**IN THE SUPREME COURT OF UTAH**

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| DALE BURNINGHAM and LANA BURNINGHAM,<br><br>Appellants,<br><br>v.<br>WRIGHT MEDICAL GROUP, INC.; WRIGHT MEDICAL TECHNOLOGY, INC.; AND HARLAN C. AMSTUTZ, M.D.,<br>Appellees. | Appeal No. 20180143-SC |

# *AMICI CURIAE* BRIEF OF THE ADVANCED MEDICAL TECHNOLOGY ASSOCIATION, AMERICAN TORT REFORM ASSOCIATION, BIOUTAH, CHAMBER OF COMMERCE OF THE UNITED STATES OF AMERICA, NATIONAL ASSOCIATION OF MANUFACTURERS, AND PHARMACEUTICAL RESEARCH AND MANUFACTURERS OF AMERICA


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## INTEREST OF *AMICI CURIAE*

*Amici* are organizations whose members include manufacturers, researchers, and other businesses that produce and sell pharmaceutical drugs and medical devices. *Amici* have a substantial interest in Utah's application of the unavoidably unsafe exception in Comment k to the Restatement (Second) of Torts § 402A, which protects products that, even when properly manufactured and accompanied by adequate warnings, must necessarily be dangerous in order to carry out their intended beneficial function. Prescription drugs, vaccines, and medical devices are the quintessential examples of such unavoidably unsafe products. *Amici*'s members would therefore be adversely impacted if this Court limited the unavoidably unsafe exception by finding its protections, already recognized for prescription drugs, do not apply to implanted medical devices.

*Amici* submitting this brief are:

- The Advanced Medical Technology Association, whose constituents include manufacturers and researchers in every industrial center and in all fifty states;
- The American Tort Reform Association, a nationwide civil justice reform coalition;
- BioUtah, the trade association in Utah dedicated to serving the state's life sciences industry;
- The Chamber of Commerce of the United States of America, the world's largest business federation;
- The National Association of Manufacturers, the largest manufacturing association in the United States; and
- Pharmaceutical Research and Manufacturers of America, the association representing the country's leading pharmaceutical research and biotechnology companies.

## INTRODUCTION & SUMMARY OF ARGUMENT

The certified questions provide this Court with the opportunity to ensure that Utah citizens have access to the best medical treatment available, while maintaining avenues for redress should patients suffer injury due to a manufacturer's negligence or a product defect. The Court chose this path when it adopted the principle Comment k embodies—that products which are unavoidably unsafe but nevertheless provide a medical benefit are immune from strict liability design defect claims—and held that it applies categorically in all prescription drug cases. *See Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991). The foundations for *Grundberg*'s application of Comment k, including "the strong public interest in the availability and affordability of prescription" medical products, apply equally to medical devices. *Id.* at 99. Further, as with pharmaceuticals, a case-by-case assessment of whether each medical device is unavoidably unsafe is simply "unworkable." *Id.* at 95. Such individualized inquiries foster inconsistent results and uncertainty, which deter the development and marketing of new medical therapies, eliminate physician choice, and undermine the goals Comment k promotes. Where a medical device, like a pharmaceutical, benefits a class of people, Comment k puts the risk-benefit analysis for its use where it belongs—with the physician and the FDA.

No sound basis exists to distinguish drugs from medical devices in applying Comment k. For both products, the FDA has engaged in the risk-benefit assessment over the product's design, which the comprehensive regulatory scheme requires, and a learned intermediary has engaged in a patient-specific risk-benefit assessment for its use. And, for Comment k purposes, it makes no difference which regulatory pathway—premarket

approval or 510(k) clearance—was used to obtain clearance to market the device. Just like the pathway to market for prescription drugs, both pathways for medical devices involve extensive premarket screening and post-market surveillance, which are designed to ensure the safety and effectiveness of each device that FDA clears for market. In fact, given that 510(k) clearance allows manufacturers to bring medical devices to market more efficiently (while still ensuring their safety and effectiveness), applying Comment k to 510(k)-cleared devices furthers the goal of making important medical products more promptly available and affordable. Thus, there is no need for a "mini-trial" on the Comment k defense in each case involving a 510(k)-cleared device, where a lay jury can second-guess the FDA's and prescribing doctor's risk-benefit assessments. Such second-guessing would undermine the health benefits the device provides to Utah's citizenry.

This Court should hold that the categorical approach it approved in *Grundberg* of providing immunity from strict liability design defect claims for all FDA-approved prescription drugs applies equally to implanted medical devices cleared by the FDA and available only through a physician.

## ARGUMENT

### I. THIS COURT SHOULD EXTEND ITS CATEGORICAL APPLICATION OF COMMENT K TO IMPLANTED MEDICAL DEVICES.

#### A. Strong Public Policy Principles Underlie This Court's Categorical Application of Comment K in *Grundberg*.

In *Grundberg*, this Court held that "all prescription drugs should be classified as unavoidably dangerous in design because of 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 the significant public policy considerations." *Id.* at 95. The Court recognized that, "by characterizing all FDA-approved prescription medications as 'unavoidably unsafe,' we are expanding the literal interpretation of comment k" to establish a "broad grant of immunity from strict liability claims based on design defects." *Id.* at 90, 99.[1]

After "reviewing the approaches of other jurisdictions," this Court categorically applied Comment k because of concerns regarding "the lack of uniformity and certainty inherent in the case-by-case approach and fear [about] the resulting disincentive for pharmaceutical manufacturers to develop new products." *Id.* at 94-95. In particular, the Court relied on the California Supreme Court's reasoning in *Brown v. Superior Court*, which detailed fundamental deficiencies with the potential case-by-case application of Comment k, including unpredictable "mini-trials" over the importance or desirability of a drug product, "conflicting conclusions" regarding the risks and benefits (and thus disparate treatment) of the same drug, and increased research, development, and insurance costs from litigation—all of which impede the development and marketing of new drugs benefitting society. 751 P.2d 470, 480-82 (Cal. 1988).

This Court agreed that the case-by-case application of Comment k could cause manufacturers to "stop producing valuable drugs because of lost profits resulting from lawsuits or the inability to secure adequate insurance," result in "delay placing new

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[1] Subsequent decisions have reaffirmed this broad grant of immunity. *See Schaerrer v. Stewart's Plaza Pharmacy, Inc.*, 2003 UT 43, ¶ 18, 79 P.3d 922, 928 ("[U]nder Utah law, comment k shields manufacturers and sellers of prescription drugs from strict liability based on allegations of a design defect.").

products on the market, even after those products receive FDA approval," and "cause the cost of medication to increase to the extent that it would no longer be affordable to consumers." *Grundberg*, 813 P.2d at 94; *see also Brown*, 751 P.2d at 479 (stating such concerns are "far from theoretical" and providing examples of drugs withdrawn from the market or their availability curtailed because of liability concerns). The Court doubted that "a *court* is the proper body to engage" in the "weighing of the drug's risks and benefits" on a case-by-case basis, instead finding it best to defer to the FDA's "extensive regulatory scheme." *Id.* at 95, 97 (internal quotation marks omitted). The Court thus held "the case-by-case method...is unworkable" and the categorical application of Comment k was "more in line with the public policy considerations in the important area of pharmaceutical product design." *Id.*

### B. *Grundberg*'s Public-Policy Foundations Apply Equally to Implanted Medical Devices.

Although *Grundberg* specifically addressed prescription drugs, this Court broadly "agree[d] with the principle Comment k embodies, that manufacturers of unavoidably dangerous products should not be liable for a claim of design defect." *Id.* at 95. Of all the categories of other products to include within this broad rule, implanted medical devices top the list. After all, implanted medical devices, like drugs, "almost always pose some risk of side effects in certain individuals," but are allowed to be marketed "because of their social benefit in saving lives and alleviating human suffering. The health care system and general standard of living in this country, for example, would be seriously impaired without such essential [medical] products." *Id.* at 95-96.

Because *Grundberg* looked to California courts for guidance in adopting and applying Comment k to prescription medicines, it makes sense to look at how California has applied Comment k to implanted medical devices. Numerous California cases extend Comment k categorically to implanted medical devices based on the same "compelling public policy reasons articulated" with respect to prescription drugs. *Hufft v. Horowitz*, 5 Cal. Rptr. 2d 377, 378 (Cal. Ct. App. 1992); *see also Plenger v. Alza Corp.*, 13 Cal. Rptr. 2d 811, 817, 818 (Cal. Ct. App. 1992) ("We...are unable to make any principled distinction in terms of policy considerations between prescription drugs and prescription implanted medical devices.").

Indeed, implanted medical devices, "like prescription drugs, are available only through a physician[,] can save lives or reduce pain and suffering," "are commonly crucial to the well-being of the patient," and may be "so important that, as is the case with prescription drugs, the patient faces death without them." *Hufft*, 5 Cal. Rptr. 2d at 383. Other devices "may have direct or indirect effects on the patient's physical, mental or emotional health" or "serve the salutary purpose of restoring a degree of normalcy to the lives of those who suffer organic dysfunctions and an impaired quality of life." *Id.*[2] These commonalities led California courts to conclude that the "risks attendant to

[2] *See also Artiglio v. Superior Court*, 27 Cal. Rptr. 2d 589, 592 (Cal. Ct. App. 1994) ("it seems sophistic indeed to suggest that medical devices which enhance esteem and add to life's enjoyment are somehow not as protectible as those which merely increase health or combat disease"); *Hufft*, 5 Cal. Rptr. 2d at 383 ("[W]hen distinctions are made among medical products, implanted medical devices must be placed in a category with prescription drugs, not wheelchairs or other important items that are of comfort or assistance to patients, but do not become an integrated part of the person.").

implanted medical devices are akin to those of prescription drugs," such that "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 383-84. The court added that, "in a world of trade-offs, society is well served by restricting avenues of monetary recovery in exchange for increasing the availability of life-saving, suffering-alleviating products" through a categorical, "bright line" bar on medical device design defect claims. *Id.* at 384.[3]

Other courts agree with this public-policy rationale. For example, the Washington Supreme Court, in a series of decisions, examined the contours and policy underlying Comment k and found it "especially applicable to medical products." *Ruiz-Guzman v. Amvac Chem. Corp.*, 7 P.3d 795, 803 (Wash. 2000); *see also Terhune v. A.H. Robins Co.*, 577 P.2d 975, 979 (Wash. 1978) (applying Comment k to medical device).[4] In deciding that "a separate determination of whether a product is unavoidably unsafe need not be made on a case-by-case basis," the court focused on policy considerations, stating:

> Comment k justifies an exception from strict liability by focusing on the product and its relative value to society, rather than on the manufacturer's position in the stream of commerce. Some products are necessary regardless of the risks involved to the user. The alternative would be that a product, essential to sustain the life of some individuals, would not be

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[3] *See also Garrett v. Howmedica Osteonics Corp.*, 153 Cal. Rptr. 3d 693, 701 (Cal. Ct. App. 2013) (stating that design liability exemption for medical devices applies to any implanted medical device "regardless of whether it is properly characterized as a 'prescription' implanted medical device").

[4] *See also Transue v. Aesthetech Corp.*, 341 F.3d 911, 915 (9th Cir. 2003) ("Under Washington law, comment k affords a blanket exemption from strict liability for design defects in medical devices or products.").

> available—thus resulting in a greater harm to the individual than that risked through use of the product.

*Young v. Key Pharm., Inc.*, 922 P.2d 59, 64 (Wash. 1996) (en banc) (quoting *Rogers v. Miles Labs, Inc.*, 802 P.2d 1346, 1351 (Wash. 1991)), *declined to be followed on other grounds by Taylor v. Intuitive Surgical, Inc.*, 389 P.3d 517 (Wash. 2017).

The Pennsylvania Supreme Court also has "taken a blanket approach applying comment k to preclude strict-liability design-defect claims for all prescription drugs," *Lance v. Wyeth*, 85 A.3d 434, 442 n.11 (Pa. 2014), which "has been consistently applied by Pennsylvania state and federal courts to medical device cases," *Wilson v. Synthes USA Prods., LLC*, 116 F. Supp. 3d 463, 465-66 (E.D. Pa. 2015) (citing case examples). The Connecticut Supreme Court similarly has adopted a categorical rule precluding design liability, finding "no principled reason to distinguish between a prescription implantable medical device...and a prescription drug." *Hurley v. Heart Physicians, P.C.*, 898 A.2d 777, 784 (Conn. 2006).[5]

Several federal appellate courts interpreting state law have additionally applied Comment k in a categorical fashion to implanted medical devices. *See, e.g., Rodriguez v. Stryker Co.*, 680 F.3d 568, 575 (6th Cir. 2012) (Tennessee law) (implanted pain pump); *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1230-31 (4th Cir. 1984) (South Carolina law) (implanted cardiac pacemaker). In other states, public policy categorically barring design liability for prescription drugs and medical devices is provided by statute. *See* N.J. Stat.

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[5] *See also Emody v. Medtronic, Inc.*, 238 F. Supp. 2d 1291, 1296 (N.D. Ala. 2003) (agreeing that "prescription medical devices are unavoidably unsafe products") (Alabama law).

Ann. § 2A:58C-3 (manufacturer or seller "shall not be liable" for design defect where "harm was caused by an unavoidably unsafe aspect of the product"); Ohio Rev. Code Ann. § 2307.75(D) ("An ethical drug or ethical medical device is not defective in design or formulation because some aspect of it is unavoidably unsafe....").

A principal reason courts and legislatures have made such policy determinations is the same concern expressed in *Grundberg*—that uncertain liability exposure will stifle innovation with respect to pharmaceuticals and medical devices. *See* Michael D. Greenberg, *Medical Malpractice and New Devices: Defining an Elusive Standard of Care*, 19 Health Matrix 423, 425 (2009) (observing that liability law acts as "a deterrent to medical innovation, and a market barrier to demand for new technologies, even where those technologies offer broad social benefits in the form of superior clinical outcomes and/or reduced administrative cost").[6] Both Congress and federal regulators have echoed these concerns. *See In re Medtronic Sprint Fidelis Leads Prods. Liab. Litig.*, 592 F. Supp. 2d 1147, 1166 (D. Minn. 2009) (recognizing that "Congress has decided to limit medical device manufacturers' liability in order to spur innovation"); *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years*, Inst. of Med., (2011), at xi (stating the FDA's "goals of the 510(k) clearance process are to 'make available to consumers devices that are safe and effective' and to 'promote innovation in the medical device industry'").

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[6] *See also* Margaret Gilhooley, *Innovative Drugs, Products Liability, Regulatory Compliance, and Patient Choice*, 24 Seton Hall L. Rev. 1481, 1483 (1994) (noting that "medical experts have expressed concern that uncertain liability standards, coupled with litigation costs, may discourage useful drug innovation").

In addition, numerous studies demonstrate that concerns with respect to impairing product innovation are not just hypothetical, but rather have real world consequences. *See, e.g.*, National Academy of Sciences, *Developing New Contraceptives: Obstacles and Opportunities* 3-4 (1990) (concluding that the net effect of surges in liability costs discouraged innovation in the pharmaceutical industry, particularly with respect to contraceptives); W. Kip Viscusi & Michael J. Moore, *An Industrial Profile of the Links Between Product Liability and Innovation*, in The Liability Maze 81-119 (Peter W. Huber & Robert E. Litan, eds., 1991) (providing statistical evidence from a number of industries that higher tort liability dampens new product development and innovation).[7]

As the California Supreme Court recognized, beneficial products such as vaccines and other drug treatments have been withdrawn from the market due primarily to liability concerns. *See Brown*, 751 P. 2d at 479-80 (providing as examples influenza vaccine, diphtheria-tetanus-pertussis vaccine, "the only antinauseant drug available for pregnant women," and a "new drug for the treatment of vision problems"). With respect to medical devices, one of the two U.S. manufacturers in the 1990s of ultra-high molecular weight polyethylene, a material commonly used in some orthopedic joints, withdrew from the medical devices market, citing liability concerns. *See Chemical Makers Back Implant Litigation Law*, 251 Chemical Mkt. Rep. 6 (1997). These liability concerns became so severe, and the supply of critical materials so scarce, that Congress intervened

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[7] *See also Reporters' Study: Enterprise Responsibility for Personal Injury*, American Law Inst., at 83-110 (1991) (subjecting products such as medical devices to both regulation and tort litigation imposes "special burdens on new products and processes and threatens innovation").

to provide a measure of relief with the enactment of the Biomaterials Access Assurance Act of 1998. *See* 21 U.S.C. §§ 1601, *et seq.* Although this law has helped safeguard the economic viability of many medical devices, liability issues remain a chief concern of medical device manufacturers and a formidable barrier to innovation. These issues are critically important to *amici* and their constituency, whose goals are to provide the best medical therapies possible for our society.

A review of the case law around the country regarding the adoption and application of Comment k to prescription drugs and medical devices, both categorically and on a case-by-case basis, reveals apparent uniformity in two key areas. First, it does not appear that any jurisdiction that has adopted Comment k with respect to prescription drugs has expressly rejected its application to implanted medical devices when presented with that question. Second, it does not appear that any jurisdiction that has adopted Comment k for prescription drugs, whether categorically or for case-by-case application, has applied it in the opposite fashion for implanted medical devices; if it is categorical for drugs, it is categorical for devices.[8] Therefore, rejecting Comment k for implanted medical devices or applying Comment k to medical devices on a case-by-case basis would make Utah product liability law an anomaly.

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[8] *See, e.g.*, *Prather v. Abbott Labs.*, 960 F. Supp. 2d 700, 707-08 (W.D. Ky. 2013) (concluding implanted medical device within purview of Kentucky's case-by-case application of Comment k); *Tansy v. Dacomed Corp.*, 890 P.2d 881, 886 (Ok. 1994) (same for Oklahoma law).

This Court should, instead, follow the sound public-policy rationales expressed in *Grundberg* and provide consistency in Comment k's application by extending the categorical bar on design defect liability to implanted medical devices.[9]

## II. THE UNAVOIDABLY UNSAFE EXCEPTION SHOULD APPLY TO ALL FDA-CLEARED IMPLANTED MEDICAL DEVICES OBTAINED THROUGH A DOCTOR.

Comment k should apply to all implanted medical devices cleared to market through ***either*** the PMA ***or*** the 510(k) process, without distinction. Not only does the comprehensive regulatory scheme governing both processes require the type of FDA risk-benefit determinations to which this Court deferred in *Grundberg*, the policy rationales underlying *Grundberg*'s application of Comment k to drugs applies equally—if not more forcefully—to 510(k)-cleared devices. Moreover, a fundamental principle underlying the application of Comment k to prescription medical products is that the prescribing physician, as the learned intermediary, conducts the ultimate risk-benefit analysis for its use, determining that the product's benefits outweigh its risks for that particular patient. This principle applies in the same way to implanted medical devices. Hence, this Court should determine that the unavoidably unsafe exception applies to all implanted medical devices that have been cleared to market by the FDA and can be obtained only through a physician.

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[9] *Cf.* Victor E. Schwartz, *Unavoidably Unsafe Products: Clarifying The Meaning and Policy Behind Comment K*, 42 Wash. & Lee L. Rev. 1139, 1148 (1985) ("The policy of encouraging innovation in the drug field would seem to be one that should not wither with time but should be encouraged now and in the future.").

### A. *Grunberg*'s Policy of Deference to FDA Regulation and Determinations Applies Equally to Implants Cleared Through the PMA or 510(k) Process.

The policy considerations this Court endorsed in *Grundberg* fully support the application of Comment k to medical devices cleared through the PMA and 510(k) processes alike. In applying Comment k to all FDA-approved prescription drugs, this Court relied, in large part, on deference to the Congressionally-created regulatory framework governing prescription drugs and the FDA's risk-benefit analysis in approving particular drugs to market. *See Grundberg*, 813 P.2d at 99. The same deference is owed to the regulatory scheme governing medical devices—regardless of whether the subject device was cleared to be marketed through the PMA or 510(k) process.

#### 1. FDA Premarket Screening.

Just as "the FDA employs a comprehensive scheme of premarket screening and post-market surveillance to ensure the safety and efficacy of all licensed medications," *id.* at 96, so too does the FDA employ a similar scheme to ensure the safety and efficacy of all medical devices. In the Medical Device Amendments of 1976 ("MDA"), 21 U.S.C. § 360, *et seq.*, to the Federal Food, Drug, and Cosmetic Act ("FDCA"), 21 U.S.C. § 301, *et seq.*, Congress directed the FDA to convene panels of medical and scientific professionals to survey existing medical devices and place them into one of three risk classifications—Class I (lowest risk), Class II (intermediate risk), and Class III (highest risk). *See* 21 U.S.C. § 360c(a)(1). For each risk classification, Congress specified a different degree of government regulation, so as to provide—for all existing and future medical devices—a "reasonable assurance of [] safety and effectiveness." *Id.*; *see also*

*Food & Drug Admin. v. Brown & Williamson Tobacco Corp.*, 529 U.S. 120, 134 (2000) ("Regardless of which category the FDA chooses, there must be a 'reasonable assurance of the safety and effectiveness of the device.'").[10]

Since passage of the MDA, this regulatory scheme has been expanded still further with the enactment of, *e.g.*, the Safe Medical Devices Act of 1990, the Food and Drug Modernization Act of 1997, and the Medical Device User Fee and Modernization Act of 2002 as later amendments to the FDCA. "These various statutory enactments substantially enhanced and further expanded the FDA's regulatory control over medical devices to better ensure their safety and effectiveness." Ralph F. Hall, et al., *Rethinking* Lohr*: Does "SE" Mean Safe and Effective, Substantially Equivalent, or Both?*, 13 Minn. J. L. Sci. & Tech. 737, 745 (2012).

Class I medical devices are typically simple devices that present a low risk, such as scalpels, bandages, tongue depressors, and medical gloves, and may be marketed if they satisfy certain "general controls." "Controls" are regulatory measures necessary to assure the safety and effectiveness of a device. *See* 21 U.S.C. § 360c. "General controls" include registration and listing requirements, good manufacturing practices, labeling requirements, compliance with quality system regulations (*i.e.*, the so-called QSR requirements generally found in 21 C.F.R. § 820), and postmarket reporting obligations. *See* 21 U.S.C. § 360c(a)(1)(A). While all medical devices—Class I, II, and III—are

[10] For medical implants in particular, the MDA was especially stringent. For a device "intended to be implanted in the human body," the medico-scientific panels had to explain why Class III treatment was "not necessary to provide reasonable assurance of its safety and effectiveness." 21 U.S.C. § 360c(c)(2)(C).

subject to general controls, Class I devices, by definition, are those devices for which general controls "are sufficient to provide reasonable assurance of [] safety and effectiveness" or which are not for "a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health" and do not "present a potential unreasonable risk of illness or injury." *Id.* Prior authorization by the FDA is typically not required to market Class I devices. *Id.*

Class II devices, in comparison, are devices for which general controls by themselves are not sufficient to provide reasonable assurance of safety and effectiveness, but for which "there is sufficient information to establish special controls to provide such assurance." 21 U.S.C. § 360c(a)(1)(B). Hence, a device may be placed in Class II only if the FDA has determined that, with special controls, it does not present an "unreasonable risk of illness or injury" that would require it to be in Class III. 21 U.S.C. § 360c(a)(1)(C). Special controls can include requirements for clinical data, bench testing, satisfaction of consensus standards, use of specific materials, patient registries, FDA guidelines and recommendations, and postmarket surveillance. *See* 21 U.S.C. § 360c(a)(1)(B); 21 C.F.R. § 860.3(c)(2); Hall, *supra*, at 772. The FDA determines which types of devices belong in Class II using medical panels whose qualifications are dictated by Congress. *See* 31 U.S.C. § 360c(b)-(d). Class II devices include ultrasonic diagnostic equipment, x-ray machines, biopsy needles, syringes, sutures, insulin pumps, and prostheses.

Unless exempted from premarket review, Class II devices are subject to the "premarket notification" or 510(k) clearance process, rather than the PMA process

reserved for Class III devices. The 510(k) clearance process is a premarket screening process through which many of these special controls are verified to have been met. *See* 21 U.S.C. § 360c(a)(1)(A)-(C); 21 U.S.C. § 360(k).[11] To obtain 510(k) clearance, a manufacturer must demonstrate to the FDA's satisfaction that its device is "substantially equivalent" to an already legally marketed predicate device. *See* 21 U.S.C. § 360c(f)(1). "Substantial equivalence" means that the device (1) has the same intended use as the predicate and (2)(a) has the same technological characteristics as the predicate ***or*** (b) has different technological characteristics but those characteristics "do not raise different questions of safety and effectiveness" and it is demonstrated that the device is "as safe and effective as" the predicate. 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b). In other words, the FDA may grant 510(k) clearance ***only if the new medical device is at least "as safe and effective" as the predicate***. 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b).[12] It is a "common law" type of system, in which safety is based on precedent—*i.e.*, a "predicate" device.

Substantial equivalence is demonstrated by way of a 510(k) application to the FDA. *See* 21 U.S.C. § 360c(i)(1); 21 U.S.C. § 360(k). The 510(k) submission must include: a statement of the device's intended use and an explanation as to why any

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[11] Indeed, the predominant special control the FDA employs today is the issuance of guidance documents for the content of 510(k) applications. *See* Jeffrey K. Shapiro, *Substantial Equivalence Premarket Review: The Right Approach for Most Medical Devices*, 69 Food & Drug L.J. 365, 369 (2014); *see also* 21 U.S.C. § 360c(a)(1)(B).

[12] Although the Safe Medical Devices Act of 1990 first codified this definition of "substantial equivalence," it was essentially the same definition that the FDA had developed administratively since the passage of the MDA in 1976. *See* Shapiro, *supra*, at 369.

difference in intended use from the predicate device does not affect safety and effectiveness; a description of the device, including its technological characteristics such as its materials, design, energy source, and other features, and a comparison of those characteristics to the predicate device; the proposed labeling for the device; "an adequate summary of any information respecting safety and effectiveness," including "detailed information regarding data concerning adverse health effects"; and any clinical or scientific data necessary to support a substantial equivalence finding. *See* 21 U.S.C. § 360c(i)(1); 21 C.F.R. § 807.87; 21 C.F.R. § 807.92.

Although it is possible to obtain clearance by submitting only descriptive information about a device, "[v]ery few 510(k) submissions rely solely on descriptive information." FDA Guidance, *The 510(k) Program: Evaluating Substantial Equivalence in Premarket Notifications [510(k)]* at 22 (July 28, 2014) ("2014 FDA 510(k) Guidance"), *available at* https://www.fda.gov/downloads/MedicalDevices/.../UCM284443.pdf. Indeed, "[i]t is not uncommon for applicants to present significant laboratory, animal, and/or clinical data running to thousands of pages," and the FDA now has "a 25 page checklist of requirements that must be met just for a 510(k) notification to be administratively accepted for review." Shapiro, *supra*, at 382. Non-clinical data can include: bench testing on, *e.g.*, mechanical, electrical, and biological engineering performance, such as fatigue, wear, tensile strength, compression, flowrate, and burst pressure; electromagnetic compatibility; sterility; stability/shelf life; and software validation, as well as non-clinical animal and/or biocompatibility studies. *See* 2014 FDA 510(k) Guidance at 22. The FDA also has the authority to require additional preclinical

and/or clinical data and design or labeling changes as necessary to establish substantial equivalence. *See* 21 U.S.C. § 360c(i)(1)(A); 21 C.F.R. § 807.100(b); Shapiro, *supra*, at 369. It takes an average of six months for the FDA to review a 510(k) application and clear the subject device to market. *See* Emergo Group, *How long it takes the US FDA to clear medical devices via the 510(k) process* at 5 (March 2017), *available at* https://www.emergogroup.com/sites/default/files/emergo-fda-510k-data-analysis-2017.pdf.

The normal use of 510(k) is to clear types of devices which the FDA, based on medical panel review, has placed in Class II as not presenting an unreasonable risk. Because that is the context in which 510(k) equivalence review is today almost always used, the rate of serious recalls is ***actually lower*** for 510(k) cleared devices than for PMA devices, even though the 510(k) process is more abbreviated. *See* Shapiro, *supra*, at 390.

Class III devices, in turn, are those high risk devices for which general controls, by themselves, are insufficient and there is insufficient information to establish special controls to provide reasonable assurance of their safety and effectiveness. *See* 21 U.S.C. § 360c(a)(1)(C). Class III devices include pacemakers, heart valves, and hemodialysis machines. With respect to the categories of implanted medical devices specifically, most are in Class II, while higher risk implants are in Class III. *See* FDA Product Classification Database, *available at* https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cfPCD/classification.cfm (showing 361 Class II implanted devices, 196 Class III implanted devices, and four Class I implanted devices).

Marketing Class III devices generally requires undergoing the PMA process, typically involving more extensive submissions, detailed analysis, advisory panel review,

a pre-approval manufacturing inspection, and the completion of non-clinical laboratory studies and premarket clinical trials. *See* 21 U.S.C. § 360c(a)(1)(C); 21 U.S.C. § 360e(a), (c), (f); 21 C.F.R. § 812.2; 21 C.F.R. Part 814.[13] Among other things, a PMA submission requires: information concerning investigations into the device's safety and effectiveness; a statement of the device's components, properties, and principles of operation; a description of the device's manufacture and processing; device samples as required; and proposed labeling. *See* 21 U.S.C. § 360e(c).

In short, the 510(k) and PMA processes are both part of a comprehensive regulatory scheme, as envisioned by Congress and executed by the FDA, specifically designed to ensure that all marketed medical devices are reasonably safe and effective. *See* 21 U.S.C. § 360c(a)(1); *see also Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 349-50 (2001) (both the PMA and the 510(k) processes are intended "to ensure...that medical devices are reasonably safe and effective" and form part of the "flexib[le]...statutory and regulatory framework under which the FDA pursues difficult (and often competing) objectives"); *id.* at 348-49 (stating the 510(k) process is a "comprehensive scheme" that "imposes upon applicants a variety of requirements"—including the submission of a whole host of information—"that are designed to enable

[13] For transitional purposes, Congress allowed the clearance of certain Class III devices if the 510(k) process showed them to be substantially equivalent to a pre-1976 device. It was in this odd context that *Medtronic, Inc. v. Lohr*, 518 U.S. 470 (1996), was decided. That transitional process is now nearly obsolete because devices have now been classified. *Lohr* thus provides no guidance with respect to the normal use of 510(k), which is for devices the FDA has placed in Class II based on the recommendation of a Congressionally-mandated medical panel. In the normal case, a 510(k) determination of "equivalence" is a safety determination.

the FDA to make its statutorily required judgment as to whether the device" may be legally marketed).

Indeed, as the FDA itself has stated, the 510(k) program is "a multifaceted premarket review process that is expected to assure that cleared devices, subject to general and applicable special controls, provide reasonable assurance of safety and effectiveness, and to facilitate innovation in the medical device industry." FDA CDRH Preliminary Internal Evaluations – Vol. 1, 510(k) Working Group Preliminary Report and Recommendations at 34 (Aug. 2010), *available at* https://www.fda.gov/downloads/AboutFDA/CentersOffices/OfficeofMedicalProductsandTobacco/CDRH/CDRHReports/UCM220784.pdf; *see also* 2014 FDA 510(k) Guidance at 7 ("Although the 510(k) process involves a comparison of a new device to a predicate device rather than an independent demonstration of the new device's safety and effectiveness, as is required for approval of a PMA, in both cases FDA's review decision reflects a determination of the level of control necessary to provide a 'reasonable assurance of safety and effectiveness.'").

Nor is there any question that, as with the licensing of drugs, the FDA's licensing of medical devices necessarily involves a determination "that the potential benefits of the product outweigh any associated risks." *Grundberg*, 813 P.2d at 96. The FDA itself has made this clear:

> While there are distinctions in the review framework for different types of medical products, as a general matter, FDA considers the benefit-risk profile of the product for each intended use during the premarket review process. In that process, FDA considers whether the established health

> benefits of the product for a particular use outweigh the identified risks of the product.

FDA, Memorandum, Public Health Interests and First Amendment Considerations Related to Manufacturer Communications Regarding Unapproved Uses of Approved or Cleared Medical Products, at 2, Docket No. FDA-2016-N-1149, Jan. 17, 2017 ("FDA Memo"), *available at* http://www.ascrs.org/sites/default/files/FDA_Memorandum--Public_Health_Interests_and_First_Amendment_Considerations_Related_to_Manufacturer_Communications_Regarding_Unapproved_Uses_of_Approved_or_Cleared_Medical_Products_Jan_2017%20%281%29.pdf. These FDA statements "reflect a body of experience and informed judgment to which courts and litigants may properly resort for guidance" and thus merit deference. *Fed. Exp. Corp. v. Holowecki*, 552 U.S. 389, 399 (2008) (internal quotation marks omitted); *see also Schaerrer*, 2003 UT 43, ¶ 28 ("While the policy statements of the FDA are by no means binding on this court, they do provide meaningful guidance....").

**2. FDA Post-Market Surveillance.**

In addition to these comprehensive premarket screening processes, medical device manufacturers must comply with post-market surveillance and adverse event reporting requirements, and these requirements make no distinction between devices cleared to be marketed through the PMA or 510(k) process. Whichever process is used, federal regulations require the manufacturer (and any importer) of the device to report to the FDA, in the form of Medical Device Reports ("MDRs"), whenever one of its devices "may have caused or contributed to a death or serious injury" or "has malfunctioned

and…would be likely to cause or contribute to a death or serious injury if the malfunction were to recur." 21 U.S.C. § 360i(a)(1); 21 C.F.R. §§ 803.40, 803.50.[14]

Nor may manufacturers simply report only that information they passively receive; rather, they must exercise due diligence in investigating and reporting adverse events. Federal regulations require manufacturers to report all information "reasonably known" to them, which includes "[a]ny information that [they] can obtain by contacting a user facility, importer, or other initial reporter" and "[a]ny information that [they] can obtain by analysis, testing or other evaluation of the device." 21 C.F.R. § 803.50(b)(1). Thus, not only must a manufacturer contact user facilities for information, it must also seek to retrieve and test the subject device. *See id.* The manufacturer must also "conduct[] an investigation of each event and evaluat[e] the cause." 21 C.F.R. § 803.50(b)(3).

The breadth of a manufacturer's post-market surveillance obligations is also evidenced by the MDR form itself. A manufacturer's MDR must contain a broad array of information, including: patient information; a description of the adverse event and any outcomes attributed to it; detailed device information including whether the device was available for evaluation or was returned to the manufacturer; and whether remedial action was taken. *See* 21 C.F.R. § 803.52. And if a manufacturer obtains additional information

[14] The timetables for submitting these MDRs are also relatively tight. While manufacturers must typically report adverse events within 30 days of becoming aware of them, 21 C.F.R. § 803.50(a), they must submit MDRs within five days of becoming aware that "[a]n MDR reportable event necessitates remedial action to prevent an unreasonable risk of substantial harm to the public health." 21 C.F.R. § 803.53(a).

regarding a reportable event after submitting its initial MDR, it must submit a follow-up MDR containing such information. *See* 21 C.F.R. § 803.56.[15]

To further advance its goal of timely and effective post-market surveillance, the FDA also imposes adverse event reporting requirements on users of the device. Device user facilities (*e.g.*, hospitals) must report (a) to the FDA and to the manufacturer, if known, whenever they "become[] aware of information that reasonably suggests that a device has or may have caused or contributed to the death of a patient," and (b) to the manufacturer, or to the FDA if the manufacturer is unknown, whenever they "become[] aware of information that reasonably suggests that a device has or may have caused or contributed to the serious illness of, or serious injury to, a patient." 21 U.S.C. § 360i(b)(1)(A)-(B); 21 C.F.R. § 803.30. Device user facilities must also submit to the FDA an annual summary of all MDRs they have made in the previous year. *See* 21 U.S.C. § 360i(b)(1)(C); 21 C.F.R. § 803.1(a).

In addition to reporting adverse events, all device user facilities, importers, and manufacturers must maintain MDR event files as well as written procedures for (a) internal systems for the timely and effective identification, evaluation, and reporting of adverse events, and (b) documentation and recordkeeping requirements for all adverse event information, MDRs, and information used to prepare annual reports. *See* 21 C.F.R.

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[15] The FDA has also issued lengthy guidance documents on MDR reporting to assist manufacturers in complying with their various reporting obligations. *See* FDA Guidance, Medical Device Reporting for Manufacturers (Nov. 8, 2016) ("2016 FDA MDR Guidance"), *available at* https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm359566.pdf.

§§ 803.17, 803.18. All MDR event files are subject to inspection by the FDA at any reasonable time. *See* 21 C.F.R. § 803.18(b)(2).[16]

The FDA also has the power to enforce these post-market surveillance requirements and otherwise ensure that all marketed devices are reasonably safe. For example, if an MDR raises concerns about a device's post-market clinical experience, the FDA may require the manufacturer to submit data to address those concerns. *See* 21 C.F.R. §§ 803.10(c)(2)(ii), 803.52(f)(2); Shapiro, *supra*, at 386. Also, if a manufacturer neglects its MDR reporting obligations, the FDA has numerous enforcement mechanisms at its disposal to police compliance, including "seizure, injunction, civil money penalties, and criminal prosecution." 2016 FDA MDR Guidance at 2. Aside from post-market surveillance, the FDA additionally has broad authority to: restrict the sale, distribution, and use of specific device types; ban unsafe devices from the market; and order mandatory device recalls and repair, refund, and notification remedies.[17] *See* Shapiro, *supra*, at 367-68. Indeed, the FDA may even reclassify devices based on post-market clinical experience: "If...evidence emerges that a Class II device type is systemically riskier than had been supposed, FDA has authority to reclassify it to Class

[16] While device distributors are not subject to reporting requirements, they too must maintain device complaint files subject to FDA inspection. *See* 21 C.F.R. §§ 803.1(a), 803.18(d).

[17] While the FDA has used its mandatory recall authority only rarely, this is largely because most recalls are voluntarily initiated by the device manufacturer—either at the FDA's recommendation or before the FDA becomes involved in a potential product issue. *See* Shapiro, *supra*, at 368 n.23.

III, retrospectively requiring all 510(k) holders to submit their marketed devices to the PMA approval process." Shapiro, *supra*, at 386 (emphasis omitted).

As the above discussion makes clear, the same deference to the FDA's regulatory scheme that undergirded *Grundberg's* application of Comment k to prescription drugs equally supports an application of Comment k to implanted medical devices—without distinction between the regulatory pathway used to assure the device's safety and effectiveness. Both the PMA and 510(k) processes are part of "an elaborate regulatory system, overseen by the FDA, to control the approval and distribution of" medical devices. *Grundberg*, 813 P.2d at 96. Just as with the licensing of drugs, the FDA's licensing of medical devices—whether through the PMA or 510(k) process—necessarily involves a determination "that the potential benefits of the product outweigh any associated risks," *id.*, as the FDA itself has stated, *see* FDA Memo at 2. And as is the case with drugs, "the FDA also conducts extensive post-market surveillance" of medical devices, *Grundberg*, 813 P.2d at 96, imposing various requirements on manufacturers and users with no distinction between devices cleared through the PMA or 510(k) process.

In sum, just as with all prescription drugs, "the FDA employs a comprehensive scheme of premarket screening and post-market surveillance to ensure the safety and efficacy of all licensed" medical devices. *Grundberg*, 813 P.2d at 96. This scheme deserves deference and merits the application of Comment k to ***all*** implanted medical devices which the FDA has determined are permissible to market.

### B. *Grundberg*'s Policies of Promoting the Prompt Availability and Affordability of Valuable Healthcare Products Apply Even More Forcefully to 510(k)-Cleared Implants.

A key policy concern supporting this Court's holding in *Grundberg* was the promotion of the prompt availability and affordability of prescription drugs. 813 P.2d at 94-95. This policy concern likewise supports application of Comment k to medical devices, and perhaps even more strongly to 510(k)-cleared devices. Endorsing the policy considerations noted in *Brown*, this Court expressed concern that (1) "drug manufacturers might stop producing valuable drugs because of lost profits resulting from lawsuits or the inability to secure adequate insurance"; (2) "consumers have a vested interest in prompt availability of new pharmaceutical products" and "[i]mposing strict liability for design defects might cause manufacturers to delay placing new products on the market, even after those products receive FDA approval"; and (3) "the added expense of insuring against strict liability and additional research programs might cause the cost of medication to increase to the extent that it would no longer be affordable to consumers." *Id.* at 94. These public policies make the case for Comment k application to 510(k)-cleared devices even stronger, not less so.

In terms of device availability, the overwhelming majority of devices that undergo the FDA's premarket screening process—as much as ninety-eight percent (98%)—reach market through the 510(k) process. *See* Shapiro, *supra*, at 390; *see also id.* at 394 n.1 ("In fiscal year 2013, FDA issued 2,895 clearances and 44 PMA approvals."); Hall, *supra*, at 740 ("Section 510(k) is widely employed by medical device manufacturers and is responsible for many of the medical devices currently on the market."). Granting

510(k)-cleared devices Comment k protection would encourage manufacturers to continue to invest in the development and marketing of such devices, thereby ensuring that consumers have access to the health products they need.

Relatedly, in terms of the ***prompt*** availability of ***affordable*** devices, the 510(k) process "creates a quicker and less expensive route for medical devices to reach the market."[18] Hall, *supra*, at 739. Indeed, the 510(k) process advances the important Utah public policy goal of promptly providing consumers with affordable healthcare, as it avoids the delay and increased costs (which are then passed on to consumers) occasioned by the PMA process for devices that do not require PMA approval to provide a reasonable assurance of safety and effectiveness. Affording Comment k protection to 510(k)-cleared devices would advance this goal still further, encouraging manufacturers to continue to market their devices through this quicker and less costly process. *Grundberg* embraced the "public interest in the development, availability, and reasonable price of drugs." 813 P.2d at 94, 99. This same Utah public interest supports applying Comment k to all implanted medical devices, PMA-approved and 510(k)-cleared alike.

[18] Of course, the fact that one process may be faster and less expensive than another does not mean it is any less effective. After all, the FDA itself has stated that, "in both [the 510(k) process and the PMA process] FDA's review decision reflects a determination of the level of control necessary to provide a 'reasonable assurance of safety and effectiveness.'" 2014 FDA 510(k) Guidance at 7. If anything, the 510(k) process is simply more efficient at reaching the same end goal. *See* Shapiro, *supra*, at 383-85.

### C. The Unavoidably Unsafe Exception Properly Applies to Implanted Medical Devices Because the Prescribing Physician, Acting as Learned Intermediary, Conducts the Ultimate Risk-Benefit Analysis.

In addition to a device's regulatory history, a fundamental principle underlying the application of the unavoidably unsafe exception to prescription medical products is the fact that the prescribing physician, the so-called "learned intermediary," has engaged in a risk-benefit analysis for its use, determining that for this particular patient the benefits of the healthcare product outweighs its risks.[19] This is true for both drugs and medical devices. The key is that they are "prescription only"—*i.e.*, available only through a physician.[20] Where a healthcare product is prescription only, as implanted medical

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[19] This Court has adopted the learned intermediary doctrine and, in doing so, recognized the key role the prescribing physician plays:

> Under [the learned intermediary] rule, manufacturers of prescription drugs have a duty to warn only the physician prescribing the drug, not the end user or patient....***It is the physician who is best situated to weigh the potential risks associated with a prescription drug against the possible benefits of the drug and the unique needs and susceptibilities of each patient.*** The physician thus has the ability to combine medical knowledge and training with an individualized understanding of the patient's needs, and is the best conduit for any warnings that are deemed necessary.

*Schaerrer*, 2003 UT 43, ¶ 20 (citations omitted; emphasis added). Although it appears this Court has not addressed the applicability of the learned intermediary doctrine to medical devices, most, if not all, states that have addressed the issue apply the doctrine to prescription drugs and medical devices equally. *See, e.g.*, *Valentine v. Baxter Healthcare Corp.*, 81 Cal. Rptr. 2d 252, 262 (Cal. Ct. App. 1999); *Terhune*, 577 P.2d at 978; *Morguson v. 3M Corp.*, 857 So. 2d 796. 801-02 (Ala. 2003); *Hurley*, 898 A.2d at 784.

[20] To be clear, "prescription only" is a shorthand used here for a medical product available only through the services of a physician:

> [T]he reasoning of *Brown* and *Hufft* applies to an implanted medical device in these circumstances regardless of whether, strictly speaking, it was available only by prescription and regardless of whether it is properly

devices are, the unavoidably unsafe exception applies—irrespective of the product's regulatory history.

Numerous courts have explained, as a matter of public policy and the realities of the medical-products field, why the prescribing decision is so central to the Comment k analysis.[21] For example, California decisions limit Comment k to prescription products available only through a physician. *See Brown*, 751 P.2d at 482-83; *Plenger*, 13 Cal. Rptr. 2d at 818; *Hufft*, 5 Cal. Rptr. 2d at 383-84. In *Artiglio*, the court applied Comment k to breast implants available only from a doctor, expressly eschewing any reliance on FDA regulation of the device market as a basis for its holding and concluding:

> [T]he imposition of the condition of "prescription" provides insulation between the manufacturer and the user [of drugs] such as to warrant elimination of the consumer protections afforded by strict liability. We find the same to be true of medical prostheses, at least as to those in the category of devices available only through the services of a physician.
>
> . . .
>
> characterized as a "prescription" implanted medical device. The public interest in the development, availability and affordability of implanted medical devices justifies an exemption from design defect strict products liability for all implanted medical devices that are available only through the services of a physician.

*Garrett*, 153 Cal. Rptr. 3d at 701 (citations omitted).

[21] In fact, in the absence of Comment k, juries would be invited to substitute their opinion for the opinion of the physician and the FDA as to which of several alternative treatments should have been chosen, a standard even higher than the medical malpractice standard that allows room for freedom of physician choice between two or more "schools of thought." *See generally Walkenhorst v. Kesler*, 67 P.2d 654, 668 (Utah 1937) (explaining that physicians' choice of treatment "will not constitute malpractice, if the treatment employed has the approval of at least a respectable portion of the profession or is in accord with the standards of those recognized in the community to treat such ailments").

> We therefore follow the lead of the *Hufft* and *Plenger* courts, and conclude that the entire category of medical implants available only by resort to the services of a physician are immune from design defect strict liability.

27 Cal. Rptr. 2d at 593-94.[22]

Washington courts similarly hinge their Comment k analysis on the fact that medical products are available only through the services of a physician. In *Terhune*, the Washington Supreme Court held *en banc* that Comment k applied to prescription drugs and medical devices because of their "prescription" status, rejecting the notion that FDA approval is a prerequisite to application of comment k:

> The principles stated in comment k do not rest upon a finding or an assumption that all drugs, vaccines or other products obtainable only through a physician have been tested by the Food and Drug Administration. Rather they have their basis in the character of the medical profession and the relationship which exists between the manufacturer, the physician and the patient. We think it safe to surmise that ordinarily a physician will not prescribe or utilize a product which he does not consider reasonably safe, and that he will take into account the amount of testing, or lack thereof, which has been done with respect to the product.

577 P.2d at 979.[23]

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[22] Courts in California consistently apply *Artiglio*'s logic. *See, e.g., Tucker v. Wright Med. Tech., Inc.*, No. 11-CV-03086-YGR, 2013 WL 1149717, at *7 (N.D. Cal. Mar. 19, 2013) ("[B]ecause the implant at issue was prescribed and installed by [a physician], the Court finds that Plaintiffs' strict liability claim based on design defect is precluded as a matter of California law."); *Garrett*, 153 Cal. Rptr. 3d at 696 ("We hold that [] the doctrine of strict products liability based on a design defect is inapplicable to implanted medical devices available only through the services of a physician."); *Rhynes v. Stryker Corp.*, No. 10-5619 SC, 2011 WL 2149095, at *6-7 (N.D. Cal. May 31, 2011); *Sukonik v. Wright Med. Tech., Inc.*, No. CV1408278BROMRWX, 2015 WL 10682986, at *10 (C.D. Cal. Jan. 26, 2015); *Markowitz v. Davol Inc.*, No. CV1502418RGKVBKX, 2015 WL 12696031, at *3 (C.D. Cal. June 19, 2015).

[23] Courts applying Washington law follow *Terhune*'s lead. *See, e.g., Ruiz-Guzman*, 7 P.3d at 803 (applying Comment k to medical products recognizes "the unique protection provided to the consumers of such products by the prescribing physician (and/or

Other courts that have applied Comment k categorically to drugs and medical devices have adopted this same rationale. *See, e.g.*, *Bravman v. Baxter Healthcare Corp.*, 984 F.2d 71, 76 (2d Cir. 1993) (holding medical device to be "unavoidably unsafe" and citing "majority rule that medical devices that must be prescribed and inserted by a physician are unavoidably unsafe products") (New York law); *cf. Brooks*, 750 F.2d at 1230-32 (discussing the importance of the physician's risk-benefit analysis—"individualized medical balancing"—in prescribing an implanted device for a particular patient) (South Carolina law).

Indeed, some states have explicitly addressed the very question at issue here and, based on the learned intermediary's necessary risk-benefit analysis in prescribing a device, have declined to distinguish between devices cleared through the PMA or 510(k) process in applying Comment k. For example, in *In re Zimmer Nexgen Knee Implant Products Liability Litigation*, a federal district court granted summary judgment under Comment k to a medical device manufacturer on the plaintiffs' strict liability claims, explaining that—just like for prescription drugs—it is a medical device's "prescription only" nature that merits Comment k protection:

> [T]he overarching rationale is that prescription medical devices, like prescription drugs, present a unique set of risks and benefits that may be harmful to one person but beneficial to another, such that comment k

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pharmacist) intermediary"); *Young*, 922 P.2d at 64; *see also Transue*, 341 F.3d at 916 ("This rationale emphasizes the presence of physicians as intermediaries between manufacturers and consumers, and recognizes that a physician possesses the medical training to assess adverse health effects of a medical product and to tailor that assessment to a particular patient.") (internal quotation marks omitted); *Adams v. Synthes Spine Co., LP.*, 298 F.3d 1114, 1117 (9th Cir. 2002).

> should apply to bar strict liability claims for injuries arising from prescription medical devices. Further, comment k's language itself suggests medical devices fall within its ambit, explaining that the rule applies to "other drugs, vaccines, *and the like,* many of which ... cannot legally be sold except to physicians, or under the prescription of a physician."

No. 11 C 5468, 2015 WL 3669933, at *34 (N.D. Ill. June 12, 2015) (Pennsylvania law) (citations and some quotation marks omitted). The court expressly rejected the plaintiffs' argument attempting to draw a distinction between clearance through the PMA or 510(k) process, finding no basis to distinguish them for purposes of applying Comment k. *See id.* at *36; *see also, e.g.*, *Rodriguez*, 680 F.3d at 575 (applying Comment k to medical device cleared through the 510(k) process); *Breen v. Synthes-Stratec, Inc.*, 947 A.2d 383, 389 (Conn. App. Ct. 2008) ("We decline...to accept the plaintiff's invitation to draw a bright line distinction between class II and class III medical devices in determining the applicability of comment (k)....[T]he plaintiff has failed to provide a persuasive reason why the rationale underlying the applicability of comment (k)...to prescription drugs...should not be applied to the plates manufactured by the defendant, which are surgically implanted by physicians.").

As the above decisions demonstrate, the policy goals underlying the unavoidably unsafe exception dictate that the linchpin of the inquiry is that, regardless of the FDA premarket review process used, a prescribing physician still conducts an individualized assessment of the device's risks and benefits in prescribing that device to a particular patient. The physician, as the learned intermediary making a specific prescribing decision, ultimately "ensure[s] that the potential benefits of the product outweigh any

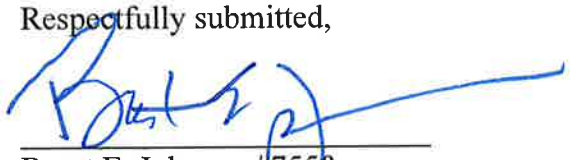
associated risks." *Grundberg*, 813 P.2d at 96. The device's precise regulatory history is not essential to this inquiry. The sound policy reasons justifying application of Comment k to prescription drugs thus apply just as much to medical devices obtained only through a physician, irrespective of the devices' regulatory pathway to market. In either case, a sufficient predicate exists to apply the unavoidably unsafe exception to a design defect claim, without the need for a fact finder to engage in a case-by-case risk-benefit analysis.

## CONCLUSION

For the foregoing reasons, *amici* respectfully recommend that the Court answer the certified questions by recognizing a categorical bar to design defect liability for all implanted medical devices obtained through a physician, regardless of how such devices were cleared by the FDA.

DATED this 5th day of October, 2018.

Respectfully submitted,



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## CERTIFICATE OF COMPLIANCE

Pursuant to Rule 24(a)(11), I certify that this brief complies with the word count limitations of Rule 24(g) because, excluding parts of the document exempted by Rule 24(g)(2), this document contains 9,078 words. I further certify that this brief complies with the requirement of Rule 21 governing public and private records.

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## CERTIFICATE OF SERVICE

I hereby certify that on this 5th day of October, 2018, I caused a true and correct copy of the foregoing *Amici Curiae* Brief of the Advanced Medical Technology Association, the American Tort Reform Association, BioUtah, Chamber of Commerce of the United States of America, National Association of Manufacturers, and Pharmaceutical Research and Manufacturers of America, to be sent via e-mail, with printed and bound copies to follow via U.S. Mail, postage prepaid, within 5 days, to the following:

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