not a species of negligence. The Third Restatement's formulation of the standards of liability in both design and warnings cases keeps the focus on the defectiveness of the product rather than the conduct of the seller, and therefore avoids any confusion with negligence.

in design and warning defect cases; otherwise strict liability will become absolute liability. Evaluating design and warning defectiveness solely by reference to consumer expectations comes close to imposing absolute liability. Consumers generally do not have specific expectations as to product designs and warnings, beyond the obvious expectation that they will be safe.

¶133 In <u>Sumnicht</u>, this court adhered to the consumer contemplation test for use in design defect cases, but also outlined a list of factors to assist in the determination of dangerous defectiveness:

The relevant factors are:

"(1) [C]onformity of defendant's design to the practices of other manufacturers in its industry at the time of manufacture; 2) the open and obvious nature of the alleged danger; . . . 3) the extent of the claimant's use of the very product alleged to have caused the injury and the period of time involved in such use by the claimant and others prior to the injury without any harmful incident. . . 4) the ability of the manufacturer to eliminate danger without impairing the product's usefulness or making it unduly expensive; and 5) the relative likelihood of injury resulting from the product's present design."

Sumnicht, 121 Wis. 2d at 372 (quoting Collins v. Ridge Tool Co., 520 F.2d 591, 594 (7th Cir. 1975)). This list sounds an awful lot like the formulation contained in the Third Restatement and its commentary, and therefore conflicts with language elsewhere in Sumnicht about the primacy of the consumer contemplation test. The majority opinion resolves this internal conflict in favor of exclusive reliance on the consumer contemplation test. I would not. As the list of factors quoted above and the Third

Restatement make clear, consumer expectations are relevant but not dispositive in the determination of whether a product design is defective and unreasonably dangerous.⁴⁴

¶134 For the foregoing reasons, I would adopt § 2 of the Third Restatement and reverse and remand this case for application of its standard of liability. That is, the alleged design defect in the latex gloves that caused an allergic

The majority opinion actually goes so far as to state that "Wisconsin strict products liability law applies the consumer-contemplation test and only the consumer-contemplation test in all strict products liability cases." Majority op. at $\P 34.$ This is a considerable overstatement. As noted above, we do not use the consumer contemplation test in cases in which the product defect is an inadequate or nonexistent warning. Similarly overstated is the majority's assertion that "under no circumstances" in a strict product liability case "must the plaintiff prove that the risk of harm presented by the product that caused his or her injury was foreseeable." Majority op. at ¶57. As noted above, liability is not imposed in strict product liability cases premised on inadequate or nonexistent warnings unless the seller knew or should have known of the danger, that is, unless the danger was foreseeable.

reaction in Linda Green would be evaluated based upon whether "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design . . . and the omission of the alternative design renders the product not reasonably safe." Restatement (Third) of Torts: Products Liability § 2(b) (1998). Accordingly, I respectfully dissent.

 $\P 135 \ \mbox{I}$ am authorized to state that Justice DAVID T. PROSSER joins this dissent.