Products Liability Law Daily Wrap Up, TOP STORY—MEDICAL DEVICES—D. Utah: Utah high court input sought on 'unavoidably unsafe' doctrine's applicability, (Feb. 16, 2018)

Products Liability Law Daily Wrap Up

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By Georgia D. Koutouzos, J.D.

The scope of the exception to strict products liability design defect claims set forth in Comment k to section 402A of the Restatement (Second) of Torts is at the root of four questions certified to the Utah Supreme Court by the federal court in that state in the context of an injured patient's lawsuit alleging defective design of surgically implanted hip joint devices. The device manufacturers asserted that the Restatement's exception for "unavoidably unsafe" products extends beyond prescription drugs to implanted medical devices but the relevant precedent they cited in support of that argument did not definitively answer the question, the federal court found (*Burningham v. Wright Medical Group, Inc.*, February 15, 2018, Parrish, J.).

Together with his wife, a patient who allegedly had sustained personal injuries from surgically implanted hip devices designed, manufactured, marketed, and sold by Wright Medical Group, Inc. and Wright Medical Technology, Inc. filed suit in Utah federal court against the companies alleging three claims sounding in strict liability—defective design. Wright moved to dismiss the claims, arguing that the devices implanted into the patient's hips were "unavoidably unsafe" products and, therefore, were categorically barred from design defect claims under the relevant exception to strict products liability set forth in Comment k to section 402A of the Restatement (Second) of Torts.

Unavoidably unsafe doctrine. The device makers failed to cite any Utah authority suggesting that the state applies the so-called unavoidably unsafe doctrine in any context other than Food and Drug Administration (FDA)-approved prescription drugs, however, and the patient objected that Utah courts have never applied the doctrine to implanted medical devices. Arguing that Utah law clearly limits the application of the exception in Comment k to FDA-approved drugs, the patient insisted that because no Utah court had applied the exception to medical devices, no Utah court would do so in the future.

Wright countered that the Utah Supreme Court's 1991 decision in *Grundberg v. Upjohn Co.*, 813 P.2d 89 (Utah 1991), answered the question, even though neither that case nor Comment k mentions medical devices, and despite *Grundberg*'s clear holding that "a broad grant of immunity from strict liability claims based on design defects should be extended to FDA-approved prescription drugs in Utah."

Certified questions. Consequently, because there appeared to be no controlling law in Utah on the issue of whether the Comment k bar extends beyond prescription drugs, the following questions were certified to the state's highest court:

1. Under Utah law, does the unavoidably unsafe exception to strict products liability in design defect claims recognized in Comment k to Section 402A of the Restatement (Second) of Torts apply to implanted medical devices?
2. If the answer to Question 1 is in the affirmative, does the exception apply categorically to all implanted medical devices, or does the exception apply only to some devices on a case-by-case basis?
3. If the exception applies on a case-by-case basis, what is the proper analysis to determine whether the exception applies?
4. If the answer to Question 1 is in the affirmative, does the exception require a showing that such devices were cleared for market through the Food and Drug Administration's premarket approval process as opposed to the clearance process under Section 510(k) of the federal Food, Drug and Cosmetic Act?

The case is No. 2:17-CV-92.

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Companies: Wright Medical Technology, Inc.; Wright Medical Group, Inc.

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