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DALE BURNINGHAM and LANA BURNINGHAM, Appellants, v. WRIGHT MEDICAL GROUP, INC.; WRIGHT MEDICAL TECHNOLOGY, INC.; AND HARLAN C. AMSTUTZ, M.D., Apellees. : Legal Brief

Utah Supreme Court

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IN THE SUPREME COURT OF THE STATE OF UTAH

DALE BURNINGHAM and LANA BURNINGHAM, Appellants, v. WRIGHT MEDICAL GROUP, INC.; WRIGHT MEDICAL TECHNOLOGY, INC.; AND HARLAN C. AMSTUTZ, M.D., Appellees.	Appellate Case No. 20180143-SC Federal Case No. 2:17-CV-92

BRIEF OF WASHINGTON LEGAL FOUNDATION AS *AMICUS CURIAE* REGARDING CERTIFIED QUESTIONS

Certified Questions from the United States District Court for the District of Utah, District Judge Jill N. Parrish

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CURRENT AND FORMER PARTIES

The parties to the proceeding in this Court and their counsel are as follows:

1. Dale and Lana Burningham, represented by Brian C. Stewart of Siegfried & Jensen, and George E. McLaughlin and Thomas R. Leemon of The Warshauer-McLaughlin Law Group, P.C.
2. Wright Medical Technology, Inc. and Wright Medical Group, Inc., represented by Elisabeth M. McOmber of Snell & Wilmer, and Dana J. Ash, Robert M. Palumbos, Sean K. Burke, and Ryan J. O'Neil of Duane Morris LLP.

The fomer parties to the underlying district court action, *Bruningham v. Wright Med. Tech., Inc.,* Case No. 2:17-cv-00092-JNP, who are not parties to the proceeding in this Court are as follows:

1. Harlan C. Amstuz, M.D., a California corporation; and
2. Harlan C. Amstuz, M.D., an individual.

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INTRODUCTION

Washington Legal Foundation (WLF) is a nonprofit, public-interest law firm and policy center with supporters in all 50 states, including Utah. WLF promotes free enterprise, individual rights, limited government, and the rule of law. To that end, WLF has appeared before both state and federal courts throughout the county to oppose the unwarranted expansion of tort liability that fosters excessive litigation and impedes development of new medical products. *See, e.g., McNair v. Johnson & Johnson*, No. 17-0519, 2018 WL 2186550 (W. Va. May 11, 2018); *Centocor, Inc. v. Hamilton*, 372 S.W.3d 140 (Tex. 2012).

WLF supports a balanced approach to products-liability rules that takes into account both the interests of consumers in adequate compensation for injuries caused by defective products and society's interest in the continued availability of products that provide significant health benefits yet are unavoidably unsafe. WLF is concerned that a decision not to apply Comment k to implanted medical devices, or to do so only on a case-by-case basis, would allow juries to question the Food and Drug Administration's (FDA) judgment about safety and effectiveness. The reasoning the Utah Supreme Court employed when recognizing Comment k's application to prescription drugs applies equally to implanted medical devices and can provide transparency and produce consistent results in court.

WLF has no direct interest, financial or otherwise, in the outcome of this litigation. Lacking any direct interest, WLF can provide the Court with a perspective distinct from that of any party.

STATEMENT OF THE ISSUES

Judge Jill N. Parrish of the United States District Court for the District of Utah certified the following questions of law to this Court:

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

Certification Order at 8 (February 15, 2018).

STATEMENT OF THE CASE

Plaintiffs Dale and Lana Burningham brought this suit in the United States District Court for the District of Utah, alleging three causes of action, including a strict liability design defect claim, against the manufacturer of medical devices implanted in both of Dale Burningham's ("Burningham") hips. Defendants (collectively, "Wright Medical") filed a motion to dismiss the strict design defect liability claim for failure to state a claim. Wright Medical argued the hip implants are "unavoidably unsafe" products and are

therefore categorically barred from strict liability design defect claims under the exception to strict products liability set forth in Comment k to Section 402A of the Restatement (Second) of Torts. The district court certified to the Utah Supreme Court the questions as outlined above. On April 2, 2018, this Court accepted the District Court's Certification of Questions of State Law. Order of Acceptance at 1-2 (April 2, 2018).

SUMMARY OF ARGUMENT

The unavoidably unsafe exception to strict products liability in design defect claims recognized in Comment k should apply categorically to all implanted medical devices. This Court adopted Comment k's policy as the law to be applied categorically to prescription drugs in Utah in 1991. *See Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991). Due to their unique characteristics, prescription drugs potentially affect each patient differently, and it is impossible to design a drug in a manner that will render it safe for all individuals. Because of this, manufacturers of prescription drugs are not strictly liable for injuries caused by these drugs, as it is impossible to design a product that provides the desired benefits while also remaining completely safe. Much the same way, implanted medical devices are unavoidably unsafe, as each device has the potential to injure certain patients based on the particular characteristics of a given individual. *Hufft v. Horowitz*, 4 Cal. App. 4th 8, 18 (1992).

Comment k will not eliminate all avenues of recovery for injured consumers. It only exempts manufacturers of implanted devices from strict products liability suits for design defects. Plaintiffs may still bring negligence claims or sue for manufacturing

defects or failure-to-warn, leaving open the ability to recover for injuries while providing some protection and clarity to manufacturers.

Public policy also favors applying Comment k categorically to implanted medical devices. Under a case-by-case approach, each case devolves into a mini-trial, allowing plaintiffs to maneuver cases to the jury, where lay jurors decide whether the benefits of a prescription drug or device outweigh the potential risks. *Grundberg*, 813 P.2d at 94-95. This leaves manufacturers unsure of which products they produce could potentially be deemed defectively designed. In many instances, manufacturers could respond by ceasing to produce devices or raising the cost and passing it on to consumers due to lost profits from lawsuits. *Id.* at 94. There is a strong public interest in favor of providing more affordable life-altering products to consumers rather than holding manufacturers to be strict insurers of their products. *Id.* at 99.

Allowing juries to decide the fate of implanted medical devices ignores the FDA approval processes. FDA analyzes implanted medical devices through the premarket approval process (PMA) or § 510(k) clearance process. FDA experts conduct a thorough risk-benefit analysis before allowing implanted medical devices to go to market. After a device is sold, doctors, who know every detail about their patients' health and individual characteristics, conduct another risk-benefit analysis to determine which device is best suitable for that particular patient, thereby further reducing the likelihood that an unavoidably unsafe implanted medical device will actually injure a patient.

The transparency and clarity of a categorical approach benefits manufacturers and consumers alike, and avoids allowing a jury to make cost-benefit determinations.

ARGUMENT

I. UNDER UTAH LAW, THE COMMENT K UNAVOIDABLY UNSAFE EXCEPTION TO STRICT PRODUCTS LIABILITY IN DESIGN DEFECT CLAIMS SHOULD APPLY CATEGORICALLY TO ALL IMPLANTED MEDICAL DEVICES

This Court, as it did in *Grundberg*, should adopt Comment k as applied categorically to medical devices. Implanted medical devices provide important benefits to consumers, yet can interact with each patient differently, making them unavoidably unsafe. The characteristics of such devices, combined with FDA oversight and the fact that doctors must prescribe them to patients before they are implanted, makes courts the wrong place to conduct risk-benefit analyses. This rationale has been recognized by court decisions from jurisdictions around the country and should apply equally in Utah.

A. Utah Applied the Comment k Exception to Prescription Drugs in *Grundberg v. Upjohn Co.*

Section 402A of the Restatement imposes strict liability on anyone "who sells any product in a defective condition unreasonably dangerous to the user or consumer, or to his property" regardless whether the seller "exercised all possible care in the preparation and sale of his product." Restatement (Second) of Torts § 402A (1965). Comment k, however, creates an exception to strict liability for "unavoidably unsafe" products. Comment k reads, in part,

> 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....Such a product, properly prepared, and accompanied by proper warning, is not defective, nor is it *unreasonably* dangerous....The seller of such products, again with the qualification that they are properly prepared and marketed, and proper warning is given...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 comment k (1965). There are some products that pose dangers even when used entirely as intended, but there is a strong public interest in making such products available, so manufacturers are not held to be strict insurers of those products. *Grundberg*, 813 P.2d at 92.

In 1991, this Court in *Grundberg* addressed the issue of whether Comment k applies in the context of prescription drugs. *Id.* at 91. In addressing the question, the Court explained that the purpose of Comment k is to "protect from strict liability products that cannot be designed more safely." *Id.* at 92. Products are deemed unavoidably unsafe if they "provide an exceptionally important benefit" yet pose a "substantial and unavoidable" risk to their users. *Id.* at 93. The Court analyzed whether prescription drugs fall into this category of products, and then considered whether Comment k should apply on a case-by-case basis or categorically to all prescription drugs. *Id.* at 93.

The Court discussed the unique characteristics of prescription drugs, noting that they can and do pose different risks to different people. *Id.* at 95. Prescription drugs fall into the category of products that can be dangerous in some circumstances even when used as intended. *Id.* It is difficult, if not impossible, to design a prescription drug that will achieve the goal of curing ailments while also causing no side effects for anyone. *Id.* Because of this, the Court held that Comment k's immunity from strict liability applies to prescription drugs. *Id.* In so holding, the Court aligned Utah with the vast majority of

states that recognize Comment k as applying to prescription drugs, thereby exempting manufacturers from strict design defect liability for injuries caused by the drugs.

The Court went a step further, holding that Comment k applies categorically to *all* prescription drugs. *Id.* at 95. The Court stated, "[W]e are troubled by the lack of uniformity and certainty inherent in the case-by-case approach and fear the resulting disincentive for pharmaceutical manufacturers to develop new products." *Id.* at 94-95. A case-by-case approach to these cases leads to "mini-trials" that have a "negative impact on the development and marketing of new drugs." *Id.* at 94 (citing *Brown v. Superior Court*, 44 Cal. 3d 1049, 1067-68 (1988)). *Grundberg* worried that adopting a case-by-case approach could "lead to disparate treatment of the same drug by different judges" and if a judge believed that "reasonable minds could differ on the question," a lay jury would decide whether a drug's benefits outweigh its inherent risks. *Id.* at 94. In fact, it is likely that this approach would not only cause confusion, but would make it more difficult for a defendant to establish Comment k immunity than to rebut a plaintiff's case of design defect under the strict liability standard. *Id.* at 95 (citing Reilly, *The Erosion of Comment k*, 14 U. DAYTON L. REV. 255, 266 (1989)). Manufacturers would be subject to more litigation under a case-by-case regime, and allowing juries to make these decisions can lead to inconsistent results. *Id.* at 94. This approach also essentially ignores FDA's regulatory process, with courts second-guessing decisions already made by the FDA. *Id.* at 95.

B. *Grundberg*'s Rationale Is Fully Applicable to Implanted Medical Devices

Implanted medical devices are extremely important (in terms of saving lives or reducing pain and suffering), go through extensive FDA review, yet inevitably lead to widely disparate outcomes based on the individual physical characteristics of each patient. Thus, the rationale from *Grundberg* should equally apply to implanted medical devices.

Like prescription drugs, implanted medical devices can be dangerous and harm certain individuals even when doctors follow all proper protocol in treating the patient. Implanted medical devices are available only through a doctor's prescription. Indeed, implanting a device physically in a patient by definition entails a doctor's assistance. *Hufft*, 4 Cal. App. 4th at 18. Devices "can save lives or reduce pain and suffering. Such products are commonly crucial to the well-being of the patient. Some devices are so important that, as is the case with prescription drugs, the patient faces death without them." *Id.*; *see also* Michael D. Green & William B. Schultz, *Tort Law Deference to FDA Regulation of Medical Devices*, 88 Geo. L.J. 2119, 2127 (2000) ("Both devices and drugs…have the potential to provide substantial social benefits."). In other cases, as with hip implants, they are vital to reducing pain and suffering and can immensely improve the quality of a patient's life. Also similar to prescription drugs, implanted medical devices "become an integrated part of the person" and pose unavoidable risk of harm to some patients dependent on the "peculiar physical characteristics of the individual." *Hufft*, 4 Cal. App. 4th at 18.

Both prescription drugs and implanted medical devices are unavoidably unsafe. *Grundberg* found, "Despite inherent risks, and in contrast to any other product, society has determined that prescription medications provide a unique benefit and so should be available to physicians with appropriate warnings and guidance as to use." *Grundberg,* 813 P.2d at 96. Likewise, implanted medical devices "are available only through a physician and can save lives or reduce pain and suffering." *Hufft*, 4 Cal. App. 4th at 18. Also like prescription drugs, "the result [of an implanted medical device] may be dependent upon the peculiar characteristics of the individual." *Id.* Even when a manufacturer seeks to market an implanted medical device by obtaining § 510(k) clearance, FDA still requires manufacturers to demonstrate that a device is at least as safe and effective as a device already on the market, the FDA determines that the benefits of implanted medical devices provide outweigh the potential risks imposed by such devices. 21 C.F.R. 807.92.

In Utah, Comment k should apply categorically to all implanted medical devices, because (as *Grundberg* explained) a case-by-case approach potentially could lead to even more confusion than maintaining strict liability. Manufacturers should have the ability to develop and produce medical devices without being strictly liable for unavoidable consequences.

C. Decisions From Other States Have Cogently Explained Why Comment K Applies Categorically to Implanted Medical Devices

The vast majority of states apply Comment k in some fashion to medical devices, relying on their reasoning for applying it to prescription drugs. And well-reasoned

decisions from across the nation support extending Comment k categorically to implanted medical devices.[1] These decisions explain why the rationale articulated in *Grundberg* applies fully to implanted medical devices.

Indeed, the only state legislature that has enacted legislation expressly applying Comment k to medical devices have done so categorically. In Ohio, the legislature enacted a law declaring that "an ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe, if the manufacturer of the ethical drug or ethical medical device provides adequate warning and instruction." Ohio Rev. Code Ann. § 2307.75(D) (West 2018).

Many courts have arrived at the same conclusion. The Washington Supreme Court held that medical devices were unavoidably unsafe, relying on comment k and the learned intermediary doctrine. *Terhune v. A.H. Robbins Co.*, 90 Wn.2d 9 (1978). The court found the unavoidably unsafe exception was based "in the character of the medical profession and the relationship which exists between the manufacturer, the physician, and the patient." *Id.* at 16.

Several state appellate courts decisions provide particularly insightful reasoning regarding the application of Comment k to implanted medical devices. Indeed, their approach is similar to that of the Utah Supreme Court in *Grundberg*.

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[1] Among the well-reasoned state court decisions that have applied Comment k categorically to medical devices are *Terhune v. A.H. Robbins Co.*, 90 Wn.2d 9 (1978) (pre-Medical Device Amendments case applying Comment k to medical device); *Hufft v. Horowitz*, 4 Cal. App. 4th 8 (1992); and *Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. 2006).

In California, courts adopt a clear categorical approach to Comment k. Beginning with *Brown* (which *Grundberg* followed when adopting Comment k), California first applied Comment k across the board to prescription drugs. *Brown*, 44 Cal. 3d at 1061. Since then, it expanded this approach to medical devices. *See Hufft*, 4 Cal. App. 4th at 11 (applying Comment k to "all implanted medical devices"). In *Hufft*, the court held that implanted medical devices "are available only through a physician and can save lives or reduce pain and suffering" and can be "so important that, as is the case with prescription drugs, the patient faces death without them." *Id.* at 18. The surgical implantation and removal of implanted medical devices poses a risk of harm akin to prescription drugs, and each patient could react differently when exposed to the device. Because of this, it is impossible to make these devices completely safe for every patient. *Id.* While there are certain inherent risks involved, the court held, "the public's interest in development, availability and affordability of medical devices demands rejection of strict liability and adoption of the Comment k standard." *Id.* at 19.

The court held, citing *Brown*, that Comment k provides a negligence standard of liability for alleged design defects, and conducting a case-by-case risk/benefit analysis of each implanted medical device would diminish the benefit of that standard. *Id.* at 19 (citing *Brown*, 44 Cal. 3d at 1069, fn. 11). Therefore, the court concluded, Comment k applies categorically to all implanted medical devices. *Id.* at 19. California holds that strict liability for design defects is never available as a matter of law. *Artiglio v. Superior Court*, 22 Cal. App. 4th 1388, 1397 (1994) (holding that medical implants available only through the services of a physician are immune from design defect strict liability).

Pennsylvania state courts have similarly concluded that the reasons for applying Comment k to prescription drugs also apply to medical devices. *See Creazzo v. Medtronic, Inc.*, 903 A.2d 24 (Pa. Super. 2006). In Pennsylvania, both the Superior Court and the Supreme Court held that Comment k precludes strict design defect liability for prescription drugs based on the policies directly expressed in Comment k. *Hahn v. Richter*, 543 Pa. 558, 560-63 (1996). The Superior Court determined that Comment k excludes prescription drugs from strict liability claims because prescription drugs are "inherently dangerous products which benefit society." *Hahn v. Richter*, 427 Pa. Super. 130, 151 (1993) *aff'd*, 543 Pa. 558 (1996).

In *Creazzo*, the Superior Court expanded Comment k's reach to implanted medical devices on a categorical basis. It agreed with the trial court's finding that, given the utility and unavoidably unsafe nature of implanted medical devices, there was no significant difference between such devices and prescription drugs from the *Hahn* decision. *Creazzo*, 903 A.2d at 31. Based on those considerations, the court concluded that there is "no reason why the same rational[e] applicable to prescription drugs may not be applied to medical devices." *Id.*

Federal courts, when called upon to interpret state law, have ruled similarly. They have relied on the policy arguments embraced in prescription drug cases to apply Comment k to medical devices.[2] The Fourth Circuit determined that, under South

[2] Several federal courts have interpreted state laws as finding medical devices to be unavoidably unsafe similar to prescription drugs. *See, e.g.*, *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230-31 (4th Cir. 1984) (applying South Carolina law, determining "certain products, particularly ethical drugs and medical devices…are deemed

Carolina law, an implanted medical device qualified as unavoidably unsafe under Comment k. *Brooks v. Medtronic, Inc.*, 750 F.2d 1227 (4th Cir. 1984). Basing its reasoning on the plain language of Comment k, the court stated, "Certain products, particularly ethical drugs and medical devices, often cause unwanted side effects despite the fact that they have been carefully designed and properly manufactured....Such products are deemed 'unavoidably unsafe,' but are not defective or unreasonably dangerous if they are marketed with proper directions for use or include adequate warnings of potential side effects." *Id.* at 1230-31.

A federal district court, applying Pennsylvania law, provides helpful guidance for why Comment k should apply to medical devices to the same extent that it applies to prescription drugs. *Soufflas v. Zimmer, Inc.*, 474 F. Supp. 2d 737 (E.D. Pa. 2007). In *Soufflas*, the court determined that Comment k applies across-the-board to implanted medical devices based on the reasoning from *Creazzo* and prescription drug cases like *Hahn*. *Id.* at 750 (citing *Creazzo*, 903 A.2d at 24, and other federal district courts that have held the same).

As the decisions of state and federal courts around the country demonstrate, the rationale for exempting prescription drugs from strict liability suits equally applies to

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'unavoidably unsafe'"); *Rodriguez v. Stryker Corp*, 680 F.3d 568, 575 (6th Cir. 2012) (applying Tennessee law, invoking comment k in case involving pain pump); *Phelps v. Sherwood Medical Industries*, 836 F.2d 296, 303 (7th Cir. 1987) (applying Indiana law, finding "no principled basis" for distinction between prescription drugs and medical devices like heart catheter at issue); *Kehm v. Procter & Gamble Manufacturing Co.*, 724 F.2d 613, 621 (8th Cir. 1983) (applying Iowa law, applying comment k broadly to include tampons); *Adams v. Synthes Spine*, 298 F.3d 1114 (9th Cir. 2002) (applying Washington law).

implanted medical devices. Prescription drugs and implanted medical devices have the potential to provide life-saving treatment for patients, and to reduce pain and suffering. Because FDA (as well as the prescribing physician) have determined that the inherent risks involved do not outweigh those benefits, juries are not the proper parties to decide that the products are subject to strict liability defective design claims. As such, the Utah Supreme Court should categorically extend Comment k to implanted medical devices

II. MANUFACTURERS OF IMPLANTED MEDICAL DEVICES SHOULD BE EXEMPTED FROM STRICT PRODUCTS LIABILITY CLAIMS FOR DESIGN DEFECTS WITHOUT REGARD TO WHETHER THE PRODUCT WAS ACCOMPANIED BY PROPER WARNINGS AND MANUFACTURED WITHOUT FAULT

Comment k only considers strict design defect liability, therefore leaving open the possibility for plaintiffs to bring other claims against manufacturers for injuries they suffer as a result of an implanted medical device, including other types of strict liability claims. Comment k does not foreclose plaintiffs from recovering for injuries. Plaintiffs in these cases often argue, however, that a manufacturer is only exempted from strict design defect liability if it can prove it also provided adequate warnings and manufactured the device properly. That argument is based on a misreading of Comment k; if a device is deemed unavoidably unsafe, a manufacturer can never be strictly liable for design defects.

Grundberg makes clear that Comment k focuses solely on design-defect allegations. That is, while the manufacturer of an unavoidably unsafe product may not be sued under Section 402A for an alleged defect in product design, it may still be sued for either of the other two types of product defects identified by *Grundberg*: manufacturing

flaws and inadequate warnings regarding use. *Grundberg*, 813 P.2d at 92 (citing Prosser & Keeton, *The Law of Torts* § 99, at 695-98 (5th ed. 1984)). According to the Utah Supreme Court,

> 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 manufacturing flaw or an inadequate warning. The purpose of Comment k is to protect from strict liability products that cannot be designed more safely.

Grundberg, 813 P.2d at 92 (emphasis added). The manufacturer's immunity from strict liability for design defects is not dependent on a showing that the product contains no manufacturing flaws and is accompanied by adequate warnings. If the plaintiff claims that the product was defectively manufactured or inadequately labeled, it may file separate causes of actions asserting those claims. But such assertions do not serve to defeat the manufacturer's Comment k defense to a design-defect strict products liability claim.

Assertions to the contrary are based on the fifth sentence of Comment k, which states that an unavoidably unsafe product, "properly prepared and accompanied by proper directions and warning is not defective, nor is it *unreasonably* dangerous." Restatement (Second) of Torts § 402A Comment k (1965); *see, e.g.* Brief of Appellee at 45, *In re: Wright Medical Technology, Inc., Conserve Hip Implant Products Liability Litigation*, No. 16-12162 (11th Cir. Aug. 31, 2016) (arguing evidence of proper manufacture and adequate warnings are prerequisites to the Comment k defense). Read in context, that sentence does not impose a limitation on Comment k defenses. Rather, the sentence in

question states that *all* Section 402A strict liability claims against an unavoidably unsafe product are foreclosed if the product is properly prepared and accompanied by proper directions and warnings. That is, the plaintiff may not assert any one of the three types of Section 402A claims against the product manufacturer. On the other hand, if the product was not properly prepared, then the plaintiff may assert a manufacturing-flaw claim (based both on Section 402A and negligence); and may assert similar failure-to-warn claims if the product is not accompanied by proper directions and warning. But the fifth sentence does not serve as a prerequisite to a manufacturer relying on the unavoidably-unsafe defense of Comment k. A contrary ruling would create "mini-trials" in each case, requiring defendants to rebut all claims in order to survive a design defect claim.

Courts have uniformly rejected this crabbed interpretation of Comment k. In California, courts have rejected the need to address manufacturing defects and adequate warnings when ruling on the question of design defect liability. *See, e.g.*, *Artiglio*, 22 Cal. App. 4th at 1393. The plaintiffs in *Artiglio* argued "that a condition to avoidance of strict liability is that the product has been marketed with adequate warnings of its potential risks." *Id.* (citing *Brown*, 44 Cal. 3d at 1061). The court disagreed, holding that, while pre-*Brown* decisions may have conflated the three theories of liability, it is now clear that each is distinguishable. The court, in rejecting the plaintiffs' arguments, noted that the *Brown* court reached "the question of strict liability based solely on design defect" and was not required to, nor did it, address whether there were manufacturing defects or a failure to warn. The court noted, however, that while Comment k exempts manufacturers of unavoidably unsafe products from strict design defect liability claims,

patients are not deprived of all recourse. Manufacturers remain liable for manufacturing defects or a failure to provide adequate warnings. *Id.*

Other courts applying California law bolster this conclusion, observing that the *Artiglio* court clearly rejected the argument that a device manufacturer can only avoid strict liability if it provides adequate warnings. *Sukonik v. Wright Med. Tech., Inc.*, 2015 WL 10682986, at *10 (C.D. Cal. Jan. 26, 2015). Rather, as the court correctly held, Comment k means that liability for defective design simply cannot be "premised on strict liability." Plaintiffs may bring negligence suits for design defect and strict liability suits for manufacturing defects and failure-to-warn, but a strict products design defect liability claim does not lie against an unavoidably unsafe product regardless whether it provided adequate warning or was manufactured without fault. *See, e.g.*, *Rhynes v. Stryker Corp.*, No. 10-5619 S.C. 2011 WL 2149095, at *7 (N.D. Cal. May 31, 2011) ("Properly read… [Comment k] means that a manufacturer of prescription medical devices can be held strictly liable only for manufacturing defects or inadequate warnings—it may not be held strictly liable for design defects….California law categorically protects manufacturers of prescription medical devices from strict liability for design defects.").

Several other courts around the country have reached the same conclusion, distinguishing design defect claims from manufacturing defect and failure-to-warn claims. Courts applying Pennsylvania law, for example, interpreted *Hahn* to mean that strict liability claims are barred in prescription medical device cases. *Killen v. Stryker Spine*, 2012 WL 4498865, at *3 (E.D. Pa. Sept. 28, 2012) (citing *Hahn*, 427 Pa. Super. at 152). Pennsylvania finds that permitting design defect claims to proceed only under a

negligence theory provides a high degree of consumer protection while also making sure a manufacturer is not strictly liable for all possible consequences. *See Hahn*, 427 Pa. Super. at 152.

The assertion that adequate warnings and no-fault manufacturing are a prerequisite to the Comment k defense is also inconsistent with the manner in which *Grundberg* addressed the products liability claims asserted in that case. In *Grundberg*, the plaintiffs brought a design defect claim as well as a failure-to-warn claim. The court permitted the plaintiffs' suit to go forward in federal court with respect to the failure-to-warn claims even as the Court held that the plaintiffs' strict liability design-defect claims were barred by Comment k. *Grundberg*, 813 P.2d at 90. If the Court had really interpreted the Comment k unavoidably-unsafe design-defect defense as inapplicable if proper directions and warning did not accompany the product, then it would not have found Comment k applicable to Grundberg's claims.

Design defect refers to the product's characteristics (as approved by FDA), whereas inadequate warnings and manufacturing defects refer to the manner in which the product is introduced to consumers. Once it is determined that Comment k covers implanted medical devices, strict products liability for design defects is precluded. S*ee Parks v. Danek Medical, Inc.*, 1999 WL 1129706, at *6 (N.D. Ind. June 17, 1999) ("The legal effect of finding a product to be 'unavoidably unsafe' under Comment k is that a plaintiff may recover based on improper or negligent preparation or inadequate warning, but not on the basis that the design of the product was defective.").

III. A RULING THAT COMMENT K IS INAPPLICABLE TO IMPLANTED MEDICAL DEVICES WOULD DETER INNOVATION AND DEPRIVE CONSUMERS OF INVALUABLE MEDICAL PRODUCTS

Borrowing from *Brown*, *Grundberg* noted several public policy reasons for applying Comment k to prescription drugs. Those policy reasons are equally applicable to implanted medical devices.

Among the policy reasons cited by the Court mitigating against imposing strict liability on manufacturers of prescription drugs were: (1) that drug manufacturers would stop producing valuable drugs due to lost profits resulting from lawsuits; (2) that consumers had a vested interest in the prompt marketing of newly discovered medical products, yet increased liability risks might cause manufacturers to delay product launches; and (3) that the added cost of insuring against strict liability suits for design defects would lead drug manufacturers to raise prices and pass those prices on to consumers, rendering the products unaffordable to some patients. *Grundberg*, 813 P.2d at 94 (citing *Brown* 44 Cal. 3d at 1064-65). Without prescription drugs to cure ailments, "the general standard of living in this country … would be seriously impaired." *Id.* at 96 (internal citation omitted). Each of these policies applies equally to implanted medical devices.

Prescription drugs, according to the Court, "have dangers associated with their use even though they are used as intended." *Grundberg*, 813 P.2d at 92. Comment k exempts prescription drugs from strict liability suits because of the "public interest in the development, availability, and reasonable price of drugs." *Id.* at 94 (citing *Brown*, 44 Cal. 3d at 1061). This logic also should apply to implanted medical devices.

The California court in *Hufft* held that implanted medical devices should be placed in the same category as prescription drugs for the same policy reasons. 4 Cal. App. 4th at 18. In *Hufft*, the court had to determine whether the reasoning of *Brown*, which held that Comment k categorically exempts manufacturers of prescription drugs from strict liability for design defects, also applies to implanted prescription medical devices. The court found that "the compelling public policy reasons articulated by the *Brown* court with regard to prescription drugs apply with equal force when the product is an implanted medical device." *Id.* at 11. Though implanted medical devices can work entirely as intended but still pose unavoidable dangers to the patients, there is a great public interest in continuing to develop life-saving medical devices that are widely available and affordable. *Id.* at 18. "Society is well served by restricting available avenues of monetary recovery in exchange for increasing availability of life-saving, suffering-alleviating products. That policy applies to medical devices and prescription drugs alike." *Id.* at 19.

Just as it applied Comment k to prescription drugs in *Grundberg*, this Court should extend Comment k to implanted medical devices categorically. A case-by-case approach is counter to the public interest, leading to mini-trials and inconsistent results. Manufacturers' focus should be on developing medical products that will best improve the quality of patients' lives, not on worrying about the possibility that a court or jury will determine that their product does not fall under the Comment k exception. *Grundberg*, 813 P.2d at 95.

IV. THE CURRENT REGULATORY STRUCTURE PROVIDES ADEQUATE PROTECTION FOR CONSUMERS, AS DEVICES CANNOT ENTER THE MARKET ABSENT SOME FORM OF FDA APPROVAL, AND DOCTORS MUST PRESCRIBE IMPLANTED DEVICES TO PATIENTS

In addition to acknowledging the public interest in the availability and affordability of prescription drugs in *Grundberg*, the Utah Supreme Court discussed the role of FDA in approving prescription drugs, noting the extensive screening process ensures the benefits of prescription drugs outweigh the risks. *Grundberg*, 813 P.2d at 96. Prescription drugs in particular are subject to years of testing and review by experts as well as postmarket surveillance to flag any potential issues that arise after the drug is on the market. *Id.* at 96-97. Comment k should and does provide a broad exemption for prescription products because they are not generally available to the public and require a doctor's prescription. *See* Michael Napoli, Jane Bockus and Sandra Zamora, *Medical Devices and Comment k: A Defense Worth Fighting For,* Rx for the Defense, DRI Newsletter (July 24, 2014), available at https://www.dykema.com/media/site_files/106_DRI%20--%20Comment%20K%20Article_5301700_2.doc. Implanted medical devices are similarly unavailable unless: (1) the FDA has approved marketing; and (2) a doctor has prescribed the medical product.

Grundberg held that Comment k applies categorically to prescription drugs based in large part on "the effectiveness of the FDA's regulatory process." *Grundberg*, 813 P.2d at 95. The Court found FDA's "extensive regulatory scheme capable of and appropriate for making the preliminary determination regarding whether a prescription drug's benefits outweigh its risks." *Id.* at 97. Combined with FDA's postmarket

surveillance of the drugs, the Court found it inappropriate to allow individual courts and juries to also "continually reevaluate a drug's risks and benefits. *Id.* To leave the question of whether a drug is unavoidably unsafe up to the jury would ignore FDA's processes.

Similarly, FDA is closely involved in the approval process of medical devices. To enter the market, FDA approves implanted medical devices in one of several ways.[3] One is the Premarket Approval (PMA), the most stringent application that requires FDA to determine whether the PMA contains sufficient valid scientific evidence that provides reasonable assurance that the device is safe and effective. *See Device Approvals, Denials, and Clearances*, U.S. Food & Drug Administration (last updated Mar. 26, 2018), https://www.fda.gov/medicaldevices/productsandmedicalprocedures /deviceapprovalsandclearances/default.htm. Many implanted medical devices are marketed only after completing the PMA approval process.

Additionally, manufacturers may obtain FDA marketing clearance by submitting a 510(k) application. *Id.* Here, manufacturers notify FDA of their intent to market a new

[3] Federal law establishes various levels of oversight for medical devices depending on the risks they present. Devices are separated into three classes, with Class I devices receiving the lowest level of oversight and Class III devices presenting the greatest risks to health and life and therefore receiving the highest level of oversight. *See generally, Riegel v. Medtronic, Inc.*, 552 U.S. 312, 316-17 (2008). Implanted devices are at the high end of FDA oversight; all are classified as either Class III devices or prescription Class II devices. WLF does not contend that simple Class I devices (*e.g.*, tongue depressors) are unavoidably unsafe or that they should qualify for Comment k exemption from strict products liability. But for all the reasons cited in *Grundberg*, *implanted* medical devices so qualify. Implanted devices—whose implantation into the human body generally requires invasive surgery—entail health risks that vary substantially and in unknown ways from patient to patient, yet at the same time they play a major role in saving lives and reducing pain and suffering.

medical device, and FDA determines whether the device is substantially equivalent to a device already on the market. *See 501(k) Clearances*, U.S. Food & Drug Administration (last updated Mar. 26, 2018), https://www.fda.gov/MedicalDevices/Productsand MedicalProcedures/DeviceApprovalsandClearances/510kClearances/default.htm. While the Section 510(k) clearance process imposes a somewhat reduced product-approval standard on manufacturers, it is nonetheless true that no device reaches the market via this process without first undergoing extensive FDA review.

FDA's review of a 510(k) application provides adequate protection for consumers before a device enters the market. FDA looks to whether a device is substantially equivalent to other legally marketed devices. It analyzes the intended use of the product, its technological characteristics, and determines whether the device is "at least as safe and effective as the legally marketed device." *Premarket Notification 510(k)*, U.S. Food & Drug Administration (last updated Mar. 27, 2018), https://www.fda.gov/medicaldevices/ deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketn otification510k/default.htm. Once a device is on the market, device manufacturers are subject to postmarket requirements and surveillance, like with prescription drugs. *Postmarket Requirements (Devices)*, U.S. Food & Drug Administration (last updated Mar. 27, 2018), https://www.fda.gov/medicaldevices/deviceregulationandguidance /postmarketrequirements/default.htm. Indeed, the U.S. Supreme Court has directly warned against the dangers of permitting state courts to second-guess the process by which FDA clears a medical device for Section 510(k) marketing, holding that (in many

instances) such products liability claims are preempted by federal law. *See Buckman Co. v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001).

Not only does FDA provide effective risk-benefit assessments, but doctors also add a layer of protection. It is the doctor's job to understand each individual patient and prescribe devices based on the patient's unique requirements. The doctor essentially conducts another risk-benefit analysis, deciding which of the available medical devices, if any, can best help a patient. While not at issue in this case, the "learned intermediary rule" provides insight into how doctors protect patients. Under this rule, a manufacturer satisfies its obligation to warn about the risks of medical products by providing such warnings to the patient's doctor. *See Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 79 P.3d 922, 928 (Utah 2003). The doctor is a learned intermediary, who receives warnings, instructions, and guidance from the manufacturer before prescribing a device for a patient. *Id.* The doctor, as the one treating a patient, is in the best position to weigh the potential dangers of implanted medical devices, and ensure, to the greatest extent possible, that a patient does not receive a device that will pose unnecessary risks. *Id.* at 928-29.

Patients are protected both by FDA and their doctors who conduct risk-benefit analyses prior to approving medical devices and later implanting them. Despite these protections, some devices still are unavoidably unsafe and can injure patients even when all necessary precautions are taken. *Hufft*, 4 Cal. App. 4th at 18. The policy behind Comment k and exempting implanted medical devices from strict product design defect liability suits is to encourage innovation in a field where human lives are at stake. It

makes no sense, then, to "impose absolute or strict liability where, in spite of the best of intentions, learning and study, a [device] did not fulfill the goal." Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying the Meaning and Policy Behind Comment k*, 42 Wash. & Lee L. Rev. 1139, 1143 (1985). FDA review and doctors' knowledge of their patients protect them from potential risks and helps ensure that the benefits of a device outweigh those risks. These protections should allow manufacturers to innovate in the implanted medical device field without fear that they will be exposed to strict liability should unavoidable injuries may occur.

CONCLUSION

For the reasons set forth in this brief, Washington Legal Foundation respectfully request the court determine that Comment k applies categorically to implanted medical devices.

Dated: October 3, 2018

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CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This brief complies with the word and page limitation of Utah R. App. P. 24(a)(11) and Utah R. App. P. 24(g)(1) because this brief contains 6,963 words, excluding the parts of the brief exempted by Utah R. App. P. 24(g)(2).
2. This brief complies with the typeface requirements of Utah R. App. P. 27 because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 13 point Times New Roman.
3. This brief complies with the requirements of Utah R. App. P. Rule 21(g).

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CERTIFICATE OF SERVICE

I hereby certify that on this 3rd day of October, 2018, I caused to be mailed, first class, postage prepaid, and also via electronic mail, a true and correct copy of the foregoing Brief of Washington Legal Foundation as Amicus Curiae Regarding Certified Questions, to the following:

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