While *Riegel* did not address express warranty claims, some courts have concluded that an express warranty claim that is based on the FDA-approved label is not preempted, even for a product that has gone through the most rigorous review, as such a claim merely provides a remedy for violation of the FDA requirements. However, other courts have held that federal law preempts an express warranty claim if it is based on FDA-approved statements in the product’s packaging and label, rather than on voluntary additional statements made by the manufacturer. A court may also perceive a conflict with the FDA’s approval of the safety and effectiveness of a device if the plaintiff claims that a manufacturer that complied with the FDA’s requirements breached an express warranty of safety and effectiveness. Most courts agree that federal law does not preempt express warranty claims that are based on voluntary additional statements made by the manufacturer.

An FDA regulation lists the UCC’s implied “warranty of fitness” as an example of a state claim that is not preempted. Implied warranty claims are less likely to be preempted if they are based on violation of FDA standards rather than on general state standards of safety and effectiveness.

**Footnotes**


230 [215] See, e.g., Wildman v. Medtronic, Inc., 874 F.3d 862 (5th Cir. 2017) (warranty claim is preempted if it is based on a guarantee that the FDA expressly or implicitly approved, but this manufacturer’s warranty goes beyond what FDA evaluated in its approval process); Hafer v. Medtronic, Inc., 99 F. Supp. 3d 844 (W.D. Tenn. 2015) (claims based on breach of express warranties that manufacturer made voluntarily are not preempted); Pinsonneault v. St. Jude Med., Inc., 953 F. Supp. 2d 1006, 1018–1019 (D. Minn. 2013) (express warranty claims escape preemption if they are based on voluntary statements, not those that FDA requires manufacturer to make); Desario v. Howmedica Osteonics Corp., 817 F. Supp. 2d 197 (W.D.N.Y. 2011); Horowitz v. Stryker Corp., 613 F. Supp. 2d 271 (E.D.N.Y. 2009); Cornett v. Johnson & Johnson, 48 A.3d 1041 (N.J. 2012). See also Ali v. Allergan USA, Inc., 78 U.C.C. Rep. Serv. 2d 515 (E.D. Va. 2012) (express warranty claims are preempted only if they, like these, are based on FDA-approved statements).


232 [217] See, e.g., Wildman v. Medtronic, Inc., 874 F.3d 862 (5th Cir. 2017); Alton v. Medtronic, Inc., 970 F. Supp. 2d 1069 (D. Or. 2013); Ramirez v. Medtronic Inc., 961 F. Supp. 2d 977 (D. Ariz. 2013); Houston v. Medtronic, Inc., 957 F. Supp. 2d 1166 (C.D. Cal. 2013); Cline v. Advanced Neuromodulation Sys., Inc., 914 F. Supp. 2d 1290 (N.D. Ga. 2012) (no preemption of claim of breach of express warranty, voluntarily made by manufacturer, that device will be free from defects in material or workmanship for one year); Medtronic, Inc. v. Malander, 996 N.E.2d 412 (Ind. Ct. App. 2013) (claim based on manufacturer’s statement to physician during surgery not preempted). But see *In re Medtronic, Inc., Sprint Fidelis Leads Products Liab. Litig.*, 623 F.3d 1200, 1207 (8th Cir. 2010) (federal law preempts claim based on express warranty that product was safe, effective, fit, and proper for its intended use, because proof that the product was not safe, effective, or fit would be contrary to FDA’s approval).


1.7.2.1.3 Warranty claims


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