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2019 UT 56

IN THE

SUPREME COURT OF THE STATE OF UTAH

DALE BURNINGHAM and LANA BURNINGHAM,
Plaintiffs-Appellants,

v.

WRIGHT MEDICAL TECHNOLOGY, INC. and
WRIGHT MEDICAL GROUP, INC.,
Defendants-Appellees.

No. 20180143
Filed September 5, 2019

On Certification from the
United States District Court for the District of Utah
The Honorable Jill N. Parrish
Case No. 2:17-CV-92

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JUSTICE PETERSEN authored the opinion of the Court, in which CHIEF JUSTICE DURRANT, ASSOCIATE CHIEF JUSTICE LEE, JUSTICE HIMONAS, and JUSTICE PEARCE joined.

JUSTICE PETERSEN, opinion of the Court:

INTRODUCTION

¶1 The federal district court certified four questions to us related to a case before it involving artificial hip implants. Plaintiff Dale Burningham had artificial hips surgically implanted in both sides of his body. He alleges that parts of both hips have failed, necessitating several surgeries to address problems with the equipment. Defendants Wright Medical Technology, Inc. and Wright Medical Group, Inc. (collectively, Wright Medical) manufactured the equipment at issue. Burningham and his wife sued Wright Medical in federal court under various theories of liability, including strict liability for design defects.

¶2 The federal court asks us to resolve whether and to what extent implanted medical devices should be immune from strict liability design defect claims under Utah law because they are "unavoidably unsafe"—meaning they are "incapable of being made safe for their intended and ordinary use," but their marketing and use is justified because of the benefit they provide. RESTATEMENT (SECOND) OF TORTS § 402A cmt. k (A.L.I. 1965). While some implanted medical devices might very well be unavoidably unsafe, we conclude that under current federal regulations, this question should be treated as an affirmative defense and determined by the factfinder on a case-by-case basis with regard to devices that enter the market through the 510(k) process. For devices that go through the more rigorous premarket approval process, the United States Supreme Court has held that federal law preempts any state law tort claims, so we do not opine on whether such devices might be unavoidably unsafe as a matter of law because they are already exempt from design defect claims.

BACKGROUND

¶3 Burningham received hip implants in both of his hips. Over time, parts of the implants failed, and Burningham underwent several revision surgeries. He and his wife sued Wright Medical in federal district court, alleging that the implanted hip devices injured Burningham. The Burninghams claimed that there were defects in

the Profemur® Modular Neck implanted in Burningham's left hip, and the metal-on-metal Conserve® components implanted in his right and left hips. Some of the Burninghams' claims rested on a theory of strict liability for design defect.

¶4 Wright Medical filed a motion to dismiss, arguing that the "unavoidably unsafe" doctrine, which Utah has adopted, should immunize its hip implant devices from strict liability design defect claims. Wright Medical supported its argument with Utah case law extending the unavoidably unsafe doctrine to categorically immunize prescription drugs from such claims. *See Grundberg v. Upjohn Co.*, 813 P.2d 89, 99 (Utah 1991). Burningham responded that while Utah has held that all prescription drugs are deemed unavoidably unsafe as a matter of law, no Utah appellate court has similarly applied the unavoidably unsafe exception to implanted medical devices.

¶5 Confronted with these issues, the federal district court determined that there was no controlling Utah law on this issue. We appreciate the federal court's recognition that "resolution of these questions will have a significant impact on the bounds of strict liability for design defect claims brought under Utah law."[2] The federal court ultimately certified the following questions to us:

1. Under Utah law, does the unavoidably unsafe exception to strict products liability in design defect claims recognized in Comment k to Section 402A of the Restatement (Second) of Torts apply to implanted medical devices?
2. If the answer to Question 1 is in the affirmative, does the exception apply categorically to all implanted medical devices, or does the exception apply only to some devices on a case-by-case basis?
3. If the exception applies on a case-by-case basis, what is the proper analysis to determine whether the exception applies?
4. If the answer to Question 1 is in the affirmative, does the exception require a showing that such

[2] Notably, *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991), was also the result of certified questions from the federal court.

> devices were cleared for market through the FDA's premarket approval process as opposed to the § 510(k) clearance process?

STANDARD OF REVIEW

¶6 "A certified question from the federal district court does not present us with a decision to affirm or reverse a lower court's decision; as such, traditional standards of review do not apply. On certification, we answer the legal questions presented without resolving the underlying dispute." *Egbert v. Nissan N. Am., Inc.*, 2007 UT 64, ¶ 7, 167 P.3d 1058 (citations omitted) (internal quotation marks omitted). We have jurisdiction to answer certified questions pursuant to Utah Code section 78A-3-102(1).

ANALYSIS

I. STRICT PRODUCTS LIABILITY AND THE UNAVOIDABLY UNSAFE EXCEPTION

¶7 Plaintiffs' causes of action against Wright Medical include strict liability design defect claims. Wright Medical argues that its hip implants should be categorically immune from such claims based on the "unavoidably unsafe doctrine," an exception to strict products liability.

¶8 We have adopted section 402A of the Restatement (Second) of Torts, which imposes liability upon "[o]ne who sells any product in a defective condition unreasonably dangerous to the user or consumer, or to his [or her] property." RESTATEMENT (SECOND) OF TORTS § 402A(1) (A.L.I. 1965); *see also Ernest W. Hahn, Inc. v. Armco Steel Co.*, 601 P.2d 152, 158 (Utah 1979). This liability is strict in that it applies whether or not "the seller has exercised all possible care in the preparation and sale of his [or her] product." RESTATEMENT (SECOND) OF TORTS § 402A(2)(a). Comment g defines a "[d]efective condition" as a condition "not contemplated by the ultimate consumer, which will be unreasonably dangerous to [that consumer]." *Id.* § 402A cmt. g; *see also Dowland v. Lyman Prods. for Shooters*, 642 P.2d 380, 381 n.2 (Utah 1982) (applying comment g).

¶9 The unavoidably unsafe doctrine is an exception to strict products liability. Comment k of section 402A describes a category of products that are incapable of being made entirely safe, but when they are "properly prepared, and accompanied by proper directions and warning, [are] not defective, nor . . . *unreasonably* dangerous." *Grundberg v. Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991) (alterations in

original) (citation omitted) (internal quotation marks omitted). Comment k provides in its entirety:

> *k. Unavoidably unsafe products.* There are some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use. These are especially common in the field of drugs. An outstanding example is the vaccine for the Pasteur treatment of rabies, which not uncommonly leads to very serious and damaging consequences when it is injected. Since the disease itself invariably leads to a dreadful death, both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidable high degree of risk which they involve. Such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it *unreasonably* dangerous. The same is true of many other drugs, vaccines, and the like, many of which for this very reason cannot legally be sold except to physicians, or under the prescription of a physician. It is also true in particular of many new or experimental drugs as to which, because of lack of time and opportunity for sufficient medical experience, there can be no assurance of safety, or perhaps even of purity of ingredients, but such experience as there is justifies the marketing and use of the drug notwithstanding a medically recognizable risk. The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given, where the situation calls for it, is not to be held to strict liability for unfortunate consequences attending their use, merely because he has undertaken to supply the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk.

RESTATEMENT (SECOND) OF TORTS § 402A cmt. k.

¶10 Almost thirty years ago, in *Grundberg*, this court agreed "with the principle comment k embodies, that manufacturers of unavoidably dangerous products should not be liable for a claim of design defect." 813 P.2d at 95. In that case we extended comment k beyond its borders to categorically immunize all prescription drugs from strict liability design defect claims. *Id.* at 99. We held that "a

drug approved by the [FDA], properly prepared, compounded, packaged, and distributed, cannot as a matter of law be 'defective' in the absence of proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval." *Id.* at 90.

¶11 At the time, we recognized this was an extension of comment k. *Id.* We noted that "[e]ven in the case of a clearly alleged design defect, . . . comment k is unclear on the scope of its protection." *Id.* at 92. But we chose to apply comment k categorically to prescription drugs for policy reasons, noting we were not "bound by the specific language of comment k and may adopt and apply its fundamental policy without restricting ourselves to what we perceive to be its literal interpretation." *Id.* at 95. Our reasons for deeming all prescription drugs to be unavoidably unsafe as a matter of law included their "unique nature and value, the elaborate regulatory system overseen by the FDA, the difficulties of relying on individual lawsuits as a forum in which to review a prescription drug's design, and . . . significant public policy considerations." *Id.*

¶12 Here, we are asked how we will apply comment k to implanted medical devices. Essentially, the question before us is whether we will treat all implanted medical devices as unavoidably unsafe as a matter of law, as we did with prescription drugs in *Grundberg*, or whether we will conclude comment k should apply differently to these devices.

¶13 Wright Medical argues that because "medical devices present the same unique risks and benefits as prescription drugs, while also being subject to premarket and post-market scrutiny from the [FDA] and physician oversight, the court should apply the same categorical protection of the unavoidably unsafe doctrine to implanted medical devices that it applies to prescription drugs." The Burninghams disagree, noting that it was the FDA's rigorous review process that convinced us all prescription drugs should receive comment k protection, and arguing that the FDA does not necessarily subject all medical devices to the same thorough screening.

II. FDA OVERSIGHT OF IMPLANTED MEDICAL DEVICES

¶14 Because the extent of the FDA's oversight is significant to this analysis, we address the FDA's regulation of medical devices. Before implanted medical devices like the ones made by Wright Medical may be marketed in the United States, the FDA categorizes

each device into one of three categories: Class I, II, or III, graded by their potential for causing serious injury.[3] *See* 21 U.S.C. § 360c(a)(1).

¶15 Class I devices are those that pose no unreasonable risk of illness or injury and are subject to only general control regulations.[4] *See id.* § 360c(a)(1)(A). Class II devices are slightly more sophisticated devices that are regulated by special controls "necessary to provide adequate assurance of safety and effectiveness."[5] *Id.* § 360c(a)(1)(B).

¶16 Unlike Class I and Class II devices, which present lesser risks, Class III devices include those that "present[] a potential unreasonable risk of illness or injury." *Id.* § 360c(a)(1)(C)(ii)(II). These are devices "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health."[6] *Id.* § 360c(a)(1)(C)(ii)(I).

¶17 Because of the risk involved, all new Class III devices must undergo a process to provide "reasonable assurance" that the devices are effective and safe for medical use before they reach the market. *Id.* § 360c(a)(1)(C)(ii)(II). There are three methods of obtaining market approval for Class III devices. *See id.* § 360e.

¶18 The most rigorous is the premarket approval (PMA) process, which requires manufacturers to provide the FDA with comprehensive information about the device, including "full reports of all information, published or known to or which should reasonably be known to the applicant, concerning investigations which have been made to show whether or not [the] device is safe and effective." *Id.* § 360e(c)(1)(A). The PMA process is focused on

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[3] These classifications were introduced in 1976 when Congress enacted the Medical Device Amendments (MDA), amending the Federal Food, Drug, and Cosmetic Act.

[4] "Examples of Class I devices include stethoscopes, tongue depressors and ice packs." Sasha B. Rieders, Note, *State Law Tort Claims and the FDA: Proposing A Consumer-Oriented Prescription in Medical Device Cases*, 25 CARDOZO L. REV. 1159, 1162 n.14 (2004).

[5] Examples of Class II devices include oxygen masks, contraceptive devices, and tampons. Rieders, *supra* note 3, at 1162 n.14.

[6] Examples of Class III devices include pacemakers and prosthetic implants. Rieders, *supra* note 3, at 1162 n.16.

evaluating a device's safety and efficacy. *See id.* This process "is a rigorous one." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 477 (1996). After the manufacturers submit the required information, "the FDA then reviews [that information], spending an average of 1,200 hours on each submission." *Id.*

¶19 In contrast, is a premarket notification process referred to as the "510(k) process."[7] The 510(k) process allows a device to be cleared for market usage when the FDA determines that the device is "substantially equivalent" to a device already on the market. *See* 21 U.S.C. § 360e(b)(1)(B). This process allows manufacturers of devices that are substantially equivalent to devices already on the market to avoid the otherwise lengthy and costly PMA process. *See id.* § 360e(b)(1).

¶20 Notably, the FDA has not evaluated devices entering the market through the 510(k) process for safety and efficacy. The FDA's substantial equivalence review is limited in scope, and the FDA considers "only whether the device is indeed the equivalent of a preexisting device—regardless of how unsafe or ineffective the grandfathered device happens to be." *Goodlin v. Medtronic, Inc.*, 167 F.3d 1367, 1369 n.1 (11th Cir. 1999) (citing *Lohr*, 518 U.S. at 478–80). Thus, the FDA does not "approve" devices entering the market through the substantial equivalence 510(k) process. 21 C.F.R. § 807.97 ("Any representation that creates an impression of official approval of a device because of complying with the [510(k)] premarket notification regulations is misleading and constitutes misbranding."). Instead, the FDA "clears" devices entering the market through this path.[8]

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[7] The term "510(k)" refers to the section number in the original Food, Drug, and Cosmetic Act. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478 (1996). United States Code section 360e and Code of Federal Regulations sections 807.81 through 807.100 contain the operative language of the 510(k) process. *See generally* 21 U.S.C. § 360e(b); 21 C.F.R. §§ 807.81–807.100.

[8] *See 510(k) Clearances*, U.S. FOOD & DRUG ADMIN. (Sept. 4, 2018), https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm referring to devices entering the market through the 510(k) process as "510(k) Clearances").

¶21 The new device does not need to be substantially equivalent to a device that passed the PMA process; rather, it is sufficient if the manufacturer can establish that the "marketed device to which a new device [is] compared . . . is a device that was legally marketed prior to May 28, 1976" (when the FDA implemented the present regulatory structure, the Medical Device Amendments (MDA)). *Id.* § 807.92(a)(3). As a result, a device that was grandfathered into legal marketability in 1976 can serve as the touchstone for future devices entering the market through the 510(k) process. *See id.* Additionally, new devices may receive 510(k) clearance by establishing substantial equivalence to a "device which has been found to be substantially equivalent through the 510(k) premarket notification process." *Id.* Thus, the applicable regulations permit an unlimited line of products marching behind a grandfathered device, none of which has ever been subjected to the FDA's scrutiny for safety or efficacy.

¶22 Furthermore, the 510(k) process relies on the manufacturer's word.[9] The FDA is not involved in investigating the safety of the product undergoing the process. A finding of substantial equivalence and satisfaction of the 510(k) process "does not in any way denote official [FDA] approval of the device." *Id.* § 807.97.[10]

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[9] In the 510(k) process, manufacturers include in their application the following statement:

> I certify, in my capacity as (position held in company), of (company name), that I have conducted a reasonable search of all information known or otherwise available about the types and causes of safety or effectiveness problems that have been reported for the (type of device). I further certify that I am aware of the types of problems to which the (type of device) is susceptible and that, to the best of my knowledge, the following summary of the types and causes of safety or effectiveness problems about the (type of device) is complete and accurate.

21 C.F.R. § 807.94(a).

[10] There is a third process, not implicated here, of gaining market approval by designating the device as innovative technology and marketing it under an "investigational device exemption" (IDE). *See id.* §§ 812.1–812.150. This method allows manufacturers to market a device before premarket approval "for the purpose of conducting (continued)

¶23 The medical devices at issue in the federal case are Class III devices. Wright Medical used the 510(k) notification process to bring its hip implant devices to market, thus avoiding the PMA process. And the FDA cleared all of the devices at issue through the 510(k) process.

III. THE CERTIFIED QUESTIONS

¶24 With this comparison of the PMA and 510(k) processes in mind, it is important to address the implications for the certified questions of two cases from the United States Supreme Court involving federal preemption of state tort claims involving medical devices. In *Riegel v. Medtronic, Inc.*, the Court held that the MDA preempts state law tort claims involving PMA-approved medical devices. *See* 552 U.S. 312, 321–25 (2008). However, the same is not true for devices that have been cleared through the 510(k) process because it is focused on equivalence, not on safety or efficacy. *See Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996). Accordingly, the Court concluded that the 510(k) process was intended to "maintain the status quo with respect to the marketing of existing medical devices and their substantial equivalents." *Id.* at 494. Maintaining the status quo "included the possibility that the manufacturer of the device would have to defend itself against state-law claims of negligent design." *Id.*

¶25 These cases affect our resolution of the certified questions. The fourth certified question asks whether the unavoidably unsafe exception requires a showing that the implanted medical device was cleared for market through the PMA process rather than the 510(k) process. However, *Riegel* holds that all state law tort claims, including strict liability design defect claims, involving a PMA-approved device are preempted by the MDA. So, regardless of our conclusion as to whether a PMA-approved device should be deemed unavoidably unsafe as a matter of law, such devices are already immune from strict products liability claims.[11] But under

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investigations of that device." *Id.* § 812.1(a); *see also* 21 U.S.C. § 360j(g) (exempting "devices for investigational use" from the PMA process requirements). The certified questions do not inquire about the IDE process, so we do not address products that enter the market this way.

[11] The parties all agreed with this conclusion at oral argument.

Lohr, the same is not true for devices that enter the market through the 510(k) process.

¶26 So, with regard to question four, we do not opine on whether PMA-approved medical devices are unavoidably unsafe as a matter of law because they are already exempt from all state product liability claims. But it remains for us to determine whether 510(k)-cleared medical devices, such as Wright Medical's hip implants, which are susceptible to state tort claims, are nevertheless immunized from strict liability design defect claims because they are unavoidably unsafe as a matter of law. We will now address questions one through three.

¶27 We conclude with regard to the first and second questions that while a particular 510(k)-cleared medical device might very well be unavoidably unsafe, this is a fact-intensive question that must be raised by a defendant as an affirmative defense and determined by the factfinder on a case-by-case basis. In *Grundberg v. Upjohn Co.*, we articulated why a case-by-case approach is problematic. 813 P.2d 89, 93–95 (Utah 1991). And we are still cognizant of the problems associated with such an approach. But we were able to avoid those problems in suits involving prescription drugs only because of the rigorous FDA approval process to which they were subject. To extend our reasoning in *Grundberg* to the medical device or any other context would require an equally compelling reason, such as a similarly rigorous oversight process.

¶28 Based on the applicable regulations, we are not persuaded that 510(k) is such a process. Comment k's premise is that there are some products that are "incapable of being made safe for their intended and ordinary use." RESTATEMENT (SECOND) OF TORTS § 402A cmt k. (A.L.I. 1965). Without an FDA evaluation of a medical device's safety, we cannot know whether the device is incapable of being made safe (although it is beneficial), or whether it is "*unreasonably* dangerous." *See id.*

¶29 For example, if a medical device is subjected to FDA scrutiny for safety, and the FDA deems the device to be either unsafe or capable of being made safer, the FDA will deny the manufacturer's application to market the device. *See* 21 U.S.C. § 360e(d)(2). Whereas, if a device enters the market through the 510(k) process, the FDA has not evaluated the device for safety, and the device has no approval from the FDA in that regard. Accordingly, we cannot know whether the device is safe, incapable of being made safe, or unreasonably dangerous.

¶30 We join the many courts that have observed the 510(k) process is concerned primarily with equivalence, not safety.[12] Because of the differences between the FDA's rigorous oversight of prescription drugs and the 510(k) process for medical devices, we decline to extend the reasoning in *Grundberg* to implanted medical devices that have entered the market through the 510(k) process.

¶31 Therefore, we answer the first certified question conditionally. Although the unavoidably unsafe exception might immunize some implanted medical devices from strict products liability, when such a device enters the market through the 510(k) process, we cannot say that this will always be the case as a matter of law. Accordingly, the answer to the second question is that courts applying Utah law should treat this exception as an affirmative defense to be determined by the factfinder on a case-by-case basis.

¶32 We now address the third question regarding the proper analysis to determine whether the exception has been met. The Burninghams argue in favor of applying the Oklahoma Supreme Court's approach in *Tansy v. Dacomed Corp.*, 890 P.2d 881 (Okla. 1994). The *Tansy* court held that comment k could be raised as an affirmative defense when a medical device was incapable of being made safe, but the societal benefit warranted its production. *Id.* at

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[12] *See generally Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 344–46 (2001) (contrasting the PMA process' safety procedures with 510(k)'s equivalence procedures); *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 478–80 (1996) (stating that the 510(k) process provides little protection to the public because it is focused on equivalence, not safety); *Tingey v. Radionics*, 193 F. App'x 747, 755 (10th Cir. 2006) (noting that "the § 510(k) process is focused on equivalence rather than safety, and therefore 'provide[s] little protection to the public.'" (alteration in original) (citation omitted)); *Mitchell v. Collagen Corp.*, 126 F.3d 902, 905 (7th Cir. 1997) (noting the "stark contrast" between the PMA process' safety requirements and the 510(k) process' equivalence requirements); *Reeves v. AcroMed Corp.*, 44 F.3d 300, 303 (5th Cir. 1995) (contrasting the PMA process' scrutiny of product safety with 510(k) process' focus on determining substantial equivalence). *But see In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 770 (5th Cir. 2018) ("[T]he [FDA] has clarified, in guidance documents, that 'principles of safety and effectiveness underlie the substantial equivalence determination in every 510(k) review.'" (citation omitted)).

885.[13] The Burninghams argue that to succeed on this defense under the *Tansy* standard, the manufacturer would need to establish that (1) "the product [was] incapable of being made safe under present technology," (2) "the social need for the product warrant[ed] its production," and (3) "the product [was] properly manufactured and contain[ed] adequate warnings." *Id.* at 885–86.

¶33 While Wright Medical argues that applying comment k to implanted medical devices on a case-by-case basis would be unworkable and bad public policy for the reasons we detailed in *Grundberg*, it asserts that if we do adopt a case-by-case approach, then it should be consistent with the Model Utah Jury Instruction (MUJI) on this issue. After some introductory language to explain the concept of an "unavoidably unsafe" product to the jury, the MUJI instruction provides:

> To establish the defense that the [product] was unavoidably unsafe, [name of defendant] must prove that:
>
> (1) when the [product] was made, it could not be made safe for its intended use even applying the best available testing and research; and
>
> (2) the benefits of the [product] justified its risk.

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[13] *See also Hill v. Searle Labs.*, 884 F.2d 1064, 1068 (8th Cir. 1989) ("We agree with th[e] courts that view comment k as an affirmative defense." (citing *Kociemba v. G.D. Searle & Co.*, 680 F. Supp. 1293, 1301 (D. Minn. 1988))); *Coursen* v. A.H. Robins Co., 764 F.2d 1329, 1338 (9th Cir. 1985) (upholding a case-by-case application of comment k); *Hawkinson v. A.H. Robins Co.*, 595 F. Supp. 1290, 1308 (D. Colo. 1984) (providing that comment k is an affirmative defense); *Moss v. Wyeth Inc.*, 872 F. Supp. 2d 162, 174 (D. Conn. 2012) (concluding comment k should provide an affirmative defense); *Allen v. G.D. Searle & Co.*, 708 F. Supp. 1142, 1149 (D. Or. 1989) (applying comment k similarly, but to prescription drugs); *Larsen v. Pacesetter Sys., Inc.*, 837 P.2d 1273, 1285–86 (Haw. 1992) (holding that a pacemaker did not fall under comment k because it was "demonstrably capable of being made safe for its intended use"); *Toner v. Lederle Labs.*, 732 P.2d 297, 308 (Idaho 1987) (concluding that comment k is an affirmative defense to a claim based on strict liability).

> If [name of defendant] proves both by a preponderance of the evidence, the [product] is not defective.
>
> This defense does not apply to [name of plaintiff]'s claims that the [product] was improperly manufactured or had inadequate warnings.

MODEL UTAH JURY INSTRS. 2d CV1051.

¶34 Both proposed standards treat the unavoidably unsafe exception as an affirmative defense. And the basic elements of both are similar. The only substantial difference is that the Burninghams argue that *Tansy* requires a defendant to prove that the product was properly manufactured and had adequate warnings as elements of the affirmative defense, while Utah's instruction does not.

¶35 Notwithstanding the Burninghams' characterization, Oklahoma's Uniform Jury Instructions suggest that Oklahoma law does not materially differ from Utah's on this point. The Oklahoma instruction reads:

> Against the claim of [Plaintiff] that the [Specify Product] was defectively designed, [Defendant] has raised the defense that the [Specify Product] was unavoidably unsafe. Some products cannot be made safe for their intended use, but their benefits are great enough to justify their risks of harm. To establish the defense that the [Specify Product] was unavoidably unsafe, [Defendant] must prove by the greater weight of the evidence that:
>
> 1. The benefits of the [Specify Product] justified its risks; and
> 2. At the time of manufacture and distribution, the [Specify Product] could not be made safer for its intended use applying the best available testing and research.
>
> *[This defense does not apply if [Plaintiff] has proved by the greater weight of the evidence that [Specify Product] was improperly manufactured or had inadequate warnings.]*

OKLA. UNIFORM JURY INSTRS. § 12.11 (emphasis added).

¶36 This does not differ materially from Utah law. We made clear in *Grundberg* that the unavoidably unsafe exception is unavailable to manufacturers who improperly manufacture the

product or who provide inadequate warnings. *See Grundberg*, 813 P.2d at 90 ("[A] drug approved by the [FDA], *properly prepared, compounded, packaged*, and distributed, cannot as a matter of law be 'defective' . . . ." (emphasis added)); *see also Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 2003 UT 43, ¶ 17, 79 P.3d 922 (holding that comment k protects manufacturers from strict liability for defects "if prepared, distributed, and marketed properly and with appropriate directions and warnings").

¶37 As we explained in *Grundberg*:

> As a condition to its application, comment k requires that the product be "properly prepared, and accompanied by proper directions and warning. . ." There are three types of product defects: manufacturing flaws, design defects, and inadequate warnings regarding use. *See* Prosser & Keeton, *The Law of Torts* § 99, at 695–98 (5th ed. 1984); *Savina v. Sterling Drug, Inc.*, 247 Kan. 105, 795 P.2d 915, 923 (1990). By its terms, comment k excepts unavoidably unsafe products from strict liability only to the extent that the plaintiff alleges a design defect; comment k's immunity from strict liability does not extend to strict liability claims based on a manufacturing flaw or an inadequate warning. The purpose of comment k is to protect from strict liability products that cannot be designed more safely. If, however, such products are mismanufactured or unaccompanied by adequate warnings, the seller may be liable even if the plaintiff cannot establish the seller's negligence. *Toner v. Lederle Laboratories,* 112 Idaho 328, 732 P.2d 297, 305 (1987). . . . [T]he prerequisite to a comment k exemption—that the drug "was properly prepared and accompanied by warnings of its dangerous propensities"—must be established on a case-by-case basis. This limitation on the scope of comment k immunity is universally recognized.

813 P.2d at 92.

¶38 However, neither *Grundberg* nor the Oklahoma Uniform Jury Instruction treat proper preparation and adequate warning as elements of the unavoidably unsafe affirmative defense. Rather, these are separate claims a plaintiff must make and prove. If a plaintiff alleges manufacturing flaws or inadequate warnings and

the factfinder finds the plaintiff has proved either one by a preponderance of the evidence, then the unavoidably unsafe exception is unavailable to a defendant as an affirmative defense. But if the plaintiff does not raise either claim, or is unable to prove them, the exception is available to the defendant.

¶39 Accordingly, when an implanted medical device enters the market through the 510(k) process, and a manufacturer raises the affirmative defense that the product is unavoidably unsafe in response to a design defect claim, the manufacturer must prove by a preponderance of the evidence that (1) when the product was made, it could not be made safe for its intended use even applying the best available testing and research, and (2) the benefits of the product justified its risk. If the plaintiff has raised an improper manufacturing or inadequate warning claim, the jury also should be instructed that this affirmative defense is unavailable if the plaintiff proves by a preponderance of the evidence either of those claims.

CONCLUSION

¶40 We first address the fourth certified question to clarify that we do not opine on whether PMA-approved medical devices are unavoidably unsafe as a matter of law because they are already exempt from all state products liability claims under the United States Supreme Court's decision in *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008).

¶41 We answer the first certified question conditionally. Although the unavoidably unsafe exception might immunize some implanted medical devices from strict products liability, when such a device enters the market through the 510(k) process we cannot say that this will always be the case as a matter of law.

¶42 Regarding the second certified question, the exception does not apply categorically to all 510(k)-cleared devices. It should be raised by the defendant as an affirmative defense and determined by the factfinder on a case-by-case basis.

¶43 As to the third certified question regarding the proper analysis to determine whether the defendant has proven the exception, we conclude that the MUJI instruction properly explains Utah law. However, some additional language must be added explaining that this affirmative defense is unavailable if the plaintiff alleges and proves by a preponderance of the evidence that the product was improperly manufactured or contained inadequate warnings.