FOR IMMEDIATE RELEASE

June 26, 2017

Amicus Brief Filed with U.S. Supreme Court in Ethicon v. Huskey

Filing Seeks Fairness On Admissibility Of 510(k) Clearance Decisions

WASHINGTON, D.C. – The Advanced Medical Technology Association (AdvaMed) issued the following statement from Matthew Wetzel, vice president and assistant general counsel, regarding last week’s filing of an amicus curiae brief with the U.S. Supreme Court in the case of Ethicon v. Huskey:

“AdvaMed’s amicus brief asks the Supreme Court to review a lower court’s ruling that prohibited a medical device manufacturer from introducing at trial its evidence of meeting FDA premarket clearance requirements. Representing much more than a disagreement over what evidence is admissible, the case provides a chance to restore fundamental principles of fairness and transparency in fact-finding efforts at trial.

“We are asking the court to grant a writ of certiorari to hear the case, which could reverse a trend of evidentiary decisions in the Fourth Circuit and beyond that prohibit defendants in medical product liability cases from presenting evidence of a product’s 510(k) premarket clearance. In effect, such decisions prevent juries from hearing the full story, which is fundamentally unfair. Worse, it can result in FDA’s assessment of a product’s safety and effectiveness being supplanted by a court ruling.”

AdvaMed Board Member Ann Bunnenberg, president and chief operating officer of Electrical Geodesics, who also chairs AdvaMed’s Legal Committee, said “We believe that the Supreme Court has an opportunity to level the playing field and give medical device manufacturers a fair shake at defending themselves.” She expressed her hope that the Supreme Court will review the matter and “set aside the Fourth Circuit’s broad and unmerited decisions to prohibit juries from hearing evidence of 510(k) compliance.”

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