NO. 21-1097
IN THE SUPREME COURT OF TEXAS

AMERICAN HONDA MOTOR CO., INC.,
Petitioner,

v.

SARAH MILBURN,
Respondent,

On Petition for Review from the Fifth Court of Appeals, Dallas, Texas
Cause No. 05-19-00850-CV

BRIEF OF THE CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA; THE AMERICAN TORT REFORM ASSOCIATION; THE ALLIANCE FOR AUTOMOTIVE INNOVATION; AND THE NATIONAL ASSOCIATION OF MANUFACTURERS AS AMICI CURIAE IN SUPPORT OF PETITIONER

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INTERESTS OF AMICI CURIAE

The U.S. Chamber of Commerce

The Chamber of Commerce of the United States of America ("Chamber") is the world's largest business federation. It represents approximately 300,000 direct members and indirectly represents the interests of more than 3 million companies and professional organizations of every size, in every industry sector, and from every region of the country. An important function of the Chamber is to represent the interests of its members in matters before Congress, the Executive Branch, and the courts. To that end, the Chamber regularly files amicus curiae briefs in cases, like this one, that raise issues of concern to the nation's business community.

As one of the largest representatives of businesses, including manufacturers, in the United States, the Chamber has a vital interest in ensuring that rules and safety standards by which manufacturers abide are clear and consistent across the nation and that fundamental principles and limitations of products liability on which companies rely in making business decisions are taken into account and enforced by the courts.

The National Association of Manufacturers

The National Association of Manufacturers ("NAM") is the largest manufacturing association in the United States, representing small and large manufacturers in all 50 states and in every industrial sector. Manufacturing employs

nearly 13 million men and women, contributes $2.91 trillion to the U.S. economy annually, has the largest economic impact of any major sector, and accounts for over half of all private-sector research and development in the nation. The NAM is the voice of the manufacturing community and the leading advocate for a policy agenda that helps manufacturers compete in the global economy and create jobs across the United States. The NAM, as the largest manufacturers association, has a special interest in ensuring limitations on products liability law are enforced by the courts.

The American Tort Reform Association

The American Tort Reform Association ("ATRA") is a broad-based coalition of businesses, corporations, municipalities, associations, and professional firms that have pooled their resources to promote reform of the civil justice system with the goal of ensuring fairness, balance, and predictability in civil litigation. For more than three decades, ATRA has filed amicus briefs in cases involving important product liability issues.

The Alliance for Automotive Innovation

Formed in 2020, the Alliance for Automotive Innovation ("Auto Innovators") is a collective organization representing the voice of the automotive industry. Focused on creating a safe and transformative path for sustainable industry growth, Auto Innovators represents the manufacturers producing nearly 98 percent of cars and light trucks sold in the U.S. Auto Innovators is directly involved in regulatory

and policy matters affecting the light-duty vehicle market across the country. Members include motor vehicle manufacturers, original equipment suppliers, as well as technology and other automotive-related companies. Auto Innovators and its members have a significant interest ensuring that the limitations on products liability law are enforced.

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No counsel for a party in this case authored this brief in whole or in part. No person or entity—other than amici, their members, or their counsel—made any monetary contributions intended for the preparation or submission of this brief.

ARGUMENT OF AMICI CURIAE

Amici write to emphasize the importance of courts rigorously enforcing two critical limitations on products liability in Texas: (1) the non-liability defense in Texas Civil Practices and Remedies Code section 82.008 for manufacturers that comply with federal safety standards; and (2) that manufacturers do not need to destroy a product's utility in favor of a safer design to avoid liability.

Products-liability claims pose special challenges. By definition, such claims arise when a consumer has been injured by a product—often tragically, as is alleged in this case. Not only do products-liability cases implicate all the classic dangers of bias when an individual sues a corporation, but the defendant also faces strict liability. *See McKisson v. Sales Affiliates, Inc.*, 416 S.W.2d 787, 788–89 (Tex. 1967) (adopting strict liability for a defective product that is unreasonably dangerous). And with the benefit of hindsight, a plaintiff's retained experts can always second-guess a product's design or manufacture, despite compliance with federal safety standards. The playing field is far from level.

Because of the breadth of potential liability and risk of hindsight bias, Texas law places important limits on products liability, including limits enacted by the Legislature to level the litigation playing field consistent with the State's goal of promoting a robust business-friendly economy. To prevent an already-broad tort from becoming entirely boundless, courts must rigorously enforce these limits.

The statutory limit on liability for products that comply with federal safety standards was enacted by the Legislature as part of broader tort-reform efforts to ensure that Texas provides a level playing field for business operating in this state, making Texas an attractive market for manufacturers and retailers. Thus, the Legislature exercised its judgment and enacted an affirmative defense, Texas Civil Practices and Remedies Code section 82.008, for manufacturers whose products comply with federal safety standards, even if the plaintiff is otherwise able to prove a product-liability tort under common law. States across the country have adopted similar laws, which provide manufacturers with clear and consistent standards for complex products and avoid the risks of costly and uncertain litigation.

The analysis in the decision below threatens to render this important liability protection meaningless. The court of appeals relied, in effect, on a deceptively simple syllogism: because the jury could have found that the seatbelt design in question was unreasonably dangerous, that same alleged evidence of defect could have also supported the jury finding that the federal safety standards were inadequate to protect the public from unreasonable risks of injury or damage. *See Am. Honda Motor Co., Inc. v. Milburn*, 668 S.W.3d 6, 19 (Tex. App.—Dallas 2021, pet. granted) (relying on alleged evidence that Honda's seat belt design was defective to support the finding that the federal standard failed to protect the public). But as Petitioner

explains, if that reasoning were correct, the presumption would be rendered meaningless. Pet'r Br. 24-25.

Correctly understood, overcoming the statutory presumption of nonliability requires that a plaintiff must satisfy a different burden, which requires different evidence. In order to give meaning to all provisions in the text of Section 82.008(a)-(b), to establish the regulation is "inadequate to protect the public," a plaintiff must show that a material change in technology or society has rendered the federal safety standard at issue so significantly out of date that no reasonable manufacturer would believe at the time of manufacture that the standard remains adequate to protect the public. A plaintiff must also show that the federal safety standard is inadequate *as a whole*—in all or substantially all applications—not merely inadequate as applied to the particular challenged product. Respondent made no attempt to make these showings, and this Court should accordingly hold that evidence that a single vehicle was (allegedly) defectively designed is legally insufficient evidence that the regulation itself was inadequate to protect the public.

The second critical limit on products liability at issue here is one well-established in this Court's cases: the requirement that an alternative proposed design not substantially impair the product's utility. *See, e.g.*, *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 384 (Tex. 1995) ("Shears offered no evidence of a safer design for a loader that could perform the same tasks as the Caterpillar model 920[.]"); *Genie*

Indus., Inc. v. Matak, 462 S.W.3d 1, 7 (Tex. 2015). ("Texas law does not require a manufacturer to destroy the utility of his product[] in order to make it safe.").

The court of appeals erred in applying this standard by holding that the possibility of using a different seatbelt with a different product—a minivan with a fold-down seat and a removeable third-row of seats—demonstrated a safer alternative design. *Am. Honda Motor*, 668 S.W.3d at 25. Under this Court's precedent, the correct legal inquiry is whether a safer alternative design exists for the product actually manufactured by Honda: a minivan with a "magic" third-row seat that folds flat into the floor. Without evidence of a safer alternative design for *this product*—and there is none—Respondent failed to prove her claim.

Often-sympathetic facts, strict liability, and the risk of hindsight bias second-guessing product designs give plaintiffs an edge in products-liability cases. Consistent with both black-letter law and Texas's business-friendly public policies, this Court should reaffirm that courts must enforce the above limits on products-liability claims and hold that Respondent presented legally insufficient evidence of regulatory inadequacy and legally insufficient evidence of a safer alternative design.

I. Section 82.008 Provides an Important Defense for Manufacturers in Products-Liability Lawsuits.

A. In enacting Section 82.008, Texas joined a coalition of states that protect manufacturers from tort liability if their products comply with all federal safety standards.

In 2003, as part of an omnibus tort reform bill, the Texas legislature enacted Section 82.008, "Compliance with Government Standards." "The impetus for enacting section 82.008 was a finding that manufacturers and sellers were being held liable in products liability cases even though the products at issue complied with all applicable federal safety standards." *Kia Motors Corp. v. Ruiz*, 432 S.W.3d 865, 869 (Tex. 2014) (citing R. Brent Cooper and Diana L. Faust, Products Liability After House Bill 4, 46 S. Tex. L. Rev. 1159, 1162 (2005)).

The Legislature recognized that although federal preemption provided a theoretical defense in some cases, it proved a thin shield in practice. R. Brent Cooper and Diana L. Faust, Products Liability After House Bill 4, 46 S. Tex. L. Rev. at 1162 (citing *Great Dane Trailers, Inc. v. Estate of Wells*, 52 S.W.3d. 737 (Tex. 2001)). Although it was possible to prevail in certain cases,[1] a manufacturer sued in Texas

[1] Even after the passage of Section 82.008, there may be cases where federal preemption rather than the statute forecloses liability. *See* David R. Iler & Krystal Pfluger Scott, Products Liability After House Bill 4, 44 The Advoc. (Texas) 137, 139 (2008) (noting that "even when [under Section 82.008] a claimant . . . successfully rebuts the no-liability presumption, federal preemption may still prevent the claimant's common law claim."). This may be one such case. *See* Pet'r's Br. at 27-31.

could not be confident that preemption would apply, even if the product fully complied with the federal safety standards and regulations governing the risks created by the product. The Legislature's goal in enacting Section 82.008 was to fill a gap in the protections for manufacturers under Texas law and limit liability where manufacturers comply with federal safety standards.

Under Section 82.008, if a product complies with federal safety standards that govern the product risk that allegedly caused harm, the manufacturer cannot be held liable[2] unless the plaintiff shows the federal safety standards "were inadequate to

[2] Although described as a "rebuttable presumption" in the statute, Section 82.008(a) is, in effect, an affirmative defense and Section 82.002(b) a counter-affirmative defense. *See* Michael R. Klatt, Elizabeth A. Cash, A Guide to House Bill 4 Provisions That Affect Substantive Pharmaceutical Litigation Issues, 46 S. Tex. L. Rev. 1137, 1148 (2005) ("The language in section 82.008 suggests that the presumption created by a manufacturer's or seller's compliance with government standards may be an affirmative defense that a defendant must plead and for which a defendant must lay a prima facie foundation. Once such a foundation is laid, the plaintiff would then attempt to establish that one of these exceptions applies."). Section 82.008(a) is a complete defense to liability once established, unless the plaintiff then proves the exception within Section 82.008(b). Classifying Section 82.008 as an affirmative defense is consistent with how courts and parties have treated Section 82.008. *See Kia Motors*, 432 S.W.3d at 870 n.5 ("Kia first raised the presumption as an affirmative defense in its pleadings."); *cf. Wright v. Ford Motor Co.*, 508 F.3d 263, 274 (5th Cir. 2007) (concluding that there was no error in submitting the Section 82.008 presumption as a jury question and treating the "presumption" as a Morgan-type presumption under Texas law that shifts the burden of both production and persuasion, rather than a Thayer-type presumption that only shifts burden of production of evidence and then falls away from the case).

protect the public from unreasonable risks of injury or damage." Tex. Civ. Prac. & Rem. Code § 82.008(b)(1).[3]

Texas is not alone in providing such protections against tort liability for manufacturers who comply with the applicable federal safety standards and regulations. Several other states besides Texas share the Legislature's policy goals and have enacted similar defenses, including Colorado, Florida, Indiana, Kansas, Kentucky, Michigan, North Dakota, Oklahoma, Tennessee, Utah, and Wisconsin.[4] Other states, such as Arkansas, Ohio, and Washington,[5] recognize that evidence of compliance with federal regulations is relevant evidence that a product is not unreasonably dangerous.

Although these statutory schemes vary in their language and scope,[6] they reflect the considered judgments of legislatures across the nation that tort liability

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[3] A plaintiff could also show that "the manufacturer, before or after marketing the product, withheld or misrepresented information or material relevant to the federal governments or agency's determination of adequacy of the safety standards or regulations at issue in the action." Tex. Civ. Prac. & Rem. Code § 82.008(b)(2). This exception is not at issue in this appeal.

[4] *See generally* Appendix A (setting forth relevant statutory schemes for these states). Texas Civil Practices & Remedies Code 82.008 is set forth in full on pages 9-10 of Appendix A.

[5] *See* Appendix A at 1, 7-8, 11.

[6] For example, New Jersey's defense is available only for products approved by the Food and Drug Administration. *See* Appendix A at 6. Oklahoma's 2014 statute, in contrast, very closely tracks Texas law. *Id.* at 8-9.

should be limited where a manufacturer complies with applicable federal safety standards. The enactment of these statutes resulted from a combination of a greater national focus on tort reform and state legislators reacting to specific case holdings.

The field of products liability law is a relatively new one, with this Court commenting in 1967 that the doctrine of strict liability "is one of comparatively recent and rapid development." *McKisson*, 416 S.W.2d at 789. It was against the backdrop of this rapidly developing field of law that legislators began to grapple with the consequences for businesses and insurers facing liability in their states. *See generally* Victor Schwartz, The Uniform Product Liability Act—A Brief Overview, 33 Vand. L. Rev. 579 (1980). Businesses were concerned that products liability insurance was becoming unaffordable and unavailable, which could give rise to a host of issues: business ceasing to exist because they could not get insurance, injured plaintiffs who would be unable to enforce product liability judgments, and manufacturers hesitating to produce products that would be useful to society. *Id.* at 579. A federal task force concluded that there was a real price increase in insurance premiums leading some small businesses to close and there was growing uncertainty about tort law, particularly the rise of retroactive products-liability rules in the common law, which were creating issues for insurers in pricing. *Id.* at 580-81. Additionally, courts, instead of treating strict liability as a means of apportioning

party responsibility, were improperly treating products liability as a compensation system. *Id.* at 581.

The U.S. Department of Commerce considered the task force's findings and developed several proposed legislative solutions. *Id.* at 581-82. Among those was the Model Uniform Products Liability Act ("MUPLA") that would serve as a model for states to adopt. *Id.* at 582. The MUPLA was published in the Federal Register in 1979. *Id.*; *see also* Model Uniform Products Liability Act, 44 Fed. Reg. 62714, 62721 (Oct. 31, 1979). Among the proposed standards contained in the MUPLA were protections for manufacturers who complied with regulatory standards. Schwartz, The Uniform Product Liability Act—A Brief Overview, 33 Vand. L. Rev. at 588-89. The MUPLA proposed that "if the injury-causing aspect of the product was in compliance with a legislative or administrative regulation relating to design or performance, the product shall not be deemed defective unless the claimant proves a reasonably prudent seller would have and could have taken additional precautions." *Id.*

While the federal task force was studying potential reforms and then following the proposal of the MUPLA, an initial wave of states adopted some form of the rebuttable presumption. Tennessee adopted the presumption in 1978,[7] before the

[7] Colorado was the earliest state to adopt such a statutory rebuttable presumption in products liability tort cases in 1977.

MUPLA, enacting Tennessee Code section 29–28–104 "to give refuge to the manufacturer who is operating in good faith and [in] compliance of what the law requires him to do." *Lake v. Memphis Landsmen, LLC*, No. W2011-00660-COA-RMCV, 2014 WL 895519, at *9 (Tenn. Ct. App. Mar. 7, 2014). Also an early adopter, Kansas enacted a rebuttable presumption statute in 1981, as part of broader tort reform efforts to "limit the rights of plaintiffs to recover in product liability suits generally and to judge a product for an alleged defect only when it is first sold." *Patton v. Hutchinson Wil-Rich Mfg. Co.*, 861 P.2d 1299, 1309 (Kan. 1993). "The Kansas Legislature's adoption of [section 60-3304] arose out of a United States Department of Commerce task force study in the late 1970's, resulting in publication of the . . . MUPLA[], which was offered for voluntary usage by the states." *Miller v. Lee Apparel Co.*, 881 P.2d 576, 584 (Kan. 1994). Kansas Statutes section 60–3304 is one of the state statutes that most closely tracks the MUPLA, as it "provides that a product is 'not defective' under certain circumstances where it was in compliance with regulatory standards when manufactured." *Delaney v. Deere & Co.*, 999 P.2d 930 (Kan. 2000); *see also* Appendix A at 3-4 (K.S.A. 60–3304).

The second wave of rebuttable presumption statutory enactments for manufacturers in compliance with federal standards came during the 1990s and 2000s as several states across the nation undertook comprehensive tort reform. *See* U.S. Chamber of Commerce Institute for Legal Reform, Tort Reform History

(available at https://instituteforlegalreform.com/history-of-tort-reform/) (noting a wave of comprehensive state-level tort reforms enacted starting in the late 1990s); *see also* American Legislative Exchange Council, Products Liability Act (available at https://alec.org/model-policy/product-liability-act/) (noting that it first proposed its Model Products Liability Act in 1995, which was subsequently updated to adopt other model legislation proposals that closely track the wording in Texas's Section 82.008).

For example, North Dakota passed its statutory scheme containing the rebuttable presumption in 1995 "to clarify and improve the method of determining responsibility for the payment of damages in products liability litigation; to restore balance and predictability between the consumer and the manufacturer or seller in product liability litigation; [and] to bring about a more fair and equitable resolution of controversies in products liability litigation*." Dickie v. Farmers Union Oil Co. of LaMoure*, 611 N.W.2d 168, 170–71 (N.D. 2000). Similarly, Wisconsin's tort reform bill containing the products liability rebuttable presumption was passed in 2011 as a means to "clarify product liability law, generally" and to displace specific case holdings that had made businesses hesitant to conduct activities in the state for fear of unpredictable tort liability. Wis. Stat. § 895.046 (legislative findings for act, including the rebuttable presumption in § 895.047); *see Murphy v. Columbus McKinnon Corp.*, 963 N.W.2d 837, 844 (2021) ("The legislature created Wis. Stat.

§ 895.047 . . . to establish what a plaintiff must show to prove a claim of strict product liability for a design defect. . . . Section 895.047 to a degree replaces and to a degree supplements common law standards on this topic[.]").

By enacting such reforms, these states recognized as sound public policy statutory protections that "reduc[e] unnecessary and cumbersome litigation where a product or service has already undergone a lengthy approval process or is designed to meet detailed government safety standards." U.S. Chamber's Institute for Legal Reform, 101 Ways to Improve State Legal Systems, Seventh Ed., at 79 (October 2022) (available at https://instituteforlegalreform.com/wp-content/uploads/2022/10/101-Ways-2022-RGB-WP-FINAL.pdf). They promote predictability in litigation outcomes and avoid inconsistent results regarding the safety of the same product. *Id.* Allowing manufacturers to evaluate legal risk predictably helps keep consumer prices low and benefits both manufacturers and consumers in allowing manufacturers to offer products that maximize both safety and cost-effectiveness.

At the same time, these statutes maintain protections for consumers by allowing them to recover if they can show "strong evidence that the government's regulation of the product or service at issue was out of date or compromised with respect to safety" because these statutes are generally structured to allow such claims to proceed through the courts, while at the same time protecting manufacturers that comply with prevailing safety standards. *Id.* at 79-80. This benefits the general

public by further incentivizing full regulatory compliance by manufacturers and encouraging safety and lawful conduct in the manufacture of products.

Consistent with that policy, the Texas legislature struck a careful balance in Section 82.008 by recognizing that manufacturers should not be subject to tort liability where their product was manufactured in compliance with the prevailing federal regulations and safety standards, but allowing a plaintiff an opportunity to overcome that defense by showing those safety standards were "inadequate to protect the public from unreasonable risks of injury" or that the manufacturer "withheld or misrepresented information or material relevant" to the federal agency setting the safety standards.

Texas's formulation of the statutory scheme containing the rebuttable presumption provides especially strong protections for manufacturers, consistent with Texas's business-friendly public policy goals. Section 82.008 does not fold the rebuttable-presumption inquiry into the merits question of whether there is a product defect. Instead, Section 82.008(a) generally prohibits liability for products complying with federal regulations even if the jury finds there is a defect. This provides helpful textual clarity regarding how the rebuttable presumption should function.[8]

[8] As addressed below, there is confusion among some courts applying certain other states' versions of the rebuttable presumption regarding the showing that a plaintiff

The Texas Legislature thus expressed its confidence that federal agencies properly exercise their expertise to weigh competing factors in setting product safety standards and properly strike a balance to protect consumers and the public at large. As a general matter, the Legislature did not want juries second-guessing expert federal regulatory agencies and imposing liability on manufacturers that complied with federal safety standards governing the risk that allegedly caused harm.

B. For Section 82.008 to have meaning, courts must distinguish whether a regulation as a whole is inadequate from whether a particular product is defective.

Here, Respondent sought to overcome the regulatory-compliance defense by proving that "the mandatory federal safety standards or regulations applicable to the product were inadequate to protect the public from unreasonable risks of injury or damage." Tex. Civ. Prac. & Rem. Code § 82.008(b)(1). The issue before this Court is whether Respondent presented legally sufficient evidence to support the jury's finding that the regulation was inadequate.

As Honda explained (on pages 24-25 of its opening brief and page 14 of its reply), for Section 82.008 to have any meaning, courts must take care to distinguish the issue of whether a particular vehicle was defectively designed (the ordinary liability question in a products-liability suit) from whether a regulation was

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must make to rebut the presumption against liability by establishing the inadequacy of a federal safety standard. The language, structure, and context of Texas's statutory scheme avoid any such confusion here. *See infra* at Part I.C.

inadequate to protect the public. And as noted above, *supra* at 16-17, the Texas legislature took care to separate the statutory defense of regulatory compliance from the merits inquiry of design defect.

If the inquiries were identical and the same evidence was legally sufficient to prove both, then Section 82.008 would be entirely superfluous. Honda captured the problem perfectly:

> • if the plaintiff wins on design defect, then the presumption would be automatically rebutted; but
>
> • if the manufacturer wins on design defect, then the manufacturer would not need the presumption.
>
> In either case, the presumption would be useless[.]

Pet'r Br. 25. To give independent effect to Section 82.008 (and distinguish a plaintiff's counter-affirmative defense from the elements of its claim), a plaintiff necessarily must satisfy a higher standard to prove regulatory inadequacy with evidence distinct from that required to prove that a particular vehicle was defective.

Here, the analysis of the court of appeals illustrates how easily Section 82.008 can be nullified by collapsing the defect and inadequacy inquiries. Respondent's evidence—which the court of appeals wrongly found sufficient—focused entirely on alleged defects in Honda's design. *E.g.*, *Am. Honda Motor*, 668 S.W.3d at 19 ("Joellen Gill, the Milburns' Human Factors Engineering Consultant, opined at trial that it should have been foreseeable to Honda that owners would not reliably maintain the seat belt [in Honda's vehicle] in the anchored position."); *id.* at 19 ("The

Milburns contend that Honda's detachable anchor seat belt design is so confusing that people are unlikely to use it correctly."). The court of appeals effectively held that, by submitting sufficient evidence that the specific vehicle in question was unreasonably dangerous, Respondent also submitted sufficient evidence that the federal seatbelt standards were inadequate to protect the public. Before this Court, Respondent embraces the conflation of the two inquiries. *See* Resp. Br. at 21 ("[T]he fact that a product is defective . . . is some evidence that the federal standards allowing such a confusing design are inadequate to protect the public."); *id.* at 22-23 (relying on "Sarah's tragic experience" as evidence of regulatory inadequacy).

This cannot be correct. For Section 82.008 to mean anything and not be entirely superfluous, it must require a plaintiff to satisfy a different, higher burden—and present different evidence—than proving merely that a particular product, here a vehicle's design, was unreasonably dangerous. As discussed below, a plaintiff must prove that the regulation was inadequate to protect the public *as a whole* by showing that a material technological or societal change rendered the regulation significantly out of date. Respondent made no attempt to make this showing (or even any other showing aimed at the regulation as a whole). Whatever the additional evidence required to prove a federal safety standard's inadequacy under Section 82.008(b)(1), Respondent failed to present it.

C. Plaintiff's experts here did not provide the type of evidence necessary to overcome the Section 82.008(a) defense by establishing the inadequacy of federal safety standards under Section 82.008(b).

This Court should provide much-needed guidance on what plaintiffs must show to establish the inadequacy of a federal safety standard under Section 82.008(b)(1). There is confusion among some courts applying the various similar statutory schemes of other states regarding what evidence is sufficient to rebut the presumption against liability for products that comply with regulatory safety standards. *See* § 14:9. Regulatory compliance defense—State reform legislation, 2 Owen & Davis on Prod. Liab. § 14:9 (4th ed.) at n.1 (exploring the confusion under different statutes as to what evidence is sufficient to rebut the presumption of non-liability). But the language, structure, context, and purpose of Texas's statutory scheme together avoid any such confusion here—especially because, here, the Respondent's evidence does not even come close to any potential minimum required showing.

Section 82.008's structure, context, and purpose, as well as traditional principles of agency deference in Texas law, illuminate the meaning of "inadequate," making clear that the statute prohibits juries from second-guessing federal regulators' expert safety judgments. *See Levinson Alcoser Associates, L.P. v. El Pistolon II, Ltd.*, 513 S.W.3d 487, 493 (Tex. 2017) ("In construing statutes, [the

Court's] objective is to give effect to the Legislature's intent that [it gleans] from the text."). Juries are ill-suited to such a task.

Amici suggest that to ensure that the presumption against liability provides meaningful protection, a plaintiff may establish the inadequacy of a federal safety standard under Section 82.008(b)(1) (thus rebutting the presumption) by showing that, since adoption of the relevant federal safety standard, there has been such a material change in technology or society that no reasonable manufacturer at the time of manufacture could believe that the standard remains adequate to protect the public.

This interpretation gives full weight to the protection for manufacturers and deference to regulators' judgment embodied in Section 82.008(a) and avoids the impermissible overlap with the product defect inquiry that would render the rebuttable presumption superfluous. *See Levinson*, 513 S.W.3d 493 (holding that courts must "interpret each word, phrase, and clause in a manner that gives meaning to them all" and "read statutes as a whole so as to render no part inconsistent, superfluous, or devoid of meaning"). The material-change standard for "inadequacy" in subsection (b)(1) gives full meaning to all provisions in Section 82.008, ensuring that none is rendered superfluous. Plaintiffs could still demonstrate that a standard is "inadequate" without juries being asked to second-guess federal regulatory judgments.

Thus, a plaintiff can prove a federal safety standard's inadequacy by showing "that the government's regulation of the product or service at issue was out of date." U.S. Chamber's Institute for Legal Reform, 101 Ways to Improve State Legal Systems, Seventh Ed., at 79-80. To make this showing, however, a plaintiff must do more than merely second-guess the relevant federal safety standards by offering an allegedly better or more complete understanding of circumstances existing at the time that the standards were adopted. Section 82.008 was designed to avoid precisely this sort of regulatory second-guessing and hindsight bias.[9]

Giving appropriate deference to regulators' judgment requires that a plaintiff must do more than present additional information about risks that existed at the time of the regulation. That would simply be an argument that the regulators erred. Here for example, the risk of seat belt misuse existed at the time of regulation—Respondent does not contend that the risk arose after the regulation was enacted. To the extent that Respondent addressed regulatory inadequacy at all (rather than simply argued that a particular vehicle was defectively designed), Respondent has simply asserted that the regulators' judgment was incorrect and failed to give adequate

[9] Second 82.008(b)(2) also allows a plaintiff to challenge the regulatory process by establishing that the manufacturer "withheld or misrepresented information or material relevant to the federal government's or agency's determination of adequacy of the safety standards or regulations at issue." Tex. Civ. Prac. & Rem. Code § 82.008(b)(2). A plaintiff making such an argument would not be asserting that federal regulators erred but would instead be asserting that regulators were deprived of then-available information necessary to make their judgment.

weight to, or investigation of, existing risks. This is exactly the sort of regulatory second-guessing that juries are ill-equipped to consider and that this Court should preclude.

Instead, a plaintiff should be required to show that a new, unforeseeable risk has arisen since enactment of the regulation. To establish that a federal safety standard is "out of date" in the sense relevant to inadequacy, a plaintiff should be required prove that there has been such an unexpected, material technological or societal change that no reasonable manufacturer could have believed at the time of manufacture that the safety standard remains adequate to protect the public. Section 82.008(a) requires courts and juries to defer to federal regulators' safety expertise and policy tradeoffs, but "inadequate" captures the fact that new situations sometimes require new rules. No matter the degree of technological change, the Section 82.008(a) defense would always remain available, but a sufficiently substantial change might satisfy the plaintiff's high burden to overcome that defense by showing regulatory inadequacy.

Proving a material change in technology or society should be the exclusive means to demonstrate that the relevant federal safety standards or regulations are inadequate to protect the public from unreasonable risks of injury or damage. *Cf. Harris Cnty. Appraisal Dist. v. Tex. Workforce Comm'n*, 519 S.W.3d 113, 118 (Tex. 2017) (explaining agency decisions where the agency exercises its expertise can only

be set aside by the courts where "unreasonable, arbitrary, or capricious" and that "[t]his methodology was purposefully designed by the Legislature so that agency decisions are afforded significant deference, and a court is not allowed to substitute its judgment for that of the agency"); *Safety v. Peck*, 751 F.2d 1336, 1343, 1345 (D.C. Cir. 1985) (Scalia, J.). (then-Judge Scalia recognizing that judges are "laymen, ill equipped to determine where the line falls" when evaluating the validity of an agency's engineering judgments).

The structure, context, and purpose of Section 82.008 should prevent a plaintiff from proving inadequacy by second-guessing federal regulators' expert safety findings and policy judgments. The entire point of the statute is to promote regulatory compliance and provide manufacturers legal certainty by deferring to those findings and that judgment. This Court should give effect to those principles by holding that a regulation is "inadequate" when there has been an unexpected material change such that no reasonable manufacturer could have believed that the standard remained adequate to protect the public. Respondent introduced no such evidence here.

Alternatively, if this Court disagrees that inadequacy requires proof of a material change and allows plaintiffs to demonstrate the inadequacy of a federal safety standard by directly attacking the issuing regulator's supporting safety findings and risk-utility policy judgments, merely showing that the agency erred

cannot be sufficient. For such a direct attack to overcome the regulatory-compliance defense, Section 82.008(b)(1) should require the plaintiff to show that the federal safety standard at issue, given the circumstances and data available at the time of its adoption, was not merely wrong, but was so completely beyond the reasonable range of regulatory judgment that the standard has been arbitrary and capricious all along.

That is a very difficult showing to make—and rightly so, precisely because anything less would neuter the presumption against liability, making it subject to the mere disagreement of unpredictable juries. It would entirely undermine a core purpose of these statutes—which turn on encouraging compliance with uniform federal safety standards—if juries could reach differing conclusions about the adequacy of those same regulations, essentially subjecting manufacturers to a fractured web of standards rather than one federal standard. Creating predictability governing product liability risks and litigation outcomes is impossible if jurors are free to dispense with the presumption through simple disagreement with an agency's regulatory judgment that a regulation adequately protects the public. Juries applying state law should rarely, if ever, be permitted to second-guess the reasoned judgment of federal safety regulators. To the extent such second-guessing is allowed at all—and it should not be—it should be limited to truly extreme regulatory misjudgments.

What's more, under either theory of regulatory inadequacy—changed circumstances or direct attack as arbitrary and capricious—a plaintiff must prove

that the federal safety standard at issue is "inadequate to protect the *public*" at large, Tex. Civ. Prac. & Rem. Code § 82.008(b)(1) (emphasis added), not merely inadequate to protect the particular plaintiff. In other words, the plaintiff must establish the inadequacy of the federal safety standard *as a whole*, not simply its inadequacy as applied to the particular product at issue.

To satisfy this high burden, a plaintiff would need to address the various factors and tradeoffs considered by the federal regulator that issued the relevant safety standard. Likely requiring expert testimony, this showing would weigh the public-safety risks, utility and clarity benefits, and other relevant factors at the level of generality of the entire regulation. Considering all these factors, the plaintiff must prove the inadequacy of a federal safety standard in all or substantially all applications weighed against *all* the regulation's benefits—not just the utility benefits for the specific product at issue. Proof of a design defect focuses on the danger, utility, and feasibility of alternative designs for the particular challenged product. By contrast, proving the inadequacy of a federal standard under Section 82.008(b)(1) requires evidence of how these factors apply to the regulated class as a whole. If a federal safety standard applies to all trucks, for example, the relevant inquiry and evidence introduced must address whether the regulation was inadequate to protect truck drivers, as a group, from unreasonable risks of injury or damage, not simply evidence of the danger from a particular truck. Likewise, the

relevant consideration in this case is not the seatbelt in the particular Honda vehicle at issue, but the broader class of vehicle approved for the type of seatbelt at issue.

And in considering whether a federal safety standard adequately protects the public as a whole, a plaintiff (like a federal agency) must address factors such as consumer acceptance (for reasons of cost and otherwise). Extremely burdensome and costly safety standards for new cars, for example, may cause consumers to drive older cars for longer, ultimately decreasing public safety as a whole. Such evidence might not be relevant to whether a particular product is defective, but expected consumer purchasing behavior is critical to determining whether an alternative safety standard would better protect the public.

To be clear, a plaintiff may not always require an expert on the regulatory process or the particular regulatory history of the federal safety standard at issue to prove its inadequacy. But a plaintiff must offer evidence (almost certainly in the form of expert testimony) addressing all the various factors relevant to the adequacy of the federal safety standard for the public as a whole, not merely the adequacy of the standard as applied to the particular product and plaintiff at issue. This additional required showing ensures that the inadequacy inquiry is distinct from the defectiveness question.

Because Respondent failed to introduce any evidence to make a showing of inadequacy here under any possible interpretation of Section 82.008(b)(1) that does

not collapse the inadequacy and defect inquiries and render subsection (a) superfluous, this Court should hold that no evidence supports the finding of regulatory inadequacy.

II. A Fundamental Principle of Products-Liability Law Is That a Manufacturer Need Not Destroy a Product's Utility To Make It Safer.

The second key limit on products liability at issue here is the bedrock principle of Texas tort law that a plaintiff must show "a safer alternative design **for the product at issue**." *Genie*, 462 S.W.3d at 3 (emphasis added). Put another way, "Texas law does not require a manufacturer to destroy the utility of his product in order to make it safe." *Id.* at 7. A safer alternative design cannot "substantially impair the product's utility." *Id.*

This is a core tenant of products liability law—that there must in fact be a reasonable alternative. Restatement (Third) of Torts: Prod. Liab. § 2(b) (1998). "Sufficient evidence must be presented so that reasonable persons could conclude that a reasonable alternative could have been practically adopted." *Id.* at cmt. (f). "Society does not benefit from products that are excessively safe—for example, automobiles designed with maximum speeds of 20 miles per hour—any more than it benefits from products that are too risky. Society benefits most when the right, or optimal, amount of product safety is achieved." *Id.* at cmt. (a). At least twenty-five states have adopted either through judicial decisions or by statute some requirement that to succeed on a product defect claim, a plaintiff must introduce evidence of an

available and reasonable alternative design. *See* Aaron D. Twerski & James A. Henderson, Jr., Manufacturers' Liability for Defective Product Designs: The Triumph of Risk-Utility, 74 Brook. L. Rev. 1061, 1106 (2009) ("But in the broad view of the national landscape set forth in this Article, there is little doubt that risk-utility balancing has carried the day.").

Consistent with these general principles, Texas courts regularly reject attempts by plaintiffs to evade this requirement by arguing that a defendant should have manufactured a different product, without the benefits of the product actually manufactured. *Genie Industries* is a perfect example. Genie manufactured a man-portable lift designed to be lightweight, portable, and fit through ordinary doorways:

> The AWP–40S is designed to be lightweight and portable. Though the lift weighs roughly 1,000 pounds, it can be rolled around, set up, and operated by a single person. The lift is well-suited for indoor work not accessible by big, heavy machinery. It can pass through ordinary doorways and can be used in tight spaces.

462 S.W.3d at 4. The plaintiff's proposed alternative designs would have destroyed this utility. *See id.* at 8 ("Permanent attachment and mechanization would presumably add to the lift's weight and size, thereby diminishing one of the lift's key utility factors—its versatility."); *id.* at 9 ("[A] two-wheeled lift would also be much harder to move than a machine on four wheels."). With such slight evidence of alternative designs, this Court readily held that the product was not unreasonably dangerous.

Genie followed the same analysis as earlier decisions of this Court. In *Timpte*, this Court held that a design that "would add to the total weight of the trailer thereby reducing the weight of the commodity that the trailer would be permitted to carry" impaired the utility of "maximizing the amount of commodity that the trailer can haul while keeping the structure of the trailer sound." *Timpte Indus., Inc. v. Gish*, 286 S.W.3d 306, 313 (Tex. 2009). Similarly, in *Caterpillar*, this Court held that there was no evidence "of a safer alternative design for a front-end loader that could fulfill the multi-purpose role of Caterpillar's model 920 with a removable ROPS." *Caterpillar, Inc. v. Shears*, 911 S.W.2d 379, 385 (Tex. 1995). For there to in fact be a reasonable alternative design, the proposed safety features must not turn the product into something new: "A motorcycle could be made safer by adding two additional wheels and a cab, but then it is no longer a motorcycle. A convertible can be made safer by fully enclosing the cab, but then it is just an ordinary car." *Id.* at 385. This Court has never permitted the law of products liability "to eliminate whole categories of useful products from the market." *Id*.

But removing a category of useful products from the market is precisely what the court of appeals' defectiveness analysis threatens here. *Timpte* emphasized that the "risk-utility analysis does not operate in a vacuum, but rather in the context of the product's intended use and its intended users." 286 S.W.3d at 312. Here, that principle requires accounting for the utility of the size of the cargo hold to the

vehicle's owner and requires that a manufacturer would not be forced to marginally increase safety where the alternative design would significantly reduce cargo capacity and destroy the product's utility. The vehicles at issue have seats that fold completely into the base of the vehicle to create a spacious cargo hold. This design has undeniable utility: like the trailer in *Timpte*, the design maximizes the cargo space in the vehicle. *Id.* at 313. This Court has already held in *Timpte* that where a proposed alternative design "results in a decrease of the amount of commodity the trailer can haul, thus reducing its overall utility to user," under a risk-utility analysis that product is not defective as a matter of law. *Id.* at 314. A design that decreases a vehicle's cargo space would be a destruction of utility not required under Texas law.

The court of appeals failed to fully account for these principles and erred in two ways in considering the decreased cargo space. First, it characterized the reduction in cargo space—64 cubic feet (a decrease of more than 40% from the existing 148 cubic feet)—as "slightly diminished cargo space." *Am. Honda Motor Co.*, 668 S.W.3d at 26; *see also* Pet'r Br. at 30. By comparison, a domestic carryon bag takes up less than two cubic feet. Indeed, the additional cargo space from the "magic seat" design would allow transportation of an additional four foot cube. Plaintiffs—and courts—cannot simply trivialize this significant decrease in utility by characterizing the loss as "slightly diminished cargo space" or the benefit as "a

little additional cargo space." *Id.* at 25-26. *Timpte* strongly suggests that a different conclusion on that issue is required as a matter of law.

Second, the reduction in cubic footage does not fully capture the decrease in utility. Anyone who has ever tried to load a bulky object into a vehicle knows that the height of a cargo area matters. Using conventional hinged folding seats rather than "magic" seats that fold flat does not shrink the cargo space slightly in every direction—it only decreases the height of the cargo area. Common experience attempting to load passenger vehicle cargo loads confirms that shrinking the vertical space available harms the utility of the vehicle far more than just generally decreased cargo space.

Even more misguidedly, the court of appeals suggested that the utility of maximizing cargo space could be preserved by making the third row of seats removable: "[I]f the third row seats can be removed, as the second row seats are designed to do, there would not even be a decrease in available cargo space." *Am. Honda Motor Co.*, 668 S.W.3d at 26. Nothing could be further from the truth: the whole point of the "magic seat" design is that the entire cargo space becomes available *without* the difficulty of removing a seat from the vehicle. The elderly or infirm may be physically incapable of removing the third row of seats, and even an able-bodied individual may not want the inconvenience of, or risk of injury from, lifting them out and then re-installing them. Removing a row of seats also requires

finding a place to store it, but consumers may lack garage access or a convenient way to transport the seats into their dwelling or other storage area. The court of appeals simply ignored these undeniable ways in which its alternative—remove the third row of seats—would harm consumers and impair the utility of the product.

Fundamentally, Respondent seeks to distort the established law of product liability to eliminate from the market an entire category of innovative products—minivans with third-row seats that fold flush into the passenger cabin floor. This Court has never allowed such a result, *Caterpillar*, 911 S.W.2d at 385, and it should not allow it in this case. Respondent never proposed a safer alternative design for the product manufactured by Honda—she proposes instead that Honda manufacture a fundamentally different product. As in *Genie*, *Timpte*, and *Caterpillar*, this Court should hold that Respondent failed to prove that the product at issue had a defective design.

CONCLUSION & PRAYER FOR RELIEF

This Court should reaffirm these important limits on the law of product liability and hold that Respondent presented legally insufficient evidence of her claims.

Dated: August 30, 2023

Respectfully submitted,

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CERTIFICATE OF SERVICE

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APPENDIX A

Arkansas:

Compliance by a manufacturer or supplier with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards of design, inspection, testing, manufacture, labeling, warning, or instructions for use of a product shall be considered as evidence that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.

Ark. Code § 16-116-205(a).

Colorado:

(1) In any product liability action, it shall be rebuttably presumed that the product which caused the injury, death, or property damage was not defective and that the manufacturer or seller thereof was not negligent if the product:

> (a) Prior to sale by the manufacturer, conformed to the state of the art, as distinguished from industry standards, applicable to such product in existence at the time of sale; or
>
> (b) Complied with, at the time of sale by the manufacturer, any applicable code, standard, or regulation adopted or promulgated by the United States or by this state, or by any agency of the United States or of this state.

(2) In like manner, noncompliance with a government code, standard, or regulation existing and in effect at the time of sale of the product by the manufacturer which contributed to the claim or injury shall create a rebuttable presumption that the product was defective or negligently manufactured.

(3) Ten years after a product is first sold for use or consumption, it shall be rebuttably presumed that the product was not defective and that the manufacturer or seller thereof was not negligent and that all warnings and instructions were proper and adequate.

(4) In a product liability action in which the court determines by a preponderance of the evidence that the necessary facts giving rise to a presumption have been established, the court shall instruct the jury concerning the presumption.

Colo. Rev. Stat. § 13-21-403.

Florida:

(1) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the product is not defective or unreasonably dangerous and the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm:

> (a) Complied with federal or state codes, statutes, rules, regulations, or standards relevant to the event causing the death or injury;
>
> (b) The codes, statutes, rules, regulations, or standards are designed to prevent the type of harm that allegedly occurred; and
>
> (c) Compliance with the codes, statutes, rules, regulations, or standards is required as a condition for selling or distributing the product.

(2) In a product liability action as described in subsection (1), there is a rebuttable presumption that the product is defective or unreasonably dangerous and the manufacturer or seller is liable if the manufacturer or seller did not comply with the federal or state codes, statutes, rules, regulations, or standards which:

> (a) Were relevant to the event causing the death or injury;
>
> (b) Are designed to prevent the type of harm that allegedly occurred; and
>
> (c) Require compliance as a condition for selling or distributing the product.

(3) This section does not apply to an action brought for harm allegedly caused by a drug that is ordered off the market or seized by the Federal Food and Drug Administration.

Fla. Stat. § 768.1256.

Indiana:

Sec. 1. In a product liability action, there is a rebuttable presumption that the product that caused the physical harm was not defective and that the manufacturer or seller of the product was not negligent if, before the sale by the manufacturer, the product:

> (1) was in conformity with the generally recognized state of the art applicable to the safety of the product at the time the product was designed, manufactured, packaged, and labeled; or
>
> (2) complied with applicable codes, standards, regulations, or specifications established, adopted, promulgated, or approved by the United States or by Indiana, or by an agency of the United States or Indiana.

Ind. Code § 34-20-5-1.

Kansas:

(a) When the injury-causing aspect of the product was, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design or performance, the product shall be deemed not defective by reason of design or performance, or, if the standard addressed warnings or instructions, the product shall be deemed not defective by reason of warnings or instructions, unless the claimant proves by a preponderance of the evidence that a reasonably prudent product seller could and would have taken additional precautions.

(b) When the injury-causing aspect of the product was not, at the time of manufacture, in compliance with legislative regulatory standards or administrative regulatory safety standards relating to design, performance, warnings or instructions, the product shall be deemed defective unless the product seller proves by a preponderance of the evidence that its failure to comply was a reasonably prudent course of conduct under the circumstances.

(c) When the injury-causing aspect of the product was, at the time of manufacture, in compliance with a mandatory government contract specification relating to

design, this shall be an absolute defense and the product shall be deemed not defective for that reason, or, if the specification related to warnings or instructions, then the product shall be deemed not defective for that reason.

(d) When the injury-causing aspect of the product was not, at the time of manufacture, in compliance with a mandatory government contract specification relating to design, the product shall be deemed defective for that reason, or if the specification related to warnings or instructions, the product shall be deemed defective for that reason.

Kan. Stat. § 60-3304.

Kentucky:

(1) In any product liability action, it shall be presumed, until rebutted by a preponderance of the evidence to the contrary, that the subject product was not defective if the injury, death or property damage occurred either more than five (5) years after the date of sale to the first consumer or more than eight (8) years after the date of manufacture.

(2) In any product liability action, it shall be presumed, until rebutted by a preponderance of the evidence to the contrary, that the product was not defective if the design, methods of manufacture, and testing conformed to the generally recognized and prevailing standards or the state of the art in existence at the time the design was prepared, and the product was manufactured.

Ky. Rev. Stat. § 411.310.

Michigan:

(1) It shall be admissible as evidence in a product liability action that the production of the product was in accordance with the generally recognized and prevailing nongovernmental standards in existence at the time the specific unit of the product was sold or delivered by the defendant to the initial purchaser or user.

(2) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a production defect, the manufacturer or seller is not liable unless the plaintiff establishes that the product was not reasonably safe at the time

the specific unit of the product left the control of the manufacturer or seller and that, according to generally accepted production practices at the time the specific unit of the product left the control of the manufacturer or seller, a practical and technically feasible alternative production practice was available that would have prevented the harm without significantly impairing the usefulness or desirability of the product to users and without creating equal or greater risk of harm to others. An alternative production practice is practical and feasible only if the technical, medical, or scientific knowledge relating to production of the product, at the time the specific unit of the product left the control of the manufacturer or seller, was developed, available, and capable of use in the production of the product and was economically feasible for use by the manufacturer. Technical, medical, or scientific knowledge is not economically feasible for use by the manufacturer if use of that knowledge in production of the product would significantly compromise the product's usefulness or desirability.

(3) With regard to the production of a product that is the subject of a product liability action, evidence of a philosophy, theory, knowledge, technique, or procedure that is learned, placed in use, or discontinued after the event resulting in the death of the person or injury to the person or property, which if learned, placed in use, or discontinued before the event would have made the event less likely to occur, is admissible only for the purpose of proving the feasibility of precautions, if controverted, or for impeachment.

(4) In a product liability action brought against a manufacturer or seller for harm allegedly caused by a product, there is a rebuttable presumption that the manufacturer or seller is not liable if, at the time the specific unit of the product was sold or delivered to the initial purchaser or user, the aspect of the product that allegedly caused the harm was in compliance with standards relevant to the event causing the death or injury set forth in a federal or state statute or was approved by, or was in compliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency responsible for reviewing the safety of the product. Noncompliance with a standard relevant to the event causing the death or injury set forth in a federal or state statute or lack of approval by, or noncompliance with regulations or standards relevant to the event causing the death or injury promulgated by, a federal or state agency does not raise a presumption of negligence on the part of a manufacturer or seller. Evidence of compliance or noncompliance with a regulation or standard not relevant to the event causing the death or injury is not admissible.

Mich. Comp. Laws § 600.2946(1)-(4).

New Jersey:

In any product liability action the manufacturer or seller shall not be liable for harm caused by a failure to warn if the product contains an adequate warning or instruction or, in the case of dangers a manufacturer or seller discovers or reasonably should discover after the product leaves its control, if the manufacturer or seller provides an adequate warning or instruction. An adequate product warning or instruction is one that a reasonably prudent person in the same or similar circumstances would have provided with respect to the danger and that communicates adequate information on the dangers and safe use of the product, taking into account the characteristics of, and the ordinary knowledge common to, the persons by whom the product is intended to be used, or in the case of prescription drugs, taking into account the characteristics of, and the ordinary knowledge common to, the prescribing physician. If the warning or instruction given in connection with a drug or device or food or food additive has been approved or prescribed by the federal Food and Drug Administration under the "Federal Food, Drug, and Cosmetic Act," 52 Stat. 1040, 21 U.S.C. § 301 et seq. or the "Public Health Service Act," 58 Stat. 682, 42 U.S.C. § 201 et seq., a rebuttable presumption shall arise that the warning or instruction is adequate. For purposes of this section, the terms "drug", "device", "food", and "food additive" have the meanings defined in the "Federal Food, Drug, and Cosmetic Act."

N.J. Stat. § 2A:58C-4.

North Dakota:

There is a rebuttable presumption that a product is free from any defect or defective condition if the plans, designs, warnings, or instructions for the product or the methods and techniques of manufacturing, inspecting, and testing the product were in conformity with government standards established for that industry or if no government standards exist then with applicable industry standards, which were in existence at the time the plans, designs, warnings, or instructions for the product or the methods and techniques of manufacturing, inspecting, and testing the product were adopted.

N.D. Cent. Code § 28-01.3-09.

Ohio:

(A) Subject to divisions (D), (E), and (F) of this section, a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation as determined pursuant to division (B) of this section exceeded the benefits associated with that design or formulation as determined pursuant to division (C) of this section.

(B) The foreseeable risks associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:

> (1) The nature and magnitude of the risks of harm associated with that design or formulation in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
>
> (2) The likely awareness of product users, whether based on warnings, general knowledge, or otherwise, of those risks of harm;
>
> (3) The likelihood that that design or formulation would cause harm in light of the intended and reasonably foreseeable uses, modifications, or alterations of the product;
>
> (4) The extent to which that design or formulation conformed to any applicable public or private product standard that was in effect when the product left the control of its manufacturer;
>
> (5) The extent to which that design or formulation is more dangerous than a resonably prudent consumer would expect when used in an intended or reasonably foreseeable manner.

(C) The benefits associated with the design or formulation of a product shall be determined by considering factors including, but not limited to, the following:

> (1) The intended or actual utility of the product, including any performance or safety advantages associated with that design or formulation;
>
> (2) The technical and economic feasibility, when the product left the control of its manufacturer, of using an alternative design or formulation;

(3) The nature and magnitude of any foreseeable risks associated with an alternative design or formulation.

(D) An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction under section 2307.76 of the Revised Code concerning that unavoidably unsafe aspect.

(E) A product is not defective in design or formulation if the harm for which the claimant seeks to recover compensatory damages was caused by an inherent characteristic of the product which is a generic aspect of the product that cannot be eliminated without substantially compromising the product's usefulness or desirability and which is recognized by the ordinary person with the ordinary knowledge common to the community.

(F) A product is not defective in design or formulation if, at the time the product left the control of its manufacturer, a practical and technically feasible alternative design or formulation was not available that would have prevented the harm for which the claimant seeks to recover compensatory damages without substantially impairing the usefulness or intended purpose of the product.

Ohio Rev. Code Ann. § 2307.75.

Oklahoma:

A. In a product liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the formula, labeling, or design for the product complied with or exceeded mandatory safety standards or regulations adopted, promulgated, and required by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.

B. The claimant may rebut the presumption in subsection A of this section by establishing that:

1. The mandatory federal safety standards or regulations applicable to the product and asserted by the defendant as its basis for rebuttable presumption were inadequate to protect the public from unreasonable risks of injury or damage; or

2. The manufacturer, before or after marketing the product, withheld or misrepresented information or material relevant to the federal government's or agency's determination of adequacy of the safety standards or regulations at issue in the action.

Okla. Stat. tit. 76, § 57.2(A)-(B).

Tennessee:

Compliance by a manufacturer or seller with any federal or state statute or administrative regulation existing at the time a product was manufactured and prescribing standards for design, inspection, testing, manufacture, labeling, warning or instructions for use of a product, shall raise a rebuttable presumption that the product is not in an unreasonably dangerous condition in regard to matters covered by these standards.

Tenn. Code § 29-28-104(a).

Texas:

(a) In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product's formula, labeling, or design complied with mandatory safety standards or regulations adopted and promulgated by the federal government, or an agency of the federal government, that were applicable to the product at the time of manufacture and that governed the product risk that allegedly caused harm.

(b) The claimant may rebut the presumption in Subsection (a) by establishing that:

(1) the mandatory federal safety standards or regulations applicable to the product were inadequate to protect the public from unreasonable risks of injury or damage; or

(2) the manufacturer, before or after marketing the product, withheld or misrepresented information or material relevant to the federal government's or agency's determination of adequacy of the safety standards or regulations at issue in the action.

(c) In a products liability action brought against a product manufacturer or seller, there is a rebuttable presumption that the product manufacturer or seller is not liable for any injury to a claimant allegedly caused by some aspect of the formulation, labeling, or design of a product if the product manufacturer or seller establishes that the product was subject to pre-market licensing or approval by the federal government, or an agency of the federal government, that the manufacturer complied with all of the government's or agency's procedures and requirements with respect to pre-market licensing or approval, and that after full consideration of the product's risks and benefits the product was approved or licensed for sale by the government or agency. The claimant may rebut this presumption by establishing that:

(1) the standards or procedures used in the particular pre-market approval or licensing process were inadequate to protect the public from unreasonable risks of injury or damage; or

(2) the manufacturer, before or after pre-market approval or licensing of the product, withheld from or misrepresented to the government or agency information that was material and relevant to the performance of the product and was causally related to the claimant's injury.

(d) This section does not extend to manufacturing flaws or defects even though the product manufacturer has complied with all quality control and manufacturing practices mandated by the federal government or an agency of the federal government.

(e) This section does not extend to products covered by Section 82.007.

Tex. Civ. Prac. and Rem. Code § 82.008.

Utah:

(1) In any action for damages for personal injury, death, or property damage allegedly caused by a defect in a product, a product may not be considered to have a defect or to be in a defective condition, unless at the time the product was sold by the manufacturer or other initial seller, there was a defect or defective condition in the product which made the product unreasonably dangerous to the user or consumer.

(2) There is a rebuttable presumption that a product is free from any defect or defective condition where the alleged defect in the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were in conformity with government standards established for that industry which were in existence at the time the plans or designs for the product or the methods and techniques of manufacturing, inspecting and testing the product were adopted.

Utah Code § 78B-6-703.

Washington:

(1) Evidence of custom in the product seller's industry, technological feasibility or that the product was or was not, in compliance with nongovernmental standards or with legislative regulatory standards or administrative regulatory standards, whether relating to design, construction or performance of the product or to warnings or instructions as to its use may be considered by the trier of fact.

(2) When the injury-causing aspect of the product was, at the time of manufacture, in compliance with a specific mandatory government contract specification relating to design or warnings, this compliance shall be an absolute defense. When the injury-causing aspect of the product was not, at the time of manufacture, in compliance with a specific mandatory government specification relating to design or warnings, the product shall be deemed not reasonably safe under RCW 7.72.030(1).

Wash. Rev. Code Ann. § 7.72.050.

Wisconsin:

(1) Liability of manufacturer. In an action for damages caused by a manufactured product based on a claim of strict liability, a manufacturer is liable to a claimant if the claimant establishes all of the following by a preponderance of the evidence:

> (a) That the product is defective because it contains a manufacturing defect, is defective in design, or is defective because of inadequate instructions or warnings. A product contains a manufacturing defect if the product departs from its intended design even though all possible care was exercised in the manufacture of the product. A product is defective in design if 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 manufacturer and the omission of the alternative design renders the product not reasonably safe. A product is defective because of inadequate instructions or warnings only if 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 manufacturer and the omission of the instructions or warnings renders the product not reasonably safe.
>
> (b) That the defective condition rendered the product unreasonably dangerous to persons or property.
>
> (c) That the defective condition existed at the time the product left the control of the manufacturer.
>
> (d) That the product reached the user or consumer without substantial change in the condition in which it was sold.
>
> (e) That the defective condition was a cause of the claimant's damages.

. . .

(3) Defenses.

. . .

> (b) Evidence that the product, at the time of sale, complied in material respects with relevant standards, conditions, or specifications adopted or approved by a federal or state law or agency shall create a rebuttable presumption that the product is not defective.

. . .

(5) Time limit. In any action under this section, a defendant is not liable to a claimant for damages if the product alleged to have caused the damage was manufactured 15 years or more before the claim accrues, unless the manufacturer makes a specific representation that the product will last for a period beyond 15 years. This subsection does not apply to an action based on a claim for damages caused by a latent disease.

(6) Inapplicability. This section does not apply to actions based on a claim of negligence or breach of warranty.

Wis. Stat. § 895.047(1), (3)(b), (5), (6).

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