IN THE UTAH SUPREME COURT

DALE BURNINGHAM and LANA BURNINGHAM, Appellants, v. WRIGHT MEDICAL GROUP, INC.; WRIGHT MEDICAL TECHNOLOGY, INC.; AND HARLAN C. AMSTUTZ, M.D., Appellees.	**JOINT BRIEF OF *AMICUS CURIAE* THE UTAH ASSOCIATION FOR JUSTICE AND THE AMERICAN ASSOCIATION FOR JUSTICE** Case No. 20180143-SC

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

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INTRODUCTION

The undersigned *amici* are the Utah and national organizations of trial lawyers. On the frontlines of litigation over dangerous and sometimes fatal medical devices, these *amicis'* members have brought to light the inadequacies of the FDA regulatory scheme and medical device manufacturers' pre-marketing misconduct. That misconduct includes withholding information from the FDA, submitting incomplete or false information to the FDA, and engaging in inadequate safety investigations in pursuit of FDA clearance to market their products to the public.

The public and this Court expect that manufacturers will engage in a reasonable safety inquiry to ensure, to the extent possible, that their medical products are safe for their intended uses. This appeal is of concern to these *amici* primarily because their many decades of experience with medical devices and the FDA have made alarmingly clear that the FDA clearance processes for medical devices are simply not an appropriate or reliable basis on which to determine that manufacturers have performed this reasonable safety inquiry, or that their products are safe. This is for two reasons.

First, the FDA simply does not have the staffing, procedures, or financial capacity to adequately investigate safety when manufacturers do not, or to double check what manufacturers submit to them. Moreover, the FDA is rife with inadequacies, loopholes and political pressures that make it an unreliable arbiter of safety.

Second, the FDA must rely on information collected and submitted exclusively by the product manufacturer—the party with the financial interest in seeing the product

cleared—and by no one else. This one-source arrangement has created predictable perverse incentives for product manufacturers. Having invested significant time and money in research and development of a product, manufacturers are incentivized to cut corners, under-investigate safety, massage study findings, commission and handsomely fund favorable study findings, bury or simply withhold inconvenient facts, and otherwise curate the perfect submission to allow the FDA to check all the boxes necessary so the product can be sold—and the manufacturer can recoup its R&D costs and make a profit—as expeditiously as possible. Then, when its product is challenged as defective in design, the manufacturer hides behind FDA clearance of its product and demands protection under the unavoidably unsafe product exception.

That the FDA procedures fail, and that manufacturers may succumb to these perverse incentives, are not remote or speculative dangers. They happen all the time. In litigating injury and death cases involving medical products, these *amici*'s members have investigated thousands of submissions to the FDA for all kinds of medical products. Time and again, these *amici*'s members have uncovered this same pattern of deliberate ignorance, creative manufacturer reporting, withheld or mismanaged safety information, and failures of the FDA's processes in screening submissions. This brief will highlight examples of this widespread problem in the context of implanted medical devices to illustrate both the gravity and the pervasive nature of the problem.

This appeal asks whether Utah law will extend blanket design defect immunity to all 510k-cleared medical devices, or whether it will first require some prerequisite

showing that the product is in fact unavoidably unsafe. Because of inadequacies in the 510k system, and the disincentives on manufacturers, the net effect of blanket application of design defect immunity would be to allow product manufacturers to be the arbiter of their own products' safety. Blanket application would reward manufacturers who fail to perform the adequate safety inquiry the public and this Court expect of them and encourage them to continue to do so. It would relieve manufacturers of design defect liability by the simple expedient of their having submitted a well-prepared (if incomplete or even outright false) submission to the FDA. That defeats the purpose of both Utah products liability law, and of comment k's exception to it. That is not the way Utahns should be protected from defective medical products, and there is no good reason to do it.

If this Court applies comment k's unavoidably unsafe product exception to medical devices, it should do so on a case-by-case basis.

STATEMENT OF THE ISSUES

Pursuant to Rule 41 of the Utah Rules of Appellate , the United States District Court for the District of Utah certified the following issues for this Court's decision:

1. Under Utah law, does the unavoidable 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?[1]

"A certified question from the federal district court does not present us with a decision to affirm or reverse a lower court's decision; as such, traditional standards of review do not apply. On certification, we answer the legal questions presented without resolving the underlying dispute."[2]

STATEMENT OF THE CASE

These *amici* adopt the Statement of the Case presented by the Plaintiffs/Appellants.

SUMMARY OF ARGUMENT

Section 402A of the Restatement (Second) of Torts provides that when a product manufacturer sells a product in a defective condition that makes it unreasonably dangerous, the manufacturer can be held responsible for harm to the end user if the

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[1] *Burningham v. Wright Medical et al*, Case No. 2:17-CV-92, Order Certifying Question to the Utah Supreme Court, doc. 51, filed Feb. 15, 2016.

[2] *Egbert v. Nissan N. Am., Inc.*, 167 P.3d 1058, 1060 (Utah 2007), quoting *Robert J. DeBry & Assocs. v. Qwest Dex, Inc.,* 144 P.3d 1079 (Utah 2006); *In re Kunz,* 99 P.3d 793 (Utah 2004), which quoted *Spackman ex rel. Spackman v. Bd. of Educ.,* 16 P.3d 533 (Utah 2000). (Internal quotation omitted).

product reaches the user without substantial change. Comment k affords relief from design defect liability for "unavoidably unsafe products." This appeal asks whether comment k's exception should apply automatically to all 510k-cleared medical devices, or whether to first require proof that the product is in fact unavoidably unsafe.

The undersigned *amici* submit that comment k's unavoidably unsafe product exception should not apply to all FDA-cleared medical devices, but should only be applied to products on a case-by-case basis. It should only apply if the jury determines that (1) the product was properly manufactured and contains adequate warnings, (2) the benefits of the product justify its risks, and (3) the product was incapable of being made safer at the time of its manufacture and distribution. FDA clearance should be afforded no deference in this analysis, as it is an inadequate substitute for this case-by-case factual determination by the jury.

ARGUMENT

I. BLANKET APPLICATION OF COMMENT K TO MEDICAL DEVICES IS A POLICY THAT WILL UNNECESSARILY HURT UTAHNS.

Generally, a product manufacturer is held strictly liable for harms caused by its products that are defective and unreasonably dangerous.[3] Comment k sets forth the unavoidably unsafe product exception to this rule for design defect claims. It reads:

> k. Unavoidably unsafe products. There are some products which, in the present state of human knowledge, are quite incapable of being made safe

[3] RESTATEMENT (SECOND) OF TORTS § 402A (1965). *See also Ernest W. Hahn, Inc. v. Armco Steel Co.*, 601 P.2d 152, 158 (Utah 1979) (adopting "the strict products liability doctrine" in Utah "in the language of Section 402A").

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

The question in this appeal is whether the Court will extent blanket immunity to design defect claims for medical devices that have been cleared by the FDA, or whether and how it will apply the exception on a case-by-case basis.

These *amici* submit that blanket immunity from design defect liability to all FDA-cleared medical devices would serve neither the purposes of comment k, nor any other compelling public policy. They further contend that the FDA's regulatory scheme for medical devices is not an adequate substitute for a jury's determination as to design defect. Comment k should be applied to medical devices on a case-by-case basis.

A. Blanket immunity from design defect claims would serve neither the purposes of comment k, nor any other compelling public policy.

The majority in *Grundberg v. Upjohn* correctly observed that this Court "need not be bound by the specific language of comment k and may adopt and apply its fundamental policy without restricting ourselves to what we perceive to be its literal interpretation."[4] These *amici* believe there remains value in examining the purposes behind comment k in determining the right policy for devices that injure or kill Utahns.

Comment k's language indicates that the exception was intended for unavoidably unsafe products,[5] properly prepared and accompanied by proper warnings,[6] where the product's usefulness justifies its risks.[7] It was not intended to apply to *avoidably* unsafe products—products that could be made safe by the application of human knowledge. It was not intended as an end run around product manufacturers' responsibility to investigate safety. It was not intended to apply to products whose usefulness does not justify their risks. The real utility in the exception is in allowing the public to enjoy the

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[4] *Grundberg v. Upjohn*, 813 P.2d 89, 95 (Utah 1991). *See also id.* at 90 ("We acknowledge that by characterizing all FDA-approved prescription medications as 'unavoidably unsafe,' we are expanding the literal interpretation of comment k").

[5] SECTION 402A OF THE RESTATEMENT (SECOND) OF TORTS, CMT. K ("some products which, in the present state of human knowledge, are quite incapable of being made safe for their intended and ordinary use").

[6] *Id.* ("such a product, properly prepared, and accompanied by proper directions and warning, is not defective, nor is it unreasonably dangerous").

[7] *Id.* (where the seller of such a product "suppl[ies] the public with an apparently useful and desirable product, attended with a known but apparently reasonable risk").

benefits of significantly useful products that are also unavoidably unsafe, where that trade-off is reasonable.[8] If blanket design defect immunity is extended to an entire class of products, regardless of whether they are unavoidably unsafe, or whether their usefulness justifies their risks, that utility is lost.

Two contrasting examples illustrate this point. Comment k speaks to the rabies vaccine, which "not uncommonly leads to very serious and damaging consequences when it is injected."[9] However, "both the marketing and the use of the vaccine are fully justified, notwithstanding the unavoidably high degree of risk which they involve" because "the disease itself invariably leads to a dreadful death."[10] The rabies vaccine was incapable of being made safe and had no alternatives, but its benefit (not dying) was tremendous and far outweighed its risk (serious and damaging side effects).

At the other end of the spectrum are products that provide a modest or optional benefit but carry a tremendous and unjustified risk. Although there were numerous methods of pain relief, medical device companies marketed pain pumps to orthopedic surgeons to infuse anesthetic medications into the joint space following joint surgery.[11]

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[8] *See Tansy v. Dacomed Corp.*, 890 P.2d 881, 885 (Okla. 1994) ("While products liability law seeks to protect the public from unreasonably dangerous products, comment k seeks to protect another facet of the public's interest—that of having available new products whose benefits are great enough as to justify associated risks").

[9] SECTION 402A OF THE RESTATEMENT (SECOND) OF TORTS, cmt. k.

[10] *Id.*

[11] *See Creech v. Stryker Corp.*, 2012 WL 33360 *2 (D. Utah 2012).

The companies did not investigate the extant human knowledge concerning the effects of medications on joint tissues, or inform surgeons that these effects were unknown to the companies.[12] Thousands of unwitting patients learned through experience what these manufacturers would have known had they engaged in an adequate pre-marketing safety inquiry: pain pumps permanently destroyed joint tissues.[13] The usefulness of the pain pump (post-surgical pain relief) was not unique to the pain pump, and it certainly did not justify the risk (permanent destruction of the joint). These *amici* see little reason to grant blanket design defect immunity to manufacturers of products like the pain pump, which are neither unavoidably unsafe, nor so useful that their risks were justified.

In arguing for wider application of design defect immunity, product manufacturers have contended that they require relief from tort liability in order to produce new useful products.[14] Justice Stewart in *Grundberg* observed that "not a shred of evidence has been presented to this Court that indicates that liability under the tort system has deterred

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[12] *Id.* at *2-*3.

[13] *Id.* at *1, including n. 1.

[14] *See Grundberg*, 813 P.2d at 90 ("public policy supporting the research and development of new drugs requires a holding that all FDA-approved prescription medications are 'unavoidably unsafe products' under comment k and, as such, manufacturers of those drugs would not be liable for a claim based on defective design"). *See also id.* at 93 (citing *Kearl v. Lederle Laboratories*, 172 Ca.App.3d. 812 (Cal. Ct. App. 1985), which "discussed the problems society would face by subjecting drugs to the same accountability as other products, allowing unlimited redress for plaintiffs injured by pharmaceutical products," including "delayed availability of needed drugs and imposition of the costs of research, development, and marketing of new products beyond that which manufacturers, especially small manufacturers, might be willing to risk").

pharmaceutical companies from introducing new drugs."[15] Indeed, in the nearly 30 years since *Grundberg*, thousands of new drugs and devices have been introduced. In 2017 alone, the FDA granted 510k clearance to some 3,175 devices,[16] and PMA approval to some 1,747 devices.[17]

These *amici* are also troubled by the implications of this argument. If it is prohibitively expensive for a product manufacturer to perform an adequate investigation into the safety of a non-essential product, they should simply not sell the product until they can do so. Justice Stewart observed: "why should those who are seriously injured or suffer because of the death of another have to stand the expense of such losses to support the high profit margins" in the medical device industry?[18] This is an especially compelling question where "medical interventions (including implantation of medical devices) are now the third leading cause of death in the U.S., killing an estimated 225,000

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[15] *Grundberg*, 813 P.2d at 103-04 (Stewart, J., dissenting).

[16] U.S. Food & Drug Administration, *510(k) Devices Cleared in 2017*, available at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/510kClearances/ucm540522.htm.

[17] U.S. Food & Drug Administration, *Medical Devices Approved in 2017*, available at https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm540012.htm. New drug approvals are so prolific that the FDA counts them in weeks, not years. *See, e.g.*, U.S. Food & Drug Administration, *Recent New and Generic Drug Approvals report for July 19, 2018 to August 1, 2018*, available at https://www.accessdata.fda.gov/scripts/cder/daf/index.cfm?event=report.page (a total of 195 approved drugs during the week of July 22, 2018 through July 28, 2018).

[18] *Grundberg*, 813 P.2d at 103 (Stewart, J. dissenting).

to 440,000 Americans each year. That's more deaths than from diabetes, murder, car accidents, and AIDS *combined*."[19] These *amici* concur with Justice Stewart and urge this Court to compare the real and proven cost of deference to FDA clearance with the imagined and unproven "risk" that drug manufacturers "may" be less inclined to distribute new drugs and devices. "[A] lessening of safety standards is an argument for strict liability, not against. Profit motivation is likely to lead to many more unnecessary [medical devices]."[20]

No compelling policy justifies depriving injured Utahns of a remedy for injuries caused by avoidably unsafe products whose benefits do not justify their risks—that is, unreasonably dangerous products. We urge the Court to decline to extend blanket design defect immunity under comment k to any class of medical devices.

B. Extending blanket design defect immunity to FDA 510k cleared medical devices is especially poor policy.

The central concern these *amici* express is at the deference the Defendants/Appellees ask the Court to extend to FDA 510k clearance of medical devices. Entrusting the FDA's 510k process with determining design defects will guarantee that Utahns will be injured by unreasonably dangerous medical devices—products which are

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[19] LENZER, JEANNE. THE DANGER WITHIN US: AMERICA'S UNTESTED, UNREGULATED MEDICAL DEVICES INDUSTRY AND ONE MAN'S BATTLE TO SURVIVE IT 12 (2017), citing Allen, M. *How Many Die from Medical Mistakes in U.S. Hospitals?*, PRO PUBLICA, 2013, https://www.propublica.org/article/how-many-die-from-medical-mistakes-in-use-hospitals. (emphasis in original).

[20] *Grundberg*, 813 P.2d at 103 (Stewart, J., dissenting).

not unavoidably unsafe, and which carry risks that far outweigh their usefulness. The 510k process is not an adequate substitute for a jury's determination of design defect.

1. Why FDA 510k clearance should not be the standard for determining defect.

There are several reasons FDA 510k clearance is an inadequate substitute for a jury determination of defect. First and foremost, the U.S. Supreme Court has acknowledged that "the 510k process is focused on equivalence, not safety . . . [and] 'substantial equivalence determinations provide little protection to the public.'"[21] "[D]evices that enter the market through § 510(k) have 'never been formally reviewed under the [Medical Device Amendments] for safety or efficacy[.]'"[22] "[T]he FDA conducts a full analysis of the product's risks and benefits when a product goes through the premarket approval process, not the 510(k) clearance process. . . The 510(k) process relates to a medical device's equivalence to a preexisting device; it does not require 'full consideration of the product's risks and benefits.'"[23] FDA regulations also state that 510k clearance "does not in any way denote official approval of the device."[24] The

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[21] *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 493 (1996) (emphasis added) .; *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 323 (2008) (Section 510(k) is focused on equivalence not safety)

[22] *Riegel,* 552 U.S. at 323 (quoting *Medtronic, Inc. v. Lohr* 518 U.S. 470, 493 (1996)).

[23] *Carroll v. Boston Sci. Corp.*, 2016 WL 1317415, at *3-4 (S.D.W. Va. Apr. 1, 2016).

[24] 21 C.F.R. § 807.97.

FDA prohibits manufacturers of medical devices cleared through the 510k process from making any representations that their devices have been approved by the FDA.[25]

A thorough study by the prestigious Institute of Medicine concluded that the 510k process "is not intended to evaluate the safety and effectiveness of medical devices [and] cannot be transformed into a premarket evaluation of safety and effectiveness."[26] The study based its conclusions in part on "problems with several devices that had been cleared through the 510k process," including artificial hip replacements and surgical mesh.[27] Indeed, the FDA's § 510(k) process is "an *exemption* from federal safety review."[28]

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[25] *Id.*; Wright Medical's analysis indicating the FDA evaluation of prescription medications is equivalent to 510(k) evaluation is seriously misleading. Wright Brief at 33-36. Prescription drug approval processes require significant evidence of safety and extensive scientific proof; 510(k) analysis requires neither.

[26] INSTITUTE OF MEDICINE, MEDICAL DEVICES AND THE PUBLIC'S HEALTH: THE FDA 510(K) CLEARANCE PROCESS AT 35 YEARS 5 (2011).

[27] *Id.*

[28] *Riegel,* 552 U.S. at 322-23 (emphasis added). *See also* Lenzer, *supra* note 20, at 7 (The FDA "does not require manufacturers to submit even a single clinical trial for the overwhelming majority of high-risk implanted medical devices it approves"), citing U.S. GOVERNMENT ACCOUNTABILITY OFFICE, GAO REPORT GAO-09-190, MEDICAL DEVICES: FDA SHOULD TAKE STEPS TO ENSURE THAT HIGH-RISK DEVICE TYPES ARE APPROVED THROUGH THE MOST STRINGENT PREMARKET REVIEW PROCESS, UNITED STATES GOVERNMENT ACCOUNTABILITY OFFICE (January 2009); Rome, BN et al, *FDA Approval of Cardiac Implantable Electronic Devices via Original and Supplement Premarket Approval Pathways*, 311(4) JAMA 385 (2014); CONG. RES. SERV. REP. NO. 42130, *FDA Regulation of Medical Devices* (Sept. 14, 2016). *See also* Lenzer, *supra* note 20, at 124, citing Dhruva, SS et al, *Strength of Study Evidence Examined by the FDA in Premarket Approval of Cardiovascular Devices*, 302(24) JAMA 2679 (2009); Garber,

This is a sobering fact, where approximately 99% of new Class III medical devices, and all Class II and Class I medical devices, enter the market through the 510k process[29]—a process that is not about safety. The manufacturer need only satisfy the FDA that its product is "substantially equivalent" to a predicate device that is already on the market in order to obtain 510k clearance. "The attraction of substantial equivalence to manufacturers is clear. 510(k) notification requires little information, rarely elicits a negative response from the FDA, and gets processed very quickly."[30] A manufacturer can even obtain 510k clearance by proving substantial equivalence to a predicate device that was itself never examined for safety, but was "grandfathered in" by the FDA.[31] "Even devices that are substantially equivalent to other devices cleared under the 510(k) process can be similarly cleared by the FDA, allowing potentially infinite iterations, a problem known as 'predicate creep.'"[32]

Courts appreciating these realities have properly declined to apply comment k to 510k-cleared products, including courts applying Utah law. In *Christiansen v. Wright*

AM, *Modernizing Device Regulation*, 174(13) N. ENGL. J. MED. 1161 (2010).

[29] *Riegel*, 552 U.S. at 317.

[30] Lenzer, *supra* note 20, at 479, quoting Adler, *The 1976 Medical Device Amendments: A Step in the Right Direction Needs Another Step in the Right Direction*, 43 FOOD DRUG COSM. L.J. 511, 516 (1988).

[31] *See Lohr*, 518 U.S. at 477-478.

[32] Lenzer, *supra* note 20, at 120, citing Rothberg, MB et al, *Patients' and Cardiologists' perceptions of the Benefits of Percutaneous Coronary Intervention for Stable Coronary Disease*, 153(5) ANN. INTERN. MED. 307 (2010).

Medical Technology, Inc.,[33] the Eleventh Circuit interpreted Utah law and refused to apply comment k as a categorical bar to design defect claims involving the 510k-*cleared* Wright Medical Conserve metal-on-metal hip implants because Wright Medical failed to show it was *approved* by the FDA.

> Wright Medical asserts that the Utah Supreme Court would extend the categorical bar against strict liability to medical devices, such as its hip replacement device. . . . Even if the Utah Supreme Court were to extend the bar against strict liability to FDA-approved medical devices, we predict that it would not extend it to the hip replacement device at issue here because the record is silent as to whether that device had obtained FDA approval. At oral argument, Wright Medical conceded that it did not present any evidence at trial as to whether its hip replacement device was approved by the FDA. Thus, even if Utah law would extend the categorical bar to FDA-approved medical devices, Wright Medical has not met its burden to provide that this affirmative defense applies to its hip replacement device.[34]

Indeed, under 21 C.F.R. § 807.97, Wright Medical can never represent it has FDA "official approval" for its 510k-cleared Wright Conserve metal-on-metal hip implant.

The Tenth Circuit Court of Appeals in the case of *Tingey v. Radionics*[35] held that UTAH CODE ANN. § 78-15-6, which recognizes a rebuttable presumption of non-defectiveness where the product complies with governmental standards, does not even apply to a 510k medical device:

> While the FDA examines § 510(k) applications with a general concern for safety and effectiveness, it does not require devices approved under that

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[33] 851 F.3d 1203, 1217 (11th Cir. 2017).

[34] *Id.*

[35] 193 Fed. Appx. 747 (10th Cir. 2006)

> section to take any particular form; the device must merely be substantially equivalent to one that existed before 1976, "marketed without running the gauntlet" of [the Medical Device Amendments] [citations omitted] . . Because the MDA approval Radionics received, that of substantial equivalence to a pre-1976 device, did not result from its compliance with a regulatory standard meeting the Restatement test, we conclude that Radionics is not entitled to the presumption in § 78-15-6(3) that the device "is free from any defect or defective condition."[36]

Unlike the FDA's drug approval process, the 510k process is not an "extensive regulatory scheme capable of and appropriate for making the preliminary determination regarding whether a [medical device's] benefits outweigh its risks."[37] Comment k was intended to apply to *unavoidably unsafe* products. 510k clearance is not about safety.

The second reason 510k clearance should not be the standard for determining design defect concerns the scope of information before the factfinder. A jury determining defect is presented with the full range of evidence concerning the product and human knowledge available at the time the product was manufactured and distributed. The FDA, in reviewing a 510k application, is presented with only the information the manufacturer chooses to submit to it, which may or may not include available information about risks. When a manufacturer withholds safety information or does not adequately investigate safety within the state of human knowledge, the interest of protecting the public from unreasonably dangerous products is compromised, not in order to supply the public with a beneficial new device, but to satisfy the manufacturer's

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[36] *Id.*

[37] *Grundberg*, 813 P.2d at 97.

need for a profit. That is not what comment k was intended to do. Justice Stewart in *Grundberg* acknowledged that manufacturers can and do withhold or decline to investigate important safety information in submissions to the FDA.[38] These *amici* have seen the same behavior regarding medical devices and detail examples of it below.[39]

Third, and perhaps most concerning, the FDA's systems are fraught with loopholes, inefficiencies and incompetence, which routinely fail to identify and protect the public from dangerous products, even when the FDA is presented with all available safety information. Justice Stewart observed that the FDA "has often approved drugs in complete ignorance of critical information relating to the hazards of such drugs which was contained either in its own files or in the published medical literature, or both."[40] These *amici* have seen the same with medical devices. The FDA's own leaders have acknowledged the problems with the 510k process, including "predicate creep." Speaking to the Medical Device Manufacturers Association, the director of the FDA's Center for Devices and Radiological Health acknowledged situations "where we started with one device a long time ago and ended up some place very, very different. And it is

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[38] *Id.* at 101 (Stewart, J., dissenting) (giving examples of drug manufacturers not submitting reports of drug-related deaths and permanent injuries).

[39] *See* Lenzer, *supra* note 20, at 17 ("Virtually every major drug and medical device company has been caught in one or more scandals, and they pay massive fines as a part of the cost of doing business.")

[40] *Grundberg*, 813 P.2d at 100 (Stewart, J. dissenting) (citing examples of FDA overlooking, being unaware of significant risk information in its possession and failing to enforce its own standards).

really hard to explain that entire complicated path that got us from where we were in 1976—[the year of the Medical Device Amendments to the Food, Drug and Cosmetic Act]—to 2009."[41] Experts in evidence-based medicine have noted that the FDA's device approval process "is so bad [that] some physicians . . . call the device market the Wild West, where a company can still 'strike gold' and where it really doesn't matter if the product works to make patients feel better or live longer."[42]

The FDA's medical device adverse event reporting system is even more problematic. Most medical device adverse events are not reported to the FDA at all,[43] and those that are reported are nearly impossible to find. One former FDA employee found that a search of the FDA's adverse event database returned a few hundred adverse event reports for the sterilization device Essure, but that the actual number of adverse events reported in all FDA filings was over a thousand. These events were buried in its database and not easily retrieved, except by someone intimately familiar with FDA practices. One out of every 25 women implanted with the device had it removed within a year, usually because of bleeding and pain, and they were 10 times more likely to have

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[41] Lenzer, *supra* note 20, at 120-21, citing *Daniel Schultz Resigns Amid CDRH Controversies*, MDDI NEWS (2009), http://www.mddionline.com/article/daniel-schultz-resigns-amid-cdrh-controversies.

[42] Lenzer, *supra* note 20, at 122, citing Phone interview with Vinay Prasad (August 1, 2016) (internal quotations omitted).

[43] Lenzer, *supra* note 20, at 107 ("underreporting is commonplace, and only a tiny fraction of adverse events and deaths related to medical devices is ever reported").

to undergo reoperation as were women who had a different sterilization procedure. Yet the device was approved because the manufacturer claimed a 99.8% success rate.[44] Researching deaths reported in connection with a vagus nerve stimulation device to treat seizures, the employee discovered that the FDA database showed just 206 deaths, while the real number of deaths in FDA filings was over ten times higher.[45]

Adding to these problems, the FDA, unlike a jury, is subject to political pressures. The head of the FDA is a political appointee. After the vagus nerve stimulation device just mentioned was rejected by the FDA, the manufacturer increased its lobbying funds to $440,000, put the former Democratic House majority whip on its board, and lobbied the FDA hard. The device was then approved by the director of the FDA's Center for Devices and Radiological Health over the unanimous objections of nine FDA scientists. It was later discovered that "the agency had spied on the dissenting scientists."[46] The product was approved despite at least 83 more unreported deaths from its use.[47]

Indeed, if the 510k clearance process were truly "sufficient protection to the public," then "the FDA would not have to recall about eleven hundred devices

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[44] *Id.* at 110-11.

[45] *Id.* at 112-13.

[46] *Id.* at 84-86.

[47] *Id.* at 99-100.

annually."[48] But it does, and thousands of patients are hurt or killed in the pursuit of profits for manufacturers of devices that have no business being implanted in our bodies.

This is one reason it is not an adequate response to allow the comment k exception to be rebutted by "proof of inaccurate, incomplete, misleading, or fraudulent information furnished by the manufacturer in connection with FDA approval."[49] If the FDA fails to identify or act on risk information or approves an unreasonably dangerous product because of political pressures, it is no help to injured patients that they may rebut comment k's exception with proof of anything the manufacturer did or did not do, because the failure did not lie with the manufacturer, but with the FDA.

"[N]o state supreme court has yet become convinced that the FDA has either adequate staffing, expertise, or data base to warrant its being substituted for the judicial system."[50] 510k clearance should never be a basis for presuming that a medical device is not defective, because it is not a safety inquiry at all, it relies on one-sided data from self-interested companies, and the FDA itself is rife with loopholes and inadequacies. The FDA should not supplant a jury in determining design defect.

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[48] *Id.* at 122.

[49] *Grundberg*, 813 P.2d at 90.

[50] *Toner v. Laderle Laboratories*, 732 P.2d 297, 313 (Idaho 1987) (Huntley, J., Concurring specially), quoted in *Grundberg*, 813 P.2d at 100 (Stewart, J., dissenting).

2. The majority of courts have rejected blanket application of comment k to 510k cleared medical devices.

Most courts that have considered this issue have declined to extend blanket application of comment k to design defect claims against manufacturers of medical devices.[51] In making a case-by-case evaluation, most courts have ultimately refused to apply comment k to 510k-cleared medical devices.[52] At least three Federal District Courts have held that Utah would most likely not apply comment k as a categorical bar to claims for design defect liability arising out of the use of 510k-cleared medical devices.[53]

Only a small minority of courts have extended blanket comment k immunity to

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[51] E.g., *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753, 772 (5th Cir. 2018) (majority of courts favor a case-by-case methodology);

[52] *In re DePuy Orthopaedics, Inc., Pinnacle Hip Implant Prod. Liab. Litig.*, 888 F.3d 753 at 772 (comment k does not bar plaintiffs' design defect claims for 510(k) metal-on-metal Pinnacle hip design); *Carroll v. Boston Sci. Corp.*, 2016 WL 1317415, at *5 (S.D.W. Va. Apr. 1, 2016) (court rejects contention that Texas's absolute bar for FDA-approved prescription drugs applies to 510(k) approved mesh which is "neither FDA-approved nor a prescription drug."); *Huskey v. Ethicon, Inc.*, 848 F.3d 151, 158 (4th Cir.), *cert. denied*, 138 S. Ct. 107 (2017) (comment k does not shield manufacturer of 510k-cleared mesh because jury could infer manufacturer could have designed mesh more safely).

[53] *See Christiansen v. Wright Medical Technology, Inc.,* 851 F.3d 1203, 1217 (11th Cir. 2017) (applying Utah law, court refused to interpret comment k to apply categorical ban against strict liability design defect claim for 510(k) metal-on-metal implant because Wright Medical failed to provide any evidence that metal-on-metal implant was "FDA-approved medical device[]"); *Robbins v. Boston Sci. Corp.,* 2015 WL 5842753, at *3-4 (S.D.W. Va. Oct. 6, 2015) (finding it likely that "the Supreme Court of Utah would not apply comment k as a categorical bar to claims for strict liability for design defect arising out of the use of medical devices" because 510(k) review is for equivalence and does not require full consideration of product's risks and benefits); *Creech v. Stryker Corp.*, 2012 WL 33360, at *5 n. 6 (D. Utah Jan. 6, 2012) ("Utah law does not preclude strict liability design defect claims against medical product manufacturers.").

medical devices.[54] Each of those decisions failed to analyze the significant differences between the extensive premarket approval (PMA) process for approving medical devices, and the 510k process for clearing medical devices, the central distinction recognized by the United States Supreme Court in both *Lohr*[55] and *Riegel*.[56] If this Court is to determine the right policy for Utah, it cannot ignore these significant differences.

3. Examples illustrating why FDA 510k clearance is not an adequate determination as to design defect.

These *amici* here provide examples of a few of the many products cleared or approved through the FDA's 510k process that were not unavoidably unsafe, but were unreasonably dangerous, but obtained 510k clearance anyway. These *amici* submit that this Court must consider the gravity of the real and proven harm to Utahns from such devices before declaring, notwithstanding these examples and numerous others, that FDA 510k clearance is incontrovertible proof of a non-defective product.

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[54] *See Creazzo v. Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006) (finding "no reason why the same rational applicable to prescription drugs may not be applied to medical devices."); *Sukonik v. Wright Med. Tech., Inc.*, 2015 WL 10682986, at *10 (C.D. Cal. Jan. 26, 2015) (holding "a plaintiff may not maintain a strict liability claim against the manufacturer of an implanted prescription medical device on the basis of an alleged design defect."); *Transue v. Aesthetech Corp.*, 341 F.3d 911, 916 n. 2 (9th Cir. 2003) (finding that under "Washington law, comment k affords a blanket exemption from strict liability for design defects in medical devices or products" based on dicta in a Washington pesticide case, but noting this a "minority" approach).

[55] 518 U.S. 470 (1996).

[56] 552 U.S. 312 (2008).

a. DePuy Metal Hip Implants

The ASR XL artificial hip was introduced by DePuy Orthopedics, a division of Johnson & Johnson, in 2005. Its distinctive feature was that both the ball and the socket were made of chrome-cobalt metal, presumably more durable than traditional plastic.[57] The ASR XL obtained 510k clearance, but the device itself was not substantially equivalent to any device then on the market. Rather, the FDA cleared DuPuy's submission by finding that each of three basic characteristics in its design was substantially similar to different predicate devices.[58]

Shortly after implanting this device into the bodies of hundreds of thousands of Americans, complaints began pouring into DePuy from patients suffering from infections, fractures, dislocations, nerve damage, and neurological difficulties. Much of the harm was traced to microscopic bits of metal that entered the blood stream.[59] Internal documents indicated that DePuy knew of but failed to disclose this known danger to the

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[57] *See Dangerous Medical Implants and Devices: Most Medical Implants Have Never Been Tested for Safety*, CONS. REP. MAG., May 2012, *available at* https://www.consumerreports.org/cro/magazine/2012/04/cr-investigates-dangerous-medical-devices/index.htm.

[58] Brent M. Ardaugh et al., *The 510(k) Ancestry of a Metal-on-Metal Hip Implant*, 368 NEW ENG. J. MED. 97 (Jan. 10, 2013).

[59] Ryan Jaslow, *Metals from hip replacements present toxic risk for millions, investigation warns*, CBS NEWS, February 29, 2012, *available at* http://www.cbsnews.com/news/metals-from-hip-replacements-present-toxic-risk-for-millions-investigation-warns/.

FDA.[60] In 2010, DePuy recalled some 93,000 of its implants, though thousands remain implanted and continue to cause injury.[61]

The Utah Association of Justice is aware of numerous cases involving Utah citizens implanted with metal-on-metal hip implants. These Utah plaintiffs have filed both in the various multidistrict litigations (e.g., DePuy ASR and Pinnacle MDLs, Stryker Rejuvenate MDL, Biomet MDL, Zimmer MDL, Wright MDL), and as individual cases. In each cases, the plaintiffs have evidence that manufacturers had available to them feasible, safer alternative designs. These Utah plaintiffs will be barred from relief for these known defects if this Court applies comment k to all 510k-cleared medical devices.

b. Transvaginal Mesh

In the early 2000s, manufacturers aggressively marketed polypropylene surgical mesh on the vaginal wall to provide bladder support to treat pelvic organ prolapse and stress urinary incontinence. The product obtained 510k clearance as substantially equivalent to mesh that had long been used to treat abdominal hernias.[62] Abdominal

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[60] Barry Meier, *Maker Hid Data About Design Flaw in Hip Implant, Records Show*, NEW YORK TIMES, January 25, 2013, *available at* http://www.nytimes.com/2013/01/26/business/johnson-johnson-hid-flaw-in-artificial-hip-documents-show.html.

[61] George R. McLaughlin, *Toxic Hip Replacements*, TRIAL (Feb 2012), at 40.

[62] *See* U.S. Food and Drug Administration, *Urogynecologic Surgical Mesh: Update on the Safety and Effectiveness of Transvaginal Placement for Pelvic Organ Prolapse,* July 2011, at 3-6 *available at* https://www.fda.gov/downloads/MedicalDevices/Safety/AlertsandNotices/UCM262760.pdf.

mesh, however, was used in a different organ and inserted laparoscopically, not through open surgery. Transvaginal insertion provided a pathway for infection and was prone to erosion and dislocation, resulting in severe pain and possible organ perforation. The mesh also became embedded in surrounding tissue, making removal extremely difficult.[63]

Despite a growing number of injury reports, most manufacturers continued to market transvaginal mesh for years.[64] It was not until 2016 that the FDA at last acknowledged that the safety and effectiveness of the device had not been established, and that "these devices present a potential unreasonable risk of illness or injury."[65]

As part of a massive multidistrict litigation involving some 70,000 transvaginal mesh injuries, District Judge Joseph R. Goodwin applied Utah law and observed that the 510k clearance process "does not require full consideration of the product's risks and benefits."[66] "In light of this reasoning, I predict that the Supreme Court of Utah would not apply comment k as a categorical bar to claims for strict liability for design defect arising out of the use of medical devices."[67]

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[63] See Lindsay Beyerstein, *A Female Surgical Nightmare*, IN THESE TIMES, June 13, 2012, *available at* http://inthesetimes.com/article/13353/a_female_surgical_nightmare.

[64] Lauren N. Wood, Colby P. Souders, et al., *The Truth Behind Transvaginal Mesh Litigation: Devices, Timelines, and Provider Characteristics*, 24 FEMALE PELVIC MED & RECONSTR. SURG. 21–25 (2018).

[65] *Obstetrical and Gynecological Devices; Reclassification of Surgical Mesh for Transvaginal Pelvic Organ Prolapse Repair*, 81 FED. REG. 354-01 (Jan. 5, 2016).

[66] *Robbins v. Boston Sci. Corp.*, 2015 WL 5842753 *4 (S.D.W. Va. Oct. 6, 2015).

[67] *Id.*

c. Intraarticular Pain Pumps

In the early and mid-2000s, manufacturers aggressively marketed anesthetic infusion devices, commonly known as "pain pumps," to orthopedic surgeons to continuously infuse anesthetic medications into the joint space following joint surgery. The FDA had cleared pain pumps for use in the operative site, but not directly to the joint,[68] notwithstanding several unsuccessful attempts by the manufacturers to obtain clearance to market the device for use in the joint. Surgeons began seeing cases of glenohumeral chondrolysis,[69] a progressive and permanent destruction of the joint space cartilage, which can be caused by continuous exposure to anesthetic medications.[70] In 2009, the FDA issued an alert reporting chondrolysis in young adults due to this use of pain pumps and requiring manufacturers of the devices to warn providers of the dangers of infusing medication directly into the joint.[71]

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[68] *See Kildow v. Breg, Inc.*, 796 F. Supp. 2d 1295, 1297 (D. Or. 2011).

[69] Damon H. Petty et al., *Glenohumeral Chondrolysis After Shoulder Arthroscopy: Case Reports and Review of the Literature*, 32 AM. J. SPORTS MED. 509 (2004).

[70] B.P. Hansen et al., *Postarthroscopic Glenohumeral Chondrolysis,* AM. J. SPORTS MED. 1-7 (2007); *see also* Katie Thomas, *Studies Link Rare Ailment to Pain Pumps*, NEW YORK TIMES, Jan. 26, 2010 (many victims were young athletes, whose careers were cut short).

[71] U.S. Food and Drug Administration, *Information for Healthcare Professionals: Chondrolysis Reported with Continuously Infused Local Anesthetics (marketed as bupivacaine, chlorprocaine, lidocaine, mepivacaine, procaine and ropivacaine)*, Nov. 13, 2009.

The FDA's 510k clearance process is not an adequate substitute for a jury's determination. It cannot ensure that medical devices it clears are unavoidably unsafe, have been adequately evaluated for risks, or provide benefits that justify their risks. Applying blanket design defect immunity to 510k-cleared medical devices would deprive Utahns of a legal remedy for injuries caused by defectively designed and unreasonably dangerous medical devices. The application of comment k should be applied to medical devices—and, these *amici* submit, to all products—on a case-by-case basis.

II. THIS COURT SHOULD ADOPT THE *TANSY* ANALYSIS FOR DETERMINING WHETHER COMMENT K APPLIES TO AN IMPLANTED MEDICAL DEVICE.

These *amici* submit that the most reasonable analysis to achieve both the purposes of comment k and uniformity of application is the analysis by the Oklahoma Supreme Court in *Tansy v. Dacomed Corp.*[72]

The *Tansy* case concerned the applicability of comment k to an implanted medical device (a penile implant).[73] In treating the purposes of comment k, the *Tansy* court observed: "There must be at the time of manufacture and distribution 'no feasible alternative design which on balance accomplished the subject product's purpose with a lesser risk,'"[74] that "the design must be as safe as the best available testing and research

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[72] 890 P.2d 881 (Okla. 1994).

[73] *Id.* at 885 (citing cases).

[74] *Id.* (citing *Toner v. Laderle Labs.*, 732 P.2d 297, 306 (Idaho 1987), *cert. denied.* 485 U.S. 942 (1988)).

permits,"[75] and that the exception "serves as an affirmative defense when the product is incapable of being made safe under present technology, but the social need for the product warrants its production."[76] The court placed special emphasis on the central importance of the risk-benefit analysis: "Comment k implicitly, by its language, requires this risk-benefit analysis; the Comment speaks of a product's utility justifying its risks."[77]

The *Tansy* court, examining all of these authorities and the language of comment k, concluded that medical device manufacturers seeking comment k protection bear the burden of proving "(1) the product is properly manufactured and contains adequate warnings, (2) its benefits justify its risks, and (3) the product was at the time of manufacture and distribution incapable of being made more safe."[78] The *Tansy* court further concluded that these questions are generally for the jury's determination, and must be answered on a case-by-case basis.[79]

There are four analytical and policy benefits of adopting the *Tansy* analysis.

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[75] *Tansy*, 890 P.2d at 885 (quoting *Toner*, 732 P.2d at 306).

[76] *Tansy*, 890 P.2d at 885 (citations omitted).

[77] *Id.* at 885. *See also id.* n.2 (citing cases applying the law of 10 other jurisdictions that use a risk-benefit analysis before applying comment k, including *Patten v. Lederle Labs.,* 676 F. Supp. 233 (D. Utah 1987)).

[78] *Tansy*, 890 P.2d at 886, citing *Allen v. G.D. Searle Co.*, 708 F.Supp. 1142, 1149 (D. Ore. 1989); *Coursen v. A.H. Robins Co.*, 764 F.2d 1329, 1338 (9th Cir. 1985).

[79] *Tansy*, 890 P.2d at 886, citing *Coursen*, 764 F.2d at 1338; *Kociemba v. G.D. Searle*, 680 F.Supp. 1293, 1300 (D. Minn. 1988).

First, the analysis serves all the policy underpinnings intended in comment k, including its application to only unavoidably unsafe products, its inherent requirement that manufacturers take reasonable action to discover knowable risks, and a risk-benefit analysis. Comment k is an exception, and exceptions require some underlying policy. Comment k's express policies are all served by this test.

Second, this analysis allows a jury to decide factual disputes rather than placing that responsibility on a court. If a manufacturer can persuade the jury that its product satisfies these three elements—that is, was truly unavoidably unsafe—then the manufacturer can claim the protection of comment k. The injured patient can present his or her contrary evidence (including information the FDA did not have), and the jury decides, just like they do all the time in countless other factual disputes.

Third, the analysis allows for uniformity in application of the rule. The test can as easily be applied to medical devices as it can to drugs, canned meat products, and hoverboards. There is no need for disparate application to different types of products when one test ably reaches them all.

Finally, the analysis does not give any deference to FDA clearance of a medical device. The 1976 Medical Device Amendments had been in place for nearly two decades by the time of the 1994 *Tansy* decision and would necessarily have reached the implanted medical device at issue there, and yet the *Tansy* Court found no need to cede the question of defect to the FDA in establishing a clear rule that would apply uniformly to all medical devices. Since the FDA's 510k process is not about safety, the *Tansy*

analysis property reserves the question of defect—including whether the product is unavoidably unsafe—for the jury.

CONCLUSION

Comment k is an exception, and it should be treated like one. If a product is unavoidably unsafe, the manufacturer may enjoy the added protection of comment k. If it is not, an FDA system that is not about safety should not supplant a jury's determination. Comment k should be applied to medical devices in Utah on a case-by-case basis, applying the *Tansy* analysis, and FDA regulatory status should not be afforded any deference in that analysis.

CERTIFICATE OF COMPLIANCE

The undersigned hereby certify that this brief complies with Rule 24(a)(11) of the Utah Rules of Appellate Procedure.

ADDENDUM

These *amici* reference materials produced in the Plaintiffs/Appellants' addendum.

Respectfully submitted this 3rd day of October 2018.

THE UTAH ASSOCIATION FOR JUSTICE

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/s/ Jeffrey R. White
Jeffrey R. White

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 *Joint Brief of Amicus Curiae The Utah Association for Justice and The American Association for Justice*, to the following:

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