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.	Appeal No. 20180143-SC

AMICUS CURIAE BRIEF OF THE INTERNATIONAL ASSOCIATION OF DEFENSE COUNSEL IN SUPPORT OF APPELLEES

John A. Anderson
john.anderson@stoel.com
Lauren E.H. DiFrancesco
lauren.difrancesco@stoel.com
STOEL RIVES LLP
201 South Main Street
Suite 1100
Salt Lake City, Utah 84111
Office: (801) 578-6930
Facsimile: (801) 578-6999
Attorneys for Amicus Curiae

TABLE OF CONTENTS

TABLE OF AUTHORITIES

CASES

STATUTES

OTHER AUTHORITIES

INTEREST OF *AMICUS CURIAE*

The International Association of Defense Counsel ("IADC"), established in 1920, is an association of approximately 2,500 corporate and insurance attorneys from the United States and around the globe whose practice is concentrated on the defense of civil lawsuits. The IADC is dedicated to the just and efficient administration of civil justice and continual improvement of the civil justice system. The IADC supports a justice system in which plaintiffs are fairly compensated for genuine injuries, culpable defendants are held liable for appropriate damages, and non-culpable defendants are exonerated and can defend themselves without unreasonable cost.

The IADC maintains an abiding interest in the fair and efficient administration of product liability actions. The IADC's Product Liability Committee consists of more than 900 members, publishes regular newsletters and journal articles, and presents education seminars both internally and to the legal community at large. The IADC has recently participated as *amicus curiae* in several cases involving product liability issues around the country, including Rafferty v. Merck & Co., 92 N.E.3d 1205 (Mass. 2018); Kim v. Toyota Motor Corp., 424 P.3d 290 (Cal. 2018); Ramos v. Brenntag Specialties, Inc., 372 P.3d 200 (Cal. 2016); and Tincher v. Omega Flex, Inc., 104 A.3d 328 (Pa. 2014).

STATEMENT OF THE ISSUE PRESENTED FOR APPELLATE REVIEW

This Court granted certification of four related questions, all of which address the following issue:

> Where a company designs, manufactures, markets and sells a prescription medical device, and where such device has been cleared by the Food and Drug Administration ("FDA") via either its premarket approval or 510(k) premarket notification process, is that company immune from strict liability claims under comment k to section 402A of the Restatement (Second) of Torts?

STATEMENT OF THE CASE

This is a case from the United States District Court for the District of Utah involving an implanted hip device designed, manufactured, marketed and sold by Wright Medical Technology ("Wright"). Plaintiff Dale Burningham brought strict liability claims against Wright, alleging that he was injured by Wright's device. In addressing Wright's motion to dismiss those strict liability claims, the district court certified the matter to this Court.

Comment k to section 402A of the Restatement (Second) of Torts exempts manufacturers from strict products liability design defect claims when an "unavoidably unsafe" product provides a benefit to society that outweighs the accompanying risks. The classic example is the rabies vaccine—injection of the vaccine leads to severely harmful side effects, but

because rabies itself invariably leads to death, both the marketing and use of the vaccine are fully justified. According to the Restatement, such products, when "properly prepared, and accompanied by proper directions and warning, [are] not defective, nor [are they] *unreasonably* dangerous." Restatement (Second) of Torts § 402A cmt. k (Am. Law Inst. 1965).

Medical devices in this country are regulated under the 1976 amendment to the Food, Drug and Cosmetic Act, also known as the Medical Device Regulation Act ("the Act"). Pub. L. No. 94-295, 90 Stat. 539 (1976). The Act categorizes devices into three classes in order of increasing risk to human health and sets forth various pre- and post-market controls for devices and manufacturers depending on a product's class rating. Id. Class III products (the most regulated) are subject to either premarket approval ("PMA") or the 510(k) premarket notification process ("510(k) notification"). Id. 510(k) notification allows devices to be cleared for market if they are "substantially equivalent" to a pre-amendment approved device. Id. Over the past five years, 5,897 devices have been cleared via PMA and 15,250 devices have been cleared via 510(k) notification.[1]

[1] U.S. Food & Drug Admin., Devices Approved in 2017, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceApprovalsandClearances/PMAApprovals/ucm540012.htm (last updated Aug. 24, 2018); U.S. Food & Drug Admin., 510(k) Devices Cleared in 2017, https://www.fda.gov/MedicalDevices/ProductsandMedicalProcedures/DeviceA

footnote continued on next page…

SUMMARY OF THE ARGUMENT

In Grundberg v. Upjohn Co., 813 P.2d 89 (Utah 1991), this Court adopted the unavoidably unsafe products exception to strict products liability as set forth in comment k to section 402A of the Restatement (Second) of Torts with respect to FDA-approved drugs. The exception applies categorically rather than on a case-by-case basis.

The IADC believes that this Court should apply the same categorical exception to medical devices, as doing so is in the interest of patients, manufacturers of medical devices, and Utah civil courts. The need for a *prescription* to use a medical device should be sufficient to establish the "unavoidably unsafe" element of comment k, regardless of how such devices are cleared for market by the FDA. Indeed, the Court's reasoning in Grundberg presents no basis for treating prescription drugs differently from prescription medical devices.

Applying comment k to medical devices on a case-by-case basis would have a chilling effect on the medical device industry in Utah, slowing innovation and depriving patients of the most advanced available treatments. Meanwhile, applying comment k to medical devices categorically would

---

pprovalsandClearances/510kClearances/ucm540522.htm (last updated Sept. 4, 2018).

prevent the foregoing difficulties and promote uniformity and certainty in products liability actions in this state.

States that apply comment k to prescription drugs have unanimously applied comment k to medical devices when faced with the issue before this Court. Moreover, a majority of such states employ a categorical approach.

Exempting prescription medical devices from strict products liability claims is also consistent with Utah's adoption of the learned intermediary doctrine. Although the doctrine deals with the duty to warn, it nonetheless emphasizes that it is *physicians* who are entrusted with "combin[ing] medical knowledge and training with an individualized understanding of the patient's needs," whereas a manufacturer's responsibility is to provide proper warnings and ensure that a product is free of defects. Christison v. Biogen Idec Inc., 199 F. Supp. 3d 1315, 1320 (D. Utah 2016) (citation omitted).

ARGUMENT

The IADC's position is best summarized by the opinion in Terhune v. A. H. Robins Co., 577 P.2d 975 (Wash. 1978), where the court applied comment k to medical devices on a categorical basis:

> 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.

Id. at 979 (emphasis added). The IADC believes that all prescription medical devices are "unavoidably unsafe" under comment k, regardless of a device's FDA clearance pedigree. Furthermore, a categorical application of comment k to such devices will lead to positive outcomes for Utah's patients, medical device industry, and civil court system. A categorical application also gives appropriate deference to physicians' choice of treatments under Utah's learned intermediary doctrine.

I. Comment k protects all prescription medical treatments, regardless of the process by which a prescription treatment is brought to market.

The IADC maintains that any *prescription* medical treatment is inherently "unavoidably unsafe," and that the Court's reasoning in Grundberg is just as applicable to prescription medical devices as it is to prescription drugs. The Court's reasoning in Grundberg closely parallels that of Brown v. Superior Court, 751 P.2d 470 (Cal. 1988), which has been cited by several state courts to support the application of comment k to medical devices. In Brown, the Supreme Court of California agreed with the notion that it would be "against the public interest" to apply strict liability to prescription drugs because of "the very serious tendency to stifle medical research and testing." Id. at 475 (citation omitted). Courts in Pennsylvania,

Oklahoma, California, and many other states have subsequently relied on or cited Brown in applying comment k's scope to medical devices. See, e.g., Dougherty v. C.R. Bard, Inc., No. 11-6048, 2012 WL 2940727, at *5–6 (E.D. Pa. July 18, 2012) (citing Brown in holding that Pennsylvania law does not recognize a strict liability claim based on design defect); Tansy v. Dacomed Corp., 890 P.2d 881, 885 (Okla. 1994) (holding that comment k essentially reclassifies certain cutting-edge devices as "unavoidably unsafe" as opposed to "defective" because of the inherent risk in pushing the boundaries of medicine); Hufft v. Horowitz, 5 Cal. Rptr. 2d 377, 383 (Ct. App. 1992) ("we find the important considerations underlying Brown apply with equal force to implanted medical devices which, like prescription drugs, are available only through a physician").[2]

Significantly, states that apply comment k to prescription drugs have unanimously applied comment k to medical devices when asked to do so. In total, 42 states apply comment k to prescription drugs either on a categorical

[2] The United States District Court for the District of Utah has already seen fit to apply comment k to medical devices in the form of drug-eluting patches. See Elkins v. Mylan Labs., Inc., No. 12-255, 2013 WL 3224599, at *4 (D. Utah June 25, 2013); Stanley v. Mylan Inc., No. 09-124, 2010 WL 3718589, at *5 (D. Utah Sept. 17, 2010) (overruled in part on other grounds); Lake-Allen v. Johnson & Johnson, L.P., No. 08-930, 2009 WL 2252198, at *3 (D. Utah July 27, 2009).

or case-by-case basis.[3] Out of those 42 states, 29 have applied comment k to medical devices and 13 states have yet to rule on the issue. *None* have declined to apply comment k to medical devices.[4] Moreover, of the states that have addressed the issue, the majority have applied comment k to medical devices categorically.[5]

Ultimately, the IADC believes that the benefits and risks associated with prescription medical devices are similar to those found with prescription drugs. Both drugs and devices must often be placed inside the human body in order to affect complex systems that are imperfectly understood by medical science. Just as with drugs, the results of using a medical device may be dependent upon the unique physiology of each individual. To hold manufacturers strictly liable for injuries connected with a device that otherwise saves or improves countless lives goes against the interests of society and the interests of justice.

---

[3] A recent discussion of the relevant law on this topic in each state can be found at James M. Beck, On Comment K and Medical Devices, Drug & Device Law (May 29, 2018), https://www.druganddevicelawblog.com/tag/comment-k/. The calculations in this brief come from a review of the Beck article, as well as the IADC's own confirming research. Because most, if not all, the relevant cases are cited in the Beck article, IADC will not repeat those citations here.

[4] Id.

[5] Id.

II. Comment k should be categorically applied to prescription medical devices, because a case-by-case application would be detrimental to patients, the medical device industry in Utah, and Utah civil courts.

The IADC believes that Utah should categorically apply comment k to all prescription medical devices because applying comment k to medical devices on a case-by-case basis would be highly problematic. First, a case-by-case application would have a chilling effect on the medical device industry in Utah, to the detriment of both manufacturers and patients. Second, a case-by-case approach would be more likely to lead to inconsistent rulings. Indeed, this Court chose to categorically apply comment k to prescription drugs in Grundberg because it was "troubled by the lack of uniformity and certainty inherent in the case-by-case approach and fear[ed] the resulting disincentive for pharmaceutical manufacturers to develop new products." 813 P.2d at 94–95.

Applying comment k to prescription medical devices on a case-by-case basis would slow the pace of innovation in the medical device industry. A 1999 study by Stanford University's Hoover Institution revealed that states that adopt liability-decreasing reforms—including reducing the use of strict liability—experienced an average 1.7 percent greater aggregate productivity

growth than states that did not adopt such reforms.[6] This finding was associated with an average increase of $1,299.35 (adjusted for inflation) in Gross State Product per worker per year.[7]

A case-by-case approach would place device manufacturers in an uncertain position with respect to their liabilities. This would likely increase overall costs, decrease productivity, and deprive patients of the most advanced available medical treatments. As noted in Hufft, the "'fear of large adverse monetary judgments' and the expense of strict liability insurance, [are] costs that could 'place the cost of medication beyond the reach of those who need it most.'" Hufft, 5 Cal. Rptr. 2d at 381 (quoting Brown, 751 P.2d at 479).

Furthermore, applying the case-by-case approach advocated by plaintiffs would likely lead to an unnecessary influx of medical device litigation in Utah. The thrust of plaintiffs' argument calls for a case-by-case application wherein 510(k) devices are not automatically entitled to comment k protection. However, consider that the number of devices cleared via 510(k) notification historically far exceeds the number of devices cleared

---

[6] Daniel P. Kessler, The Economic Effects of the Liability System, Hoover Inst. (June 1, 1999), https://www.hoover.org/research/economic-effects-liability-system.

[7] Id.

via PMA. The list of devices with 510(k) clearance is extensive and ranges from non-invasive equipment such as blood pressure monitors to life-supporting products such as implantable heart valves. Plaintiffs' proposed case-by-case approach could lead to Utah civil courts seeing an increase in medical device litigation without clear guidance on comment k's application.

Meanwhile, expanding comment k to categorically include medical devices would prevent the foregoing difficulties, promote a regulatory regime that encourages competition between manufacturers to produce the best devices, and promote uniformity and certainty in products liability actions in line with this Court's reasoning in Grundberg.

III. Categorically applying comment k to medical devices is consistent with the principles underlying Utah's adoption of the learned intermediary doctrine, and this Court should not distinguish between devices cleared via PMA or 510(k) notification.

As adopted in Utah, the learned intermediary doctrine is consistent with categorically including prescription medical devices within comment k's protections. Although the doctrine deals with the duty to warn, it nonetheless emphasizes that it is physicians—not manufacturers or courts—who are in the best position to assess a patient's situation. The IADC believes that applying comment k to prescription medical devices gives proper deference to the intercession of professional judgment by trained physicians.

A case-by-case approach to cases involving medical devices would only complicate matters by involving Utah courts in decisions that are the purview of medical professionals. Many innovative medical devices are cleared via both 510(k) notification *and* PMA. Such devices often require prescriptions from doctors who (1) have ideally weighed the risks and benefits of a treatment in relation to each patient's unique needs, and (2) likely prioritize a device's effectiveness over its FDA clearance pedigree. Indeed, the IADC believes it is telling that no court has decided to specifically subject 510(k) devices as a class to strict liability.

CONCLUSION

For the reasons stated above, the IADC respectfully asks the Court to categorically include all prescription medical devices under comment k's exemption from strict liability.

Dated this 5th day of October, 2018.

INTERNATIONAL ASSOCIATION
OF DEFENSE COUNSEL

/s/ Lauren DiFrancesco
John A. Anderson
Lauren E.H. DiFrancesco
STOEL RIVES LLP
Attorneys for Amicus Curiae

CERTIFICATE OF COMPLIANCE

I hereby certify that:

1. This brief complies with the type-volume limitation of Utah R. App. P. 24(g)(1) because this brief contains 2,445 words, excluding the parts of the brief exempted by Utah R. App. P. 24(g)(2).

2. This brief complies with the typeface requirements of Utah R. App. P. 27(b) because this brief has been prepared in a proportionally spaced typeface using Microsoft Word 2010 in 13 point Century font.

3. This brief complies with Utah R. App. P. 21(g) regarding public and non-public filings.

Dated this 5th day of October, 2018.

/s/ Lauren DiFrancesco

John A. Anderson
Lauren E.H. DiFrancesco
STOEL RIVES LLP
Attorneys for Amicus Curiae

CERTIFICATE OF SERVICE

I hereby certify that on this 5th 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 *Amicus Curiae* Brief of the International Association of Defense Counsel in Support of Appellees, to the following:

Dana J. Ash
Sean K. Burke
Solomon David
Ryan J. O'Neil
DUANE MORRIS LLP
30 S 17th St.
Philadelphia, PA 19103-1104

Elizabeth M. McOmber
SNELL & WILMER (UT)
15 W South Temple, Suite 1200
Salt Lake City, UT 84101

Attorneys for Appellee Wright Medical Group

Thomas R. Leemon
George E. McLaughlin
WARSHAUER-MCLAUGHLIN LAW GROUP PC
1890 Gaylord St.
Denver, CO 80206-1211

Brian C. Stewart
SIEGFRIED & JENSEN
5664 S Green Street
Salt Lake City, UT 84123

Attorneys for Appellants Dale Burningham and Lana Burningham

and also via electronic mail to:

supremecourt@utcourts.gov
kims@utcourts.gov (Supreme Court clerk)

/s/ Lauren DiFrancesco
John A. Anderson
Lauren E.H. DiFrancesco
STOEL RIVES LLP
Attorneys for Amicus Curiae

19272817.1