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

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Introduction

U.S. product liability law has continued to evolve over the past year, particularly with regard to the scope of personal jurisdiction and the applicability of federal preemption to tort claims addressing pharmaceutical products. Additionally, given the prevalence of multi-district litigation ("MDL") that now encompasses a substantial portion of civil cases in federal court – especially those involving product liability claims – problems pertaining to MDLs have garnered significant attention in recent years. Proposed MDL rule changes, if implemented, would likely alter the product liability landscape. Finally, as the design, manufacturing, and function of traditional products rapidly 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;
- Multi-district Litigation (MDL); 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"). 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), *petition for cert. filed*, No. 18-998 (Jan. 31, 2019); *Aspen Am. Ins. Co. v. Interstate Warehousing, Inc.*, 90 N.E.3d 440, at 447-48 (Ill. 2017) ("[T]hat 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

corporations activities in Illinois"). This theory will likely see continued litigation across the country as plaintiffs attempt to circumvent the recent 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 and assert claims in California. *Id.* at 1782.

Courts across the country have consistently applied *BMS* to stop 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); *Campbell v. Acme Insulations, Inc.*, 2018 IL App (1st) 173051, 105 N.E.3d 984 (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, several 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"). 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").

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 federal courts in recent years and remains one of the most hotly contested issues in product liability cases.

Pharmaceutical Preemption

In *PLIVA, Inc. v. Mensing*, 564 U.S. 604 (2011), a case with far-reaching implications for pharmaceutical preemption, plaintiffs alleged that manufacturers of a generic drug failed to adequately warn of the risk of a severe neurological disorder. 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.

Plaintiffs argued that 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 bases, noting FDA's position 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. Accordingly, plaintiffs' claims were 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.

Two years later, the Supreme Court again found that state tort claims against the manufacturer of a generic drug were impliedly preempted. *Mut. Pharm. Co. v. Bartlett*, 133 S. Ct. 2466 (2013). In *Bartlett*, as in *Mensing*, a defendant manufacturer argued 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. The Supreme Court held 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.

Subsequent to *Mensing* and *Bartlett*, manufacturers of *brand name* pharmaceuticals have succeeded in arguing that state law failure-to-warn claims are likewise subject to "impossibility preemption", particularly where plaintiffs have not identified "newly acquired information" required for manufacturers to invoke the CBE process. *See, e.g., McGee v. Boehringer Ingelheim Pharms., Inc.*, No. 4:16-cv-2082, 2018 WL 1399237 (N.D. Ala. Mar. 20, 2018) (dismissing failure to warn claim where "the complaint at best contains ambiguity about the newly-available data that [the defendant manufacturer] had or should have had after [its drug's] approval and before [plaintiff's] injury"); *Maze v. Bayer Healthcare Pharms. Inc.*, No. 4:18-cv-21, 2019 WL 1062387 (E.D. Tenn. Mar. 6, 2019)

(dismissing claims based on failure to warn where plaintiff's "complaint cannot plausibly be read to contain any newly acquired information or even a new analyses of previously submitted data, on the basis of which [the defendant manufacturer] could have changed the [drug] label using the CBE process", and thus federal law "would not have allowed [defendant] to modify the [drug] label, which had already been approved by the FDA, in the way that plaintiffs suggest is necessary to make its stroke warning adequate"). *But see, e.g., In re Fosamax Prods. Liab. Litig.*, 852 F.3d 268, 293 (3d. Cir. 2017) (reversing district court's ruling that plaintiffs' claims were preempted due to FDA's denial of additional warnings on the drug's label, and holding that what FDA would have done had plaintiffs' requested warnings been presented to FDA was a question for the jury). The U.S. Supreme Court has granted *certiorari* in *In re Fosamax*, 138 S. Ct. 2705 (2018), and held oral arguments on January 7, 2019. Regardless of outcome, the Court's opinion will likely provide significant guidance on the scope of implied preemption of failure-to-warn claims related to pharmaceutical products.

Several noteworthy opinions have also recently addressed whether *design defect* claims are pre-empted, where defendants similarly could not 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 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"); *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"); *Robinson v. Eli Lilly & Co.*, No. 5:17-cv-338, 2018 WL 4039703, at *6 (E.D. Ky. Aug. 23, 2018) (dismissing design defect claim as preempted, because defendant "could not have independently made such fundamental changes to [its drug's] formula"). *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").

In 2013, FDA proposed a rule that would have permitted generic drug manufacturers to change labels through the CBE process, which, as discussed in *Mensing*, is currently only available to brand-name manufacturers. If implemented, the rule change would have curtailed preemption of failure to warn claims brought against generic manufacturers, who could no longer argue the inability to independently supplement product warnings. However, the FDA withdrew the proposed rule in December 2018. Among other reasons, the Agency explained that "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". FDA Statement (Dec. 13, 2018), available at: https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm628339.htm.

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* inconsistently.

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.

However, in a recent opinion, 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. The Ninth's Circuit's decision also departs 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).

Courts have recently relied on *Buckman* to also hold that other tort claims against pharmaceutical manufacturers are impliedly preempted. For instance, in *Markland v. Insys Therapeutics, Inc.*, -- F. App'x --, 2018 WL 6666385 (11th Cir. Dec. 19, 2018), the Eleventh Circuit affirmed dismissal of plaintiff's state law claims that a pharmaceutical manufacturer "engaged in a 'fraudulent' and 'unlawful' marketing scheme to push doctors to prescribe [the drug] 'off label'". *Id.* at *1. The court explained that 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". *Id*. at *2. In other words, "[a]s with the *Buckman* plaintiffs, [plaintiff] seeks to enforce a duty that 'exists solely by virtue of the FDCA'". *Id*. (Quoting *Buckman*, 531 U.S. at 353.)

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 subsequently rejected plaintiffs' attempts to circumvent *Riegel*. *See, e.g., Caplinger v. Medtronic, Inc.*, 784 F.3d 1335, 1340-42 (10th Cir. 2015) (rejecting 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); *Ezell v. Medtronic PLC*, No. 3:17-cv-796, 2018 WL 6928917, at *7 (W.D. La. Dec. 19, 2018) (similar); *Reed v. St. Jude Med.*, No. 17-5560, 2018 WL 4293146, at *4 (D. Minn. July 24, 2018) (similar); *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"). 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").

Multidistrict Litigation (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, 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, 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 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, http://www.jpml.uscourts.gov/overview-panel-0.

In 2018, there were 207 active MDLs (see, www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2018.pdf). By some measures, MDLs now contain more than half of all civil cases pending in federal court (*see*, www.law360.com/classaction/articles/1138928/mdls-surge-to-majority-of-entire-federal-civil-caseload). Of the 207 currently pending MDLs, 68 of them are classified as "Products Liability" litigation, the largest of any category. (*See*, www.jpml.uscourts.gov/sites/jpml/files/JPML_Calendar_Year_Statistics-2018.pdf.)

Defence and plaintiff practitioners have argued, however, 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 November 2018, the Committee reported that it was "still in the information gathering phase". Meeting of the Advisory Committee on Civil Rules, 35 (Nov, 1, 2018), *available at* https://www.uscourts.gov/sites/default/files/2018-11_civil_rules_agenda_book_0.pdf. Further, the Committee has not yet determined whether "rules are necessary or whether a manual and increased education would be better alternatives". *Id*. at 35. Some Committee members have raised "skepticism about the necessity or ability to devise a specialized set of rules for MDL proceedings", recognising that MDLs require some level of "flexibility, innovation, and discretion". Meeting of the Advisory Committee on Civil Rules, 29 (Apr. 10, 2018), available at https://www.uscourts.gov/sites/default/files/2018-04-civil-rules-agenda-book.pdf. It remains to be seen whether any proposed rule changes will gain traction. Even if they do, their implementation likely remains "at least three years" away. *Id*. In the meantime, 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 certain to become the subject of future product liability litigation. Two highly publicised developments likely to affect product liability law involve the internet of things and autonomous vehicles.

Internet of Things

The expansive and growing development of internet-connected consumer products, also known as internet of things ("IoT") devices, have prompted consumer privacy and product liability concerns arising out of alleged manufacturing and design defects. Indeed, in May 2018, the U.S. Consumer Product Safety

Commission "conduct[ed] a public hearing to receive information from all interested parties about potential safety issues and hazards associated with internet-connected consumer products", with the goal of "inform[ing] future Commission risk management work". *See* Federal Register, "The Internet of Things and Consumer Product Hazards" (Mar. 27, 2018), available at www.federalregister.gov/documents/2018/03/27/2018-06067/the-internet-of-things-and-consumer-product-hazards.

Case law has similarly begun to develop. In *Flynn v. FCA US LLC*, for instance, the Southern District of Illinois addressed class claims brought on behalf of purchasers and lessees of Chrysler vehicles, alleging design flaws in the cars' "UConnect system", an "infotainment system that allows integrated control over phone, navigation, and entertainment functions in certain vehicles". 327 F.R.D. 206, 213 (S.D. Ill. 2018). The system's "design and installation" allegedly "makes it vulnerable to hackers seeking to take remote control of one of the affected vehicles …". *Id*. Plaintiffs alleged, among other things, that defendants "concealed and suppressed information about the severity of the cybersecurity defects in the class vehicles". *Id.* at 214. Granting in part and denying in part defendants' motions for summary judgment, the court held that there was sufficient evidence "to demonstrate a genuine dispute between the parties as to whether the class vehicles have defects". *Id*. at 215. The court also granted in part plaintiffs' motion for class certification, finding that "there appears to be no difference among [state-wide] class members with respect to proving merchantability and the defectiveness of class vehicles". *Id*. at 226.

In *In re VTech Data Breach Litigation*, plaintiffs sued the manufacturer of children's learning toys that were linked to certain web-based services, 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 that "[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. The court dismissed plaintiffs' initial complaint, holding that they "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". *In re VTech Data Breach Litig*., No. 15 CV 10889, 2017 WL 2880102, at *4 n.5 (N.D. Ill. July 5, 2017). Plaintiffs then filed an amended complaint, which the court again dismissed for failure to plead a cognizable claim. 2018 WL 1863953 (N.D. Ill. Apr. 18, 2018).

Medical devices that use integrated autonomous software have also been the subject of recent product liability litigation. In *Ross v. St. Jude Medical, Inc.*, plaintiff brought a putative class action alleging "severe security vulnerabilities found in [defendant's] cardiac devices" designed with remote tracking capabilities. According to the complaint, "by forging, altering, or replying to previously captured transmissions to or from an implanted cardiac device, a bad actor could monitor and modify the implant". No. 2:16-cv-06564 (C.D. Cal. Aug. 26, 2016) [ECF No. 1] ¶¶ 17, 26. The case, however, was voluntarily dismissed in December 2016.

Given the quantity of IoT devices on the market and their rapid development, the number of consumer claims involving IoT devices likely will continue to grow, 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 greenhouse gas emissions, and generate free time. Nevertheless, they also may lead to new liability risks. Indeed, high-profile product liability lawsuits have already emerged against the manufacturers of self-driving vehicles. *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 a self-driving Uber vehicle that struck and a killed pedestrian).

In addition, developing regulations continue to address standards surrounding autonomous vehicles, with most states considering or already enacting legislation. (*See*, www.ncsl.org/research/transportation/autonomous-vehicles-self-driving-vehicles-enacted-legislation.aspx.) The National Highway and Transportation Safety Administration has also released federal guidelines for "Automated Driving Systems". State regulations and federal guidelines remain in their infancy, and will undoubtedly continue to evolve with this developing technology.

Note

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