International Comparative Legal Guides

Product Liability 2020

A practical cross-border insight into product liability work

18th Edition

Featuring contributions from:

Addleshaw Goddard LLP
Advokatfirman Glimstedt
Allen & Gledhill LLP
Arnold & Porter
AZB & Partners
Bae, Kim & Lee LLC
Bahas, Gramatidis & Partners
BLD Bach Langheid Dallmayr
Clayton Utz
Faus & Moliner Abogados
Harris Kyriakides LLC
Herbert Smith Freehills LLP
Iwata Godo Law Offices
Kellerhals Carrard
Latham & Watkins LLP
Lee and Li, Attorneys-at-Law
Legaltree
LR LEX Avvocati Associati
Pinheiro Neto Advogados
Rahmat Lim & Partners
Sidley Austin LLP
Soemadipradja & Taher
Squire Patton Boggs
TURUNÇ

ICLG.com

Expert Chapters

Q&A Chapters

U.S. Product Liability Law: Recent Developments, Trends, and Future Outlook


Daniel A. Spira


Teri H. Peeples

Sidley Austin LLP

Introduction

U.S. product liability law has continued to evolve over the past year. Courts have arguably narrowed the scope of federal personal jurisdiction, and have continued to interpret the applicability of federal preemption to tort claims addressing pharmaceutical products. Additionally, given the prevalence of multi-district litigation ("MDL") that continues to encompass a substantial portion of civil cases in federal court – especially those involving product liability claims – problems pertaining to MDLs have garnered significant attention. Proposed MDL rule changes, if implemented, would likely alter the product liability landscape. Finally, as the design, manufacturing, and function of traditional products evolve through the advent of new technologies, courts, regulators, practitioners, and companies are being forced to re-examine, develop, and adapt product liability law.

This chapter summarises and provides updates on each of the following topics pertaining to U.S. product liability law:

- Personal Jurisdiction;
- Federal Preemption;
- MDLs; and
- Emerging Areas of Product Liability Law.

Personal Jurisdiction

The constitutional requirement of personal jurisdiction protects defendants from being sued in jurisdictions in which they do not have certain minimum contacts. *See Int'l Shoe Co. v. Wash.*, 326 U.S. 310, 316 (1945). For a court to exercise jurisdiction, the defendant must also have purposefully availed itself of the privileges of conducting activities within the forum. *See Walden v. Fiore*, 571 S. Ct. 1115, 1122 (2014).

There are two different types of personal jurisdiction, without either of which a case must be dismissed. "General jurisdiction" exists when a defendant has such substantial contacts with a forum that it is essentially "at home" in the forum and can be subject to any claim there, regardless of whether the lawsuit relates to the forum. *See Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 924-25 (2011). By contrast, "specific jurisdiction" can be invoked even when a defendant has few contacts with the forum, as long as the claim arises directly out of those contacts. *Id.* at 414 & n.8.

In recent years, case law has narrowed the scope of general and specific jurisdiction, with significant implications for product liability suits and other cases.

General Jurisdiction

The U.S. Supreme Court clarified the scope of general jurisdiction in *Daimler Ag v. Bauman*, a landmark case in which the Court found that a corporation is typically only "at home" in its "place of incorporation and principal place of business". 134 S. Ct. 746, 760 (2014). Only in an "exceptional" case will "a corporation's operations in a forum other than its formal place of incorporation or principal place of business … be so substantial and of such a nature as to render the corporation at home in that state". *Id.* at 761-62 & n.19 (declining to find general jurisdiction over Daimler in California despite its subsidiary's sales of $4.6 billion in the state) (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)).

In *BNSF Ry. Co. v. Tyrrell*, the Supreme Court further described the narrow circumstances under which general jurisdiction over a defendant may be found. 137 S. Ct. 1549, 1554, 1559 (2017). The Court held that there was no general personal jurisdiction over BNSF in Montana, when BNSF was not incorporated in Montana and did not maintain its principal place of business there, even though the company had over 2,000 miles of railroad track and more than 2,000 employees in the state. *Id.* at 1559. These contacts were not substantial enough for general jurisdiction, because they represented only a small portion (less than 10 per cent) of BNSF's total presence in the United States. *Id.* at 1554, 1559.

These cases are of significance to defendants in product liability litigation, where hundreds or thousands of plaintiffs may individually sue the same defendant manufacturer over the same product or device. Narrowing the venues in which these defendants are considered "at home" can critically curtail plaintiffs' efforts to "forum shop" in seemingly favourable jurisdictions. In a recent attempt to dull the impact of *Daimler* and *BNSF*, plaintiffs have argued that defendants "consented" to jurisdiction anywhere they are registered to do business. *See, e.g., Bors v. Johnson & Johnson*, 208 F. Supp. 3d 647 (E.D. Pa. 2016) ("[B]ecause [defendant] was authorized to do business in Pennsylvania, it was subject to the exercise of personal jurisdiction by Pennsylvania courts"); *see also Williams v. Takeda Pharms. America, Inc.*, No. 18-4774, 2019 WL 2615947, at *3 (E.D. Pa. June 26, 2019) ("Without any further analysis from the Supreme Court or the Third Circuit, a foreign corporation's registration to do business in Pennsylvania establishes consent to personal jurisdiction"). Several courts, however, have recently declined to embrace this argument. *See, e.g., Waite v. All Acquisition Corp.*, 901 F.3d 1307, 1318-22 (11th Cir. 2018) (registration to do business in Florida did not subject the corporate defendant in a product liability suit to jurisdiction in the state), *cert. denied*, 139 S.Ct. 1384 (2019); *Sullivan v. A.W. Chesterton, Inc.* (*In re Asbestos Prod. Liab. Litig.*), 384 F. Supp. 3d 532, 545 (E.D. Pa. 2019) ("Pa. Statutory scheme requiring foreign corporations to register to do business and, therefore, to consent to general personal jurisdiction in Pennsylvania, offends the Due Process Clause and is unconstitutional"); *Aspen Am. Ins. Co. v. Interstate Warehousing, Inc.*, 90 N.E.3d 440, at 447-48 (Ill. 2017) ("that a foreign corporation has

registered to do business under the Act does not mean that the corporation has thereby consented to general jurisdiction over all causes of action, including those that are completely unrelated to the corporation's activities in Illinois"). This theory will likely see continued litigation across the country as litigants attempt to test the limitations put in place by the Supreme Court.

Specific Jurisdiction

The U.S. Supreme Court's 2017 decision in *Bristol-Myers Squibb Co. v. Superior Court of Calif.* ("*BMS*") significantly limited the forums in which specific jurisdiction may be invoked to those connected to a particular plaintiff's claims. BMS, a pharmaceutical company, was sued in a product liability lawsuit in California state court by a group of plaintiffs, 80 per cent of whom were out-of-state residents. 137 S. Ct. 1773, 1778 (2017). Where plaintiffs lived, purchased, or were prescribed the drug in California, the court had specific jurisdiction over BMS for injuries that arose out of BMS's conduct in that state, and plaintiffs were permitted to bring an action against BMS in California. *Id.* at 1779. But non-resident plaintiffs whose claims had no relation to California were not allowed to piggyback onto the specific jurisdiction over the resident plaintiffs' claims and assert their own claims against BMS in California. *Id.* at 1782.

Courts across the country have consistently applied *BMS* to limit forum shopping by out-of-state plaintiffs asserting product liability claims. *See, e.g., Jordan v. Bayer Corp.*, 4:17-cv-00865, 2018 WL 837700, at *4 (E.D. Mo. Feb. 13, 2018) (granting motion to dismiss because non-Missouri plaintiffs' "allegations are simply too attenuated to serve as a basis for specific personal jurisdiction over Bayer"); *Hinton v. Bayer Corp.*, No. 4:16-cv-1679, 2018 WL 3725776, at *4 (E.D. Mo. July 27, 2018) (similar); *Timpone v. Ethicon*, No. 4:19 CV 821 RWS, 2019 WL 2525780, at *2 (E.D. Mo. June 19, 2019) (also similar); *In re Zostavax (Zoster Vaccine Live) Prods. Liab. Litig.*, 358 F. Supp. 3d 418, 423-424 (E.D. Pa. Jan. 7, 2019) (Defendant's in-state activities not involving the alleged injury-causing product were not jurisdictional contacts); *Campbell v. Acme Insulations, Inc.*, 2018 IL App (1st) 173051, 105 N.E.3d 984, 995 (2018) (In *BMS* "the United States Supreme Court rejected the notion that specific jurisdiction could be asserted under a 'sliding scale' theory"; rather, "for purposes of specific personal jurisdiction, there must be a connection between the forum and the specific claims at issue") (internal quotations omitted).

In the context of class actions, some courts have similarly recognised that *BMS* requires dismissal of non-resident putative class members' claims that have no connection to the forum. *E.g., Mussat v. IQVIA Inc.*, No. 17 C 8841, 2018 WL 5311903, at *5 (N.D. Ill. Oct. 26, 2018) ("Following the Supreme Court's lead in [*BMS*] and applying its core reasoning here, due process … requires a connection between the forum and the specific claims at issue. This recognition bars nationwide class actions in fora where the defendant is not subject to general jurisdiction. Whether it be an individual, mass, or class action, the defendant's rights should remain constant"); *DeBernardis v. NBTY, Inc.*, No. 17 C 6125, 2018 WL 461228, at *2 (N.D. Ill. Jan 18, 2018) ("The Court believes that it is more likely than not … that the courts will apply [*BMS*] to outlaw nationwide class actions in a for[u]m, such as in this case, where there is no general jurisdiction over the Defendants"); *Chavira v. OS Restaurant Services, LLC*, No. 18-cv-10029-ADB, 2019 WL 4769101, at *6 (D. Mass. Sept. 30, 2019) (motion to strike non-resident class action allegations was granted, noting that *BMS* applies to all cases, including class actions). Other courts have maintained that *BMS* is inapplicable to proposed class members' claims, resulting in a split of authority. *See, e.g., In re: Chinese-Manufactured Drywall Prod. Liab. Litig.*, No. 09-2047, 2017 WL 5971622, at *12 (E.D. La. Nov. 30, 2017) ("[*BMS*] was not a class action …. [T]his factor materially distinguishes this action from *Bristol-Myers* because in class actions, the citizenship of the unnamed plaintiffs is not taken into account for personal jurisdiction purposes") (internal quotations omitted); *Cabrera v. Bayer Healthcare, LLC*, No. CV 17-08525, 2019 WL 1146828, at *7-8 (C.D. Cal. Mar. 6, 2019) (discussing split of authority and holding that "decisions concluding that *Bristol-Myers* does not apply in the class action context are more persuasive").

BMS may also serve to limit specific jurisdiction where plaintiffs' alleged injuries only occurred in the jurisdiction as a result of a product traveling there through the "stream of commerce". Under the "stream of commerce" theory, plaintiffs allege that minimum contact with the forum is established merely because defendant's product ultimately reaches a state and the product allegedly causes injury in that state. Recently, the Supreme Court granted certiorari regarding reliance on a stream of commerce theory to establish specific jurisdiction in automobile cases. *See Bandemer v. Ford Motor Co.,* 931 N.W.2d 744 (Minn. 2019), *cert. granted*, No. 19-369, 2020 WL 254152 (Jan. 17, 2020) and *Ford Motor Co. v. Montana Eighth Judicial Dist. Court*, 443 P.3d 407, *cert. granted*, No. 19-368, 2020 WL 254155 (Jan. 17, 2020). Because the automobiles at issue in those cases were not purchased, manufactured or designed by defendants in the state where the injuries occurred, the question for the Court is whether the defendant nevertheless has sufficient contacts with the forum under a "stream of commerce" theory to confer specific jurisdiction over the matter. The Supreme Court's approach to this question could have a significant impact on the jurisdictions available for plaintiffs to bring suits against broad classes of manufacturers whose products are placed in the stream of commerce and ultimately are widely distributed by third parties.

Federal Preemption

Where state law conflicts with federal law, state law is preempted under the Supremacy Clause of the U.S. Constitution. U.S. Const. art. VI, cl. 2. Preemption may be expressed in an explicit provision of federal law or implied in the structure and scope of the federal regulatory scheme. *See, e.g., Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001). Preemption with respect to pharmaceutical products and medical devices approved by the U.S. Food and Drug Administration ("FDA") has received considerable attention from courts in recent years and remains one of the most hotly contested issues in product liability cases.

Pharmaceutical "Impossibility" Preemption

In *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), a case with significant implications for pharmaceutical preemption, plaintiffs alleged that manufacturers of a generic drug failed to adequately warn of the risk of a neurological disorder, as required under state law. The manufacturers argued that the claims were preempted because federal law requires generic medications to carry warnings identical to their brand-name equivalents, making compliance with both federal law and the alleged duty under state law impossible (a recognised ground for implied preemption). *Id.* at 610; *see also id.* at 617-18. ("Where state and federal law directly conflict, state law must give way", and "state and federal law conflict where it is impossible for a private party to comply with both state and federal requirements".)

Plaintiffs argued that compliance was not impossible, because the manufacturers could have independently modified the warnings by: (1) using FDA's changes-being-effected ("CBE") process; (2) sending Dear Doctor letters to physicians; or (3) proposing stronger warnings to the FDA. *Id.* at 614-16. The

Court rejected the first two arguments, noting that a generic drug maker cannot unilaterally strengthen its labelling through the CBE process or disseminate a Dear Doctor letter. *Id.* at 614-15. As to the third basis, the Court held that it was not clear that the FDA would have permitted a new warning. *Id.* at 619-20. Plaintiffs' claims were therefore preempted: "[W]hen a party cannot satisfy its state duties without the Federal Government's special permission and assistance, which is dependent on the exercise of judgment by a federal agency, that party cannot independently satisfy those state duties for pre-emption purposes." *Id.* at 623–24.[1]

In *Mut. Pharm. Co. v. Bartlett*, 570 U.S. 472 (2013), the Supreme Court found that state design-defect claims against the manufacturer of a generic drug were impliedly preempted. Similar to *Mensing*, a defendant manufacturer argued in *Bartlett* that it was impossible to comply with both its alleged state law duty to strengthen the warnings for its drug, and its federal law duty not to alter its approved labelling. Although the Court of Appeals held that plaintiff's claims were not preempted, as defendant "could escape the impossibility of complying with both its federal- and state-law duties by choosing not to make [the drug] at all", the Supreme Court rejected that reasoning, holding that "an actor seeking to satisfy both his federal- and state-law obligations is not required to cease acting altogether in order to avoid liability". *Id.* at 488.

Notwithstanding the availability of the CBE process to manufacturers of *brand-name* pharmaceuticals (unlike the *generic* drug manufacturers in *Mensing* and *Bartlett*), brand-name manufacturers have likewise succeeded in arguing that state law failure-to-warn claims are subject to "impossibility preemption". Specifically, whereas it was "impossible" for the *generic* drug manufacturer in *Mensing* to comply with state law warning duties because federal law does not allow generic manufacturers to invoke the CBE process to supplement drug warnings, so too is it "impossible" for *brand-name* manufacturers to comply with state law warning duties where plaintiffs have not identified "newly required information" of the type that is required before federal law permits such manufacturers to invoke the CBE process. *See, e.g., Sabol v. Bayer Healthcare Pharm, Inc.*, No. 18 Civ. 11169, 2020 WL 705170, *14 (S.D.N.Y. Feb. 12, 2020) ("Plaintiff does not sufficiently plead that . . . [defendant] had reasonable evidence of a causal association between [the pharmaceutical at issue] and a clinically significant adverse reaction in patients with normal kidney function. Thus, [plaintiff] does not plead facts showing that [defendant] had or should have had newly acquired information permitting it to unilaterally add her claimed warning under the CBE regulations. Consequently, [plaintiff's] claims against [defendant] are preempted"); *Drescher v. Bracco Diagnostics Inc.*, No. CV-19-00096, 2020 WL 699878, at *4-6 (D. Ariz. Jan. 31, 2020) (similar); *Pradaxa Cases*, No. CJC-16-004863, 2019 WL 6043513, at *2 (Cal. Super. Ct. Nov. 8, 2019) (granting summary judgment for defendant on claim that warning label was inadequate, because "between the inception of Pradaxa in the U.S." and the "date of [plaintiff's injury], there was no relevant 'newly acquired information' about Pradaxa that, under federal law, would permit [defendant] to change the Pradaxa label"). *But see, e.g., Holley v. Gilead Sciences, Inc.*, 379 F. Supp. 3d 809, 826, 829 (N.D. Cal. May 10, 2019) (dismissing certain failure to warn theories for failure to sufficiently plead "newly acquired information", but finding impossibility preemption inapplicable to other failure to warn theories alleging that defendant "should have submitted different warnings" *before* FDA approval of a drug, because there is "no federal law that would prevent a drug manufacturer from submitting a different warning label to the FDA prior to initial approval"). In *Merck Sharp v. Dohme Corp.*, 139 S. Ct. 1668, 1676 (2019), the Supreme Court reaffirmed that "a judge, not the jury, must decide the pre-emption question", ensuring that courts will continue to grapple with the "impossibility" of drug manufacturers complying with both state law duties to warn and federal limitations on their ability to do so.

Several noteworthy opinions following *Mensing* and *Bartlett* have also addressed whether state law *design defect* claims are preempted, where defendants could not, pursuant to federal law, unilaterally make "major changes" to pharmaceutical drug designs without FDA approval. *See, e.g., Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298-300 (6th Cir. 2015) (claims were preempted because "once a drug, whether generic or brand-name, is approved [by the FDA], the manufacturer is prohibited [by federal law] from making any major changes to the qualitative or quantitative formulation of the drug product …", and plaintiff's additional argument that the defendant could have utilised a different design "in the first instance" *before* obtaining FDA approval was similarly preempted, in part because "Defendants could not have complied with whatever pre-approval duty might exist without ultimately seeking the FDA's approval prior to marketing [the product], and certainly prior to [plaintiff's] use of the drug"); *Gustavsen v. Alcon Labs.*, Inc., 903 F.3d 1, 10 (1st Cir. 2018) ("federal law preempts plaintiffs' [design defect] cause of action because defendants cannot lawfully make such a [design] change without prior FDA approval"); *Drescher*, 2020 WL 699878, at *8 ("Because it would constitute a major change under the [federal] regulations, Defendants were not able to alter their [pharmaceutical formulations] without obtaining prior FDA approval", and plaintiff's design defect claim was therefore preempted); *Thomas v. Bracco Diagnostics Inc.*, 3:19-cv-00493, 2020 WL 1016273, at *9 (W.D. La. Feb. 27, 2020) (Defendant "could not have independently adopted an alternative design for [its pharmaceutical product] after the FDA approved the drug because federal drug regulations prohibit [defendant] from altering its composition. Accordingly, any state requirement that [defendant] should have adopted an alternative design after FDA approval is preempted."). *But see, e.g., Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1206-08 (E.D. La. 2016) (rejecting "the Sixth Circuit's reasoning in *Yates* concerning preemption in the *pre*-FDA approval context", because "[f]ederal law does not prevent a drug manufacturer from complying with this state-imposed duty [to consider feasible, alternative designs] before seeking FDA approval"); *Paulsen v. Abbott Labs.*, 368 F. Supp. 3d 1152, 1173 (N.D. Ill. 2019) (whether design defect claims are preempted under *Bartlett* is a question that "has divided federal courts across the country").

Buckman Preemption

In *Buckman Co. v. Plaintiffs' Legal Comm.*, the U.S. Supreme Court addressed claims that plaintiffs suffered injuries from the use of orthopaedic bone screws, and that the manufacturer of the device and its consultant "made fraudulent representations to the [FDA] in the course of obtaining approval to market the screws". 531 U.S. 341, 343 (2001). The Court held that "plaintiffs' state-law fraud-on-the-FDA claims conflict with, and are therefore impliedly preempted by, federal law. The conflict stems from the fact that the federal statutory scheme amply empowers the FDA to punish and deter fraud against the Administration, and that this authority is used by the Administration to achieve a somewhat delicate balance of statutory objectives. The balance sought by the Administration can be skewed by allowing fraud-on-the-FDA claims under state tort law". *Id.* at 348. Almost 20 years later, courts continue to apply *Buckman* with varying interpretations and results.

For instance, in 2013, the Ninth Circuit held that federal law did not impliedly preempt Arizona state law failure-to-warn claims predicated on a medical device manufacturer's alleged failure to

"report to the FDA any complaints about the product's performance". *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1232 (9th Cir. 2013) (*en banc*). The court distinguished *Buckman* on the ground that the plaintiff's "claim specifically alleges, as a violation of Arizona law, a failure to warn the FDA", *id.* at 1233, whereas "the plaintiffs in *Buckman* alleged no state-law claim and were concerned exclusively with alleged fraud on the FDA that had occurred as part of that approval process". *Id.* at 1230. In other words, unlike in *Buckman*, the plaintiff in *Stengel* asserted "a state-law duty that paralleled a federal-law duty …" *Id.* at 1232. *See also, e.g., Bledsoe v. Medtronic, Inc.*, No. 2:18-cv-133, 2020 WL 43107, at *7 n.4 (N.D. Ind. Jan. 3, 2020) (narrowly interpreting *Buckman* as only barring claims that assert "fraud on the agency").

However, the Supreme Court of Arizona unanimously rejected the Ninth Circuit's interpretation of Arizona law. *Conklin v. Medtronic, Inc.*, 431 P.3d 571 (Ariz. 2018). Holding that failure to warn claims against the manufacturer of a medical device were impliedly preempted, the court explained that *Stengel* "was based on the unsupported premises that Arizona law contemplates a warning to a third party such as the FDA", whereas "established law does not recognise a claim merely for failing to provide something like adverse event reports … to a government agency that has no obligation to relay the information to the patient". *Id.* at 579 (internal quotations omitted). "Absent an independent state law duty to submit adverse event reports to the FDA, [plaintiff's] failure-to-warn claim, at bottom, is an attempt to enforce a federal law requirement", and is therefore preempted. *Id.* at 578; *see also, e.g., McNeil-Williams v. DePuy Orthopaedics, Inc.*, 384 F. Supp. 3d 570, 576-77 (E.D.N.C. 2019) (suggesting that North Carolina similarly "does not recognize an independent state law duty to make adverse event reports to the FDA"). The Ninth Circuit's decision also departed from the holding of some other courts that allegations that a manufacturer "failed to provide the FDA with sufficient information and did not timely file adverse event reports, as required by federal regulations", are "foreclosed by [the FDCA] as construed in *Buckman*". *In re Medtronic, Inc., Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1205–06 (8th Cir. 2010); *see also, e.g., Tinkler v. Mentor Worldwide, LLC*, 1:19-cv-23373, 2019 WL 7291239, at *4 (S.D. Fla. Dec. 30, 2019) ("*Buckman's* holding—i.e., that fraud-on-the-FDA claims are impliedly preempted—extends to failure-to-warn claims where the plaintiff alleges the device's warnings were inadequate because the defendant-manufacturer failed to provide sufficient information to the FDA").

Courts have relied on *Buckman* to also hold that other tort claims against pharmaceutical and medical device manufacturers are impliedly preempted. *See, e.g., Markland v. Insys Therapeutics, Inc.*, 758 F. App'x 777, 778-80 (11th Cir. 2018) (affirming dismissal of state law claims that the pharmaceutical manufacturer "engaged in a 'fraudulent' and 'unlawful' marketing scheme to push doctors to prescribe [the drug] 'off label'", because plaintiff "has not pointed to any traditional state-law duty owed by [defendant] to [plaintiff] that was breached by the company's marketing of [the product] for off-label use. It is only because of the FDCA and FDA enforcement decisions that the promotion of off-label uses is prohibited", and, therefore, "[a]s with the *Buckman* plaintiffs, [plaintiff] seeks to enforce a duty that 'exists solely by virtue of the FDCA'"); *Green v. Medtronic, Inc.*, 2019 WL 7631397, at *5 (N.D. Ga. Dec. 31, 2019) ("a claim for negligence per se is impliedly preempted insofar as it is premised on breaches of duties created by the FDCA", because under *Buckman* "there is no private right of action for violations of the FDCA") (internal quotations omitted).

Express Preemption of Claims Against Manufacturers of Certain Medical Devices

The express preemption of claims against medical device manufacturers has also received considerable attention in recent years. In 2008, the U.S. Supreme Court held that claims against manufacturers of Class III pre-market approved ("PMA") devices are expressly preempted to the extent they would impose requirements "different from, or in addition to the requirements imposed by federal law". *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 330 (2008) (internal quotation omitted). This ruling shields manufacturers from tort liability for most claims related to PMA devices, which are subject to the most rigorous FDA review. *Id.* at 318-20. *Riegel* left open, however, the possibility that plaintiffs could plead viable "parallel" state law claims, where PMA-approved medical devices deviate from federally-imposed, device-specific requirements, in violation of both federal and state law. *Id.* at 330.

Numerous courts have rejected plaintiffs' attempts to circumvent *Riegel*. *See, e.g., Lawrence v. Medtronic,* 791 F. App'x 679, 680 (9th Cir. 2020) (affirming dismissal of state law claims, where plaintiff "identifies no federal authority that requires medical-device manufacturers to send removed medical devices anywhere for evaluation", such that "a tort claim premised on such a course of conduct would impose a requirement that is 'different from' and 'in addition to' what is required under federal law"); *id.* (affirming dismissal of "product-defect theories of recovery", because plaintiff "fail[s] to identify any specific federal requirement that was violated or the specific nature of the [product's] purported defects"); *Green v. Medtronic, Inc.*, No. 1:19-cv-3242, 2019 WL 7631397, at *4 (N.D. Ga. Dec. 31, 2019) (dismissing manufacturing defect claim as expressly preempted, because "Plaintiff does not identify the specific federal regulations or statutes that the Defendants purportedly violated"); *Walls v. Medtronic, Inc.*, No. 19-3690, 2019 WL 6839942, at *4 (E.D. Pa. Dec. 16, 2019) (dismissing claims that the PMA medical device was defective, lacked adequate instructions and warnings, and was negligently designed, because plaintiffs "have not identified any violations of specific FDA regulations"). Other courts, however, have diverged from these analyses and rejected arguments that claims regarding PMA devices are expressly preempted under *Riegel*. *See, e.g., Bull v. St. Jude Med., Inc.*, No. 17-1141, 2018 WL 3397544, at *8 (E.D. Pa. July 12, 2018) ("Plaintiff's state law failure to warn claim identified a state duty to warn physicians of risks inherent in its medical devices that is parallel to St. Jude's duty to comply with MDR reporting requirements …. As such, it parallels these federal requirements, and is not expressly pre-empted").

MDL Trends

The nature of product liability litigation can lead to a substantial volume of individual claims in different courts, each alleging, for instance, similar injuries arising from exposure to the same pharmaceutical product or medical device. Handling these cases on an individual basis can become unwieldy and expensive. As a result, plaintiffs and/or defendants may support the centralisation or coordination of litigation before one judge in one court. 28 U.S.C. § 1407 provides one mechanism for doing so, allowing lawsuits "involving one or more common questions of fact" to be coordinated or consolidated in one federal district court for pre-trial proceedings, called an MDL. The general purposes of an MDL are "to avoid duplication of discovery, to prevent inconsistent pretrial rulings, and to conserve the resources of the parties, their counsel and the judiciary". U.S. Judicial Panel on Multidistrict Litigation, Overview of Panel, https://www.jpml.uscourts.gov/overview-panel-0.

As of year-end 2019, there were 190 active MDLs. *See* https://www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2019_1.pdf. By some measures, MDLs now contain more than half of all civil cases pending in federal court, *see* https://www.law360.com/classaction/articles/1138928/mdls-surge-to-majority-of-entire-federal-civil-caseload, although

the number of MDL dockets has been declining. *See* Meeting of the Advisory Committee on Civil Rules, 207 (April 2–3, 2019), available at https://www.uscourts.gov/sites/default/files/2019-04_civil_rules_agenda_book.pdf. Of the 190 MDLs pending in 2019, 65 of them are classified as "Products Liability" litigation, the largest of any category. (*See* https://www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2019_1.pdf.)

In recent years, defence and plaintiff practitioners have argued that several aspects of MDLs and the manner in which they are litigated undermine their effectiveness for resolving their substantial inventory of cases. Accordingly, in November 2017, the Advisory Committee on Civil Rules formed an MDL subcommittee to consider rules to address commonly raised concerns with MDLs, including, among others, (1) their tendency to attract (and failure to weed out) meritless claims, (2) infrequent appellate review of pre-trial decisions, and (3) high pressure to engage in bellwether trials. *See* https://www.uscourts.gov/sites/default/files/2017-11-CivilRulesAgendaBook_0.pdf.

Industry groups have proposed several Federal Rule revisions to the Committee, including: requiring claimants to disclose preliminary evidence showing the cause and nature of the injury alleged; allowing mid-case appellate review of decisions on topics that have litigation-wide implications, such as preemption or expert testimony; requiring disclosure of plaintiffs' outside sources of funding; barring use of bellwether trials without party consent; and increasing pleading standards to discourage meritless claims. *See id.* at 469-542.

In October 2019, the Committee reported that it "has continued to explore and gather information about the issues"; however, "it remains unclear whether rule changes would be helpful". Meeting of the Advisory Committee on Civil Rules, 189-190 (October 29, 2019), available at https://www.uscourts.gov/sites/default/files/2019-10_civil_rules_agenda_book.pdf. The Committee continues to highlight particular areas of focus for potential rule changes, such as interlocutory appellate review of preemption and *Daubert* rulings, and MDL transferee judge review of proposed settlements. *Id.* The discussion of whether to limit claims through the use of Plaintiff Fact Sheets has evolved to the proposal for a "census" of cases in an MDL that would permit an initial assessment of plaintiffs' claims. *Id.* at 193. One MDL judge has plans to pilot the "census" in a pending litigation. *Id.* Although new rules are not imminent, MDLs continue to have an immense impact on product manufacturers and other defendants faced with these centralised cases.

Emerging Areas of Product Liability Law

As technologies advance and change at an accelerating pace, new products entering the market are likely to become the subject of future product liability litigation. Among the numerous advancements that continue to create unique product liability challenges are the "internet of things" ("IoT") and autonomous vehicles.

IoT

The expansive development of internet-connected consumer products, also known as IoT devices, have prompted consumer privacy and product liability concerns arising out of alleged manufacturing and design defects.

For instance, the FDA now recognises that "[m]edical devices are increasingly connected to the Internet, hospital networks, and other medical devices to provide features that improve health care and increase the ability of health care providers to treat patients. These same features also increase the risk of potential cybersecurity threats. Medical devices, like other computer systems, can be vulnerable to security breaches, potentially impacting the safety and effectiveness of the device. Threats and vulnerabilities cannot be eliminated, therefore, reducing cybersecurity risks is especially challenging. The heath care environment is complex, and manufacturers, hospitals, and facilities must work together to manage cybersecurity risks". U.S. FDA, "Cybersecurity", available at https://www.fda.gov/medical-devices/digital-health/cybersecurity.

In January 2019, the U.S. Consumer Product Safety Commission ("CPSC") also released "A Framework of Safety for the Internet of Things", intended "to provide an overview of technology-neutral best practices to ensure consumer product safety in the design and deployment of devices, software and systems used with Internet-connected consumer products". U.S. CPSC, "A Framework of Safety for Internet of Things: Considerations for Consumer Product Safety", available at https://www.cpsc.gov/s3fs-public/A_Framework_for_Safety_Across_the_Internet_of_Things_1-31-2019_0.pdf?1KJ.t4Tn04v9OtEBr2s0wyLAP.KsuuQ3. The Commission advised that "[p]roduct designers need to be aware of the capabilities of every component of their final product and predict unintentional uses and intentional misuses that could lead to foreseeable hazardous conditions. These best practices will help ensure that devices and components of devices are designed to prohibit unsafe system actions, command and control critical safety functions, and signal precursors to hazardous events as reliably as possible over the expected lifespan of the system." *Id.*; *see also* CPSC, "Status Report on the Internet of Things (IoT) and Consumer Product Safety", Sept. 25, 2019, available at https://www.cpsc.gov/s3fs-public/Status-Report-to-the-Commission-on-the-Internet-of-Things-and-Consumer-Product-Safety.pdf?6sv9HwTXKHrkdmAyAkQ0_TsKCkpl1lR2.

Lawsuits have similarly emerged pertaining to IoT devices. For instance, several class action lawsuits consolidated in the Central District of California were recently brought against Ring LLC and Amazon.com, Inc., regarding the companies' "Wi-FI cameras" that are "designed to be strategically placed throughout a property, enabling authorized users to see covered areas in high definition and to communicate directly with occupants via a two-way speaker-microphone system". *Orange v. Ring LLC, et al.*, No. 2:19-cv-10899 (C.D. Cal. Dec. 26, 2019), Compl. (Dkt. No. 1) ¶ 6. Plaintiffs – asserting negligence, invasion of privacy, breach of implied contract, breach of implied warranty, and unjust enrichment claims on behalf of themselves and putative class members – allege that "[l]ax security standards and protocols render [defendants'] camera systems vulnerable to cyber-attack. Indeed, over the past several months numerous Ring customers reported that their camera systems had been hacked by malicious third parties who gained access to the video and two-way speaker-microphone system which they used to invade the privacy of customers' homes and terrorize unsuspecting occupants, many of whom are children." *Id.* ¶ 7; *see also id.* ¶ 28 (describing alleged "hacking incidents"). This litigation remains in its early stages, but the manner in which litigants and courts handle these and similar cases have the potential to impact future cases involving a broad spectrum of IoT products. Indeed, given the quantity and increasing breadth of IoT devices on the market and their rapid development, regulatory challenges and consumer claims involving IoT devices will almost certainly continue to grow and evolve, causing a re-examination of security, privacy, and traditional notions of product liability law.

Autonomous Vehicles

Autonomous vehicles, also known as driverless cars, have the potential to reduce traffic, increase safety, lower energy usage, and generate free time. Nevertheless, they also may lead to new

liability risks. In fact, high-profile product liability lawsuits have already emerged against the manufacturers of self-driving vehicles. *E.g., Huang v. Tesla Inc.*, No. 19-cv-346663 (Cal. Super. Ct. Apr. 26, 2019) (alleging negligence/wrongful death, strict liability, and other claims based on an auto-accident and death that resulted when Tesla's allegedly defective Autopilot feature caused a car to accelerate into a concrete median).

In addition, developing regulations continue to address standards surrounding autonomous vehicles, with most states considering or enacting legislation. *See* https://www.ncsl.org/research/transportation/autonomous-vehicles-self-driving-vehicles-enacted-legislation.aspx. The U.S. Department of Transportation has also released a series of principles for "Automated Vehicles", on which it has invited public comment. *See* U.S. Dept. of Transportation, "Automated Vehicles 4.0", available at https://www.transportation.gov/av/4. State regulations and federal guidelines remain in their infancy, and will undoubtedly continue to evolve with this developing technology.

Note

This chapter has been prepared for informational purposes only and does not constitute legal advice. This information is not intended to create, and the receipt of it does not constitute, a lawyer-client relationship. Readers should not act upon this without seeking advice from professional advisers. The content therein does not reflect the views of the firm.

Endnote

1. Although the FDA proposed a rule in 2013 that would have permitted generic drug manufacturers, like brand-name manufacturers, to change their warning labels through the CBE process, the rule was withdrawn in December 2018. *See* FDA Statement (Dec. 13, 2018), available at https://www.fda.gov/news-events/press-announcements/statement-fda-commissioner-scott-gottlieb-md-and-director-fdas-center-drug-evaluation-and-research (explaining that the "the new policy would have resulted in labels for the same drug that varied between different generic manufacturers", which "could have led to consumer and provider confusion").

Daniel A. Spira, a litigation lawyer in Sidley's Chicago office, focuses his practice on the defence of product liability cases and consumer class actions. In both state and federal trial and appellate courts, Dan has represented clients in a wide array of industries, including pharmaceuticals, medical devices, nutritional supplements, food and beverages, automotives, construction products and consumer goods. In addition to first-chair jury trial experience in federal court, Dan has extensive experience managing multi-district litigation, writing and arguing successful motions at various stages of litigation, taking and defending depositions, working with medical and economic expert witnesses and managing complex discovery. Dan's track record of securing favourable judgments for his clients spans every phase of litigation, including motions to dismiss, summary judgment, class certification, trial and appeal. Dan has also advised clients through pre-litigation risk assessments, as well as regarding regulatory reporting obligations to the Consumer Product Safety Commission (CPSC).

Sidley Austin LLP
One South Dearborn
Chicago, IL 60603
USA

Tel: +1 312 853 7000
Email: dspira@sidley.com
URL: www.sidley.com

Teri H. Peeples practises in the Product Liability and Mass Torts group in the firm's New York office. Her practice focuses on representing clients in the life sciences industry, including pharmaceutical and medical device companies, in federal and state courts, as well as in multi-district litigation and class actions. Teri advises clients at all stages of the litigation process, but maintains an emphasis on the scientific and medical issues involved in these types of matters. This includes causation and mechanism of action, safety-related allegations and the pre-clinical and clinical development of the products at issue. Teri is critically involved in the development of the defence strategy, identification and development of expert witnesses, preparation of, taking and defending fact and expert witness depositions, arguing discovery motions in state and federal court and day-to-day case management. Teri also counsels multinational pharmaceutical and medical device companies in comprehensive FCPA risk reviews and conducts internal FCPA investigations.

Sidley Austin LLP
787 Seventh Avenue
New York, NY 10019
USA

Tel: +1 212 839 5300
Email: tpeeples@sidley.com
URL: www.sidley.com

Sidley Austin LLP is a premier law firm with a practice highly attuned to the ever-changing international landscape. The firm has built a reputation for being an adviser for global business, with more than 2,000 lawyers in 20 offices worldwide. Sidley successfully represents clients on complex and multidisciplinary transactional, regulatory and litigation matters spanning a range of legal areas. From its offices in the commercial, financial and regulatory centres of the world, Sidley harnesses its knowledge to provide thoughtful advice for the myriad legal and business challenges that clients face.

www.sidley.com

SIDLEY

ICLG.com

Current titles in the ICLG series

Alternative Investment Funds
Anti-Money Laundering
Aviation Finance & Leasing
Aviation Law
Business Crime
Cartels & Leniency
Class & Group Actions
Competition Litigation
Construction & Engineering Law
Consumer Protection
Copyright
Corporate Governance
Corporate Immigration
Corporate Investigations
Corporate Tax
Cybersecurity
Data Protection
Derivatives
Designs
Digital Business
Digital Health
Drug & Medical Device Litigation
Employment & Labour Law
Enforcement of Foreign Judgments
Environment & Climate Change Law
Family Law
Fintech
Foreign Direct Investment Regimes
Franchise
Gambling
Insurance & Reinsurance
International Arbitration
Investor-State Arbitration
Lending & Secured Finance
Litigation & Dispute Resolution
Merger Control
Mergers & Acquisitions
Mining Law
Oil & Gas Regulation
Outsourcing
Patents
Pharmaceutical Advertising
Private Client
Private Equity
Product Liability
Project Finance
Public Investment Funds
Public Procurement
Real Estate
Renewable Energy
Restructuring & Insolvency
Sanctions
Securitisation
Shipping Law
Telecoms, Media & Internet
Trade Marks
Vertical Agreements and Dominant Firms

@ICLG_GLG

The International Comparative Legal Guides are published by:

global legal group