[J-29-2011]
IN THE SUPREME COURT OF PENNSYLVANIA
WESTERN DISTRICT

CASTILLE, C.J., SAYLOR, EAKIN, BAER, TODD, McCAFFERY, ORIE MELVIN, JJ.

JEFFREY K. BEARD, AS ADMINISTRATOR OF THE ESTATE OF SANDRA L. SELEPEC, DECEASED,	:	No. 35 WAP 2010
Appellant	:	Appeal from the Order of the Superior Court entered October 23, 2009 at No. 925 WDA 2008 reversing the Judgment of the Court of Common Pleas of Allegheny County entered May 13, 2008 at GD 04-17685.
v.	:	
JOHNSON AND JOHNSON, INC.; ETHICON, INC., A SUBSIDIARY COMPANY OF JOHNSON AND JOHNSON, INC.; ETHICON ENDO-SURGERY, INC., A SUBSIDIARY COMPANY OF JOHNSON AND JOHNSON, INC.; CARDINAL HEALTH, INC., T/D/B/A CARDINAL HEALTH; AND CARDINAL HEALTH 414, INC., T/D/B/A CARDINAL HEALTH,	:	ARGUED: April 13, 2011
Appellees	:	

OPINION

MR. JUSTICE SAYLOR **DECIDED: MARCH 22, 2012**

This appeal arises out of a medical-device product liability action in which a strict-liability, design-defect theory was asserted. Given that the surgical instrument in issue is said to have multiple applications, we are asked to determine whether a trial court's threshold risk-utility analysis should be limited to the particular one alleged to have

caused the plaintiff harm. Additionally, appeal was allowed to consider the degree to which an appellate court is bound by such weight and credibility determinations as may be made by a trial court in a risk-utility assessment.

By way of background, the pertinent medical device is a linear cutting and stapling instrument, used in place of traditional scalpel-and-suture techniques in various surgical applications. In highly simplified terms, the elongated device consists of: a hand-held control mechanism resembling a pistol grip; a thin shaft; and a compact, distal-end jaw. This jaw incorporates compression, cutting, and stapling features useful in transecting organ tissue, while seaming and sealing resultant segments. Through a cartridge inserted into the jaw, linear, parallel rows of staples are fired into compressed tissue on both sides of the blade during incision, ideally leaving the divided and seamed tissue ends hemostatic (or not bleeding). This process is repeated, as needed, to form longer staple-line seams.

The decedent, Sandra Selepec, underwent gastric bypass surgery in August 2002. As part of the procedure, her stomach was transected to create a smaller stomach pouch. The surgeon used a product manufactured by Ethicon Endo-Surgery, Inc. ("Appellee"), known as an ETS-Flex45 Articulating Endoscopic Linear Cutter, or an "endocutter," as described above. As is apparent from its name and shape, the instrument was designed for use in endoscopic surgery (less invasive procedures accomplished through small incisions in which a magnifying camera, a light source, and surgical instruments are inserted).[1] However, Appellee also marketed its product as

[1] The parties generally refer to the relevant form of endoscopic surgery as laparoscopic surgery, which, in general terms, is endoscopic surgery in the area of the abdomen. See generally STEDMAN'S MEDICAL DICTIONARY 1047 (28th ed. 2006) (explaining that a laparoscope is an "endoscope for examining the peritoneal cavity").

being useful in more traditional surgery, in which larger incisions are made to expose organs to open view and accessibility.[2] Mrs. Selepec's surgery was of this latter kind.

Of additional relevance to the litigation, in Mrs. Selepec's operation, the surgeon employed a buttressing material -- known as peri-strips -- to reinforce the staple lines. Furthermore, after the surgery, the particular endocutter used was discarded (as is apparently the common practice for these instruments intended for use in a single surgery).

During recovery, Mrs. Selepec experienced complications, and surgeons reentered her abdomen. They discovered that staples were absent in two small line segments, with the operative report indicating: "What we found was a defect on the staple line both on the left side of the gastric pouch as well as the gastric remnant. These findings were consistent with mechanical staple failure." N.T., May 17, 2007, at 275. A repair was effectuated; however, leaked stomach contents fostered sepsis, and Mrs. Selepec died.

The estate administrator ("Appellant") commenced the present product liability action against Appellee and others.[3] The complaint identified multiple theories of liability, including an asserted defective design of the endocutter. Presumably in light of Appellant's inability to examine the actual instrument used in Mrs. Selepec's surgery, however, the primary liability theory emerging in the pre-trial proceedings was one of

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[2] For example, the manufacturer's specification sheet for the endocutter indicates that "[t]he instruments have application in multiple open or minimally invasive general, gynecologic, urologic . . ., thoracic, and pediatric surgical procedures." R.R. at 1842 (emphasis added).

[3] The action was initially commenced by Mrs. Selepec's husband in his own right and as estate administrator; the present administrator became the named plaintiff upon a later substitution after Mr. Selepec's own death.

strict-liability product malfunction. See generally Barnish v. KWI Bldg. Co., 602 Pa. 402, 410-14, 980 A.2d 535, 540-43 (2009) (setting out prevailing Pennsylvania law on this subject and explaining that "malfunction theory permit[s] 'a plaintiff to prove a defect in a product with evidence of the occurrence of a malfunction and with evidence eliminating abnormal use or reasonable, secondary causes for the malfunction'' (quoting Rogers v. Johnson & Johnson Prods., Inc., 523 Pa. 176, 182, 565 A.2d 751, 754 (1989))). Appellee defended, inter alia, on the basis that Appellant had failed to satisfy his obligation, under malfunction theory, of excluding alternative causes. See id. In particular, Appellee had contended that the surgeon failed to account for the peri-strips he elected to use in selecting among three available staple sizes (differentiated by color-coding of the cartridges). According to Appellee, the surgeon should have employed the longest staple length, given that the peri-strips added material width impacting staple formation. Such asserted mistake, Appellee had claimed, was a more probable cause of any staple failure than the alleged product malfunction.

The day before trial, Appellant submitted a supplemental expert report from his primary liability expert, Frederick Hetzel, Ph.D. Mr. Hetzel opined that the endocutter was defective in design, because it failed to incorporate a measuring device to aid surgeons in determining tissue thickness and, thereby, appropriate staple length. Alternatively, the supplemental report suggested the incorporation into the design of some safeguard to prevent the jaws from closing around tissue too thick to allow for proper staple formation.[4]

Appellee objected to the late submission of this design-defect theory. Appellant's attorney responded that the contemplated testimony was in the nature of rebuttal (to address Appellee's assertion of an alternative cause) and claimed that, as such, there

[4] In their arguments, the parties have referred to such a feature as a "locking device."

was no issue with the timing. See N.T., May 16, 2007, at 48 ("This is like every other case here. There's nothing special about this case that that [sic] requires any extraordinary measures.").[5] Although the trial court found it "unfair at the 11th hour to make this [defect] assertion," the remedy it afforded was to permit Dr. Hetzel to be deposed by the defense during breaks in the trial proceedings. Id. at 66. The court also denied a defense motion for continuance.

At trial, Appellant opened his case in chief with the testimony of a general surgeon, I. Michael Leitman, M.D. Dr. Leitman testified to the increased prevalence and success of gastric bypass surgery. See id. at 172-73. He described the benefits of the procedure, including improvement of health and lifestyle for persons suffering from obesity. See id. According to Dr. Leitman, the procedure is not without attendant risk, as one in two-hundred patients may die from the surgery "for a variety of reasons [including] a leak." Id. at 174. In describing the particular bypass technique employed, encompassing the use of the endocutter, Dr. Leitman indicated that, in gauging organ tissue thickness, physicians rely on tactile sense, as well as an unforced closure of the endocutter's compression mechanism, manifested by a "click." See id. at 176-79, 189, 201. He also noted that stomach tissue is not homogeneous in thickness. See id. at 179.

Next, Dr. Leitman reviewed the notes from the operating surgeon, Athan Georgiades, M.D. He explained that Dr. Georgiades employed the endocutter appropriately, and, consistent with standard medical practices, inspected the staple line

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[5] As developed below, however, the design-defect theory ultimately was presented to the jury as a stand-alone, alternative theory of liability. Such presentation of a design-defect claim does, in fact, require special treatment, including the undertaking of a threshold risk-utility assessment. See Azzarello v. Black Bros. Co., 480 Pa. 547, 558, 391 A.2d 1020, 1026 (1978) (discussed infra).

and tested for leaks. See id. at 185, 187. According to Dr. Leitman, Dr. Georgiades' selection of an intermediate-size staple was appropriate, and this was evidenced by the overall adherence of the seam. See id. at 183 ("If he had chosen an inappropriate cartridge and something would have happened, the whole thing would have likely fallen apart, but it was just one small area."); see also id. at 203. Of central importance to Appellant's present arguments concerning product defect, Dr. Leitman also testified that there are other devices on the market, used in different cutting and stapling applications, that have a gauge to permit a surgeon to accurately measure thickness. See id. at 190.

On cross-examination, however, Dr. Leitman disavowed any suggestion that he believed the endocutter should have a thickness gauge and confirmed that he still uses endocutters in his practice. See id. at 196 ("I never said this particular instrument had to have a thickness meter[.]"), 199. He also noted that the products offered by another major endocutter manufacturer also do not incorporate such a device. See id. at 196-197 ("There's no linear endocutter on the market that has a thickness gauge."). In response to questions eliciting additional details about the different cutter-stapler referenced in his direct testimony, Dr. Leitman disclosed that it was a circular, intraluminal instrument with substantially different functionality as compared to the endocutter. See id. at 197 (reflecting the witness's agreement that an intraluminal stapler cannot be used to divide the stomach). Finally, Dr. Leitman acquiesced in the understanding that the package insert accompanying Appellee's product indicates that, if a surgeon elects to use buttressing material such as peri-strips, he should consider using a larger size staple. See id. at 203 ("Selection of the appropriate staple cartridge should be based upon the combined thickness of both the tissue and the staple line buttressing materials.").

Appellant presented Dr. Georgiades as his next witness. Among other things, Dr. Georgiades confirmed his adherence to appropriate procedures and testing in Mrs. Selepec's surgery; indicated that he had no problems using Appellee's endocutter in the procedure; and explained that he had been satisfied after the procedure that everything had gone well. See, e.g., id. at 218-22. He also confirmed that gastric leaks are among the major complications of bypass surgery. See id. at 226.

The next relevant witness was Peter Naman, M.D., a general surgeon who participated in repairing the leaks which ensued after Mrs. Selepec's surgery. He confirmed that the recorded notes of the remedial operation alluded to "mechanical stapler failure," N.T., May 17, 2007, at 277; reiterated his belief that the leaks resulted from a "technical problem"; and testified that this "could be either related to the operator or to the instrument used." Id. at 290. Dr. Naman could not identify the cause of the small openings in the staple-line seaming with any certainty. See id. at 282.

The next major liability witness was Mr. Hetzel. On voir dire, it was developed that the witness's educational background is in chemistry. See id. at 303. Although he has no formal training in engineering, Mr. Hetzel emphasized his previous work in product research and development and his maintenance of a consulting practice working with lawyers in "forensic failure analysis of medical devices." Id. at 303-06. To date, his consultations and/or attendant testimony have included the finding of product defects in surgical staplers, failed knee and hip replacements, breast implants, pacemakers, automotive seatbelts and batteries, ventilation bags, children's toys,

cigarette lighters, cookware handles, Styrofoam cups, hoses, and safety glass. See id. at 308-18.[6]

After the voir dire, the defense renewed its motion to preclude Mr. Hetzel from testifying. In response, the trial court repeatedly expressed its concern that proof of design-related deficiencies in a sophisticated, mechanically-engineered product required testimony from an engineer.[7] Nevertheless, the court indicated that it wished to hear evidence of Mr. Hetzel's methodology in assessing product defect, and that it would defer its ruling until after such presentation. See id. at 344-48.

Before the jury, Mr. Hetzel then opined that Appellee's endocutter suffers from an inherent design defect, as it does not provide surgeons with accurate feedback concerning tissue thickness. See id. at 349-51. The witness explained that he tested the endocutter by firing the smallest-sized staples into "simulated tissue" consisting of paper wads, upon which he uncovered various permutations of staple malformation.

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[6] Mr. Hetzel also testified that his last-three-years' receipts from his litigation-related activities represented nearly 100 percent of his total income. See N.T., May 17, 2007, at 314-16.

In light of the above, it is difficult to overlook Appellee's assertions that Mr. Hetzel is a professional witness. See generally Cooper v. Schoffstall, 588 Pa. 505, 522-23, 905 A.2d 482, 493 (2006) (commenting on the professional witness phenomenon). Further discussion of the use by plaintiffs and/or defendants of such witnesses in litigation is beyond the scope of this opinion.

[7] See, e.g., N.T., May 17, 2007, at 331 ("And the Court would think that obviously when you're looking to develop an instrument that would do that type of routine measurement, that you would have to have some sort of engineering background[.]"), 334-35 ("The intrinsic nature of the product and its complicated design can and must weigh in the analysis of whether a person is capable to say why that product failed and then go beyond that and offer a corrective measure to that product."), 340 ("Now, the Court would feel that a measuring device attached to this surgical stapler would involve a high degree of sophistication[.]").

See id. at 351; N.T., May 18, 2007, at 400-11. He proceeded to review complaints Appellee had received concerning the endocutter, including reports of malformed staples and leakage. See N.T., May 17, 2007, at 354-57. From these documents and his testing, Mr. Hetzel concluded "the staple is failing, and it's injuring people[.]" Id. at 357.

On cross-examination, Mr. Hetzel conceded the many benefits associated with stapling over suturing, including decreased incidents of patient injury. See N.T., May 18, 2007, at 399. As to his testing, he acknowledged that he did not consider density differences between the paper he used and human organ tissue, and he could offer no correlation between the two. See id. at 405, 432.

After the testimony, Appellee renewed its exclusionary motion. The trial court responded that, in its view, Dr. Hetzel was "one of the worst witnesses it's ever heard, period." Id. at 458. In terms of the methodology about which the court was concerned, it stated:

> Now, his testing consists of -- the best we could get out of that is his idea of compression, of course we're talking about tissue here, and documenting it -- tissue when compressed has a multitude of elements in it from water and fat and all these other things, and that his use of paper, that he tried to analyze paper . . .. You know, the Court has emphasized that's not a very -- at least in the Court's way of thinking as a fact finder -- a good comparison or analogy of compression, compression tissue, compression with paper.
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> The Court in trying to review the doctor's methodology, the Court cannot be oblivious to the fact that, as the Court indicated, he's a chemist, not an engineer, and the Court had previously -- and I'm saying the degree of sophistication does merit analysis in terms of the products he reviewed. . . ..

> And the Court noted that while it's noteworthy that he is looking to [the] design [of] a circular staple[r], I don't know if that was for the bowel or whatever, but here in this instance when he did the testing, it seemed like he only used the white staple, which obviously is the thinnest of it.
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> Although the Court has indicated, the more you get into the medical field, and although he has analyzed products in the medical field, the Court feels that a greater degree of sophistication is needed engineeringwise and the like to determine what is lacking in a product.

Id. at 458-62.

In responsive arguments, Appellant's counsel stressed that his primary liability theory was product malfunction, and thus, contended that role of the design-defect evidence was of a limited nature. For example, he indicated:

> [W]e don't even know if [the gastric leaks were] caused by tissue thickness because there are so many instances where these things fire, and they don't form staples. We don't know if it's always caused by tissue thickness or not. They may have been bent for all we know in the cartridge or come out bent.
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> All we know is that he fired them. He checked them. They didn't form a proper B, and they came out. That's malfunction. The Plaintiff doesn't even have to prove a specific defect. All this stuff they're talking about is going to product defect, and they're saying -- they're saying it was too thick. We don't know if it was too thick.

Id. at 482-83.[8]

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[8] Accord N.T., May 18, 2007, at 545 ("We don't have to prove -- there are many reasons why it could have happened. It could have happened because they came out of the stapler crooked. For whatever reason, it didn't perform the function that it was intended to do based on the fact that it failed, and that subsequent events confirmed that. That is (continued . . .)

In response to the arguments, the trial court again deferred a definitive ruling. Since Mr. Hetzel had "made a career obviously of reviewing various products and determining whether these products are defective or unsafe for their intended use," id. at 462, the court felt his experience was relevant and wished to hear the defense evidence before further addressing the admissibility issue. See id. at 463.

At the close of Appellant's case, Appellee sought a nonsuit on several grounds, including insufficient evidence to support Appellant's design defect theory of liability. The motion was denied.

In the defense case, Appellee developed its theory that the most likely cause of the gastric leaks was a failure, on the part of Dr. Georgiades, to account for the peri-strips in selecting among the available staple sizes. See, e.g., N.T., May 21, 2007, at 684-92 (reflecting, inter alia, the testimony of Appellee's representative, a mechanical engineer, that, applying "simple math," the addition of peri-strips dictates the use of

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(. . . continued)
our theory."); id. at 854 (reflecting the closing argument of Appellant's counsel to the effect that: "We don't know why the staples came out in that area. . . . Nobody knows why. Maybe the staples were bent in the cartridge. How do we know? Maybe they came out funny that day.").

At this juncture, we observe that there are a number of theoretical inconsistencies running through this case which tend to cloud the analysis of the issues. For example, as to counsel's argument above, if Appellant could not prove that a design defect relating to tissue thickness caused Mrs. Selepec's death, it simply could not prevail on a design-defect theory of liability, since causation is an essential element on which Appellant bore the burden of proof. See Berkebile v. Brantly Helicopter Corp., 462 Pa. 83, 93-94, 337 A.2d 893, 898 (1975); see also Davis v. Berwind Corp., 433 Pa. Super. 342, 354, 640 A.2d 1289, 1295 (1994).

Although this matter is beyond the scope of the issues accepted for consideration here, the fact that Appellant obtained a jury verdict on a theory of liability which, throughout trial, he maintained was unprovable, at the very least, adds an element of dissonance to the review.

largest-size staple in an endocutter); id. at 783 (opinion of a general surgeon to similar effect). Additionally, Appellee highlighted the instructions and cautions accompanying its product, see, e.g., id. at 684-92, and the relative rarity of adverse events compared with the millions of incidences in which endocutters are fired. See id. at 702, 758. Furthermore, Appellee presented testimony from a mechanical engineer that size is a material design constraint pertaining to endoscopic cutter-staplers. See id. at 607.

Prior to the jury charge, the defense again requested a ruling on the motion to exclude Mr. Hetzel's testimony, to which the trial court responded that it had "made its ruling on the parameters" of the testimony. N.T., May 22, 2007, at 811. [9]

In closing arguments, Appellant's counsel described Pennsylvania strict-liability law to the jurors as follows:

> It's very simple. If you drive a car and your brakes fail, the manufacturer [as] the cost of doing business is required to stand by its products, and out of their profits they're required to compensate someone that's injured if the product has failed, and its no -- it's strict liability.
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> We don't look at the manufacturer and say they're a nice company and they didn't do this intentionally. You don't look at if your brakes fail, they can't come back and say to you, well, maybe you should have inspected them last year -- that's not relevant. The only thing that's relevant is did the product fail to perform as it was expected to perform[.]

[9] The meaning of this response is unclear, since the record reflects that, to that point in the trial proceedings, the court had continually deferred ruling on the defense motion.

> Did the product form the staples or did they not? That's called a malfunction. And it doesn't matter. The Court will tell you the company became a guarantor. They guarantee the product when it's on the market. It's as simple as that.

Id. at 850-51.[10]

The jury returned a verdict favorable to Appellant, awarding the estate $5,000,000. In doing so, the jurors expressly rejected Appellant's malfunction theory, predicating the award solely on Appellant's design defect case.

In response to Appellee's post-trial motions, the court provided the following very brief analysis of its risk-utility calculus:

> The endocutter's defect exposed patients to a high risk of serious or fatal injury. The defect and its risks are unavoidable, despite the best care or training of the surgeon.
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> The seriousness of the danger posed by the challenged design is clear; trial testimony included the likelihood of the occurrences of the danger even when the surgeon exercised care and had proper training. Further, the stapler could have been designed so that it would not fire if tissue was too thick or the defect could have been eliminated if the endocutter was equipped with a measuring device as used in other staplers.
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> While there are certainly benefits to society by the use of the endocutter, the foregoing analysis shows that the utility and

[10] Counsel's example is problematic for several reasons, including its failure to account for the plaintiff's burden, under malfunction theory, of addressing alternative causes. See Barnish, 602 Pa. at 410-14, 980 A.2d at 540-43. Moreover, the example suggests the law implements a scheme of forced insurance, a position which this Court consistently has eschewed. See Azzarello, 480 Pa. at 555, 391 A.2d at 1025; see also Cafazzo v. Cent. Med. Health Servs., Inc., 542 Pa. 526, 535, 668 A.2d 521, 526 (1995) ("To assign liability for no reason other than the ability to pay damages is inconsistent with our jurisprudence.").

> benefit of this endocutter are outweighed by the danger it poses.

Selepec v. Johnson & Johnson, Inc., GD 04-17685, slip op.at 6 (C.P. Allegheny, Oct. 30, 2008) (citations omitted).

On appeal, a divided Superior Court panel vacated the award in a memorandum opinion and directed the trial court to enter judgment notwithstanding the verdict in Appellees' favor. Initially, the majority observed that, under prevailing Pennsylvania law, in a design-defect case pursued under strict-liability theory, the trial judge must make a threshold determination as to whether the utility of the product is outweighed by the risk. By way of further explanation, the majority quoted Schindler v. Sofamor, Inc., 774 A.2d 765, 772 (Pa. Super. 2001), as follows:

> The question of whether a product is unreasonably dangerous is a question of law. Azzarello v. Black Brothers Co., 391 A.2d, 1020, [sic] 1026 (Pa. 1978). In answering this question a court is essentially making a social policy determination and acting as both a social philosopher and a risk-utility economic analyst. Fitzpatrick v. Madonna, 623 A.2d 322, 324 (Pa. Super. 1993). In Dambacher by Dambacher v. Mallis, 485 A.2d 408, 422 (Pa. Super. 1983), this Court identified certain factors to consider in making this determination:
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> > The gravity of the danger posed by the challenged design; the likelihood that such danger would occur; the mechanical feasibility of a safer design; and the adverse consequences to the product and to the consumer that would result from a safer design (citation omitted).

Beard v. Johnson & Johnson, Inc., 925 WDA 2008, slip op. at 4 (Pa. Super. Oct. 23, 2009). Rather than carrying out such an evaluative inquiry, the intermediate-court majority opined, the trial court merely relied upon "conclusory language." Id. at 4. According to the majority, "a full reading of the record leads to the conclusion that there

is only a minor likelihood that danger would occur and there is no feasibility of a safer design that would enable the product to accomplish its goal." Id. at 5.

In its reasoning, the majority relied on the testimony adduced by both parties' witnesses confirming the substantial, net benefits of stapling as compared to suturing. Furthermore, the court stressed the absence of expert testimony elaborating on the proposed alternative design additions within the constraints applicable to endocutters. See id. at 5-6 ("There is no testimony, apart from going back to the old method before laparoscopic surgery that utilized a full incision and sutures, indicating that it would be possible to make an endocutter that can function with a measuring device or locking mechanism." (emphasis in original)); id. at 2 ("If we were to maintain the position that this device is unreasonably dangerous because it had no locking or measuring capabilities, then no laparoscopic bypass surgery could ever be performed." (emphasis in original)).

The majority also appeared to credit the defense theory that Dr. Georgiades' usage of the endocutter was the most likely cause of Mrs. Selepec's death. See id. at 6 ("The surgeon did not read the instructions on the peri-strips or the endocutter, which were accurate and would have made the use of the device safe and avoided what happened here."); see also id. at 7 ("Of course, the doctors would know that they could not measure the thickness and therefore know that they had to use the right sized cartridge."). Additionally, the majority rejected Appellant's allusions to measuring devices associated with intraluminal circular staplers, since "they are not used for laparoscopic surgery." Id. at 6.[11] The majority concluded:

[11] In fact, the witnesses at trial did not make clear whether or not the circular staplers to which they were referring were, or were not, designed to be used in endoscopic surgery.

> Overall, there is no showing that the endocutter is not superior to other methods or that there is a way to make it safer than it currently is. . . . [A] full review of the record shows that there was no evidence of malfunction, the endocutter is a safe mechanism when used properly, and there is no feasible way a measuring device or locking mechanism can be installed without making the endocutter unusable.

Id. at 7.[12]

Appellant sought reargument on the basis that the court erroneously directed its analysis to endoscopic use of the endocutter, when, in the relevant instance, the instrument was in fact used in open surgery. These efforts were unsuccessful, however.

In his present arguments before this Court, Appellant maintains that the Superior Court erred by centering its analysis on laparoscopic surgery, a "use" for the endocutter which he believes had no relevance to Mrs. Selepec's case. Moreover, mirroring the intermediate court's criticism of the trial court's reasoning, Appellant challenges the intermediate court's own analysis as being highly superficial. See, e.g., Brief for Appellant at 12 ("Not only does [the Superior Court] ignore the fact that, absent a measuring device, a doctor is unable to determine the thickness of the tissue to be stapled (and thus the length of the staple to use) but [it] also specifically mentions traditional open surgery 'requir[ing] an abdominal incision' without recognizing that Mrs. Selepec received the older, open procedure." (emphasis in original)).

Appellant also offers a series of policy arguments to support his broader contention that the risk-utility assessment of a product designed and marketed for multiple uses should be limited solely to the one implicated by the circumstances of a

[12] Judge Colville issued a short dissent, expressing his view that the trial court's finding that the endocutter is unreasonably dangerous was supported by sufficient evidence of record.

plaintiff's injury. Initially, Appellant believes that a wider focus would "muddy the waters" for the parties in presenting and defending design defect claims, as well as add needless expense and burden to an already complex and expensive litigation process. Id. at 16. According to Appellant, narrowing the analysis to the use in question "strikes the most equitable balance between the interests of a product's designers and the injured consumer." Reply Brief for Appellant at 2.

Appellant also discusses the underpinnings of Pennsylvania strict-liability theory in Section 402A of the Restatement Second and the idiosyncratic developments attending it, as reflected in Azzarello and its progeny. See generally Schmidt v. Boardman, 608 Pa. 327, 353, 11 A.3d 924, 940 (2011) (explaining that Azzarello's "no-negligence-in-strict-liability rubric has resulted in material ambiguities and inconsistencies in Pennsylvania's procedure.").[13] In particular, Appellant develops that Azzarello's efforts to isolate strict-liability jurisprudence from negligence theory has led to the practice of threshold risk-utility balancing by trial judges, with reference to a series of factors set out in the works of Dean John Wade. See generally Dambacher, 336 Pa. Super. at 50 n.5, 485 A.2d at 423 n.5 (citing John Wade, On the Nature of Strict Liability for Products, 44 Miss. L.J. 825, 837-38 (1973)). According to Appellant, an examination of these factors demonstrates that underlying policies -- entailing a balancing of the manufacturer's interests in the production and distribution of a product against the safety of the consuming public -- is served only where an independent inquiry is conducted for each intended use of a multi-use product.

Appellant has no difficulty acknowledging that, in the case of laparoscopic surgery, the risk-utility calculus may favor Appellee. See, e.g., Brief for Appellant at 24

[13] While the lead opinion in Schmidt is, in part, an opinion announcing the judgment of the Court, the above observations gained majority support.

("The Superior Court's statements about the health benefits of laparoscopic surgery may be well placed and the endocutter may very well be the best tool available for use in laparoscopic surgery."); Reply Brief for Appellant at 13 ("A finding that it is unreasonably dangerous in open surgeries does not take away from its use in laparoscopic surgeries where it may very well be the case that its benefits outweigh its risks for that type of procedure."). Appellant argues, however:

> The analysis could not be more different, however, for the endocutter as a tool in open surgery. The record demonstrates that it would be possible to affix a safety device, such as a measurer, to the endocutter without sacrificing function as an open surgery tool. Indeed, there are surgical staplers that have measuring devices. Thus, as to its use in traditional open surgeries, the consideration of (alleged) necessity of the endocutter's design that was weighed against its risk of harm is simply not present. It is critical to note that this design change does not implicate, the endocutter's availability for use in laparoscopic surgery -- a completely different procedure.

Brief for Appellant at 21 (emphasis in original; citations omitted); id. at 24 ("[T]he fact there is no better alternative for laparoscopy should not be used as an excuse to place open surgery patients at needless risk from the device's shortcomings where safe alternatives exist."). Appellant also stresses the seriousness of the potential injuries (such as death in Mrs. Selepec's case) and the policy of loss-spreading inherent in Section 402A.

Appellant's second argument is that, in the Superior Court risk-utility discussion, it erred by disregarding the trial court's findings of fact and determinations of weight and credibility relative to trial witness testimony. In particular, Appellant's arguments, and those of his amicus, the Pennsylvania Association for Justice, criticize the Superior Court majority's independent weighting of the testimony, as between Mr. Hetzel and Appellee's witnesses, concerning the product hazards, the potential gravity of the harm,

and sensibility of alternative designs. Amicus also observes that the intermediate court made an overt credibility determination, contrary to evidence of record, in its statement that Dr. Georgiades did not read the product inserts for the endocutter or for peri-strips. See N.T., May 16, 2007, at 233-35 (reflecting Dr. Georgiades' testimony that he had read these inserts, but that he simply does not read them every time he performs surgery).

Appellee opens its brief by cataloguing several asserted structural difficulties with Appellant's argument. For example, Appellee observes that, in light of Appellant's trial position that his product defect evidence was mere rebuttal secondary to his malfunction theory, he never asked the trial court to perform the required threshold risk-utility assessment. Furthermore, Appellee notes, Appellant did not object to the defense evidence regarding the utility and design constraints associated with the use of its endocutter in the circumstance for which it was designed and named, i.e., endoscopic surgery. Nor did Appellant limit his own evidence to open procedures, Appellee explains. See, e.g., N.T., May 17, 2007, at 349-50 (reflecting Mr. Hetzel's generalized assertions that "there is an inherent defect in the stapler"). In light of the above, Appellee asserts that it should come as no surprise that the trial court also made no such distinction between open and laparoscopic surgery in its post-trial risk-utility evaluation. See Brief for Appellee at 23 ("[N]owhere did [the court] even note that Mrs. Selepec received open surgery as opposed to closed surgery, let alone tailor [its] analysis around any unspoken distinctions between the two.").

Appellee also highlights Appellant's various acknowledgements that its endocutter is not unreasonably dangerous (or at least that it had not been shown to be so) in endoscopic use. According to Appellee, such concession poses an insurmountable theoretical obstacle, since Appellant has conceded that there was and

is no call for a different design of the endocutter, but rather, merely an admonition that it should not be used in open surgery. Nevertheless, Appellant limited his own case at trial to malfunction and design defect theories. See Brief for Appellee at 25 ("[A] claim that [Appellee] should have marketed the device for some procedures while warning against its use in connection with other procedures is not a design defect claim: it is either a breach of warranty claim or a failure to warn claim. And those claims were either never pleaded or were never presented to the jury. They cannot fairly be argued here in the first instance.").

On the merits, Appellee argues that: courts applying the risk-utility analysis have always considered the risks, benefits, and design constraints associated with all intended uses of a product; to artificially limit the risk utility analysis to the particular use to which a plaintiff put a product in a particular case would be to ignore the inherent, essential characteristics that informed the design; and to hold multi-use products to the same standard as single-use products would be tantamount to requiring the sale of multiple single-use products, which would be inefficient and impractical, if not impossible.[14] Appellee observes that neither Appellant nor his amicus cites any

[14] See Brief for Appellee at 26-27 (citing David G. Owen, et al., MADDEN & OWEN ON PRODUCTS LIABILITY §8:4 n.14 (3d ed. 2010) (cautioning against the tendency to "narrowly compare the individuated costs of precaution and safety benefits of the particular accident at hand, which of course is never the proper form of cost-benefit calculation for establishing design defectiveness" (emphasis added)), Crespo v. Chrysler Corp., 75 F. Supp. 2d 225, 228 (S.D.N.Y. 1999) (explaining that alternative designs must be "safer to the relevant set of users overall, not just the plaintiff," and dismissing an argument to the contrary as "an absurd position" (emphasis added)), and Owens v. Allis-Chalmers Corp., 326 N.W.2d 372, 377-78 (Mich. 1982) (recognizing that "[a]ny determination of the reasonableness of the design of a product is essentially an inquiry as to whether safety under a variety of conditions was given sufficient consideration" and rejecting the notion that such an inquiry would be "too open-ended to be competently adjudicated" (emphasis added))).

authority, from Pennsylvania or otherwise, militating to the contrary. Moreover, according to Appellee, acceptance of Appellant's approach would increase product costs and decrease availability. In particular, it explains:

> [I]f multifunctional products are to be evaluated only as to the one particular use to which they are put by one particular plaintiff in one particular case, then manufacturers will have no incentive to design and produce multifunctional products. Indeed, the law will encourage manufacturers to make a different model of a product for each of its different uses. The inefficiency and impracticability of such a suggestion are easy to demonstrate and hard to overstate.
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> * * *
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> It is undisputed that [Appellee's] endocutter is a widely used, highly useful product in state-of-the-art laparoscopic gastric bypass procedures; that laparoscopic procedures are better for patients and surgeons than other options; and that non-laparoscopic gastric bypass procedures are no longer the norm. Yet [Appellant] would have the Court ignore those undisputed facts and replace a highly useful, multifunctional endocutter with a supposedly fool-proof product that is utterly useless except in the outdated "open" procedures that relatively few surgeons still perform.
>
> Even if such a product were feasible – and there is no evidence that it is – there is no reason to believe that any medical device manufacturer is going to invest the capital to design, manufacture and market it to a small and shrinking market. The end result would be that no one would make such a product, and surgeons who still prefer to perform open procedures would be obliged to go without a stapler altogether – resorting to the previous practice of suturing. That, of course, would be bad public policy at every conceivable level. Which, with all due respect, is true of the change in the law that [Appellant] is advocating here. It would stifle innovation, limit choice, decrease predictability, and increase costs. No rational "social policy philosopher" or "economic analyst" could credibly claim that such a system would benefit anyone . . ..

Brief for Appellee at 38-40.

Compounding these problems, Appellee asserts, Appellant has provided no workable definition for the concept of multi-use products for purposes of limiting risk-utility analysis, opening up a new and wide corridor for "unpredictability and inconsistency in an already unpredictable and inconsistent area of the law." Id. at 41. Appellee describes such an ungrounded approach as particularly untenable, since plaintiffs have options other than design theory to vindicate their legitimate interests (claims in negligence, breach of warranty, failure to warn, etc.) where a multi-function product poses risks peculiar to specific uses.

In terms of the Superior Court's asserted disregard of trial-court weight and credibility determinations, Appellee begins by explaining that the risk-utility assessment, in a strict-liability defective design case, was christened by this Court as a question of law, see Azzarello, 480 Pa. at 558, 391 A.2d at 1027, a category of issues which is generally subject to plenary appellate review. See, e.g., Meyer v. Cmty. Coll. of Beaver County, 606 Pa. 539, 543, 2 A.3d 499, 501 (2010). Moreover, as Azzarello has been applied, trial-court risk-utility analysis is to be conducted on the plaintiff's averments, reading the record in the light most favorable to him. See Schmidt, 608 Pa. at 353, 11 A.3d at 940; Azzarello, 480 Pa. at 558, 391 A.2d at 1027; see also Brief for Appellee at 55 ("[T]he trial judge in this case and other defective design cases does not find the facts based upon a full, fair, or objective consideration of all the evidence, because fact-finding is supposed to be the province of the jury."). Appellee also identifies particular incongruities in the present case given: the eve-of-trial advancement of Appellant's design defect theory; the assertions of Appellant's trial counsel that the claim was in the nature of rebuttal and that no additional procedures were required; the subsequent, contrary treatment of the claim as a stand-alone theory of relief in the jury instructions;

and the overarching absence of engineering and economic information relative to the design changes proposed by Appellant.

Appellee concludes its arguments with a summary of the continuing confusion over the foundation of Pennsylvania strict-liability law, as developed most recently by this Court in Schmidt and the United States Court of Appeals for the Third Circuit in Covell v. Bell Sports, Inc., 651 F.3d 357 (3d Cir. 2011) (reflecting the continued application in the federal courts of the prediction from Berrier v. Simplicity Manufacturing, Inc., 563 F.3d 38 (3d Cir. 2009), that this Court would overturn Azzarello in favor of the liability scheme set forth in the Restatement Third). Appellee asks that we take this opportunity to follow the approach favored by a three-Justice concurrence in Phillips v. Cricket Lighters, 576 Pa. 644, 841 A.2d 1000 (2003), and adopt the approach of the Restatement Third of Torts: Products Liability. See id. at 675-79, 841 A.2d at 1019-21 (Saylor, J., joined by Castille, J. and Eakin, J.); see also Bugosh v. I.U. N. Am., Inc., 601 Pa. 277, 279, 971 A.2d 1228, 1229 (2009) (Saylor, J., dissenting, joined by Castille, C.J.).

As the arguments before us concern matters of law, our own review is plenary.

I. The Present State of Pennsylvania Product Liability Law

As in Schmidt and before, we again recognize the continuing state of disrepair in the arena of Pennsylvania strict-liability design defect law. See Schmidt, 608 Pa. at 352-55, 11 A.3d at 939-41. While, as Appellee notes, several Justices have favored review of the foundational questions in past decisions and have expressed their views as to the appropriate remedy, a majority consensus has not yet been attained in any case. Mr. Chief Justice Castille and this author also have advocated restraint in the acceptance of subsidiary issues, pending remediation of the foundational deficiencies. See Berrier v. Simplicity Mfg., Inc., 598 Pa. 594, 595, 959 A.2d 900, 901 (2008) (Saylor,

J., joined by Castille, C.J., concurring in a denial of certification). As has been previously noted, "[o]bviously, all Justices are not of a like mind on this subject, as this appeal involves subsidiary issues." Schmidt, 608 Pa. at 352 n.13, 11 A.3d at 939 n.13.

II. The Appropriate Focus of Risk-Utility Balancing

In terms of the appropriate focus of design defect risk-utility analysis, for many of the reasons identified by Appellee, we decline to limit it to a particular intended use. For better or worse, this Court's decisions have relegated our trial courts in the unenviable position of "social philosopher" and "risk-utility economic analyst." This having been done -- and as the present case does not provide an appropriate opportunity for reconsideration of such assignment – we decline to require the trial courts to put on blinders. It should be enough to say that a product's utility obviously may be enhanced by multi-functionality, so that it would be imprudent to deny trial courts the ability to assign some weight to this factor in assessing product design. Cf. supra note 14. Moreover, Appellant simply does not address why the other theories which may be available to a plaintiff, such as failure to warn, do not provide sufficient protection against deficient marketing and instruction practices. In this void, it is difficult to disagree with Appellee's observation that Appellant's concessions of the net social utility calculus in the area of the endocutter's primary design (endoscopic surgery) are irreconcilably inconsistent with his claim of an inherent design defect.[15]

We are sensitive to the difficulty faced by plaintiffs in proving product defect, particularly where, as here, the instrument in issue has been destroyed by others. In

[15] This open- versus laparoscopic-use of an endocutter also provides a somewhat strained platform for discussion of multi-use products, since, other than in the method of insertion and use of specialized viewing equipment, the endocutter appears to be mechanically applied in the same fashion in either type of surgery.

numerous ways (such as by way of acceptance of malfunction theory), this Court has acted to alleviate that burden. We also must bear in mind, however, that there is much at stake in the condemnation of a product's design, above and beyond any individual damages award or awards, including the impact on product costs and design innovation.[16] On balance, we differ with Appellant's position that the desire to streamline a particular facet of products litigation should be accorded priority over the wider-ranging assessment which was obviously intended from the outset, as manifested in the above characterizations of the trial court's role, in the open-ended factors which have been accepted by Pennsylvania courts as the basis for risk-utility review, and otherwise.

III. Weight and Credibility Determinations

As Appellee asserts, this case presents obstacles to addressing threshold risk-utility balancing, since there is every indication that the trial court never performed this function on a pre-trial basis in the first instance. Nevertheless, under prevailing Pennsylvania law as has been determined by the highest court to address the matter to date, in absence of overt pre-trial risk-utility balancing, courts are to assume that the trial court properly undertook the process nonetheless. See Dougherty v. Edward J. Meloney, Inc., 443 Pa. Super. 201, 216, 661 A.2d 375, 382 (1995).[17]

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[16] Various social policy and pragmatic justifications for limiting the liability of manufacturers include: incentivizing safer design by rewarding careful manufacturers; the recognition that a verdict for a plaintiff in a design-defect case is tantamount to a determination that the entire product line is defective; and the concern with burdening manufacturers and their customers with the costs of insuring against all possible loss. See Prentis v. Yale Mfg. Co., 365 N.W.2d 176, 185 (Mich. 1984).

[17] To our knowledge, the Superior Court has not been very clear as to why a presumed decision based on pre-trial submissions may be subsequently evaluated based on an ensuing trial record. Given that this Court has not yet addressed the matter and it (continued . . .)

In terms of the Superior Court's specific review, Appellant's amicus aptly challenges the Superior Court's rejection of Dr. Georgiades' testimony that he read product inserts for the endocutter and peri-strips. See, e.g., N.T., May 16, 2007, at 235. That consideration, however, does not appear to have been a predominate one, and other than that, Appellant's complaint appears to be more with the intermediate court's balancing of factors than with more traditional weight and credibility considerations associated with true factual findings. As Appellee explains, though, Azzarello conceived such risk-utility balancing as entailing a legal determination. See Azzarello, 480 Pa. at 558, 391 A.2d at 1027. We decline, at this late juncture, to insulate a decision framed by the Court as a legal one from the attendant consequences in terms of the ensuing review. See Meyer, 606 Pa. at 543, 2 A.3d at 501 (explaining that an appellate court's review of legal determinations is plenary).[18]

We do not discount Appellant's position that the Superior Court's review appears to be abbreviated and, to some extent, conclusory. Indeed, one fair perspective is that the appellate court acted simply to substitute one somewhat perfunctory analysis for another. Certainly, reasonable minds may disagree as to the respective conclusions drawn. We agree with Appellee, however, that the dearth of engineering and economic

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(. . . continued)
resides beyond the scope of the present issues accepted for review, we will assume this is appropriate.

[18] It may be cogently argued that risk-utility balancing is more legitimately assigned to a jury, acting in its role as a voice for the community and with the power to decide facts, rather than to a trial judge acting on a summary record. Indeed, such is the approach of the Restatement Third.

information on this record left those courts with little else to do but to draw somewhat abstract conclusions.[19]

Finally, we again acknowledge the loss-spreading rationale motivating Azzarello. Nevertheless, and again, Azzarello itself sought to implement some sort of rational limits, manifested in its prescription for a meaningful risk-utility evaluation. In light of such constraint, contrary to the argument of Appellant's trial counsel to the trial judge and jury, Appellant's design defect claim was never a simple matter. Accord N.T., May 16, 2007, at 60 (reflecting the trial court's remark: "Well, this is an obviously complicated case.").[20]

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[19] In terms of the engineering dynamic, for example, while Appellant stresses the feasibility testimony relative to a circular, intraluminal stapler, he presented no concrete evidence demonstrating how this different device's design and functionality related to Appellee's endocutter. Cf. N.T., May 18, 2007, at 475 (reflecting the trial court's remark directed to Appellant's counsel that "your expert, nobody really had something in there that would say that [incorporation of the proposed safeguards into Appellee's endocutter] could be easily done"). The same is true relative to economic information.

Parenthetically, Appellant complains of various criticisms by Appellee of Mr. Hetzel's trial testimony, since a cross-petition for allowance of appeal challenging such testimony was denied by this Court. As the trial court remarked on repeated occasions, however, many of the complications presented in this case are overlapping and interdependent. See, e.g., N.T., May 16, 2007, at 50 (reflecting the trial court's comment that "the Court just wants to make known that the Court's in an awkward position trying to touch all the bases when each argument sort of involves the next step of every other argument"). We have developed Mr. Hetzel's testimony and the associated controversies at some length both because they provide integral background for the proceedings and since the looseness in the expert proffers and/or testimony impede a developed risk-utility assessment.

[20] In view of the framing of the issues presented for review, as well as the state of the record as discussed above, we decline to undertake an independent risk-utility evaluation.

We hold that trial courts are not restricted to considering a single use of a multi-use product in design defect, threshold, risk-utility balancing. We also decline to disturb the Superior Court's legal determination as to the appropriate risk-utility calculus.

The order of the Superior Court is affirmed.

Mr. Chief Justice Castille, Mr. Justice Eakin and Madame Justice Orie Melvin join the opinion.

Mr. Justice Baer files a concurring opinion in which Madame Justice Todd and Mr. Justice McCaffery join.