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The International Comparative Legal Guide to:

Product Liability 2018

16th Edition

A practical cross-border insight into product liability work

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General Chapters:

Country Question and Answer Chapters:

EDITORIAL

Welcome to the sixteenth edition of *The International Comparative Legal Guide to: Product Liability*.

This guide provides corporate counsel and international practitioners with a comprehensive worldwide legal analysis of the laws and regulations of product liability.

It is divided into two main sections:

Seven general chapters. These chapters are designed to provide readers with an overview of key issues affecting product liability law, particularly from the perspective of a multi-jurisdictional transaction.

Country question and answer chapters. These provide a broad overview of common issues in product liability laws and regulations in 23 jurisdictions.

All chapters are written by leading product liability lawyers and industry specialists and we are extremely grateful for their excellent contributions.

Special thanks are reserved for the contributing editors Adela Williams and Tom Fox of Arnold & Porter for their invaluable assistance.

Global Legal Group hopes that you find this guide practical and interesting.

The *International Comparative Legal Guide* series is also available online at www.iclg.com.

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PREFACE

I'm delighted to have been asked to introduce the sixteenth edition of *The International Comparative Legal Guide to: Product Liability*.

The guide continues to be an ideal reference point with seven excellent general chapters covering significant developments in European, Asian and US law. This edition also has a special focus on product recalls, a practical guide around costs issues and considerations in the context of group actions in England & Wales and finally commentary on liability and insurance matters in the context of driverless cars.

As always, the bulk of the edition remains the enormously helpful country question and answer section, covering 23 jurisdictions, new to the guide this year being Albania and Kosovo.

I frequently have cause to make reference to the guide for matters concerning product liability all over the world and will continue to do so as the guide remains a thoroughly informative and comprehensive publication.

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Update on U.S. Product Liability Law

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Introduction

Product liability law has continued to evolve dramatically within the past year. Recent U.S. Supreme Court opinions have narrowed the jurisdictions in which product manufacturers can be haled into court, *see Bristol-Myers Squibb Co. v. Superior Court of Calif.*, 137 S. Ct. 1773, 1778 (2017); *BNSF Ry. Co. v. Tyrrell*, 137 S. Ct. 1549, 1554, 1559 (2017), while various courts' interpretations of law on federal pre-emption, the admissibility of expert causation testimony, and class certification requirements continue to impact the defences available to companies facing product liability litigation.

Although the use of multi-district litigation ("MDL") has decreased in recent years, it continues to be a major vehicle for product liability litigation, and one capable of subjecting defendants to significant litigation, particularly through industry-wide MDLs and multi-plaintiff trials.

As the design, manufacturing, and function of traditional products rapidly evolve through the advent of new technologies, courts, regulators, practitioners and companies alike will be forced to reexamine, develop, and adapt product liability law in the years to come.

This chapter provides updates on each of the following topics:

- Personal Jurisdiction;
- Federal Preemption;
- Class Actions;
- Multidistrict Litigation (MDL) Trends;
- Admissibility of Expert Causation Testimony; and
- Emerging Areas of Product Liability Law.

Personal Jurisdiction

The requirement of personal jurisdiction, which is grounded in the Due Process Clause of the Fourteenth Amendment to the U.S. Constitution, protects defendants from being sued in jurisdictions in which they do not have certain minimum contacts. Personal jurisdiction allows a court to exercise its authority over a company, such as by requiring the company to appear in court, produce documents and witnesses for deposition or trial, and enforce a judgment against the company.

Personal jurisdiction requires the defendant to have sufficient contacts with the judicial forum to make it reasonable for the defendant to defend the lawsuit in the forum state. *See Int'l Shoe Co. v. Wash.*, 326 U.S. 310, 316 (1945). The defendant must have also purposefully availed itself of the privileges of conducting activities within the forum, which ensures that the contact within the forum is the result of the defendant's own actions, as opposed to those of the plaintiff or a third party. *See Hanson v. Denckla*, 357 U.S. 235, 253 (1958); *Walden v. Fiore*, 571 S. Ct. 1115, 1122 (2014).

There are two different types of personal jurisdiction: general; and specific. A court must have one of these two forms of jurisdiction over a defendant; otherwise, the claims against it must be dismissed. "General jurisdiction" exists when a defendant has such a substantial connection to a forum that it justifies jurisdiction over the defendant based on *any* claim that may arise, regardless of whether the lawsuit relates to conduct that occurred in the jurisdiction. *See Helicopteros Nacionales de Colombia v. Hall*, 466 U.S. 408, 414 & n.9 (1984). By contrast, "specific jurisdiction" can be invoked even when the defendant has relatively few contacts with the forum, as long as the claim arises directly out of those contacts. *Id.* at 414 & n.8.

Case law in recent years has dramatically impacted the scope of both general and specific jurisdiction, narrowing the jurisdictions in which plaintiffs asserting product liability or other claims can sue defendants.

General Jurisdiction

A corporation is subject to general jurisdiction in the forum where the corporation's affiliations are so "continuous and systematic" as to render it "at home" in that forum. *Goodyear Dunlop Tires Operations, S.A. v. Brown*, 564 U.S. 915, 924–25 (2011). Historically, the U.S. Supreme Court provided little guidance for what constituted "at home" for purposes of general jurisdiction over corporations. But in 2014, the Court addressed this question in *Daimler AG v. Bauman*, and narrowed the scope of general jurisdiction over a nonresident defendant, finding that the paradigm bases for general jurisdiction are the "place of incorporation and principal place of business". 134 S. Ct. 746, 760 (2014). The determination of whether a corporation is "at home" for purposes of general jurisdiction "does not focus solely on the magnitude of the defendant's in-state contacts . . . General jurisdiction instead calls for an appraisal of a corporation's activities in their entirety, nationwide and worldwide. A corporation that operates in many places can scarcely be deemed at home in all of them". *Id.* at 762 n.20. 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 n.19; *see also id.* at 761–62 (declining to find general jurisdictional over Daimler in California despite its subsidiary's sales of $4.6 billion in the state, because "the same global reach would presumably be available in every other State in which [the subsidiary's] sales are

sizable. Such exorbitant exercises of all-purpose jurisdiction would scarcely permit out-of-state defendants 'to structure their primary conduct with some minimum assurance as to where that conduct will and will not render them liable to suit'") (citing *Burger King Corp. v. Rudzewicz*, 471 U.S. 462, 472 (1985)).

The ruling in *Daimler* has since had significant implications for the application of general jurisdiction on defendants in product liability litigation and other actions alike. Recent cases analysing jurisdiction under *Daimler*'s framework show that it is "incredibly difficult to establish general jurisdiction in a forum other than the place of incorporation or principal place of business". *Monkton Ins. Servs., Ltd. v. Ritter*, 768 F.3d 429, 432 (5th Cir. 2014).

Indeed, in *BNSF Ry. Co. v. Tyrrell*, the Supreme Court recently reaffirmed *Daimler* and further demonstrated the narrow circumstances under which general jurisdiction over a defendant may be found. Specifically, 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 BNSF had over 2,000 miles of railroad track and more than 2,000 employees in the state. 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. 137 S. Ct. 1549, 1554, 1559 (2017).

Other courts have recently reached similar conclusions. *See, e.g., Hood v. Ascent Med. Corp.*, 691 F. App'x 8, 10–11 (2d Cir. 2017) (general jurisdiction in New York inapplicable to a medical supplies company registered in Oman that was operating an office and conducting product sales in New York); *Martinez v. Aero Caribbean*, 764 F.3d 1062, 1064–65 (9th Cir. 2014) (general jurisdiction in California did not attach to a French airplane manufacturer that had no physical presence and was not licensed to do business in that forum, even though the manufacturer purchased parts from California suppliers, advertised there, and had multimillion-dollar contracts to sell planes to a California corporation).

However, subsequent to *Daimler*, courts have continued to differ with regard to whether registering to do business in a state is sufficient to establish general jurisdiction over a corporation. Notably, certain courts enforce state statutes providing that registering to do business in the forum state confers "consent" to general jurisdiction in that forum. *See, e.g.*, *Bors v. Johnson & Johnson*, 208 F. Supp. 3d 648, 653 (E.D. Pa. 2016); *see also Acorda Therapeutics, Inc. v. Mylan Pharm. Inc.*, 78 F. Supp. 3d 572, 588 (D. Del. 2015), *aff'd*, 817 F.3d 755 (Fed. Cir. 2016), *cert. denied sub nom. Mylan Pharm. v. Acorda Therapeutics*, 137 S. Ct. 625 (2017) ("*Daimler* does not eliminate consent as a basis for a state to establish general jurisdiction over a corporation which has appointed an agent for service of process in that state, as is required as part of registering to do business in that state"). By contrast, an influential Delaware state court recently held that registering to do business and maintaining an agent for service of process in a state alone does not establish general jurisdiction. *See Genuine Parts Co. v. Cepec*, 137 A.3d 123, 148 (Del. 2016) (no general jurisdiction over Georgia corporation that registered to do business in compliance with a Delaware registration statute; compliance with the statute did not constitute "consent" to the general jurisdiction of the Delaware courts).

Specific Jurisdiction

Specific jurisdiction may attach over a dispute that arises out of the company's direct or indirect activities in the forum state. *See Int'l Shoe*, 326 U.S. at 316.

The U.S. Supreme Court's 2017 decision in *Bristol-Myers Squibb Co. v. Superior Court of Calif.* (*BMS*) changed the rules of specific jurisdiction in product liability and mass tort litigation by greatly limiting the available forums for plaintiffs to file lawsuits to those in which the specific plaintiff herself has contacts with the forum. BMS 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 in, 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 and assert claims in California. *Id.* at 1782. The Court found that the actions of plaintiffs and their connections to the forum – and not just the actions of the defendant in selling products in California – were relevant to the inquiry. *Id.* at 1781.

District courts have consistently applied *BMS*, putting the proverbial "nail in the coffin" to forum shopping by out-of-state plaintiffs. *See, e.g.*, *Jordan v. Bayer Corp.*, 4:17-cv-00865, 2018 WL 837700 (E.D. Mo. Feb. 13, 2018) ("[S]ince *Bristol-Myers Squibb* . . . judges in this district have held that the issue of personal jurisdiction is now the more straightforward inquiry."); *Dyson v. Bayer Corp.*, 4:17-cv-02584, 2018 WL 534375 (E.D. Mo. Jan. 24, 2018); *Covington v. Janssen Pharm., Inc.*, No. 4:17-CV-1588, 2017 WL 3433611, at *6 (E.D. Mo. Aug. 10, 2017); *Spratley v. FCA US LLC*, No. 3:17-CV-0062, 2017 WL 4023348, at *7 (N.D.N.Y. Sept. 12, 2017). These decisions have a significant impact for product liability defendants who manufacture and sell products nationwide, and who can no longer be dragged into unfavourable or inconvenient forums by plaintiffs whose claims have little or no connection to those forums.

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. In deciding whether a claim is preempted, courts determine whether Congress intended the federal law at issue to supplant state law. *See, e.g., Cipollone v. Liggett Grp., Inc.*, 505 U.S. 504, 516 (1992). 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 continued to receive considerable attention from federal courts, and will continue to evolve in 2018.

Pharmaceutical Preemption

In a case with far-reaching implications for pharmaceutical preemption, the U.S. Supreme Court held that certain product liability claims brought against generic drug makers are impliedly preempted. *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011). In *Mensing*, plaintiffs alleged that the manufacturers of a generic drug failed to adequately warn of the risk of a severe neurological disorder. *Id.* at 610. 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.*

Plaintiffs asserted three bases on which the manufacturers could have independently modified the warnings: (1) by using FDA's changes-being-effected ("CBE") process; (2) by sending Dear

Doctor letters to physicians; or (3) by proposing stronger warnings to the FDA. *Id*. at 614–16. The Court rejected the first two bases, noting FDA's position that a generic drug maker – unlike a brand name manufacturer – could not unilaterally strengthen its labelling by using the CBE process or disseminating a Dear Doctor letter. *Id*. at 614–15. As to the third basis, the FDA, writing as *amicus curiae*, urged the Supreme Court to hold that there was no true "impossibility" of complying with federal and state law, because it was undisputed that the manufacturers could ask the FDA to strengthen the warnings but had never done so; absent such a request, plaintiffs and the FDA contended the manufacturers' preemption defence should fail. *Id*. at 620. The Court rejected this argument, because even if the generic manufacturer had proposed different labelling from the FDA, it was not clear that the agency, in exercise of its public health judgment, would have agreed and permitted the new warning. *Id.* at 619–20. "[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.

Two years later, the Supreme Court again found state tort claims brought against the manufacturer of a generic drug impliedly preempted. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). In *Bartlett*, as in *Mensing*, a defendant generic drug manufacturer argued that it was impossible to comply with both its alleged state law duty to strengthen the warnings for its drug (as proposed by the plaintiff), and its federal law duty not to alter its approved labelling. After the First Circuit held that the plaintiff's claims were not preempted because the manufacturer could simply stop manufacturing the drug entirely and thus comply with both state and federal law, *id*., the Supreme Court reversed, explaining that its preemption cases "presume 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 2477. If the option of ceasing to act defeated a claim of impossibility, impossibility preemption "would be all but meaningless" because any conflict could be avoided if the regulated actor simply ceased acting. *Id*. (internal quotations omitted).

Subsequent to *Mensing* and *Bartlett*, manufacturers of generic and brand name pharmaceuticals have continued to succeed in arguing that state law tort claims are likewise subject to "impossibility preemption". *See, e.g., Beswick v. Sun Pharm. Indus., Ltd.,* No. 10-CV-00357A, 2018 U.S. Dist. LEXIS 15012, at *18, 23 (W.D.N.Y. Jan. 30, 2018) (holding that plaintiffs' warranty claims were essentially "state law tort claims attacking a drug label warning as insufficient" and echoing *Mensing* that stopping sales would make impossibility preemption "all but meaningless" (citation omitted)); *Cerveny v. Aventis Inc.*, 855 F.3d 1091, 1099, 1105 (10th Cir. 2017) (holding plaintiffs' failure-to-warn claim preempted because it would have been impossible for Aventis to comply with both FDA regulations and state law); *Yates v. Ortho-McNeil-Janssen Pharms., Inc.*, 808 F.3d 281, 298-300 (6th Cir. 2015) (holding claims 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 the plaintiff's additional argument that the defendant could have utilised a different design "in the first instance" *before* obtaining FDA approval was "too attenuated"); *Houston v. U.S.*, 638 F. App'x 508, 513 (7th Cir. 2016) (rejecting failure to warn, design defect, negligence, and other product liability claims because "[f]ederal law imposes on [a generic drug manufacturer] an 'ongoing duty of sameness' to ensure that [a drug's] chemical design and labeling are the same as its brand-name counterpart", and "[t]he duty preempts a state-law claim against a generic manufacturer if, as here, that claim would require the manufacturer to redesign its drug, change its labeling, or exit the market in order to avoid liability"). *But see, e.g., In re Fosamax Prods. Liab. Litig.*, 852 F.3d 268, 293 (3d. Cir. 2017) (reversing the district court's ruling that the plaintiffs' claims were preempted due to FDA's denial of additional warnings to the drug's label regarding the risk of femur fractures, and holding that what FDA would have done had plaintiffs' requested warnings been presented to FDA was a question for the jury); *Guidry v. Janssen Pharms., Inc.*, 206 F. Supp. 3d 1187, 1206-08 (E.D. La. 2016) (holding that "[a]ny state requirement that a brand name drug manufacturer should have adopted an alternative design to a prescription drug *after* it was approved by the FDA is preempted", but rejecting "the Sixth Circuit's reasoning in *Yates* concerning preemption in the *pre*-FDA approval context", and holding that "[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") (emphasis added).

In the past year, there have been several noteworthy opinions addressing whether design defect claims are preempted where a manufacturer can unilaterally change the design of its drug prior to FDA approval. In *Trejo v. Johnson & Johnson*, 13 Cal. App. 5th 110, 155–56 (2017), the court reversed the district court's opinion and held that a plaintiff's design defect claim was preempted where it sought changes that severely altered that drug's chemical composition and would have required preapproval by the FDA. There, the plaintiff had argued the manufacturer should have withdrawn its product (Motrin) from the market and changed its chemical compound, and the jury had found the defendant strictly liable for a defective design. The court of appeals reversed judgment, finding that based on *Yates*, a design defect claim is preempted where it seeks design changes that would significantly alter the chemical composition and require FDA preapproval.

But, the court in *In re Xarelto Prods. Liab. Litig.,* MDL No. 2592, 2017 WL 1395312, at *3–4 (E.D. La. April 13, 2017) came to a different conclusion. There, the court held that design defect claims were not preempted because state and federal law are "complimentary". The court found that Louisiana law "imposes a duty on all manufacturers to consider feasible, alternative designs and reasonably weigh the risks and utility of the final product before it leaves the manufacturer's control [and] [f]ederal law does not prevent a drug manufacturer from complying with this state-imposed duty before seeking FDA approval". The court also concluded that the defendant could have strengthened the label post-approval.

The FDA had previously proposed a rule that would permit generic drug manufacturers to unilaterally change their product labels through the CBE process, which, as discussed in *Mensing*, is currently only available to brand-name manufacturers. The rule, originally introduced in 2013, was supposed to be finalised in April 2017. *See* Federal Register, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products", available at www.federalregister.gov/documents/2013/11/13/2013-26799/supplemental-applications-proposing-labeling-changes-for-approved-drugs-and-biological-products (last visited Jan. 25, 2017); Office of Information and Regulatory Affairs, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological Products", available at www.reginfo.gov/public/do/eAgendaViewRule?pubId=201604&RIN=0910-AG94 (last visited Jan. 25, 2017). If implemented, the rule change would have significantly curtailed preemption of failure to warn claims brought against generic manufacturers, who could no longer argue the inability to independently supplement product warnings. The FDA, however, withdrew the rule on Sep. 29, 2017. *See* Federal Register, "Supplemental Applications Proposing Labeling Changes for Approved Drugs and Biological

Products", 83 Fed. Reg. 1867 (Jan. 12, 2018) (withdrawn Sep. 29 2017). It is not certain whether this rule will be re-introduced, and companies should continue to monitor the legislation.

Buckman Preemption

In *Buckman Co. v. Plaintiffs' Legal Comm.*, the U.S. Supreme Court addressed claims that plaintiffs suffered injuries from the use of orthopedic 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 pre-empted 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. More than 15 years later, courts continue to disagree regarding the application of the *Buckman* Court's "fraud on the FDA" holding.

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", about which the product's labelling did not otherwise warn. *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 McClellan v. I-Flow Corp.*, 776 F.3d 1035, 1040 (9th Cir. 2015) (negligent failure to warn and strict liability claims based on inadequate warnings were not preempted under *Buckman*, because the plaintiff's claims were not for "fraud-on-the-agency", but rather were "parallel" to federal law).

More recently, in *In re Incretin*, the Ninth Circuit analysed claims that defendants did not adequately warn plaintiffs about the risk of pancreatic cancer in connection with prescription diabetes drugs. *In re Incretin-Based Therapies Prod. Liab. Litig.* No. 15-56997, 2017 WL 6030735 (9th Cir. Dec. 6, 2017). The district court granted summary judgment in favour of the defendants, holding that plaintiffs were relying on "fraud-on-the-FDA" allegations that were preempted under *Buckman*. *In re Incretin*, 2017 WL 603075, at *2. The Ninth Circuit reversed and remanded, however, holding that plaintiffs were *not* seeking discovery under a "fraud on the FDA" theory, but instead were pursuing a traditional failure-to-warn claim like in *Stengel*. *Id.* (citing *Stengel v. Medtronic Inc.*, 704 F.3d 1224, 1233 (9th Cir. 2013) (*en banc*)).

The Ninth Circuit's decisions continue to depart 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., Cerveny v. Aventis Inc.*, 855 F.3d 1091, 1099, 1105 (10th Cir. 2017) (failure to warn claim was preempted because the FDA would not have approved an additional warning about the risks of taking the drug (Clomid) prior to pregnancy and FDA's conclusion "controls here"); *Aaron v. Medtronic, Inc.*, 209 F. Supp. 3d 994, 1010 (S.D. Ohio 2016) (failure to warn, negligence, and product liability claims were impliedly preempted, because "[a]ny tort claim based on an alleged failure to submit adverse-event reports to the FDA would not be relying on traditional state tort law which had predated the FDCA") (internal quotation omitted); *Pearsall v. Medtronics, Inc.*, 147 F. Supp. 3d 188, 202 (E.D.N.Y. 2015) (declining to follow *Stengel*, because the "Plaintiff's failure to warn claim is predicated on Defendant's alleged failure to provide the required reports to the FDA", and "authority to enforce that claim rests with the FDA").

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 federal courts 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 a viable "parallel" state law claim, where a PMA-approved medical device deviated from a federally-imposed, device-specific requirement, in violation of both federal and state law. *Id*. at 330.

Numerous federal courts of appeals and district courts have subsequently rejected plaintiffs' attempts to circumvent *Riegel*. *See, e.g., Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340–42 (10th Cir. 2015) (rejecting the plaintiff's design defect, breach of warranty, failure to warn, negligence, and negligent misrepresentation claims, because the plaintiff failed to offer a "parallel" federal requirement that had been violated); *Otis-Wisher v. Medtronic, Inc.*, 616 F. App'x 433, 434 (2d Cir. 2015) (affirming dismissal of design defect and failure to warn claims, because the plaintiff sought "to impose safety-related requirements on the device or its labeling beyond those imposed by the FDA"); *Burrell v. Bayer Corp*., 260 F. Supp. 3d 485, 491 (W.D.N.C. 2017) (appeal docketed June 12, 2017) (dismissing plaintiffs' design defect and failure to warn claims among others because Essure is a Class III medical device regulated by the FDA, and plaintiffs failed to fall within the "narrow gap" left open by *Buckman*); *Olmstead v. Bayer Corp.*, 3:17-CV-387, 2017 WL 3498696, at *4 (N.D.N.Y. Aug. 15, 2017) (dismissing plaintiff's negligent misrepresentation, strict liability, failure to warn, and breach of warranty claims because allowing a suit to continue would impose "standards that are 'different from, or in addition to' those imposed by the MDA – precisely the result that the MDA preemption provision seeks to prevent" (citation omitted)).

Other courts, however, have diverged from these analyses and rejected arguments that claims regarding Class III PMA devices are expressly preempted under *Riegel*. *See, e.g., Cline v. Advanced Neuromodulation Sys., Inc.*, 17 F. Supp. 3d 1275, 1285 (N.D. Ga. 2014) (declining to reject negligence claim as expressly preempted, even though plaintiff only alleged violations of clinical good manufacturing practices ("CGMPs") generally applicable to medical devices, rather than device-specific PMA requirements); *Rosen v. St. Jude Med., Inc.*, 41 F. Supp. 3d 170, 181 (N.D.N.Y. 2014) ("[T]he Court finds that at the pleading stage, where a plaintiff has limited access to the PMAs *at the time she files her complaint*, allegations that the defendant violated either the PMA [requirements] or CGMPs, so long as they are supported by sufficient factual evidence

of the violation and demonstrate a causal connection to the alleged injuries, are all that is required to . . . avoid preemption under . . . *Riegel*") (emphasis in original).

Class Actions

"The class action is an exception to the usual rule that litigation is conducted by and on behalf of the individual named parties only." *Wal-Mart Stores, Inc. v. Dukes*, 564 U.S. 338, 348 (2011) (quotation omitted). Under Federal Rule of Civil Procedure 23, a plaintiff can proceed with claims on behalf of absent class members by demonstrating numerosity, commonality, typicality, and adequacy of representation, as set forth in Rule 23(a), and meeting at least one of the criteria in Rule 23(b). One common area of class litigation in recent years has been claims of consumer fraud, pursuant to which plaintiffs seek damages for economic losses based on a manufacturer's alleged misrepresentations about a product.

Claims of individual putative class members, particularly in the area of consumer fraud, often involve small potential recoveries. On their own, they may have a difficult time justifying the legal costs required to obtain recovery; however, if class certification is granted, the overall, classwide recovery and attorneys' fees available in these cases can be significant. *See, e.g., Amchem Prods., Inc. v. Windsor*, 521 U.S. 591, 617 (1997) ("The policy at the very core of the class action mechanism is to overcome the problem that small recoveries do not provide the incentive for any individual to bring a solo action prosecuting his or her rights. A class action solves this problem by aggregating the relatively paltry potential recoveries into something worth someone's (usually an attorney's) labor") (citation omitted). As such, denial of class certification or resolution of a case prior to class certification can be critical for corporate defendants.

In recent years, courts have continued to clarify the circumstances under which they will allow litigation to proceed on behalf of proposed classes.

Article III Standing for Injunctive Relief

The doctrine of standing serves to determine which matters brought before federal courts qualify as justiciable cases or controversies within the requirements of Article III of the U.S. Constitution. *See* U.S. Const. art. III. § 2. Among other Article III standing requirements, a plaintiff must show that it is likely that his or her injury will be "redressed" by a favourable decision by the court. The party invoking federal jurisdiction must demonstrate constitutional standing separately for each form of relief requested. *Friends of the Earth, Inc. v. Laidlaw Envtl. Servs. (TOC), Inc.*, 528 U.S. 167, 185 (2000). In the context of putative class actions, named plaintiffs must individually demonstrate that they have standing to seek the relief sought. *Warth v. Seldin*, 422 U.S. 490, 502 (1975) ("Petitioners must allege and show that they personally have been injured, not that injury has been suffered by other, unidentified members of the class to which they belong and which they purport to represent").

Recently, federal courts have grappled with the issue of standing as it applies to injunctive relief sought by class action plaintiffs asserting consumer fraud claims. The issue often arises where individual plaintiffs allege that they purchased a product based on a misrepresentation later learned to be deceptive or misleading, and seek injunctive relief in the form of a court order enjoining the product manufacturer from continuing the complained of practice, for example by ending a "misleading" advertising campaign. The standing issue arises in part because injunctive relief is a forward-looking remedy, seeking to stop behaviour that may cause individual consumers future harm. When such prospective relief is sought, a named plaintiff who now knows of the deceptive behavior and has no intention of buying the product in the future must nevertheless show that "he [i]s likely" to suffer that future harm, and that the injunctive relief sought would therefore "redress" his injury. *See City of Los Angeles v. Lyons*, 461 U.S. 95, 105 (1983). In recent years, federal courts of appeals have differed in their approaches to Article III standing under these circumstances.

On one hand, several circuits embrace the argument that consumer plaintiffs lack standing because they are in actuality "former" customers who now know of the defendant's allegedly deceptive practice, and are not in any danger of being mislead in the future. In *Nicosia v. Amazon.com, Inc.*, 834 F.3d 220 (2d. Cir. 2016), for instance, plaintiff brought a putative class action arising out of Amazon's sale of a weight loss pill, alleging that the product contained an undisclosed amount of a stimulant drug that had been removed from the market by the FDA due to an association with cardiovascular risks. *Id.* at 226–27. The district court granted Amazon's motion to dismiss, in part because the plaintiff lacked standing to seek injunctive relief. On appeal, the Second Circuit affirmed, because Plaintiff had not adequately shown that he would be subject to any future injury. *Id.* at 239. The Court explained that by the time of the lawsuit, Amazon had taken the particular product off the market, and Plaintiff did not allege that he would purchase *any* Amazon products in the future, let alone the complained-of diet pill. *Id.*; *see also, e.g., Kommer v. Bayer Consumer Health*, – F. App'x –, 2018 WL 627498, at *1 (2d Cir. Jan. 31, 2018) (affirming dismissal of plaintiff's complaint and rejecting request for injunctive relief because "[a]s [plaintiff] concedes, now that he knows of Defendants' alleged deception and false advertising, . . . he is no longer likely to purchase another [of Defendants' products] ever again. . . . Accordingly, he has no standing under Article III to enjoin the defendants' sales practices") (internal quotations omitted); *McNair v. Synapse Group Inc.*, 672 F.3d 213, 224–25 (3d Cir. 2012) (injunctive relief inappropriate where plaintiffs "h[ad] effectively acknowledged that they, unlike the class members they [sought] to represent, [were] not Synapse customers and are thus not [] subject to Synapse's allegedly deceptive techniques for obtaining subscription renewals. . . . Perhaps they may accept a Synapse offer in the future, but, speaking generally, the law accords people the dignity of assuming that they act rationally, in light of the information they possess"); *Ulrich v. Probalance, Inc*., No. 16 C 10488, 2017 WL 3581183, at *7 (N.D. Ill. Aug. 18, 2017) ("Most courts to have considered the issue agree . . . that consumer plaintiffs cannot pursue injunctive relief if they are already aware of the alleged deceptive practice").

The Ninth Circuit Court of Appeals, however, recently broke from this trend and held that "a previously deceived consumer may have standing to seek an injunction against false advertising or labeling, even though the consumer now knows or suspects that the . . . advertisement or label was false in the past". *Davidson v. Kimberly-Clark Corp.*, 873 F.3d 1103, 1115 (9th Cir. 2017). In *Davidson*, plaintiff alleged that she had paid a premium for sanitary wipes that defendant had advertised as "flushable" but that she alleged could cause damage to home plumbing. She sought to represent a class of consumers of the wipes, seeking, *inter alia,* an injunction barring defendant from advertising its wipes as "flushable". The District Court dismissed plaintiffs' claims for injunctive relief, finding that that she "ha[d] no intention of purchasing the same Kimberly-Clark product in the future". *Id.* at 1112. However, the Ninth Circuit rejected the view that injunctive relief is never available to a consumer who learns that a label is false: "In some cases, the threat of future harm may be the consumer's plausible allegations that she

will be unable to rely on the product's advertising or labeling in the future, and so will not purchase the product although she would like to." *Id.* at 1115. The court also seemed to weigh the policy implications of denying standing under these circumstances. *Id.* at 1115–16 (explaining that "our holding alleviates the anomalies the opposite conclusion would create", and suggesting that finding no standing could effectively "gut" California's consumer protection laws). Kimberly-Clark petitioned the Ninth Circuit for a rehearing of the issue *en banc*.

The Ascertainability Requirement

In addition to the requirements of Federal Rule 23, certain courts have recognised an implicit "ascertainability" requirement for class certification. A plaintiff must demonstrate that class members are identifiable through objective criteria without resort to extensive and individualised inquiries. In part, ascertainability eliminates "serious administrative burdens that are incongruous with the efficiencies expected in a class action", protects absent class members by facilitating the "best notice practicable" in a Rule 23(b)(3) action, and protects defendants by ensuring that those who will be bound by the final judgment are identifiable. *Marcus v. BMW of N. Am., LLC*, 687 F.3d 583, 593 (3d Cir. 2012) (citations omitted).

Conflicting decisions among the Courts of Appeals continue to muddy the waters regarding what standard should determine whether a class is "ascertainable". At one end of the spectrum, the Third Circuit has imposed a heightened ascertainability requirement that requires plaintiffs to demonstrate an "administratively feasible mechanism" for identifying putative class members. *See Byrd v. Aaron's Inc.*, 784 F.3d 154, 169–70 (3d Cir. 2015) (a class must be defined by (1) objective criteria, and (2) via an administratively feasible method).

However, a number of other appellate courts have rejected this "heightened" ascertainability standard. Specifically, the Sixth, Seventh, Eighth, and Ninth Circuits have ruled that plaintiffs do not have to meet the "administrative feasibility" standard, and instead a class merely must be defined by objective criteria. *Rikos v. Procter & Gamble Co.*, 799 F.3d 497, 525-26 (6th Cir. 2015); *Mullins v. Direct Digital, LLC*, 795 F.3d 654, 659-60 (7th Cir. 2015); *Sandusky Wellness Ctr., LLC v. Medtox Sci., Inc.*, 821 F.3d 992, 995–96 (8th Cir. 2016); *Briseno v. ConAgra Foods, Inc.*, 844 F.3d 1121, 1125-26 (9th Cir. 2017).

Two recent decisions from the Second Circuit highlight the varying applications of the ascertainability requirement. Prior to 2017, the Second Circuit appeared to have joined the Third Circuit in embracing the "administrative feasibility" requirement. *See Brecher v. Republic of Argentina*, 806 F.3d 22, 24 (2d Cir. 2015) ("A class is ascertainable when defined by objective criteria that are administratively feasible"). This same standard was applied by the Second Circuit in February 2017 in affirming a lower court's decision to deny class certification in *Leyse v. Lifetime Entm't Servs., LLC*, 679 F. A'ppx 44, 47 (2d Cir. 2017) (citing *Brecher*). The plaintiff in *Leyse* proposed identifying class members by soliciting individual affidavits; however, the court affirmed the trial court's finding that such a method was not administratively feasible. *Id.* at 47. Despite what appeared to be growing Second Circuit precedent, the court reversed course in its July 2017 decision in *In re Petrobras Sec. Litig.*, 862 F.3d 250 (2d Cir. 2017). In *Petrobras*, the court explicitly noted that "*Brecher* did not create an administrative feasibility requirement". *Id.* at 269. Instead, the court relied on precedent from other circuits rejecting the "administrative feasibility" standard, and affirmed the lower court's finding that the class was ascertainable as long as the class was defined by objective criteria. *Id.*

In *Briseno*, the Ninth Circuit similarly upheld the district court's ruling that plaintiffs need only define a class by an objective criterion. *Briseno*, 844 F.3d at 1132–33. Central to the court's ruling was the plain meaning of Rule 23, which does not explicitly include an "administrative feasibility" requirement: "Because the drafters specifically enumerated '[p]requesites', we may conclude that Rule 23(a) constitutes an exhaustive list." *Id.* at 1125. The court also rejected arguments that the heightened ascertainability standard was necessary to "mitigate the administrative burdens of trying a Rule 23(b)(3) class action", to protect absent class members from fraudulent claims, or to protect defendants' rights. *Id.* at 1127–29. The U.S. Supreme Court declined to grant *certiorari* in *Briseno* on October 10, 2017, leaving district and appellate courts to continue to grapple with this issue.

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Given the massive implications that class certification has on the potential value of consumer fraud lawsuits pertaining to the purchases of inexpensive products, courts' efforts to clarify the criteria for certification, including with regard to Article III standing and ascertainability, will continue to have significant implications for product manufacturers.

Multidistrict Litigation (MDL) Trends

The nature of product liability litigation can lead to plaintiffs filing a large 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 an unwieldy and expensive process for plaintiffs and defendants alike. As a result, at times, one or both sides 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, by 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 a Multidistrict Litigation or "MDL". The general purposes of an MDL is "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, http://www.jpml.uscourts.gov/overview-panel-0.

To form an MDL, one of the parties petitions the Judicial Panel on Multidistrict Litigation or "JPML", which is comprised of seven sitting federal judges tasked with making determinations on MDL centralisation. The JPML also decides the venue for the MDL and the judge who will preside over it. If the JPML grants the petition, all related federal cases are transferred to the JPML's chosen venue and judge for pretrial proceedings. *See* 28 U.S.C. § 1407. Once the MDL is created, the JPML makes no procedural or substantive decisions in the case; instead the JPML defers to the transferee court.

As of December 31, 2017, there were 221 active MDLs. *See* U.S. JPML, Calendar Year Statistics, Jan. through Dec. 2017, available at http://www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2017.pdf (last visited Feb. 13, 2018). Although this number is significant, there has been a trend over the last several years against centralisation. For example, in 2009, the JPML granted more than 80 per cent of MDL petitions. In 2017, however, the panel granted fewer than 50 per cent of the petitions before it (19 of 40). *Id.* In fact, the 19 MDLs created in 2017 constituted the lowest number in more than 25 years. *Id.* Despite the overall trend against centralisation, the JPML continues to create more MDLs in product liability litigation than in any other type of case. Of the 221 currently pending MDLs, 70 of them (31.7 per cent) are classified by the JPML as "Products Liability" litigation. *Id.*

Factors in JPML Decisions Whether to Create an MDL

Pursuant to 28 U.S.C. § 1407(a), the Panel is authorised to create an MDL "upon its determination that transfers for such proceedings will be for the convenience of parties and witnesses and will promote the just and efficient conduct of such actions. . . ". In applying this flexible standard, the Panel often considers the following factors:

Number of actions. The JPML considers the number of actions filed (or potentially to be filed) when deciding whether to certify an MDL. In cases where there are a small number of filed actions, the petitioner "bears a heavier burden to demonstrate that centralization is appropriate". *In re Xytex Corp. Sperm Donor Prod. Liab. Litig.*, 223 F. Supp. 3d 1351, 1352 (JPML 2016) (MDL certification denied); *In re California Wine Inorganic Arsenic Levels Prods. Liab. Litig.*, 109 F. Supp. 3d 1362, 1363 (JPML 2015). Even where there are common factual issues, a small number of cases and the potential for informal coordination between the parties are often weighed against centralisation. *See id.* At times, the JPML will consider the number of unfiled cases, but that is not always sufficient to sway the Panel. *See In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig.* ("*In re Mirena IUS No. 1*"), 38 F. Supp. 3d 1380, 1381 (JPML 2014) ("[a]lthough plaintiffs assert that the number of actions is likely to expand substantially, the mere possibility of additional actions does not convince us that centralisation is warranted"); *but see In re AndroGel Prods. Liab. Litig.*, 24 F. Supp. 3d 1378, 1379 (JPML 2014) (MDL certification granted where "related cases will number in the thousands").

Number of counsel and informal coordination. In cases where many of the plaintiffs are represented by the same counsel and there are a limited number of defense counsel, the JPML has promoted voluntary coordination as a preferable alternative to centralisation through an MDL. *In re Sorin 3T Heater-Cooler System Prods. Liab. Litig.*, 273 F. Supp. 3d 1357 (JPML 2017); *In re Mirena IUS No. 1*, 38 F. Supp. 3d at 1381.

Pending 28 U.S.C. § 1404 requests for transfer. Under 28 U.S.C. § 1404, the parties can move to transfer a lawsuit to another district court. The JPML strongly prefers the transfer of cases to the same district court rather than centralising the cases in an MDL. *In re 3M Company Lava Ultimate Prods. Liab. Litig.*, 222 F. Supp. 3d 1347, 1348 (JPML 2016) ("transfer under Section 1404 is preferable to centralization").

Procedural posture of existing cases. The JPML has not been consistent on whether the maturity of a litigation weighs in favour of or against centralisation. *Compare, e.g., In re Yellow Brass Plumbing Component Prods. Liab. Litig.*, 844 F. Supp. 2d 1377, 1379 (JPML 2012) (MDL certification denied; "relatively advanced progress" of one action would inconvenience parties), *with In re Mirena IUS No. 1*, 38 F. Supp. 3d at 1381 (MDL certification denied; cases that "are in their infancy" are less likely to be centralised and "are well-positioned for informal coordination"); *see also In re Mirena IUS Levonorgestrel-Related Prods. Liab. Litig. ("In re Mirena IUS No. 2")*, 249 F. Supp. 3d 1357, 1360-61 (JPML 2017) (creating an MDL and deferring to the transferee judge to formulate pretrial procedures that take into account differences in the procedural postures of the cases in the MDL). The JPML recently decided not to certify an MDL of cases involving the drug Cymbalta, where the procedural posture of the 41 personal injury actions varied significantly. Some of the actions had already gone to trial with millions of pages in discovery produced, whereas others did not even have scheduling orders. *In re Cymbalta (Duloxetine) Prods. Liab. Litig. (No. II)*, 138 F. Supp. 3d 1375, 1376 (JPML 2015). But in cases related to talcum powder products, the advanced nature of related state court proceedings weighed in favour of creating an MDL, because, the JPML held, the MDL judge could use the prior state court discovery as a guide to resolve similar discovery issues in the federal actions. *In re Johnson & Johnson Talcum Powder Prods. Mktg., Sales Practices & Prods. Liab. Litig.*, 220 F. Supp. 3d 1356, 1358 (JPML 2016).

Need for individual fact determinations. If a party demonstrates that individualised factual issues will predominate in the litigation, the JPML is more likely to deny MDL centralisation. In *In re Proton Pump Inhibitor Prod. Liab. Litig. No. 1*, the JPML denied centralisation of cases against manufacturers of proton pump inhibitors, in part because a significant amount of discovery would be defendant-specific, arising from each drug's "unique development, testing, and marketing history". 273 F. Supp. 3d 1360 (JPML 2017). The case came back to the JPML a few months later, and this time the JPML ordered centralisation because the defendants no longer opposed centralisation, the number of cases had grown, the actions all shared certain factual issues and involved the same kinds of injuries, and several plaintiffs took more than one drug at issue. *In re Proton Pump Inhibitor Prods. Liab. Litig. No. 2*, 261 F. Supp. 3d 1351, 1354 (JPML 2017). The factual similarities, therefore, generated enough overlap for the JPML to order centralisation.

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In short, the rule governing whether the JPML will create an MDL is extremely flexible, often allowing the Panel to weigh the same factors for or against centralisation depending on the outcome that the Panel believes will best serve the parties and courts in a given scenario.

The JPML's decision whether or not to establish an MDL can have significant implications, as the creation of an MDL can encourage the filing of additional lawsuits, place pressure on defendants faced with hundreds or thousands of cases to consider settlement, and raise the stakes of transferee court decisions that may impact the outcome of many or all cases pending in an MDL.

Factors in JPML Decisions Regarding Where to Send an MDL

Once the JPML decides to create an MDL, it also has broad discretion in determining the court and judge before which the cases will be centralised. Indeed, there is no rule governing that aspect of the JPML's decision. Factors often considered include the court in which the largest number of cases are pending, the courts in which cases have already progressed the furthest, where cost and inconvenience will be minimised, and the experience, skill, and caseloads of available judges. Manual for Complex Litigation (Fourth) § 20.131 (2010). Again, the JPML has significant leeway to utilise those and other factors in different ways to fit the desired outcome in a given case. *Compare, e.g., In re 100% Grated Parmesan Cheese Mktg. & Sales Practices Litig.*, 201 F. Supp. 3d 1375, 1379 (JPML 2016) ("centralization in this district allows us to assign the litigation to Judge Gary Feinerman, an able and experienced jurist who has not had the opportunity to preside over an MDL"), *with In re: Fluoroquinolone Prods. Liab. Litig.,* 122 F. Supp. 3d 1378, 1381 (JPML 2015) (assigning MDL to a judge in part because his "experience in overseeing [another MDL] will benefit the parties and facilitate the just and efficient conduct of this litigation").

Industry/Class-Wide MDL Certification

Plaintiffs have increasingly brought class-wide or industry-wide product liability lawsuits alleging that a class of products sold by several different pharmaceutical manufacturers has caused similar injuries in hundreds or thousands of people. At first glance, these class-wide lawsuits appear to be prime candidates for an MDL. They

typically involve a large number of plaintiffs and have a common set of factual issues because the plaintiffs allege that the drugs treat the same conditions in the same or similar patient populations and act in a similar way in the body.

However, these cases have their own unique set of challenges for the JPML when deciding whether to create a class/industry-wide MDL, create an MDL for each product/manufacturer, or defer to some other method of coordination. One of the concerns with class/industry-wide litigation is the need to protect trade secrets and confidential information from disclosure among direct competitor manufacturers. For this reason, the JPML is "typically hesitant to centralize litigation against multiple, competing defendants which marketed, manufactured and sold similar products". *In re Yellow Brass*, 844 F. Supp. 2d at 1378; *In re Spray Polyurethane Foam Insulation Prods. Liab. Litig.*, 949 F. Supp. 2d 1364 (JPML 2013); *In re AndroGel*, 24 F. Supp. 3d at 1378. Another consideration is how cases that involve a plaintiff who has taken more than one of the implicated drugs will impact the decision to centralise. In recent years, the JPML has both granted and denied centralisation of class/industry-wide MDLs that raise these concerns:

- In *In re Fluoroquinolone Prods. Liab. Litig.*, plaintiffs requested centralisation of cases against the manufacturers and distributors of fluoroquinolone antibiotics, alleging peripheral neuropathy injuries. All defendants opposed centralisation. The JPML acknowledged, but dismissed, its hesitancy to centralise litigation on an industry-wide basis. Instead, the court relied on the virtually identical class warnings required by the FDA and the resulting shared factual questions regarding general causation, science, and regulatory issues in deciding to create the MDL. 122 F. Supp. 3d 1378, 1379 (JPML 2015).
- In *In re Invokana (Canagliflozin) Prods. Liab. Litig.*, plaintiffs alleged that SGLT-2 inhibitors (a class of anti-diabetes medication) caused injuries such as diabetic ketoacidosis and kidney damage. The SGLT-2 inhibitors were manufactured by several competing drug companies, but the majority of the lawsuits were filed against Janssen for Invokana/Invokamet. Plaintiffs proposed either an Invokana/Invokamet-only MDL or a class-wide MDL, and defendants opposed one or both proposals. The JPML created an Invokana/Invokamet-only MDL, and declined to include combination-use cases involving Invokana and another SGLT-2 inhibitor, citing concerns about protecting market competitors' trade secrets and confidential information, and prolonging pretrial proceedings with the need for separate discovery tracks. The court also mentioned the "relatively small number" of cases involving the other non-Janssen drugs as grounds for excluding the other manufacturers from the MDL. 223 F. Supp. 3d 1345, 1348 (JPML 2016).
- In *In re Proton Pump Inhibitor Prods. Liab. Litig. No. I*, plaintiffs alleged that various proton pump inhibitors manufactured by different defendants caused kidney injuries, including acute interstitial nephritis, chronic kidney disease, end-stage renal disease, and kidney failure. The JPML initially declined to centralise the actions into an MDL relying in part on the justification that the defendants were competitors in the market; "[c]entralizing competing defendants in the same MDL likely would complicate case management due to the need to protect trade secrets and confidential information". 273 F. Supp. 3d at 1360. In re-considering the case, however, the JPML established an MDL, this time brushing over the concerns of competition and trade secrets, seemingly because, at that point, the defendants all supported centralisation. *In re Proton Pump Inhibitor Prods. Liab. Litig. No. 2*, 261 F. Supp. 3d at 1354.

Multi-Plaintiff Trials after MDL Certification

Although the parties have the right to have their cases remanded to their originating courts for trial, with the consent of the parties, an MDL judge often selects a few cases to be tried. These "bellwether" trials are intended to be representative of the range of cases in the MDL. *See Manual for Complex Litigation, Fourth*, § 22.315. The goal is for the bellwether cases to promote judicial efficiency by allowing the court and parties to determine the nature and strength of the claims, and provide ranges of values for possible settlement. *Id*.

Typically, MDL courts try individual cases as bellwethers, but a recent trend has developed of consolidating or "batching" cases for trial. FRCP 42(a) grants courts the broad discretion to consolidate cases for trial "[i]f actions before the court involve a common question of law or fact", and certain MDL judges have taken full advantage of this rule.

In the *Ethicon* MDL, for instance, the court batched 39 cases for trial, citing the application of common laws and similar allegations. *In re Ethicon, Inc., Pelvic Repair Sys. Prods. Liab. Litig.*, No. 12-md-02327 (S.D. W.Va. July 1, 2015) (ECF No. 1619). In the *DePuy* MDL, the judge simply borrowed the JPML's decision to establish the MDL as the basis for batching five cases for a bellwether trial. The judge reasoned that the MDL was established because all cases "share[d] factual questions" as to whether the device was defective and had adequate warnings. *In re DePuy Orthopaedics, Inc. Pinnacle Hip Implant Prods. Liab. Litig.*, MDL Docket No. 11-md-02244, at 4 (N.D. Tex. Jan. 8, 2016) (ECF No. 606). The *DePuy* judge has since tried another six-plaintiff consolidated bellwether trial. *See* Cara Salvatore, "Trial Bundling Comes Under Fire In Boston Scientific Appeal", Law360, Oct. 31, 2016.

Many of these consolidated trials have resulted in sizeable plaintiffs' verdicts, which defendants have appealed, arguing that grouping trials encourages unfair outcomes. Boston Scientific appealed a $27 million verdict won by four plaintiffs in a pelvic floor repair kit suit, but the Eleventh Circuit rejected the argument that plaintiffs' cases were too distinct to be consolidated in a single bellwether trial and that the jury became confused as a result. Accordingly, the Court held that the trial court did not abuse its discretion to consolidate the cases. *Eghnayem v. Boston Sci. Corp.*, 873 F.3d 1304, 1314 (11th Cir. 2017). Johnson & Johnson is appealing a $150 million verdict (reduced from a $502 million jury verdict) awarded to five plaintiffs in the *DePuy* hip implant multi-plaintiff bellwether trial, a $543 million verdict (reduced from a $1 billion jury verdict) awarded to six plaintiffs in another multi-plaintiff trial, and a $247 million verdict awarded to six more plaintiffs. Shayna Posses, "J&J Can't Speed Up Appeal in Hip MDL, Patients Tell 5th Circ.", Law360, July 26, 2016; Tina Bellon, "Johnson & Johnson Hit With $247 Million Verdict in Hip Implant Trial", Thomson Reuters, Nov. 16, 2017.

The potential confusion and prejudice that arises when mixing different plaintiffs' facts presents obvious concerns for defendants, particularly in light of these sizable plaintiffs' verdicts in consolidated bellwether trials. It remains to be seen whether additional appellate courts will reject or affirm the use of consolidated bellwether trials.

What to Watch in 2018: The Opioid Crisis MDL

In December 2017, the JPML centralised cases in which plaintiffs alleged improper marketing and distribution of prescription opiate medications across the United States. *In re National Prescription Opiate Litig.*, MDL No. 2804, 2017 WL 6031547 (JPML Dec. 5, 2017). The MDL, pending in the Northern District of Ohio, involves

numerous cities, counties, and states, including political divisions, that allegedly have been damaged by widespread addiction to narcotic painkillers. Most of the actions have been filed against three defendants who distribute over 80% of the drugs at issue in the case, although several additional defendants have been sued in certain of the centralised cases. In establishing the MDL, the JPML cast aside concerns about the diversity of plaintiffs and injuries, and found that common questions of fact predominate. The JPML, perhaps cognizant of the MDL's far-reaching impact, warned that "this litigation might evolve to include additional categories of plaintiffs and defendants, as well as different types of claims", thus foreshadowing a potentially massive MDL that will likely take years to resolve. *Id.* at *3.

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Although the overall number of MDLs being established has diminished in recent years, they continue to play a significant role in products liability litigation. Through industry-wide MDLs, multi-plaintiff bellwether trials, or simply the pooling of hundreds or thousands of cases together for settlement considerations, MDLs can have an immense impact on product manufacturers and other defendants faced with these centralised cases.

Admissibility of Expert Causation Testimony

Product liability cases "involving pharmaceuticals, toxins or medical devices involve complex questions of medical causation beyond the understanding of a lay person, and thus expert testimony is required". *In re Mirena IUD Prod. Liab. Litig.,* 202 F. Supp. 3d 304, 311 (S.D.N.Y. 2016) (internal citations omitted) *aff'd*, No. 16-2890-CV(L), 2017 WL 4785947 (2d Cir. Oct. 24, 2017). In most jurisdictions, expert testimony is required in a product liability action for the plaintiff to satisfy his or her burden of proof on the issue of whether the product caused the alleged injury. Moreover, in pharmaceutical and toxic tort cases, a plaintiff generally is required to show by expert testimony both that exposure to a substance can cause a particular injury (general causation), and that such exposure was a cause of his or her individual injury (specific causation).

To ensure that any and all expert testimony is based on a reliable methodology and helpful to the trier of fact, the rules of evidence impose a "gatekeeping" responsibility on trial courts. Courts exercise their gatekeeping function by excluding unsubstantiated and unreliable expert testimony and ensuring that the jury only hears reliable scientific principles, methods and results. Although all federal courts and most state courts apply the rigorous standard for admissibility of expert testimony set forth in *Daubert v. Merrell Dow Pharms, Inc.*, 509 U.S. 579, 589, 592–93 (1993), some state courts apply their own varying standards. No matter the standard applied, the exclusion of expert testimony can have profound effects on litigation at any phase. The following notable cases of 2017 highlight the significant and dispositive impact *Daubert* rulings can have in complex medical and scientific cases.

In re Mirena IUD Products Liability Litigation. In the *Mirena* litigation, plaintiff-appellants claiming secondary uterine perforation following insertion of an intrauterine device (IUD) asserted product liability claims against the device manufacturer. The key issue in dispute was general causation – *i.e.* whether Mirena *can* cause the injury alleged. *In re Mirena IUD Prod. Liab. Litig.,* No. 16-2890-CV(L), 2017 WL 4785947, at *1 (2d Cir. Oct. 24, 2017). Plaintiffs proffered three general causation experts, but the District Court excluded all three purported experts for failing to meet the *Daubert* standard because "their testimony was not reliable and thus not helpful to the trier of fact". *Id*. Following its *Daubert* ruling, the District Court granted an MDL-wide summary judgment motion because plaintiffs could not prove that secondary perforation could occur from Mirena. *In re Mirena IUD Prods. Liab. Litig.*, 202 F. Supp. 3d at 327–28.

Plaintiffs-appellants appealed both decisions to the United States Court of Appeals for the Second Circuit. The Second Circuit affirmed both District Court decisions and, in so doing, highlighted three "particularly noteworthy" problems with the opinions offered by plaintiffs' general causation experts. *In re Mirena IUD Prod. Liab. Litig.,* 2017 WL 4785947, at *2. First, the experts' theories were not accepted in the wider obstetrics and gynecological scientific community. *Id.*, at *3. "Not only do the experts fail to identify any authorities that directly support the existence of secondary perforation, but what scientific authority there is casts doubt on the phenomenon's existence." *Id.* Second, the experts "developed their theories for the purposes of this litigation". *Id.* And third, "finding no direct support in the literature for secondary perforation and having conducted no prior research on the subject, the experts all assumed the existence of the very phenomenon in dispute and then hypothesized how it could occur". *Id.* Because the parties disputed whether secondary perforation had ever occurred, "[t]he experts thus begged the very question they were trying to answer". *Id.* Having concluded that the District Court properly excluded plaintiffs' general causation experts, the panel further agreed with the District Court's order granting the defendant's motion for summary judgment, finding that "no reasonable juror could find general causation more likely than not based on the Plaintiffs' admissible evidence". *Id.* at *4.

In re Accutane Litigation. Plaintiffs in 2,076 multicounty litigation cases in New Jersey state court brought products liability claims against the manufacturer of the prescription acne medication Accutane alleging that it caused them to develop Crohn's disease. Defendants, Hoffman–La Roche Inc. and Roche Laboratories Inc., filed a motion to bar the general causation testimony of plaintiffs' experts – a statistician and gastroenterologist. After conducting a hearing to determine the admissibility of plaintiffs' experts' opinions, the trial court granted the motion, concluding that under New Jersey's standard for admissibility of expert testimony (*Kemp*), Plaintiffs had the burden to demonstrate that the methodology used by their experts was "consistent with valid scientific principles accepted in the scientific and medical communities", and they had failed to do so. *In re Accutane Litigation*, No. 271, 2015 WL 753674 at *6 (N.J. Super. Ct. Law Div. Feb. 20, 2015). Although the trial court found that "both Plaintiffs' experts are eminently qualified", it determined that their reasoning and methodology is slanted away from objective science and in the direction of advocacy, making it unreliable. *Id.* at *17 ("the opinions expressed by Plaintiffs' experts are motivated by preconceived conclusions, and . . . they have failed to demonstrate that the data or information used were soundly and reliably generated and are of a type reasonably relied upon by comparable experts") (internal citations and quotation marks omitted). Accordingly, the court granted defendant's motion to exclude testimony of plaintiffs' experts and subsequently issued an order dismissing the 2,076 claims with prejudice. *Id.* at *22.

Plaintiffs appealed and, in July 2017, the Appellate Division reversed the trial court's exclusion of plaintiffs' experts and reinstated the more than 2,000 cases to which it applied. *In re Accutane Litig.,* 165 A.3d 832 (N.J. Super. Ct. App. Div. 2017). The Appellate Court explained that although "[i]n most cases, the proponent of scientific evidence must demonstrate that the opinions are 'generally accepted, within the relevant scientific community'" (the *Frye* standard) (*id.* at 855 (citing cases)), the New Jersey Supreme Court relaxed the standard for admissibility of expert testimony "in tort cases involving injuries caused by toxic substances or medications, involving new or

developing theories of causation". *Id.* Under the relaxed standard, "[a] court's assessment of scientific expert evidence should include an evaluation of the studies upon which the experts rely, but the court must not substitute 'its own assessment of the studies for that of an acknowledged expert'". *Id.* at 857 (quoting *Rubanick v. Witco Chem. Corp.,* 593 A.2d 733, 749 (N.J. 1991). Thus, the Appellate Division concluded that the "trial court took too narrow a view in determining whether the experts were using accepted scientific methodologies to analyse the evidence, and improperly determined the weight and credibility of the experts' testimony. Among other things, the judge inappropriately condemned the experts for relying on relevant scientific evidence other than epidemiological studies, despite their plausible explanations for doing [s]o". *Id*. at 837; *id.* at 867 ("regardless of a trial judge's view of the weight a party's evidence deserves, the judge should trust the jury to evaluate witness credibility and decide what weight to give each side's evidence. It is the jury's core function to weigh the credibility of expert witnesses, and the trial court should not use a *Kemp* hearing as a vehicle to dismiss a case the court perceives as weak") (internal citations and quotation marks omitted).

In August 2017, defendants filed a petition for certification to the New Jersey Supreme Court urging it to clarify the New Jersey standard for evaluating expert testimony and suggesting that the court adopt the more stringent admissibility test applied by federal courts and the majority of state courts. On December 8, 2017, the Supreme Court granted the manufacturer's petition and agreed to review the New Jersey Appellate Division's decision reinstating 2,000+ cases. *In re Accutane Litig.,* No. 079958, 2017 WL 6728709 (N.J. Dec. 8, 2017).

California State Court Talcum Powder Litigation. After a four-week trial of the first case in the California state court coordinated proceeding involving claims that plaintiffs developed ovarian cancer as a result of using talcum powder products, a Los Angeles County jury returned a $417 million verdict against Johnson & Johnson and its subsidiary and co-defendant Johnson & Johnson Consumer. After the jury returned the verdict, defendants moved for a new trial and for judgment notwithstanding the verdict ("JNOV"), arguing that plaintiff failed to present sufficient evidence that talcum powder was the probable cause of her ovarian cancer. Specifically, defendants argued that plaintiff's one specific causation expert (1) failed to present epidemiology showing that talc was the more probable than not cause of her cancer, and (2) used an improper methodology to reach her desired conclusion. *In re Johnson & Johnson Talcum Powder Cases*, No. BC628228, 2017 WL 4780572, at *11 (Cal. Sup. Ct. Oct. 20, 2017). The expert's methodology, as she explained it, was "differential etiology", which she testified "involved identifying risks for a disease; ruling out risk factors that you don't believe apply; and ruling in what you believe is the cause of the cancer". *Id.* at 12 (internal citations and quotation marks omitted).

Under California law, if, after trial, "the Court is convinced that there is no substantial conflict in the evidence and that the tendered expert opinions do not show specific causation (which, under *Jones v. Ortho. Pharm. Corp.* (1996) 163 Cal. App. 3d 396, must be shown by expert testimony in a case alleging cancer) a JNOV is properly granted". *In re Johnson & Johnson Talcum Powder Cases*, 2017 WL 4780572, at *13 (citing *Osborn v. Irwin Mem'l Blood Bank*, 5 Cal. App. 4th 234, 275 (1992)). Upon reviewing the testimony and evidence introduced at trial, the California court granted defendants' motions to set aside the verdict, finding that plaintiff's specific causation expert both failed to rule in talc as a probable cause of plaintiff's ovarian cancer and failed to rule out other causes and was therefore insufficient as a matter of law to support the verdict. *Id.* at *15. ("The Court is of the firm view that [the expert's] 'ruling out' of age and ovulatory cycles, amounted to no more than speculation. Her testimony that it was 'probable' the cause of the cancer was unknown, but then putting a 'less than 50% chance' on same (with no reasoning) likewise amounted to mere speculation. Those facts show that the expert did not properly employ the methodology she espoused and independent of the fact that there was no evidence of substance to rule talc 'in', persuade the Court that JNOV must be granted to JCCI and Johnson & Johnson on the basis that no specific causation was shown.")

Emerging Areas of Product Liability Law

New products and changing technologies are likely to be susceptible to a variety of product liability and tort claims in years to come. The following are three examples of the challenges and potential liabilities growing industries may face.

Three-Dimensional Printing

Three-dimensional ("3D") printing, also known as "additive manufacturing," refers to the creation of a 3D object by building successive layers of raw material, whereby each new layer is attached to the previous one until the object is complete. Objects are produced from a digital 3D file, such as a computer-aided design drawing or a Magnetic Resonance Image. While its applications are many, 3D printing has already begun to impact traditional health care treatments, including implantable and non-implantable medical devices and prescription drugs. 3D printing also has the potential to open the door for novel health care treatments. For example, physicians are using custom 3D-printed medical models to prepare for complex surgeries, and to create devices that are formatted for the particular patient.

But if these health-related 3D objects do not function as intended, medical device companies using 3D printing technology may face product liability litigation as well as other tort claims. The FDA has been laying the foundation for a comprehensive regulatory framework for 3D-printed medical devices through broad-based research and discussion, and provided recent guidance on 3D printing to medical device manufacturers, which culminated in the Dec. 4, 2017 Technical Considerations for Additive Manufactured Devices.[1] This guidance advises device manufacturers on the technical aspects of 3D printing, clarifies the FDA's recommendations on the pathway 3D-printed device manufacturers must follow to receive FDA approval, and provides manufacturers with transparency on the FDA's requirements for device design, function, durability, and quality as approval applications move forward. The FDA characterised the technical guidance as a "leap-frog" guidance that is intended to provide manufacturers with FDA's initial thoughts on a rapidly evolving technology, noting that the FDA intends to establish a comprehensive regulatory framework through the application of existing laws and regulations that govern device manufacturing to non-traditional manufacturers, such as hospitals or academic institutions that create patient-matched devices. Although FDA has issued guidance, many questions remain, and extensive developments and challenges are expected in the years to come.

Internet of Things

Internet-connected household products, also known as internet of things ("IoT") devices, have prompted consumer privacy concerns as well as product liability claims arising out of alleged manufacturing and design defects. While such alleged manufacturing defects have caused privacy advocacy groups to petition the U.S. Consumer Product Safety Commission for a recall of certain IoT devices, it

remains unclear how consumers will challenge such devices under the traditional product liability framework, and how IoT device manufacturers may shield themselves against such liability.

In *In re VTech Data Breach Litigation*, Plaintiffs sued the manufacturer of children's learning toys that were linked to certain web-based services for breach of contract, breach of warranty of merchantability, and violations of state consumer protection laws, after a hacker bypassed security measures, obtained customer data such as profile pictures, emails, passwords, and nicknames, and provided the data to a journalist. The journalist's story, quoted in the complaint, noted, "[VTech] left thousands of pictures of parents and kids and a year's worth of chat logs stored online in a way easily accessible to hackers". No. 15 CV 10889 (N.D. Ill.) [ECF No. 44] at 11. Defendants moved to dismiss the complaint, alleging that plaintiff suffered no actual injury and therefore lacked standing, because the complaint did not plead that the data travelled beyond the hacker, journalist, and a security analyst. The Court granted the motion to dismiss without prejudice, finding that the plaintiffs were unable to establish that they suffered actual harm as a result of the breach and that their alleged injuries were too "speculative" for the lawsuit to move forward. *In re VTech Data Breach Litig.*, No. 15 CV 10889, 2017 WL 2880102, at *4 (N.D. Ill. July 5, 2017). "With respect to this data breach, plaintiffs have not plausibly alleged a substantial risk of harm sufficient to confer standing . . . Harm need not be literally certain to confer standing, but allegations of future harm based on poor data security, without allegations to support an inference that someone with potentially malicious intent will access the data, is too speculative to confer standing." *Id.* at *4, n.5. Thereafter, Plaintiffs filed an amended complaint, and VTech filed another motion to dismiss, which currently remains pending.

Medical devices that use integrated autonomous software have also been the subject of recent product liability litigation. In *Graves v. CAS Med. Sys., Inc.*, 735 S.E.2d 650 (S.C. 2012), plaintiffs brought a strict liability design defect claim against the manufacturer of a monitor that tracked the heart rate of a premature baby. The child died, and her parents subsequently filed a products liability lawsuit contending the monitor was defectively designed and failed to alert them when the baby's heart rate slowed. Although the plaintiffs offered the testimony of three experts, the court noted that "none of the experts did much actual testing of the software". *Id.* at 653. Further, none of the experts conclusively determined that the software in the monitor malfunctioned, causing the child's death. *Id*. The court affirmed summary judgment for the defendant, noting that this is "one such case [that requires reliable expert testimony] because it involves complex issues of computer science. Although we use computers in some form or fashion almost every day of our lives, the design and structure of the software they run is beyond the ordinary understanding and experience of laymen". *Id.* at 659.

Given the number of IoT devices currently on the market and the expected expansion of these devices in the future, the number of consumer claims likely will continue to grow, causing the reexamination of security, privacy, and traditional notions of product liability law.

Autonomous Vehicles

Autonomous vehicles, also known as driverless cars, are the future of transportation. They have the potential to reduce traffic, increase safety on the road, lower harmful greenhouse gas emissions, and generate more free time for individuals who otherwise would be occupied by driving. While the technology advancements and automated features may improve the safety of our roads, they also may lead to new liability risks. While theories of liability may be similar to those asserted in standard product liability cases involving vehicles (*e.g.*, negligence, strict liability, design defect, failure to warn, etc.), autonomous cars raise many additional difficult questions about liability, adequate warnings, and data security. With respect to liability, autonomous cars are designed to supplant the driver. Consequently, whether an accident was caused by a defect rather than driver error is likely to be a contentious battle ground. Indeed, within the past year, lawsuits and media attention related to driverless car accidents have emerged. *See, e.g., Nilsson v. Gen. Motors LLC*, No. 4:18-cv-471 (N.D. Cal. Jan. 22, 2018) (suing manufacturer of self-driving vehicle for negligence, where motorcycle driver was struck by vehicle in "self-driving mode"); *Sheikh v. Tesla, Inc.*, No. 5:17-cv-2193 (N.D. Cal. Apr. 19, 2017) (putative class action on behalf of purchasers and lessees of certain Tesla models, based on allegations that "Enhanced Autopilot capabilities" are "unusable and demonstrably dangerous"); "Uber, Ariz. Self-Driving Car Victim's Family Reach Deal", Law360, Mar. 30, 2018 (discussing resolution without litigation of matter involving self-driving Uber vehicle that struck and killed a pedestrian). In addition, future regulations and litigation will likely address questions concerning the sufficiency of warnings, and whether consumer training will be required. Most states are considering legislation regarding autonomous cars and a few, including California, Florida and Michigan, have already passed legislation. An entire regulatory body will undoubtedly grow to govern autonomous vehicle technology, but for now, these regulations are in their infancy.

Endnote

1. See Statement by FDA Commissioner Scott Gottlieb, M.D., on FDA ushering in new era of 3D printing of medical products; provides guidance to manufacturers of medical devices, available at https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587547.htm (last accessed Jan. 17, 2018).

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