LESLIE MULLIN ET AL. *v.* GUIDANT CORPORATION
(AC 29829)

DiPentima, Gruendel and Schaller, Js.

Argued January 12—officially released May 12, 2009

(Appeal from Superior Court, judicial district of Waterbury, Complex Litigation Docket, Stevens, J.)

Harold J. Geragosian, for the appellants (plaintiffs).

Andrew D. Carpenter, pro hac vice, with whom were *Frank H. Santoro* and *Scott D. Kaiser*, and, on the brief, *Calum B. Anderson* and *R. Cornelius Danaher, Jr.*, for the appellee (defendant).

Opinion

GRUENDEL, J. The plaintiffs, Leslie Mullin and Vincent Mullin, appeal from the judgment of the trial court dismissing their product liability action. On appeal, the plaintiffs claim that the court improperly concluded that their two count complaint was preempted by the Medical Device Amendments of 1976, 21 U.S.C. § 360c et seq. (MDA). We agree with the court that the plaintiffs' action is preempted by federal law. The court, however, improperly concluded that it lacked subject matter jurisdiction over the case. Therefore, although the defendant, Guidant Corporation, nevertheless prevails, we must reverse the judgment of the trial court dismissing the plaintiffs' action and remand the case with direction to render judgment in favor of the defendant.[1]

The record, viewed in the light most favorable to the plaintiffs; see *Martinelli* v. *Fusi*, 290 Conn. 347, 350, 963 A.2d 640 (2009); reveals the following facts. In July, 1999, Leslie Mullin, who at the time was in her early thirties, suffered a cardiac arrest and respiratory distress. She was resuscitated successfully and transported to a hospital where medical personnel diagnosed her as having suffered from a ventricular fibrillation arrest. After additional testing, her physician recommended that she receive an implantable cardioverter defibrillator (implant).[2] The implantation was performed on July 9, 1999, using a Ventak Mini IV Model 1793 manufactured by the defendant.

Some two years later, in October, 2001, Leslie Mullin's implant began beeping. Her physicians determined that the device was malfunctioning and had reverted to a "failsafe" mode. The physicians recommended that the implant be removed and replaced as soon as possible. On November 8, 2001, the device was replaced with a different model, which also was manufactured by the defendant. The hospital and medical expenses associated with the replacement of the implant were borne by the defendant.

On October 25, 2004, the plaintiffs filed their two count complaint in the Superior Court. In the first count, the plaintiffs asserted a cause of action under the Connecticut Product Liability Act, General Statutes § 52-572m et seq. The count contained several allegations relating to the implant's safety, design, manufacture and distribution, including breach of implied and expressed warranties, failure to evaluate the safety of the implant, and subjecting Leslie Mullin to unreasonable danger. In the second count, the plaintiffs claimed that Vincent Mullin, Leslie Mullin's husband, suffered physical and emotional distress, loss of consortium and fiscal expense as a result of the failure of his wife's implant. The defendant filed an answer to the complaint in which it denied liability and asserted several special defenses, including federal preemption of the plaintiffs' causes

of action.

On December 14, 2007, the defendant filed a motion for summary judgment. In its motion and accompanying memorandum, the defendant asserted that it was entitled to judgment as a matter of law because (1) there was no evidence that the implant was defective or that there had been a breach of any warranty and (2) the plaintiffs' claims were preempted by federal law. On April 8, 2008, the court issued its memorandum of decision in which it found that the causes of action were preempted by the MDA and that the court therefore lacked subject matter jurisdiction to hear the case. It thus treated the defendant's motion for summary judgment as a motion to dismiss under our holding in *Lewis* v. *Chelsea G.C.A. Realty Partnership, L.P.*, 86 Conn. App. 596, 607, 862 A.2d 368 (2004), cert. denied, 273 Conn. 909, 870 A.2d 1079 (2005), and dismissed the plaintiffs' action. This appeal followed.

Before addressing the plaintiffs' claims on appeal, we first set forth the applicable standards of review. "Practice Book § 17-49 provides that summary judgment shall be rendered forthwith if the pleadings, affidavits and any other proof submitted show that there is no genuine issue as to any material fact and that the moving party is entitled to judgment as a matter of law. In deciding a motion for summary judgment, the trial court must view the evidence in the light most favorable to the nonmoving party. . . . The party moving for summary judgment has the burden of showing the absence of any genuine issue of material fact and that the party is, therefore, entitled to judgment as a matter of law." (Internal quotation marks omitted.) *Byrne* v. *Burke*, 112 Conn. App. 262, 267, 962 A.2d 825, cert. denied, 290 Conn. 923, 966 A.2d 235 (2009). Our review of the trial court's decision on a motion for summary judgment "is plenary and we must decide whether the trial court's conclusions are legally and logically correct and find support in the facts that appear in the record." (Internal quotation marks omitted.) Id., 268. In addition, our review of the court's decision to dismiss the case for lack of subject matter jurisdiction is likewise plenary. *Bloom* v. *Miklovich*, 111 Conn. App. 323, 335, 958 A.2d 1283 (2008).

I

The dispositive issue on appeal is whether the MDA preempts the plaintiffs' claims arising under state law. Before addressing that substantive issue, however, we must first determine if the court properly treated the defendant's motion for summary judgment as a motion to dismiss for lack of subject matter jurisdiction. We conclude that it did not. Federal preemption of a state law or cause of action does not necessarily implicate the court's subject matter jurisdiction. "It is well established that, in determining whether a court has subject matter jurisdiction, every presumption favoring juris-

diction should be indulged." (Internal quotation marks omitted.) *Lawton* v. *Weiner*, 91 Conn. App. 698, 714, 882 A.2d 151 (2005).

Our Supreme Court has held that a claim of federal preemption of a state cause of action is waived unless pleaded as a special defense. See *Stokes* v. *Norwich Taxi, LLC*, 289 Conn. 465, 488–89, 958 A.2d 1195 (2008) ("[b]ecause the defendants did not file a special defense of federal preemption to the plaintiff's claims . . . and did not object to any of the evidence introduced to support the plaintiff's claims . . . the defendants waived this special defense"). It is axiomatic, however, that "[t]he subject matter jurisdiction requirement may not be waived by any party . . . ." *Peters* v. *Dept. of Social Services*, 273 Conn. 434, 441, 870 A.2d 448 (2005). Because a preemption defense may be waived but jurisdictional defects may never be waived, we conclude that the MDA's preemptive effect does not implicate our courts' subject matter jurisdiction.[3] Consequently, the court improperly dismissed the case for lack of subject matter jurisdiction.[4]

II

This determination does not indicate, however, that the court improperly concluded that the plaintiffs' claims were preempted and that the defendant was entitled to summary judgment. We begin our analysis of the preemption issue by providing some background on the federal statute at issue, the MDA.

A

"The Federal Food, Drug, and Cosmetic Act . . . has long required [Food and Drug Administration (FDA)] approval for the introduction of new drugs into the market. Until the statutory enactment at issue here, however, the introduction of new medical devices was left largely for the States to supervise as they saw fit. . . .

"The regulatory landscape changed in the 1960's and the 1970's, as complex devices proliferated and some failed. Most notably, the Dalkon Shield intrauterine device, introduced in 1970, was linked to serious infections and several deaths, not to mention a large number of pregnancies. Thousands of tort claims followed. . . .

"Congress stepped in with the passage of the [MDA] which swept back some state obligations and imposed a regime of detailed federal oversight. The MDA includes an express pre-emption provision that states: 'Except as provided in subsection (b) of this section, no State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—(1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and (2) which relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to

the device under this chapter.' [21 U.S.C.] § 360k (a). The exception contained in subsection (b) permits the FDA to exempt some state and local requirements from pre-emption.

"The new regulatory regime established various levels of oversight for medical devices, depending on the risks they present. . . . The devices receiving the most federal oversight are those in Class III, which include replacement heart valves, implanted cerebella stimulators, and pacemaker pulse generators . . . . In general, a device is assigned to Class III if it cannot be established that a less stringent classification would provide reasonable assurance of safety and effectiveness, and the device is 'purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health,' or 'presents a potential unreasonable risk of illness or injury.' [21 U.S.C.] § 360c (a) (1) (C) (ii). . . .

"[The MDA] established a rigorous regime of premarket approval for new Class III Devices . . . . A manufacturer must submit what is typically a multivolume application. . . . It includes, among other things, full reports of all studies and investigations of the device's safety and effectiveness that have been published or should reasonably be known to the applicant; a 'full statement' of the device's 'components, ingredients, and properties and of the principle or principles of the operation'; 'a full description of the methods used in, and the facilities and controls used for, the manufacture, processing, and, when relevant, packing and installation of, such device'; samples or device components required by the FDA; and a specimen of the proposed labeling. [21 U.S.C.] § 360e (c) (1). . . .

"Once a device has received premarket approval, the MDA forbids the manufacturer to make, without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness. . . . If the applicant wishes to make such a change, it must submit, and the FDA must approve, an application for supplemental premarket approval, to be evaluated under largely the same criteria as an initial application. . . .

"After premarket approval, the devices are subject to reporting requirements. . . . These include the obligation to inform the FDA of new clinical investigations or scientific studies concerning the device which the applicant knows of or reasonably should know of . . . and to report incidents in which the device may have caused or contributed to death or serious injury, or malfunctioned in a manner that would likely cause or contribute to death or serious injury if it recurred . . . . The FDA has the power to withdraw premarket approval based on newly reported data or existing information and must withdraw approval if it determines that

a device is unsafe or ineffective under the conditions in its labeling." (Citation omitted.) *Riegel* v. *Medtronic, Inc.*, U.S. , 128 S. Ct. 999, 1002–1005, 169 L. Ed. 2d 892 (2008).

Leslie Mullin's implant, the Ventak Mini IV, was classified as a class III medical device under the MDA and the FDA's regulations. As such, the defendant submitted a premarket approval application to the FDA. On December 2, 1998, the FDA issued premarket approval for the implant, permitting its distribution and use. The FDA's approval of the device was in effect throughout the events that form the factual basis for the plaintiffs' claims.

B

In light of the statutory language purporting to preempt all state law requirements for medical devices "different from, or in addition to" those provided by federal law; 21 U.S.C. § 360k (a); the question we must answer is whether the claims set forth in the plaintiffs' complaint under the state product liability statutes would impose requirements "different from, or in addition to" the requirements set forth in the federal statute and the FDA's premarket approval of the device at issue. See *Riegel* v. *Medtronic, Inc.*, supra, 128 S. Ct. 1006. "The question of preemption is one of federal law, arising under the supremacy clause of the United States constitution." (Internal quotation marks omitted.) *Hackett* v. *J.L.G. Properties, LLC*, 285 Conn. 498, 504, 940 A.2d 769 (2008). Federal laws and regulations may preempt state laws and causes of action in several ways. See *Papic* v. *Burke*, 113 Conn. App. 198, 206, 965 A.2d 633 (2009). For the purposes of the present case, the relevant method by which federal law preempted state law is that of express preemption: "Congress can define explicitly the extent to which its enactments pre-empt state law. . . . Pre-emption fundamentally is a question of congressional intent . . . and when Congress has made its intent known through explicit statutory language, the courts' task is an easy one." (Citations omitted.) *English* v. *General Electric Co.*, 496 U.S. 72, 78–79, 110 S. Ct. 2270, 110 L. Ed. 2d 65 (1990); accord *Hackett* v. *J.L.G. Properties, LLC*, supra, 504.

In 2008, the United States Supreme Court decided *Riegel* v. *Medtronic, Inc.*, supra, 128 S. Ct. 999, in which it determined the scope of the MDA's express preemption clause as it relates to causes of action under state law. Specifically, the court addressed "whether the preemption clause enacted in the [MDA] bars common-law claims challenging the safety and effectiveness of a medical device given premarket approval by the [FDA] . . . ." *Riegel* v. *Medtronic, Inc.*, supra, 1002. Although the present case involves, at least in part, statutory claims rather than common law claims; see General Statutes § 52-572m et seq.; this is a distinction without a difference.[5] The *Riegel* case is analogous to the present

case, and the opinion, as an interpretation of federal law by the United States Supreme Court, is binding on our decision.

In *Riegel*, the Supreme Court determined that the premarket approval process "imposes 'requirements' under the MDA . . . . [T]he FDA *requires* a device that has received premarket approval to be made with almost no deviations from the specifications in its approval application . . . ." (Citations omitted; emphasis added.) *Riegel* v. *Medtronic, Inc.*, supra, 128 S. Ct. 1007. In deciding whether the product liability claims at issue in that case imposed requirements "different from, or in addition to" those set forth under the federal regulatory regime, the court stated: "State tort law that requires a manufacturer's [medical devices] to be safer, but hence [potentially] less effective, than the model the FDA has approved disrupts the federal scheme no less than state regulatory law to the same effect. Indeed, one would think that tort law, applied by juries under a negligence or strict-liability standard, is less deserving of preservation [than state regulations]."[6] Id., 1008. Therefore, in light of the precedent set by the *Riegel* decision, the tort claims raised in the plaintiffs' complaint are preempted by federal law.[7]

C

The plaintiffs also assert, however, that their claims would not create requirements that are different from or in addition to the federal requirements, but rather they "parallel" the federal requirements. The *Riegel* decision left the door open for such parallel claims: "State requirements are preempted under the MDA only to the extent that they are 'different from, or in addition to' the requirements imposed by federal law. . . . Thus, § 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." Id., 1011, citing *Medtronic, Inc.* v. *Lohr*, 518 U.S. 470, 495, 116 S. Ct. 2240, 135 L. Ed. 2d 700 (1996). A review of the plaintiffs' complaint does not reveal any claim or request for relief that could be construed to allege a violation of FDA regulations. As such, the plaintiffs do not set forth a parallel claim that might entitle them to relief.

We conclude that the plaintiffs' claims are expressly preempted by federal law. See 21 U.S.C. § 360k. Therefore, viewing the pleadings and evidence in the light most favorable to the plaintiffs, the defendant is entitled to judgment as a matter of law. See *Byrne* v. *Burke*, supra, 112 Conn. App. 267.

The form of the judgment is improper. The judgment dismissing the action is reversed and the case is remanded with direction to render judgment for the defendant.

In this opinion the other judges concurred.

[1] As will be discussed in greater detail in part I, the court treated the defendant's motion for summary judgment as a motion to dismiss. Although the court properly determined that the plaintiffs' claims are preempted by federal law, it improperly determined that it lacked subject matter jurisdiction to hear the claims. As such, the defendant was entitled to judgment as a matter of law rather than a dismissal for lack of subject matter jurisdiction.

[2] "These devices are implanted, in a manner similar to that of permanent pacemakers, in patients at high risk of sudden cardiac death from ventricular arrhythmias. The device continuously monitors cardiac activity, and if the heart rate exceeds a certain programmable threshold for a specified time . . . the [implant] delivers an appropriate intervention, such as an electrical shock." L. Lilly, Pathophysiology of Heart Disease (4th Ed. 2007) p. 285.

[3] We recognize that in certain circumstances, federal preemption may deprive state courts of subject matter jurisdiction. See, e.g., *Cox Cable Advisory Council* v. *Dept. of Public Utility Control*, 259 Conn. 56, 70–71, 788 A.2d 29 (addressing express preemption provision in federal Cable Communications Policy Act of 1984, 47 U.S.C. § 521 et seq., as it relates to section in same act specifically setting forth jurisdiction of state courts), cert. denied, 537 U.S. 819, 123 S. Ct. 95, 154 L. Ed. 2d 25 (2002); *Lewis* v. *Chelsea G.C.A. Realty Partnership, L.P.*, supra, 86 Conn. App. 605 (federal preemption in field of bankruptcy deprives Connecticut courts of jurisdiction to hear state law unfair trade practices claim asserting that action brought in federal Bankruptcy Court improper). In the present case, however, our Supreme Court's holding in *Stokes* v. *Norwich Taxi, LLC*, supra, 289 Conn. 465, indicates that the preemption clause at issue does not deprive our courts of jurisdiction.

[4] Our conclusion that the preemption provision of the MDA does not deprive our courts of subject matter jurisdiction is consistent with the holding of the United States Court of Appeals for the First Circuit in *Violette* v. *Smith & Nephew Dyonics, Inc.*, 62 F.3d 8 (1st Cir. 1995), cert. denied, 517 U.S. 1167, 116 S. Ct. 1568, 134 L. Ed. 2d 667 (1996). In that case, the court held that the MDA's preemption provision was not jurisdictional: "[W]here Congress has designated another forum for the resolution of a certain class of disputes . . . such designation deprives the courts of jurisdiction to decide those cases. . . . Where, however, the question is whether state tort or federal statutory law controls, preemption is not jurisdictional and is subject to the ordinary rules of appellate adjudication, including timely presentment and waiver. . . . This case presents a 'choice-of-law' question and thus falls squarely within the later category. Preemption is not here jurisdictional . . . ." (Citations omitted.) Id., 11–12.

[5] In enacting the Connecticut Product Liability Act, General Statutes § 52-572m et seq., the General Assembly "was merely recasting an existing [common law] cause of action and was not creating a wholly new right for claimants harmed by a product." *Lynn* v. *Haybuster Mfg., Inc.*, 226 Conn. 282, 292, 627 A.2d 1288 (1993).

[6] We briefly mention the recent United States Supreme Court decision, *Wyeth* v. *Levine*, U.S. , 129 S. Ct. 1187, 173 L. Ed. 2d 51 (2009), in which the court determined that federal law and FDA approval do not preempt state tort claims relating to prescription medication. That opinion could be read as being at odds with both *Riegel* and our disposition of the present case. The distinction, however, is that the MDA contains an express preemption provision, 21 U.S.C. § 360k (a), whereas there is no equivalent provision for prescription drugs. See *Wyeth* v. *Levine*, supra, 1200. Although the *Wyeth* decision may be indicative of a new trend in the law of federal preemption of medical product liability claims, *Riegel* still governs preemption of claims involving medical devices approved through the FDA's premarket approval process.

[7] We note that the *Riegel* decision determined that federal law preempted both the tort claims of the individual directly harmed by the allegedly defective medical device and the derivative loss of consortium claim of the plaintiff's spouse. *Riegel* v. *Medtronic, Inc.*, supra, 128 S. Ct. 1006. Likewise, in the present case, the claims of both Leslie Mullin and Vincent Mullin are preempted.