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IN THE SUPREME COURT OF PENNSYLVANIA

Docket No. 26 EAP 2021

MELISSA EBERT,

Plaintiff-Appellant,

v.

C.R. BARD, INC. and BARD PERIPHERAL VASCULAR, INC.,

Defendants-Appellees.

BRIEF OF AMICI CURIAE ELLA EBAUGH, SUZANNE EMMET, THE PENNSYLVANIA ASSOCIATION FOR JUSTICE, AND THE AMERICAN ASSOCIATION FOR JUSTICE

On certification from the United States Court of Appeals
for the Third Circuit, upon a certification petition
filed on June 24, 2021 in Docket No. 20-2139

Tobi L. Millrood
Immediate Past President
American Association for Justice
777 6th Street N.W., Suite 200
Washington, D.C. 20001
(202) 965-3500

Counsel for Amicus Curiae,
The American Association for Justice

Charles L. Becker
Ruxandra M. Laidacker
Kline & Specter, P.C.
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
(215) 772-1000

Counsel for Amicus Curiae,
Ella Ebaugh, Suzanne Emmet,
The Pennsylvania Association for Justice,
and The American Association for Justice

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STATEMENT OF INTEREST

Ella Ebaugh. Ms. Ebaugh is a 54 year-old woman living in York County, Pennsylvania. In 2005, she was diagnosed with stress urinary incontinence and urgency by her gynecologist. Her symptoms were mild and did not cause her pain, urethral or bladder dysfunction, or sexual dysfunction. In 2007, Ms. Ebaugh's gynecologist implanted her with pelvic mesh manufactured by Ethicon, Inc. to treat her stress urinary incontinence. The mesh caused Ms. Ebaugh to suffer significant life-long injuries, including erosion into her vagina, loss of bladder function, inability to have sexual relations, and ongoing pelvic pain.

In July 2013, Ms. Ebaugh filed suit against Ethicon. Her claims included negligence and strict liability under Pennsylvania law. *See Ebaugh v. Ethicon, Inc.*, Phila CCP, July Term 2013, No. 866. In September 2017, a jury returned a verdict that Ethicon was both negligent and strictly liable for Ms. Ebaugh's injuries. The jury awarded $7.1 million in compensatory damages and $50 million in punitive damages. Ethicon subsequently sought judgment as a matter of law on the basis that Pennsylvania law does not recognize a cause of action for strict liability against the manufacturer of an implanted medical device under comment k of the Restatement (Second) of Torts, Section 402A. Based on a reading of *Lance v. Wyeth*, 85 A.3d 434 (Pa. 2014), Ethicon also sought judgment on the basis that Pennsylvania law requires a plaintiff to plead and prove that a product is "too dangerous to be used by anyone" to establish a prima

facie case for negligence against a pharmaceutical or medical device manufacturer. The trial court upheld the jury's verdict in these regards.

The Superior Court of Pennsylvania heard oral argument on May 18, 2020 at docket number 463 EDA 2018. The parties reached a resolution in Ms. Ebaugh's case while appeal was pending and thus the Superior Court never decided these issues. While Ms. Ebaugh's case is resolved, Ms. Ebaugh personally retains a significant interest in these issues and writes to the Court from her perspective as an individual who has suffered catastrophic personal injury from a defective medical device. Her involvement underscores that whether and how Pennsylvania law permits strict liability or negligence claims against medical device manufacturers affects many people and many types of cases.

Suzanne Emmet. Ms. Emmet is a 58 year-old woman living in Lancaster, Pennsylvania. In 2006, she was diagnosed with stress urinary incontinence and pelvic organ prolapse by her gynecologist. Like Ms. Ebaugh, her symptoms were mild and did not cause her pain, urinary dysfunction, or sexual dysfunction. In 2007, Ms. Emmet's gynecologist implanted her with pelvic mesh manufactured by Ethicon to treat those issues. Like Ms. Ebaugh, she has suffered life-long injuries from the mesh, including mesh erosion into her vagina, chronic incontinence, recurrent urinary infections, inability to have sexual relations, and ongoing pelvic pain.

In July 2013, Ms. Emmet filed suit against Ethicon. Her claims included strict liability under Pennsylvania law. *See Emmet v. Ethicon, Inc.*, Phila CCP, July Term 2013,

No. 1495. In January 2019, a jury returned a verdict that Ethicon was strictly liable for Ms. Emmet's injuries. The jury awarded $15 million in compensatory damages and $25 million in punitive damages to Ms. Emmet, and $1 million to Mr. Emmet for loss of consortium. As in *Ebaugh*, Ethicon argued in post-trial motions and on appeal that Pennsylvania law does not recognize a cause of action for strict liability against the manufacturer of an implanted medical device under comment k. Federal court decisions concerning Pennsylvania law figured consistently in the briefing. The trial court rejected Ethicon's argument.

On appeal, the Superior Court heard oral argument on July 14, 2020 at docket number 1078 EDA 2019. As with Ms. Ebaugh, the parties resolved Ms. Emmet's claim while the appeal was pending and thus the Superior Court had no opportunity to issue a decision. Like Ms. Ebaugh, Ms. Emmet retains a significant interest in these issues and writes to the Court from her perspective as an individual who has suffered catastrophic personal injury from a defective medical device. As with Ms. Ebaugh, her involvement underscores that whether and how Pennsylvania law permits strict liability claims against medical device manufacturers affects many people and many types of cases.

The Pennsylvania Association for Justice. The Pennsylvania Association for Justice is a non-profit organization with a membership of over 2,000 men and women of the trial bar of the Commonwealth of Pennsylvania. Since 1968, the Association has promoted the rights of individual citizens by advocating the right to trial by jury, full

and just compensation for innocent victims, and the maintenance of a free and independent judiciary. The certified questions concern the basic parameters of Pennsylvania's negligence and strict liability law in the context of medical device litigation. As such, the certified questions vitally affect the Association, its members' clients and every citizen of Pennsylvania.

The American Association for Justice. The American Association for Justice (the "AAJ") is a voluntary national bar association whose trial lawyer members practice in every state, including Pennsylvania. AAJ was founded in 1946 to safeguard access to the courts for workers and consumers to seek legal recourse when they have been wrongfully injured. AAJ appreciates the importance of the certified questions to the basic structure of Pennsylvania tort law and recognizes that this Court's answer to the certified questions will profoundly shape the ability of injured persons to seek redress for injuries caused by defective medical devices under Pennsylvania law.[1]

ARGUMENT

When granting summary judgment on the plaintiff's strict liability claim, the district court reasoned that (a) Pennsylvania law would immunize a medical device manufacturer under the reasoning of the Restatement (Second) of Torts, Section 402A, comment k, if the subject device was "unavoidably unsafe" within the meaning of

[1] No one other than the *amicus curiae*, its members or counsel and her law firm paid in whole or in part for the preparation of the *amicus curiae* brief or authored in whole or in part the *amicus curiae* brief.

comment k; and (b) as a matter of law, the implanted device here met comment k's definition of "unavoidably unsafe." *See Ebert v. C.R. Bard*, 459 F. Supp. 3d 637, 651-52 (E.D. Pa. 2020). The district court additionally reasoned that this Court's decision in *Lance* required that a plaintiff could assert a valid negligence claim against a medical device manufacturer only if the plaintiff could prove that the manufacturer knew or should have known that the device was "so dangerous that it should not be taken by anyone." *Id.* at 644. Under this reading of Pennsylvania law, a medical device manufacturer is immune from negligence except within the precise factual formulation averred in *Lance*.

The Third Circuit now has certified two questions for this Court's review:

> 1. Under Pennsylvania law, must a plaintiff bringing a negligent design claim against a prescription medical device manufacturer prove that the device was too harmful to be used by anyone, or may the plaintiff also prevail on other theories of liability where appropriate?
>
> 2. Under Pennsylvania law, are prescription implantable medical devices categorically subject to strict liability, categorically immune from strict liability, or immune from strict liability on a case-by-case basis? If they are immune on a case-by-case basis, what test should a court apply to determine whether a particular device is immune?

As to the first question, the answer is no. Under Pennsylvania law, an entity must exercise reasonable care when designing a product. This duty applies generally, including as to entities that are medical device manufacturers. Such manufacturers do not have special exemptions from Pennsylvania tort law. They are not entitled to common-law immunity from negligence claims sounding in design defect, whether

under the nomenclature of "immunity" or under an industry-specific construction of negligence law that states the duty of such manufacturers in narrower terms than exist generally in Pennsylvania law. These manufacturers have the same duties as everyone else. And hence a plaintiff may pursue a negligence claim against a medical device manufacturer with the same latitude that any plaintiff may pursue any negligence claim against any defendant. Whether the defendant will be liable or not liable will depend on the facts and evidence, of course. And certainly a plaintiff *may* pursue a negligence claim on evidence that the medical device is "too harmful to be used by anyone," as plaintiff did in *Lance*. But such averments do not define the outer limits of a cognizable negligence claim against a medical device manufacturer.

As to the second question, medical devices and their manufacturers are not immune from strict liability. Pennsylvania cases make clear that all entities are capable of being held responsible for their mistakes and that no judge-made immunities exist as a threshold matter. Of course, whether a medical device manufacturer is actually liable under a theory of strict liability will depend on the facts on the individual case. So liability always will be determined case-by-case depending on the unique facts presented. But Pennsylvania law does not immunize medical device manufacturers as a threshold matter—not from strict liability, or not from any other species of tort theory.

I. Pennsylvania law does not immunize medical device manufacturers from strict liability claims.

A. No immunity for medical device manufacturers.

Amici address the second question first. The starting point for any argument that medical device manufacturers are immune from strict liability claims under Pennsylvania law is *Hahn v. Richter*, 673 A.2d 888 (Pa. 1996). In *Hahn*, the plaintiff presented with back pain to his physician, who treated the pain with spinal injection of Depo-Medrol. The Depo-Medrol label advised about reports of scarring following spinal injection. The plaintiff developed this scarring. When the physician removed the scar tissue, he severed a nerve root. The plaintiff sued the physician and resolved the malpractice claim. He separately filed negligence and strict liability claims against the drug manufacturer sounding in failure-to-warn. During trial, the trial court declined to instruct the jury on strict liability for failure-to-warn. The jury found for the defendant. *Id.* at 889. The Superior Court affirmed in an *en banc* decision. The plaintiff sought further review.

This Court also affirmed the judgment in a 3-2 decision. The majority reasoned that "where the adequacy of warnings associated with prescription drugs is at issue, the failure of the manufacturer to exercise reasonable care to warn of dangers, *i.e.*, the manufacturer's negligence, is the only recognized basis of liability." *Id.* at 891. For this negligence-only proposition, the majority relied largely on comment k of Section 402A of the Restatement (Second) of Torts, a publication of the American Law Institute. *Id.*

In comment k, the American Law Institute expressed skepticism about allowing strict liability under design-defect theory for products that, "in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use." Restatement (Second) of Torts § 402A, comment k (1965). The Institute reasoned that such products are "especially common in the field of drugs," which may have great social utility but may lead to serious and damaging consequences in some patients. *Id.* In comment k, the Institute identified the rabies vaccines as a product that may lack complete assurance of safety such that a finding of product defect would be inappropriate because of the particular characteristics of that vaccine. The comment suggested that similar vaccines or drugs likewise should not be found defective. Nothing in the comment suggests that the Institute saw itself as inviting a common-law or statutory immunity on design defect claims in favor of the drug or vaccine industry as a categorical matter, or any other industry.

Justice Cappy dissented in *Hahn*, joined by Justice Castille, reasoning that the majority's decision immunized drug manufacturers from strict liability failure-to-warn claims without appropriate consideration of an important competing policy. Justice Cappy wrote that by immunizing drug manufacturers, "the majority has thrust the expense of defective prescription drugs onto those whom these products were supposed to aid. In essence, the majority's holding has created a class of unpaid guinea pigs. I find this to be unconscionable." *Hahn*, 673 A.2d. at 891 (Cappy, J., dissenting, joined by Castille J.).

In *Tincher v. Omega Flex, Inc.*, 104 A.3d 328 (Pa. 2014), the *Hahn* dissent shifted into the mainstream of Pennsylvania law through an opinion authored by Chief Justice Castille. *Tincher* embraced the *Hahn* dissent's premises that strict liability plays a valuable role in deterring wrongdoing by product manufacturers and that such manufacturers should not be exempt from the risk of strict liability simply by virtue of the category of defendant or type of product at issue. *Id.* at 404. A fact-finder instead must determine whether the product subject to suit is in fact "defective" pursuant to the facts presented in evidence, rather than have that matter determined as an *a priori* matter.

Working from these premises, the Supreme Court rejected an argument that proof of alternative design was required to prove strict liability sounding in design defect. The Court reasoned that an alternative-design requirement amounted to judicially-created "categorical exemptions for some products—such as novel products with no alternative design—but not others." *Id.* at 395. In reaching its anti-immunity conclusion, *Tincher* ratified a core premise of Pennsylvania law that every person is capable of being held liable for its misconduct based on the facts and circumstances presented, absent a legislatively-created immunity. As the Court explained, "[i]mmunity or exemption from liability is the exception to the general rule that an entity must meet the obligations it incurs in functioning." *Id.* at 396, quoting *Scampone v. Highland Park Care Center*, 567 A.3d 582, 599 (Pa. 2012).

The Court referred questions concerning tort immunity to the legislature, explaining that a court addresses evidence in individual cases and is "neither positioned,

nor resourced, to make the kind of policy judgments required to arrive at an *a priori* decision as to which individual products, or categories and types of products, should be exempt." *Id.* Unless the legislative branch has created a specific statutory immunity, "the default general rule of possible liability operates." *Id.* The Court stated that any question of "special tort-insulated status" for manufacturers "requires an assessment and balancing of policies best left to the General Assembly." *Id.*

Tincher repudiates *Hahn*'s premise that the judiciary may exempt a class of manufacturers from tort liability. It also destroys any notion that the American Law Institute or the Restatements occupy a privileged place capable of driving dramatic course deviations in Pennsylvania law. As this Court explained, the American Law Institute is a private organization that develops and publishes the Restatements of the Law. The Court has "adopted" some Restatement provisions as offering accurate descriptions of Pennsylvania law when "the cause of action and its contours are consistent with the nature of the tort and Pennsylvania's traditional common law formulation." *Id.* But even when "adopted," Restatements provisions are not "controlling in the manner of a statute." *Id.* at 354. They are not substitutes for common-law reasoning by an independent judiciary. They do not decide individual cases and do not anoint "winners" or "losers" regarding particular conduct under Pennsylvania law. *Id.* at 396. And as the Court has further made clear, no "adoption" of a Restatement provision may be viewed as derogating judicial or law-making authority to the American Law Institute. *Id.* Simply put, Pennsylvania courts define

Pennsylvania's common law. *Id.* at 354; *see also Harrison v. Cabot Oil & Gas Corp.*, 110 A.3d 178, 185-86 (Pa. 2015) (refusing to "diminish" the plaintiffs' contractual rights under Pennsylvania law based on arguments about different law in other states).

Tincher also emphasized that judicial decisions must be read against their facts to prevent "wooden application of abstract principles to circumstances in which different considerations may pertain." *Tincher*, 104 A.3d at 356, quoting *Scampone*, 57 A.3d at 605. Given *Tincher*'s framing of the applicable principles, especially its rebuke of judicially-created immunity, perhaps *Hahn* could be read as supporting immunity in a case involving facts that are precisely the same as those presented in *Hahn* itself. But if *Hahn* can extend beyond its facts, it cannot extend very far. For purposes of this case, the salient point is that *Hahn* did not involve strict liability design-defect claims at all. It did not involve claims against device manufacturers. It did not even contemplate (let alone announce) a common-law rule immunizing device manufacturers from strict liability. These considerations militate against reading *Hahn* as announcing immunity for an entirely different industry, class of products, and legal theory than addressed in *Hahn*.

Tellingly, this Court has never applied *Hahn*'s holding to strict liability claims against medical device manufacturers. For example, in *Beard v. Johnson & Johnson,* 41 A.3d 823 (Pa. 2012), the plaintiff brought a strict liability claim sounding in design defect against Johnson & Johnson as manufacturer of a surgical instrument. The plaintiff won at trial. On appeal, the Supreme Court addressed certain factors affecting the risk-utility analysis but did not question the threshold availability of the claim. *Id.* at 848. The Court

implicitly acknowledged the viability of a strict liability claim involving a medical device. *Id. Beard* underscores that whatever force *Hahn* may retain within its particular factual landscape, it has none in a different landscape of medical device claims that *Hahn* never addressed.

Any notion that *Hahn* compels immunity in the medical device, strict liability landscape is further undermined by this Court's decision in *Lance v. Wyeth*. In *Lance*, a pharmaceutical case, the defense argued that Pennsylvania common law immunized drug manufacturers from negligence claims sounding in design defect under comment k. The Court rejected the defense's invitation based on a formulation of the American Law Institute to generally immunize drug manufacturers under Pennsylvania law. In particular, the Court explained that it had not immunized drug companies from Pennsylvania's negligence law and that the drug manufacturers remained subject to the "entire continuum" of negligence duties that Pennsylvania law imposes on such manufacturers. *Lance*, 85 A.3d at 459-60. The Court would not use policy considerations to "scale back the existing duty of pharmaceutical companies." *Id.* at 454-55. The Court added that comment k was not "a model of clarity" and that it could not be considered beyond the scenario presented therein. *Id.* at 451. *Lance*'s rejection of comment k underscores the necessity to limit *Hahn* to its facts.

Tincher, *Scampone*, and *Lance* make clear that Pennsylvania does not *a priori* immunize medical device manufacturers from strict liability. *Tincher* held that "no product is expressly exempt" from strict liability and that "the presumption is that strict

liability may be available with respect to any product, provided that the evidence is sufficient to prove a defect." *Tincher*, 104 A.3d at 382. The Court added that "categorical exemptions" from tort liability exist only where "the General Assembly has acted to create explicit policy-based immunities." *Id.* at 395-96. This result is strengthened by *Lance*, where the Court agreed that exemptions to liability in Pennsylvania are "legislative-type judgments" requiring information that is "better considered in that branch." *Lance*, 85 A.3d at 456. It is further strengthened by the Court's decision in *Scampone*, which described the principle of Pennsylvania tort law that "an entity must meet the obligations it incurs in functioning" and further disavowed common-law immunity. *Scampone*, 57 A.3d at 599.

Especially in the face of *Tincher*, *Scampone*, and *Lance*, the Superior Court should not be viewed as having created a categorical immunity in favor of medical device manufacturers in *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. 2006). *Creazzo* involved an implantable electrical pulse generator, the "Itrel 3," used to alleviate pain by passing a stimulus through nerves in the spinal cord. In February 2002, plaintiff filed a complaint alleging that his Itrel 3 failed and asserting strict liability claims sounding in failure-to-warn and manufacturing defect. After suit commenced, the plaintiff underwent surgery to remove the device. The plaintiff did not take steps to preserve the device, which was discarded. The trial court dismissed the entire case on spoliation grounds. It also ruled that the learned intermediary doctrine barred the strict liability

claim sounding in failure-to-warn, and that such claim was not recognized under comment k. The plaintiff filed a *pro se* appeal.

The Superior Court affirmed on spoliation grounds. *Id.* at 26-31. Having already affirmed on spoliation grounds, the Court added that comment k barred plaintiff's strict liability claim. Using *Hahn* as a reference point, the Court reasoned that "[c]omment k excludes certain products from the definition of 'unreasonably dangerous' used in section 402A on the basis that they are incapable of being made safe for their intended use, but are useful nonetheless." *Id.* at 30. The Court further reasoned that the Itrel 3 had potential utility; the *pro se* plaintiff had not significantly analyzed comment k in its brief; and the *pro se* plaintiff had not cited authority that comment k did not apply to medical devices. Under these conditions, the Court found "no reason" why the *Hahn* rationale "may not be applied to medical devices." *Id.*

Creazzo's casual suggestion that *Hahn* immunizes medical device manufacturers is probably dicta given the spoliation analysis that completely resolved the case. *Id.* at 31. In any event, the Superior Court offered no indicia that it viewed the decision as announcing a sweeping immunity applicable to a large sector of America's manufacturing industry. No other case has accorded such respect to *Creazzo* or even remotely suggested it could stand for that proposition.

Even in the instant case, the district court gave "little persuasive weight" to *Creazzo* given that the decision "is supported by scant reasoning and in the fourteen years since *Creazzo*, the Pennsylvania Supreme Court has not relied on it." *Ebert*, 459 F.

Supp. 3d at 652. The district court's skepticism toward *Creazzo* is especially appropriate where this Court has held repeatedly that judge-made immunity is simply inconsistent with the judiciary's role in the constitutional system. *Tincher*, 104 A.3d at 396 (immunity is legislative decision). *Lance*, 85 A.3d at 456 (same); *Scampone*, 57 A.3d at 599 (same).

The Court's reasoning on that issue has been consistent and unambiguous. The Court's decisions make clear that medical device manufacturers are not immune from strict liability. They are not categorically immune. Or immune on a case-by-case basis. They are never immune. Instead, they get the same deal that every product manufacturer gets under Pennsylvania's strict liability law: the plaintiff can seek to prove strict liability based on defect in the product, and whether the manufacturer is liable will vary case-by-case depending on the evidence. In other words, a medical device manufacturer is capable of being held liable based on the facts of the case. It is not immune based on its status as a manufacturer of a particular product. If a plaintiff's evidence is not sufficient to prove defect then, as in any other case, a court may enter judgment as a matter of law for the defendant. *Tincher*, 104 A.3d at 407.

In the end, Pennsylvania law has not provided—and should not provide—that medical device manufacturers are immune from strict liability claims as a threshold proposition. There may be any number of reasons that a medical device manufacturer ultimately is not *liable* in a strict liability case. Immunity is not one of them.

B. The district court got it wrong.

Amici appreciate that this case lies before the Court on certified questions from the Third Circuit and thus that the Court is not squarely looking at the district court's grounds for summary judgment. Amici respectfully suggest that some useful perspective is gained by considering the distinction attempted by the district court between categorical immunity for medical devices and case-by-case immunity depending on the characteristics of the medical device at issue.

The district court reasoned that although medical device manufacturers are not categorically immune from strict liability, they are immune when the medical device is "unavoidably unsafe" as that term is used in comment k—i.e., the device is "quite incapable of being made safe for [its] intended and ordinary use." Restatement (Second) of Torts § 402A, comment k (1965). In turn, the district court decided that the product at issue here was "unavoidably unsafe" and hence that immunity applied. *See Ebert*, 459 F. Supp. 3d at 651-52. This was wrong for two reasons.

First, in deciding that Pennsylvania law would immunize medical device manufacturers from strict liability on a case-by-case basis, depending on whether the medical device fell within the ambit of comment k, the district court fashioned a difference that is meaningless from the standpoint of Pennsylvania law's prohibition against status-based categorical immunity. Almost by definition, no device physically implanted within the human body is perfectly safe for every person. It carries at least some unavoidable degree of risk. That is why the FDA regulates implanted medical

devices. Suggesting that Pennsylvania law immunizes medical device manufacturers based on the existence of some generic risk associated with the device (here, an inferior vena cava filter—obviously a device where risk-benefit considerations must be carefully assessed) creates categorical immunity by another name. No actual difference exists between an *a priori* immunity and one that depends on whether a medical device carries some risks.

In effect, the district court converted comment k into an element of a strict liability tort under Pennsylvania law. Plaintiff always must establish a *prima facie* case of duty, breach, causation, and damages to reach the jury in strict liability claims. *See Tincher*, 104 A.3d at 384-91 (reviewing the elements of the strict liability tort under Pennsylvania law). And under the district court's reasoning, plaintiffs pursuing strict liability claims must also establish a *prima facie* case that the subject device is not "unavoidably unsafe"—a fifth element never before recognized by this Court.

This additional element emphatically is not part of Pennsylvania law. A core holding of *Tincher* was that Pennsylvania law did not contain an additional requirement of showing alternative feasible design. A plaintiff's burden of proof is the same regardless of the consumer product at issue. This Court specifically rejected the invitation to anoint special "winners" or "losers" depending on the nature of the product. *Id.* at 394-96. Having rejected an additional element to strict liability in *Tincher*, the Court did not silently impose one through a silent "adoption" of comment k as to medical devices. This is especially true given this Court's categorical rejection of status-

based immunity for strict liability claims and its blunt assessment that pronouncements of the American Law Institute do not drive Pennsylvania law. *Id.* at 353-54.

Tincher also made clear that Restatement provisions are "not controlling in the manner of a statute." *Id.* at 354. In establishing comment k (not even the Restatement provision itself) as an element for establishing a *prima facie* case for strict liability, the district court envisioned comment k as imposing a legal standard that could be interpreted and applied to control outcomes under Pennsylvania law. It did the opposite of what this Court said Pennsylvania law requires.

It is also important to understand that comment k is an illustration of Section 402B and not a separate requirement that a plaintiff must plead and prove to establish liability for a defective pharmaceutical or a medical device. Where a plaintiff pleads and proves a specific design defect in the product, the analysis is focused on the risks and utility or consumer expectations concerning the particular aspect of the design that caused the injury. *Id.* at 390 ("[T]he issue properly litigated almost always concerns the narrow 'micro-balance' of pros and cons of a manufacturer's failure to adopt some particular design feature that would have prevented the plaintiff's harm."). Comment k is an illustration focused on whether a product is "unavoidably unsafe" where the complained-of defect is concerned. Thus, while an inferior vena cava filter carries some unavoidable risks generally, a manufacturer whose design could have been improved to avoid a particular risk, and that risk came to fruition and injured plaintiff, the manufacturer may nevertheless be liable for the injury. And whether the design of a

medical device should have been improved to avoid injury is subject to expert testimony and not an *Azzarello*-type policy call by the trial court within the rubric of comment k. As *Tincher* explained, "trial courts simply do not necessarily have the expertise to conduct the social policy inquiry into the risks and utilities of a plethora of products and to decide, as a matter of law, whether a product is unreasonably dangerous except perhaps in the most obvious of cases (*e.g.*, where injury is caused by a knife), where a gate-keeper's function is hardly necessary." *Id.* at 379-80.

If comment k represents an element of the strict liability tort in the specific context of medical device claims, the normal rules of summary judgment still apply. Any evidence must be considered in the light favorable to the non-moving party, with all inferences taken in the non-moving party's favor. *See Scott v. Harris*, 550 U.S. 372, 379 (2007). Here, the district court "conclude[d]" that the filter was "unavoidably unsafe" as a matter of law. *Ebert*, 459 F. Supp. 3d at 651-52. In effect, the district court reached a legal conclusion without reviewing the evidence in the light favorable to the plaintiff, which in this context would require giving full consideration to the *defendant's* expert reports and perspective on the evidence (which insist that the product is perfectly safe). That odd result flows from the district court's insisting that a plaintiff must be able to prove that a product is *not* unavoidably unsafe as a precondition for being able to prove the traditional elements of duty, breach, causation, and damages. One does not normally think of summary judgment having to proceed from a *defendant's*

perspective on the evidence. But that is the inevitable result of the district court's incorrect reading of Pennsylvania law.

The district court never considered the practical implications of its ruling: medical device manufacturers can be strictly liable for products carrying no risk, but are immune from strict liability for products that bear risks no matter how poorly designed or how insufficient the warnings. This outcome cannot be squared with this Court's decisions, which repeatedly frown upon common-law immunity. Under Pennsylvania law, there are no threshold immunities for strict liability claims—not under comment k, not under anything. What remains is litigating cases based on their facts. That is as it should be, especially in a state that constitutionally guarantees the right to seek a remedy. *See* PA. CONST. art I, Sec. 11.

II. Pennsylvania law does not immunize medical device manufacturers from negligence claims under any circumstance, whether those circumstances pled in *Lance* or others.

The Third Circuit has asked whether a plaintiff asserting a negligence claim sounding in design defect against a medical device manufacturer has a valid claim only when the plaintiff can prove that the device was "too harmful to be used by anyone." The high burden of such standard on a plaintiff is evident: a defendant may escape liability for a terrible product by producing one witness who was not (yet) been harmed by it. This is immunity by another name, and it is not Pennsylvania law. As general matter, Pennsylvania negligence law does not confine a plaintiff's negligence claim to any specific pleading and proof formulations. The question is whether there is

something about medical device litigation such that a negligence claim can proceed against a medical device manufacturer only if the claim fits within a precise factual landscape—a condition that would be unique in Pennsylvania law.

The question is answered in the negative on foundational legal principles as well. As noted above, Pennsylvania's negligence law begins with the general rules that "an entity must meet the obligations it incurs in functioning," that immunity from negligence liability represents a strict exception from that general rule, and that a defendant is not immune from negligence absent a specific legislative declaration of immunity. *See Scampone*, 57 A.3d at 599. Pennsylvania law thus frowns on "categorical exemptions from liability" and especially disfavors immunity by "judicial fiat." *Id.* Indeed, this Court has specifically rejected "any entreaty to carve out a special tort-insulated status" for individual categories of tort defendants under common-law reasoning. *Id.* "[T]he question of tort insulation requires an assessment and balancing of policies best left to the General Assembly." *Id.* Absent action by the General Assembly or another express declaration of immunity, "the default general rule of possible liability operates." *Id.*

Of course, the General Assembly has enacted immunity from negligence claims in favor of the Commonwealth and local subdivisions. *See* 42 Pa.C.S. §§ 8522(a), 8542(a). It has not erected immunity for medical device manufacturers.

The question now arises whether this Court's decision in *Lance* created such an immunity with respect to medical device manufacturers unless the plaintiff's negligence

claim fits within a specific factual formulation. A review of *Lance*'s facts and procedural posture help answer the question.

In *Lance*, Wyeth marketed Redux for use as a weight-loss drug with a warning of increased risk of pulmonary hypertension. In early 1997, Ms. Lance ingested Redux. Several months later, following news reports that Redux caused coronary impairment, Wyeth withdrew Redux from the market. In 2004, Ms. Lance died from pulmonary hypertension. *See Lance*, 85 A.3d at 436-37. Ms. Lance's mother sued Wyeth for negligence sounding only in design defect. The complaint alleged that Wyeth owed a duty "not to introduce onto the market a drug that was unreasonably dangerous for any person to use." *Id.* at 437. It alleged that Redux was "so unreasonably dangerous and defective in design that it should never have been on the market." *Id.* Wyeth moved for summary judgment on grounds that pharmaceutical companies were immune under Pennsylvania law from allegations that a drug was defectively designed such that it should not have been sold at all. The trial court granted summary judgment.

The Superior Court reversed and found that Ms. Lance had a cognizable claim for negligence sounding in design defect. This Court affirmed the reversal of summary judgment. The Court characterized Wyeth as advocating immunity for pharmaceutical companies "even for a patent lack of due care so deleterious as to create an untenable threat to human health." *Id.* at 449-50. Referencing *Hahn*, *supra*, the Court noted that "while this Court has declined to extend strict liability into the prescription drug arena, it simply has not immunized drug companies from other governing aspects of

Pennsylvania tort law delineating product-manufacturer duties and liabilities." *Id.* at 453. The Court affirmed that pharmaceutical companies have an "existing duty… to independently and vigilantly protect against unreasonable health risks which may be posed by products made for human consumption." *Id.* at 454-55. The Court added that Pennsylvania law imposed a continuum of duties on pharmaceutical manufacturers, ranging from adequate warnings to discontinuing a drug when the product simply should not be used. *Id.* at 459-60. This "entire continuum is within the scope of the general framework of the applicable duty of care." *Id.* The Court rejected the invitation "to scale back the existing duty of pharmaceutical companies." *Id.* at 454-55.

When validating Ms. Lance's negligence claim, the Court did not limit claims for negligence sounding in design defect to *Lance*'s facts. To the contrary, the Court's starting point was that pharmaceutical companies (like everyone else) must exercise care and that they are potentially liable for their conduct. The Court refused to "scale back" the tort duties owed by pharmaceutical companies. It refused to place pharmaceutical companies on a different footing relative to the rest of the world concerning tort law. *Id.* at 459-60. Had the Court created a limited immunity in that circumstance (which it did not), *Lance* still would be confined to its facts given Pennsylvania's emphatic default rules favoring non-immunity. *See Scampone*, 57 A.3d at 599; *Maloney v. Valley Med. Facilities, Inc.*, 984 A.2d 478, 486 (Pa. 2009). So it bears reminding that *Lance* was not a medical device case. It did not comment on medical devices. It did not immunize device manufacturers under any circumstances.

The certified question invites this Court to consider whether the facts pled in *Lance* represent the only facts that could support liability under Pennsylvania law in a negligence claim sounding in design defect against a medical device manufacturer, despite the absence of any language in *Lance* that would justify that narrow outcome and despite specific language in *Lance* refusing to "narrow" tort duties under Pennsylvania law. *Lance*, 85 A.3d at 459-60. The Court should decline the invitation to immunize medical device manufacturers under a radical rewrite of *Lance*. It must decline the invitation under *Lance* and *Scampone*.

CONCLUSION

The Court should answer the certified questions so as to make clear that the architecture of Pennsylvania law is as open with respect to claims involving medical device manufacturers as it is for any other kind of tort defendant. The Court should make equally clear that common-law immunities are disfavored and disapproved and that medical device litigation contains no special exemption from the general principles of Pennsylvania law.

Thus, as to the first question, the Court should explain as follows: Under Pennsylvania law, a plaintiff asserting a negligent design claim against a medical device manufacturer has the burden to prove that the manufacturer deviated from the standard of care, and that its negligence was a substantial factor in causing plaintiff's harm. As in any case, a plaintiff may prevail on negligence in a range of factual circumstances. These include, without limitation, factual circumstances where the device is too harmful to be

used by anyone. But medical device litigation does not circumscribe or narrow the general principles of Pennsylvania law that are described in *Scampone* and *Tincher*. A manufacturer's duty is not narrower in medical device litigation as compared to other kinds of litigation. Medical device manufacturers are not entitled to immunity from negligence claims sounding in design defect under any circumstances, whether those circumstances pled in *Lance* or others. The suggestion otherwise mistakes the facts pled in a single case for the outer parameters of Pennsylvania's law of negligence.

And as to the second question, the Court should explain as follows: Under Pennsylvania law, manufacturers of prescription implantable medical devices are subject to strict liability just as other manufacturers of other products are subject to strict liability. Of course, whether a manufacturer will actually be subject to liability in a given case will depend on the facts of the case. Any outcome ranging from preliminary dismissal to a jury verdict in the plaintiff's favor may eventuate based on the facts. But the manufacturers of medical devices are not immune from strict liability as a threshold matter—not categorically, not on a case-by-case basis, not on any basis whatsoever. Each case will produce an outcome on liability or non-liability depending on the facts. But no judge-created immunity exists as a threshold matter with respect to strict liability claims involving medical devices.

Respectfully submitted,

By: /s/ Charles L. Becker
Charles L. Becker
Identification No. 81910
Kline & Specter, P.C.
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
(215) 772-1000

By: /s/ Ruxandra M. Laidacker
Ruxandra M. Laidacker
Identification No. 206908
Kline & Specter, P.C.
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
(215) 772-1000

Attorneys for Amici Curiae Ella Ebaugh, Suzanne Emmet, the Pennsylvania Association for Justice, and The American Association for Justice

By: /s/ Tobi L. Millrood
Tobi L. Millrood
Identification No. 77764
Immediate Past President
American Association for Justice
777 6th Street N.W., Suite 200
Washington, D.C. 20001
(202) 965-3500

Counsel for Amicus Curiae The American Association for Justice

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CERTIFICATE OF WORD COUNT

I certify that this brief includes 6,469 words as calculated with the word-counting feature of Microsoft Office, excluding the materials specified in Pa.R.A.P. 2135(b).

By: /s/ Charles L. Becker
Charles L. Becker
Kline & Specter, P.C.
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
(215) 772-1000

Dated: September 28, 2021

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I certify that this filing complies with the provisions of the Public Access Policy of the Unified Judicial System of Pennsylvania: Case Records of the Appellate and Trial Courts that require filing confidential information and documents differently than non-confidential information and documents.

/s/ Charles L. Becker

Charles L. Becker
Identification No. 81910
Kline & Specter, P.C.
1525 Locust Street, 19th Floor
Philadelphia, PA 19102
(215) 772-1000

Dated: September 28, 2021

CERTIFICATE OF SERVICE

I served the foregoing brief on the following counsel through the Court's electronic filing system and via U.S. mail, postage prepaid:

Richard B. North, Jr.
Michelle W. Johnson
Matthew E. Brown
Nelson Mullins Riley & Scarborough LLP
Atlantic Station
201 17th Street NW, Suite 1700
Atlanta, GA 30363

William J. McDonough
Debra A. Djupman
Reed Smith
1717 Arch Street
Three Logan Square, Suite 3100
Philadelphia, PA 19103

Andrew J. Trevelise
O'Brien Firm
325 Chestnut Street, Suite 1320
Philadelphia, PA 19106

Howard J. Bashman
2300 Computer Avenue, Suite G-22
Willow Grove, PA 19090

Michael S. Katz
Lopez McHugh
214 Flynn Avenue
Moorestown, NJ 08057

Ben C. Martin
Martin & Baughman
3141 Hood Street, Suite 600
Dallas, TX 75219

/s/ Charles L. Becker

Dated: September 28, 2021 Charles L. Becker