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Physician and Device Manufacturer Tort Liability for Remote Patient Monitoring Devices

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I THE LANDSCAPE OF REMOTE AND DIAGNOSTIC DEVICES

New technologies allow patients to use, wear, or even have implanted remote patient monitoring (RPM) devices that collect data, which can be sent directly to physicians.[3] These data can be used to identify disease-related events that require medical intervention. RPM includes diagnostics performed by patients at home, without direct physician involvement, that had traditionally been performed in a clinical setting (such as a mobile sleep study), as well as services that combine routine monitoring and diagnosis (such as a heart rate monitor). For example, pacemakers that used to primarily support a patient's cardiac rhythm can now be used to transmit information to a cardiologist, potentially detecting arrhythmias that may lead to medical treatment at a presymptomatic stage.[4] Wearable glucose monitors, like Abbott's FreeStyle Libre 2, and seizure detection devices, like Empatica's Embrace2, can alert patients or caregivers to low glucose levels and seizure activity that require attention.[5]

With the increasing prevalence of RPM devices, questions remain about the liability protections for patients who use them. State laws, in particular tort law, provide some potential safeguards by enabling patients to sue device manufacturers and physicians for causing them harm. While a variety of state and federal laws impose

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[3] For the purposes of this chapter, device means "intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man … or intended to affect the structure or any function of the body of man." 21 USC § 321(h)(1)(B).

[4] Stefan Simovic et al., The Use of Remote Monitoring of Cardiac Implantable Devices During the COVID-19 Pandemic: An EHRA Physician Survey, 24 EP Europace 473 (2022).

[5] *Freestyle Libre* 2, *Abbot*, www.freestyle.abbott/us-en/products/freestyle-libre-2; *Embrace2*, *Empatica*, www.empatica.com/embrace2/.

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obligations on manufacturers,[6] tort law is a major tool to hold these actors accountable for injuries they cause to patients.[7]

The stakes are high. A cardiac monitor or a seizure detection device, like Embrace2, that malfunctions could result in brain damage or death, opening the manufacturer to large jury verdicts, particularly for widely used products. Physicians who improperly use or rely on RPM devices to notify them of such activity and fail to monitor patients could also face substantial damage claims.

Despite the significance of potential injury for patients and liability for manufacturers and physicians, it is not clear how these claims should be evaluated or resolved. To clarify when liability might arise, this chapter first explains how tort liability applies to manufacturers of RPM devices, physicians who prescribe them, and patients who use them (and their caregivers). It then proceeds to analyze how variation in device market entry, patient access, and use – through federal regulatory protections, physician prescriptions for devices, and patient and caregiver uses – can affect the viability of tort claims.

II LIABILITY FOR DEVICE MANUFACTURERS AND PHYSICIANS

Tort law contains two primary standards of liability typically applicable to devices like RPM devices (Table 8.1).[8] The first is negligence, which requires one to act with "reasonable care" when undertaking an activity. For a plaintiff to succeed in a lawsuit based on negligence, the plaintiff must prove that another failed to act with reasonable care, and that such failure caused harm to the plaintiff. The second is strict liability, which does not require such a showing; in theory, there is "no fault" because tort law imposes liability on the person who caused the injury regardless of whether that person acted with reasonable care. Both negligence and strict liability can apply to RPM manufacturers. Typically, only negligence applies to physicians.

A *Manufacturer Liability for Product Defects*

i Negligence

Manufacturers have a duty to use reasonable care in manufacturing, designing, and marketing a product.[9] They are, therefore, liable for injuries caused to users by

[6] For example, Iowa Code §155A.42 (2018).

[7] In the case of devices, contract law also plays a significant role in the liability analysis. Tort and contract law provide different legal tests, and some states allow contract but not tort claims. Nevertheless, the two are sufficiently similar that analyzing tort claims provides a reasonable overview of how courts are likely to respond to claims in contract, even if courts ultimately resolve claims differently. For this reason, and because of space limitations, we focus here only on tort claims. We also do not discuss various civil and criminal penalties for violations of federal and state statutes.

[8] Tort law also imposes liability on manufactures who make misrepresentations about their products, but we do not discuss such causes of action in this chapter.

[9] *Merrill* v. *Navegar, Inc.*, 28 P.3d 116, 124 (Cal. 2001).

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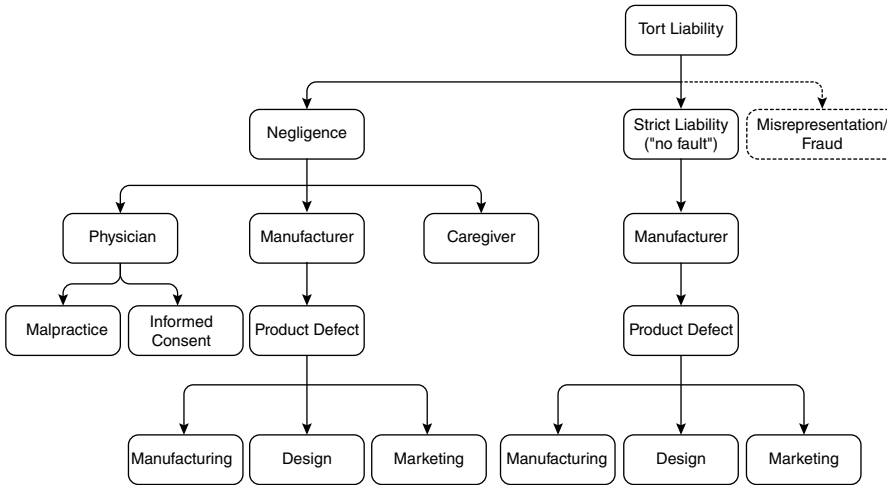
TABLE 8.1 *Schematic of tort liability for manufacturers, physicians, and caregivers*



This table depicts the potential tort causes of actions against physicians, manufacturers, and caregivers arising from RPM devices. Misrepresentation/fraud claims are depicted in dotted lines to indicate potential causes of action that are not discussed in this chapter.

failing to reasonably warn of product risks or failing to use reasonable care in designing or manufacturing the product. The standard for negligence claims primarily focuses on the reasonableness of the manufacturer's behavior. Although evidence of industry custom is admissible in determining the relevant standard of care, industry custom does not determine the relevant standard of care.[10] That is a determination left to the fact-finder, and if it is a jury, with assistance from the judge.

ii Strict Liability

Manufacturers can also be liable under the theory of strict liability for the same three types of product defects (manufacturing, design, marketing) as they can be liable for in negligence. Unlike negligence, however, strict liability does not require the injured party to prove any negligent conduct by the manufacturer – only that the product defect existed when it left the manufacturer's hands.[11] Manufacturing defect claims allege that a defect arose in the production of the product that differed from the manufacturer's design, and that this defect caused harm to the plaintiff.[12] Design defect claims allege that, even if manufactured properly, the manufacturer's design was particularly unsafe and, therefore, defective, and that

[10] *Rossell* v. *Volkswagen of Am.*, 709 P.2d 517, 523 (Ariz. 1985).
[11] But see *Banks* v. *ICI Americas, Inc.*, 450 S.E.2d 671, 672 (Ga.1994) (applying reasonableness and negligence principles to evaluate design defect claims).
[12] *BIC Pen Corp.* v. *Carter*, 346 S.W.3d 533, 540 (Tex. 2011).

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the defect caused injury to the plaintiff.[13] Finally, marketing defect claims – also called "failure to warn" or "inadequate warning" claims – allege that the manufacturer failed to provide to the patient with sufficient warnings about the risks of using the product.

iii Scope of Strict Liability Claims

Whether and how negligence or strict liability theories apply can depend on the type of defect alleged, the jurisdiction in which the lawsuit is filed, and the type of product at issue. The type of defect alleged can affect what the plaintiff must prove – with requirements occupying three places along a spectrum. At one end of the spectrum are manufacturing defect claims, for which the only questions are whether the product was manufactured according to the manufacturer's design and specifications and, if not, whether that defect caused the plaintiff's injury.[14] For example, liability under this theory would arise if a patient was injured by a pacemaker that malfunctioned because, during manufacturing, the manufacturer failed to install a computer chip required to process heart rhythms.

At the other end of the spectrum are failure to warn claims, for which the standards for strict liability and negligence are identical – the only question is whether the manufacturer reasonably warned the consumer of the product risks.[15] For example, a manufacturer of vaginal mesh may be liable on this theory for failing to warn that mesh removal may be required if the product fails.[16]

Somewhere in the middle are design defect claims. Here, the plaintiff must show either that "the product failed to perform as safely as an ordinary consumer would expect when used in an intended or reasonably foreseeable manner" or that "the product's design proximately caused his injury and the defendant fails to establish, in light of the relevant factors, that, on balance, the benefits of the challenged design outweigh the risk of danger inherent in such design."[17] In negligence, courts tend to ask how to balance the device's risk of harm against its utility, while in strict liability, they tend to emphasize the existence and monetary costs of using an alternative safer design.[18] For example, the manufacturer of an air conditioning compressor was found liable for injuries caused by an explosion it could have prevented by simply and costlessly relocating a safety groove from the inside to the outside of the

[13] In re Coordinated Latex Glove Litig., 121 Cal. Rptr. 2d 301 (Ct. App. 2002).

[14] *Derienzo* v. *Trek Bicycle Corp.*, 376 F. Supp. 2d 537, 560 n. 28 (SDNY 2005).

[15] Nancy K. Plant, The Learned Intermediary Doctrine: Some New Medicine for an Old Ailment, 81 Iowa L. Rev 1007, 1012 (1995).

[16] *Eghnayem* v. *Bos. Sci. Corp.*, 873 F.3d 1304, 1322 (11th Cir. 2017).

[17] *Barker* v. *Lull Eng'g Co.*, 573 P.2d 443, 454–56 (Cal. 1978); *Sparks* v. *Owens-Illinois, Inc.*, 38 Cal. Rptr. 2d 739 (Ct. App. 1995) (holding the tests were mutually exclusive); *Dawson* v. *Chrysler Corp.*, 630 F.2d 950 (3d Cir. 1980) (outlining factors to consider).

[18] *Toner* v. *Lederle Lab'ys, a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 311 (Idaho 1987). But see *Lance* v. *Wyeth*, 85 A.3d 434, 459 (Pa. 2014) (refusing to apply this approach to prescription drugs).

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compressor's insulating glass.[19] In some cases, medical devices like hip implants may be subject to a similar analysis when the device fails.[20]

Jurisdictions may differ, however, on whether strict liability applies. In some jurisdictions, a design defect claim for devices that are "incapable of being made safe for their intended and ordinary use"[21] will immunize a manufacturer from design defect claims if the manufacturer properly manufactures and warns consumers about the product's risks.[22] In such cases, adequate warnings immunize manufacturers from strict liability design defect claims.

All this suggests that the *type* of device – whether it is "incapable of being made safe" – can also influence whether strict liability applies. Some courts have found that prescription and implantable medical devices count.[23] Others disagree or think that the question must be resolved on a case-by-case basis by weighing the risk-utility tradeoff presented by the device,[24,25] sometimes casting the issue as one the defendant manufacturer must raise and prove as an affirmative defense.[26] Finally, there remains something of an open question about whether software itself can be a "product" subject to strict liability.[27]

Device type and jurisdictional issues can also interact to affect potential tort claims. So, even if immunity from strict liability applies, it may apply only to design defect claims (leaving strict liability claims for manufacturing and marketing defects),[28] or it may bar *all* strict liability claims.[29] In some jurisdictions, however, immunity from strict liability claims does not apply to negligence claims.[30]

[19] *Emerson Electric Co.* v. *Johnson*, 627 S.W.3d 197, 208 (Tex. 2021), reh'g denied (September 3, 2021); *Kaiser* v. *Johnson & Johnson*, 947 F.3d 996, 1002 (7th Cir. 2020).

[20] *Burningham* v. *Wright Med. Tech.*, Inc., 448 P.3d 1283, 1292 (Utah 2019).

[21] Restatement (Second) Torts § 402A cmt. k (Am. L. Inst. 1965). Most of the cases implicating comment k involve prescription drugs rather than devices.

[22] *Tansy* v. *Dacomed Corp.*, 890 P.2d 881, 885 (Okla. 1994); *Creazzo* v. *Medtronic, Inc.*, 903 A.2d 24, 31 (Pa. Super. Ct. 2006).

[23] Plant, supra note 13, at 1040; *Hufft* v. *Horowitz*, 5 Cal. Rptr. 2d 377 (Ct. App. 1992).

[24] Burningham, 448 P.3d at 1290 (holding that comment k does not apply to implantable devices cleared through the 510(k) process).

[25] *Johansen* v. *Makita USA, Inc.*, 128 N.J. 86, 96 (1992).

[26] For example, Burningham, 448 P.3d at 1290; Tansy, 890 P.2d at 886; *Mele* v. *Howmedica, Inc.*, 808 N.E.2d 1026, 1041 (Ill. 2004) (using risk-benefit analysis to determine if immunity applies).

[27] Bexis, New Decision Directly Addresses the "Is Software a Product" Question, *Drug & Device L. Blog* (May 2, 2022), www.druganddevicelawblog.com/2022/05/new-decision-directly-addresses-the-is-software-a-product-question.html. We assume, for the purposes of this chapter, that RPMs will include a physical device that incorporates software but not a standalone software that might fall outside the definition of "product" or "good" for the purposes of product liability law under either tort or contract.

[28] *Toner* v. *Lederle Lab'ys, a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 308 (Idaho 1987); *Transue* v. *Aesthetech Corp.*, 341 F.3d 911, 917–19 (9th Cir. 2003); *Grundberg* v. *Upjohn Co.*, 813 P.2d 89, 92 (Utah 1991).

[29] *McPhee* v. *DePuy Orthopedics, Inc.*, 989 F. Supp. 2d 451, 461 (W.D. Pa. 2012).

[30] *Slisze* v. *Stanley-Bostitch*, 979 P.2d 317, 319 (Utah 1999) (product's liability statute did not preclude simultaneous strict liability and negligence claim); *Scott* v. *C.R. Bard, Inc.*, 180 Cal. Rptr. 3d 479, 489 (Ct. App. 2014); *Rogers* v. *Miles Lab'ys, Inc.*, 802 P.2d 1346, 1353 (Wash. 1991); *Toner* v. *Lederle Lab'ys, a Div. of Am. Cyanamid Co.*, 732 P.2d 297, 309–10 (Idaho 1987).

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iv The Learned Intermediary Doctrine

Claim type and use, including the process by which a consumer use occurs, can also affect liability by shifting obligations from one party to another. Marketing defect claims, for instance, require the plaintiff to prove that a product was unreasonably dangerous because it lacked adequate warnings or instructions.[31] This duty ordinarily requires manufacturers to warn consumers directly. But when a physician prescribes the product, the "learned intermediary doctrine" requires a manufacturer to adequately warn only the prescribing physician subject to three limited exceptions.[32,33]

Because warning the physician may require different disclosures than warning a consumer, the learned intermediary doctrine can alter the manufacturer's explanation of device risks. This can also affect other claims. For example, a manufacturer that successfully defends a failure to warn claim may also be able to defeat liability for a design defect claim, since immunity from some design defect claims requires adequate warnings. At the same time, however, the learned intermediary doctrine will not affect manufacturing defect claims because they do not turn on whether the manufacturer gave proper warnings.

B *Physician Liability for Lack of Informed Consent and Negligence*

The learned intermediary doctrine is also related to the doctrine of "informed consent," which imposes on physicians a duty to obtain, prior to treatment, patient consent by informing them of the material risks associated with the treatment. In some jurisdictions, the sufficiency of informed consent is based on whether "the physician's failure to inform fell below the medical community's standard of care."[34] In others, the question of sufficiency is based on a record of the disclosure of facts that would influence the patient to consent to a particular procedure or treatment.[35]

Informed consent is often considered part of tort law's general requirement to act reasonably under the circumstances – a requirement that applies to physicians as

[31] *Lawson* v. *G. D. Searle & Co.*, 356 N.E.2d 779, 783 (Ill. 1976); *Ortho Pharm. Corp.* v. *Chapman*, 388 N.E.2d 541, 545 (Ind. Ct. App. 1979); *Hamilton* v. *Hardy*, 549 P.2d 1099, 1108 (Colo. App. 1976), overruled by *State Bd. of Med. Examiners* v. *McCroskey*, 880 P.2d 1188 (Colo. 1994).

[32] *O'Connell* v. *Biomet, Inc.*, 250 P.3d 1278, 1281–82 (Colo. App. 2010); *Ellis* v. *C.R. Bard, Inc.*, 311 F.3d 1272, 1280 (11th Cir. 2002) (applying Georgia law); *Beale* v. *Biomet, Inc.*, 492 F. Supp. 2d 1360, 1367–68 (S.D. Fla.2007) (collecting cases and applying Florida law); *Pumphrey* v. *C.R. Bard, Inc.*, 906 F. Supp. 334, 337 (NDW Va.1995) (applying West Virginia law).

[33] *Edwards* v. *Basel Pharms.*, 116 F.3d 1341 (10th Cir. 1997). New Jersey has created an exception for contraceptives marketed directly to consumers. *Perez* v. *Wyeth Lab'ys Inc.*, 734 A.2d 1245, 1259–60 (N.J. 1999).

[34] *Gorab* v. *Zook*, 943 P.2d 423, 427 (Colo. 1997).

[35] *Scott* v. *Bradford*, 606 P.2d 554 (Okla. 1979); *Hurley* v. *Kirk*, 398 P.3d 7, 9 (Okla. 2017).

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well as manufacturers. Like the standard for manufacturers in negligence actions, the standard for physicians in negligence actions focuses on the reasonableness of the physician's behavior. Unlike the standard of negligence for manufacturers, however, the standard of negligence for physicians is often determined by custom. What is reasonable, in other words, is determined by the jury based on what an actual doctor in that field of expertise would actually have done in the situation, rather than on what a reasonable doctor under the circumstances would have done.[36] This standard of care, however it is determined, applies to physicians who prescribe and use RPM devices. Thus, tort law will hold physicians liable if their failure to warn of device risks (if the learned intermediary doctrine applies) or to take reasonable care in monitoring or treating a patient, which can include inadequate training on how to use a device, causes harm to the patient.[37]

C *Defenses*

Both physicians and manufacturers may have various defenses to claims involving defective products or negligent care. One is that the patient was negligent in using the device, and that negligence caused some or all of the harm suffered. In tort, a plaintiff's negligence can affect his or her claims by (1) barring recovery entirely (contributory negligence), (2) reducing recovery by the percentage the plaintiff is at fault (pure comparative negligence), or (3) reducing recovery if the plaintiff's fault is as great as or not greater than the defendant, otherwise barring recovery (modified comparative negligence). Most jurisdictions apply some version of modified comparative negligence when the plaintiff asserts a negligence claim. When the plaintiff asserts a claim in strict liability, contributory and comparative negligence defenses may still be available,[38] though they may be limited to certain evidentiary issues, such as risk-utility balancing or causation,[39] and circumscribed by statute.[40] Of course, even when comparative negligence applies, parceling liability may be challenging.

III FACTORS AFFECTING LIABILITY DETERMINATIONS

Building on the previous discussion, this part shows that how a device reaches the market and is used – through federal regulation, physician prescription, and patient and caregiver use – can also influence liability determinations.

[36] *Braswell* v. *Stinnett*, 99 So. 3d 175, 178 (Miss. 2012).

[37] *Manzi* v *Zuckerman*, 384 A.2d 541 (NJ Super. Ct. App. Div. 1978) (duty to monitor for conditions during pregnancy); *Marcano Rivera* v. *Turabo Med. Ctr. P'ship*, 415 F.3d 162 (1st Cir. 2005) (duty to monitor fetal heart signs using monitors, which includes proper training).

[38] *West* v. *Caterpillar Tractor Co.*, 336 So. 2d 80, 92 (Fla. 1976); *Gen. Motors Corp.* v. *Sanchez*, 997 S.W.2d 584, 587 (Tex. 1999); *Austin* v. *Raybestos-Manhattan, Inc.*, 471 A.2d 280, 288 (Me. 1984).

[39] *Johansen* v. *Makita USA, Inc.*, 607 A.2d 637, 645–46 (NJ 1992).

[40] *Emps. Mut. Ins. Co.* v. *Oakes Mfg. Co.*, 356 N.W.2d 719, 723 (Minn. Ct. App. 1984).

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A *Regulation*

How a device reaches the market can influence manufacturer liability for injuries caused by the device. RPM devices reach the market in two principal ways. New, high-risk devices (class III) must file a premarket notification approval (PMA) application that requires the manufacturer to demonstrate "reasonable assurance of the safety and effectiveness" of the device.[41] By contrast, if a manufacturer can justify that its device is "substantially equivalent" to a device already legally on the market, the device qualifies for clearance under section 510(k) of the Food, Drug, and Cosmetic Act (FDCA), an exception to the PMA process (class II).[42] Almost all devices that require premarket review enter the market through the 510(k) pathway, though the FDA does have the power to reclassify devices based on data showing novel risks.[43]

Which of these two pathways applies to an RPM device can have important liability implications for the manufacturer and injured patient because the Supreme Court ruled that the Medical Device Amendments of 1976 (MDA) expressly or impliedly preempted state tort claims for high-risk devices that meet the "federal requirements" necessary for the approval of a PMA application.[44] Express preemption does not apply to devices cleared through the 510(k) pathway, which lacks the close regulatory review for safety and effectiveness present in a PMA review (Table 8.2).[45]

Implied preemption defeats only those parallel claims that would not exist but for the FDCA.[46] For 510(k)-devices, for example, implied preemption bars claims only when the manufacturer's fraudulent representations caused the FDA to allow the marketing of a device it otherwise would not have (so-called state-law "fraud-on-the-FDA claims") (Table 8.3).[47]

As a result, a manufacturer's liability exposure may turn on the type of product it manufactures and whether any similar product currently exists on the market. For example, if the heart rate monitoring feature of an implantable pacemaker is cleared through a 510(k) pathway, then the manufacturer would be liable for most harm that occurs as a result of a product defect.[48] If, by contrast, the feature required a PMA, then the manufacturer for which the PMA is granted would be immune from most lawsuits alleging injuries caused by the monitoring features of the device. Generally

[41] 21 USC § 351(f); 21 USC §§ 360e, (d)(1)(A)(ii), (d)(1)(B)(iii).

[42] 21 USC §§ 360c(a)(1)(B), (i), (f), 360(k), 360j.

[43] Inst. Med. Nat'l Acads., *Medical Devices and the Public's Health: The FDA 510(k) Clearance Process at 35 Years* (2011). Of all devices subject to FDA premarket review, 90 percent pass through the 510(k) pathway, but only about one-third of all devices entering the market pass through the 510(k) pathway. Id. at 4, 170. Most devices, however, require no review because they are low risk, class I devices.

[44] *Riegel* v. *Medtronic, Inc.*, 552 US 312 (2008); 21 USC § 360k(a).

[45] *Medtronic, Inc.* v. *Lohr*, 518 US 470, 471 (1996).

[46] For example, *Glover* v. *Bausch & Lomb, Inc.*, 275 A.3d 168, 175 (Conn. 2022).

[47] *Buckman Co.* v. *Plaintiffs' Legal Comm.*, 531 US 341, 352 (2001).

[48] We assume that preemption would not apply but recognize that this conclusion is complicated by devices with some components that are cleared and others that are approved. For example, *Shuker* v. *Smith & Nephew, PLC*, 885 F.3d 760, 773–76 n.14–15 (3d Cir. 2018).

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TABLE 8.2 *Express preemptive effect of MDA on tort claims, by defect alleged*

	Type of claim expressly preempted		
FDA review	*Manufacture*	*Design*	*Marketing*
PMA	Yes*	Yes*	Yes*
510(k)	No	No	No
De Novo†	No (presumably)	No (presumably)	No (presumably)
None	No	No	No

"Yes" means the claim is expressly preempted; "No" means the claim is not expressly preempted.

* Preemption does not bar parallel state claims.

† The de novo process has not yet been the subject of a preemption analysis. Given that it is designed to provide a 510(k)-like process for new devices, however, it is reasonable to assume that preemption analysis for devices authorized under the de novo review would be the same (or substantially the same) as those cleared through the 510(k) process. Courts analyzing the issue, however, may disagree with this assumption and make a contrary holding.

TABLE 8.3 *Express and implied preemptive effect of MDA on tort claims, by claim type*

FDA review	Preemption type	Type of claim preempted		
Pathway	*Express or Implied*	*Fraud-on-FDA*	*Parallel*	*Other State Law*
PMA	Express and Implied	Yes	Some	Yes
510(k)	Implied	Yes	No	No
De Novo†	Implied	Yes (presumably)	No (presumably)	No (presumably)
None	Implied	Yes	No	No

"Yes" means the claim is expressly preempted; "No" means the claim is not expressly preempted. "(presumably)" means that courts would presumably find federal law impliedly preempted (or not) claims against manufacturers of devices authorized through the de novo pathway.

† *The de novo process has not yet been the subject of a preemption analysis. Given that it is designed to provide a 510(k)-like process for new devices, however, it is reasonable to assume that preemption analysis for devices authorized under the de novo review would be the same (or substantially the same) as those cleared through the 510(k) process. Courts analyzing the issue, however, may disagree with this assumption and make a contrary holding.*

speaking, then, devices that undergo a more complete FDA review before market entry are subject to less tort liability than devices that undergo a less complete or no FDA review before market entry.

Consider the Sunrise Sleep Disorder Diagnostic Aid, which uses jaw movements to detect sleep apnea.[49] The device had no analogue on the market, but Sunrise filed to

[49] FDA Device Classification Under Section 513(f)(2)(De Novo), Sunrise Sleep Disorder Diagnostic Aid, De Novo Number DEN210015 (January 7, 2022).

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have its product cleared for the market without a PMA through an alternative mechanism, which may be treated similarly to the 510(k) process for preemption purposes.[50] While this choice likely saved Sunrise substantial capital, it could also increase its potential liability exposure. When deciding between a less stringent review and a PMA, Sunrise may have determined that the lower costs associated with less stringent review outweighed the benefits of liability protection afforded by a PMA.

Complicating things further, devices with a PMA are not immune from all lawsuits in all jurisdictions; such devices can be the subject of so-called "parallel claims" – state law causes of action that mirror FDA requirements but are not based solely upon them. For example, a state law manufacturing defect claim premised on, but not dependent on, a violation of federal manufacturing regulations could be a parallel claim provided that state law did not impose additional requirements on the manufacturer.[51] Here, jurisdictional issues can reappear because federal courts differ on what counts as a "parallel" claim that evades preemption.[52]

B *Path to Market and Patient*

How an RPM device reaches the consumer can also influence physician and manufacturer liability. For example, Phillips manufactures the BioSticker System, which is an RPM device that attaches to the skin and measures physiological data, such as heart rate, respiratory rate, skin temperature, and other symptomatic or biometric data. This information is displayed on a dashboard that physicians can access and monitor.

The device, which was cleared under the 510(k) process,[53] originally required a physician's prescription but, under a COVID-19 Emergency Use Authorization (EUA), is now available over the counter.[54] Before the EUA, this meant that the manufacturer could discharge its duty to warn by providing adequate instructions and warnings to the physician prescribing the device. The physician would then have an independent duty to obtain informed consent from the patient. After the EUA, however, consumers could access the device without a physician's prescription, requiring that the warnings be made to the patient directly.

Because the learned intermediary doctrine affects manufacturer liability only for failure-to-warn claims, Phillips could still be liable for harm caused by manufacturing defects in the BioSticker System even prior to the EUA. Consider a situation in

[50] 21 USC § 360c(f)(2); 21 CFR §§ 860.3, 860.200–860.260 (de novo classification request procedures).

[51] Some parallel claims may also be impliedly preempted. For example, Buckman, 531 US at 352.

[52] For example, Compare *Weber* v. *Allergan, Inc.*, 940 F.3d 1106, 1112 (9th Cir. 2019), cert. denied, 140 S. Ct. 2555 (2020) with *Bass* v. *Stryker Corp.*, 669 F.3d 501, 510 (5th Cir. 2012); compare *Mink* v. *Smith & Nephew, Inc.*, 860 F.3d 1319, 1330 (11th Cir. 2017) with *Bayer Corp.* v. *Leach*, 153 N.E.3d 1168, 1185 (Ind. Ct. App. 2020).

[53] FDA 10(k) Premarket Notification, BioSticker System, 510(K) Number K191614 (December 18, 2019).

[54] BioIntelliSense, *BioStickerTM Instructions for Use* (2022), https://biointellisense.com/assets/biosticker-supplemental-instructions-for-use.pdf?v=2.

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which, because of a manufacturing defect, the Biosticker device failed to transmit information to a physician showing an irregular heart rate and respiratory function. If the patient died as a result of the physician's failure to intervene, and if the failure to intervene was caused by the device not having been manufactured according to specifications, then Phillips could be liable for the patient's death.

Manufacturers may also be liable for some design defect claims even when the learned intermediary doctrine applies. The scope of this liability may depend on whether the device is prescribed by a physician and the type of device at issue. Phillip's Biosticker was previously used by prescription, making it likely that Phillips could obtain immunity from strict liability design defect claims by adequately warning the physician of the risks posed by the device – for example, its inability to be used for more than a certain period of time or in water.[55]

Once the FDA issued the EUA authorizing the device to be sold directly to consumers without a prescription, no amount of warning to physicians would likely insulate Phillips from strict liability design defect claims; however, in some, but by no means all, jurisdictions, adequately warning consumers may immunize manufacturers from design defect claims. A company like Empatica, for example, may try to immunize itself by warning physicians and consumers about the Embrace2's ability to notify only emergency contacts, potentially foreclosing claims that Empatica defectively designed the Embrace2 since it lacked the capability to notify physicians or emergency responders. Regardless of whether strict liability immunity applies, a showing of adequate warning would not necessarily make Phillips immune from negligent design defect claims because of jurisdictional differences.

Besides the jurisdictional variations, it is unclear how courts would resolve such claims. While design defect claims often turn on the existence of available safer designs, along with the costs of developing and implementing them, some courts have been reluctant to apply this reasoning to prescription drugs.[56] Prescription RPM devices may be treated similarly. If they are not, however, such claims will turn on a fact-intensive analysis of the costs associated with changing the device to make it safer – rarely a question that can be resolved definitively and early in litigation.

In addition to its effect on manufacturer liability for information-based claims like failure to warn, the learned intermediary doctrine also opens physicians to more claims from patients injured by RPM devices. For example, suppose a physician prescribes to a patient, and the patient uses, a bracelet like the Embrace2 to detect seizure activity that automatically notifies designated caregivers.[57] If a seizure occurs and the device contacts a caregiver who cannot respond in time, the injured patient

[55] Id.

[56] *Brown* v. *Super. Ct.*, 751 P.2d 470, 479 (Cal. 1988); Restatement (Third) of Torts: Prods. Liab. § 6(c) (Am. L. Inst. 1998). But see *Freeman* v. *Hoffman-La Roche, Inc.*, 618 N.W.2d 827, 837 (Neb. 2000).

[57] See Embrace, supra note 388.

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may attempt to sue the physician based on the theory that he or she would not have used the device if it was impossible for the device to alert someone who could more immediately help.[58]

To avoid liability, physicians will need to properly inform and educate patients and caregivers about the devices' risks and limitations. For devices like the Embrace2, part of this risk may be avoided by working with device manufacturers to notify parties who can respond in case of emergency and obtaining written and verbal consent, after explanation, for patient responsibilities in using the device and how the physicians can and will monitor the device data.

For example, physicians who recommend or prescribe a device like the Biosticker have a duty to understand how to use the product, including its limitations, as well as how and when they will be monitoring the data from the device. These physicians also have a duty to explain this clearly to the patient. If a physician will not be monitoring the device for real-time alerts, but instead using it as a data-gathering tool to obtain a more complete picture of the patient, they would do well to say so (and to document that conversation with the patient). The duty might include explaining to patients what to do if the device detects unusual behavior, including who they should contact and how they should interpret the data. Simply advising patients to "call 911" if there is an emergency may seem like a failsafe, but it also may create undue stress on the health care system if a device provides a variety of alerts. This may require new office procedures, points of contact, and protocols for reassessments of patients whose devices create particular kinds of alerts.

C *Patient and Caregiver Use*

Physicians are not the only individuals who can affect the liability of RPM device manufacturers. When patients use RPMs, they may be responsible for some or all of the harm the device causes, and their damages could be reduced or eliminated under the doctrine of comparative negligence. Similar to device manufacturers, how responsible patients are may turn on the type and nature of the device at issue.

Some RPM devices operate automatically and without any patient initiation, reducing the probability that a patient is responsible for harm suffered when using the device. RPM devices like the BioSticker or a pacemaker that monitors cardiovascular status, for example, collect information with minimal patient engagement. Without any patient action, it may be harder to show that the patient's negligence, rather than the device, is the cause of any harm that occurred while the patient used the device.

However, other devices may require the patient to initiate, operate, or respond to them, and to do so under particular conditions or in a particular manner. For example, Google announced that it was developing a dermatology app that deploys

[58] David A. Simon, et al., The Hospital-At-Home Presents Novel Liabilities for Physicians, Hospitals, Caregivers, and Patients, 28 Nat. Med. 438 (2022).

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artificial intelligence and machine learning to analyze user-uploaded photographs to track skin lesions over time and provide diagnostic information.[59] Hyfe, a smartphone app that likely will apply for 510(k) clearance,[60] uses similar technology to monitor cough data that the patient captures by affirmatively initiating the application. Patients who fail to track skin lesions at certain intervals using Google's dermatology app or fail to initiate Hyfe may find that false negatives are their own fault, rather than the device's. Moreover, patients who do not reasonably act on alerts from devices like RPMs may reduce or eliminate their ability to recover if they are injured as a result.

Patients could also see damages reduced or claims eliminated entirely when they use and rely on these devices in environments where manufacturers specifically state that they will not operate accurately. Thus, a patient who does not operate Hyfe or Google's app in the recommended sound or lighting conditions, does not track coughs or skin lesions at the intervals required for the app to function optimally, or uses the device to predict asthma attacks or detect skin cancer (purposes for which they are not designed) may eliminate or reduce the probability of liability for manufacturers or physicians.

Similar issues apply to devices – like ResMed's AirSense Elite 10 continuous positive airway pressure (CPAP) machine with built-in RPM – which not only treats sleep apnea, but also collects information about the person wearing it, that could be used to detect important health events, including a lack of oxygen being delivered to the user.[61] Patients who improperly place the mask on their face or use the device only sporadically will encounter challenges when suing manufacturers because a device did not detect a respiratory event. This may be true even if the device itself did not function properly.

Additionally, RPM devices may require manual patient data input to function properly. Medtronic offers a patient management system that uses both sensor-based RPM and self-reporting by patients to monitor and evaluate respiratory health, in particular patients with COVID-19.[62] Patients who enter information incorrectly may cause the system to incorrectly not recommend further care or alert the appropriate parties. If that happens and the patient is injured or dies as a result of the delay or absence of care, the patient may bear some or all of the responsibility for the harm, reducing or eliminating their recovery under the doctrine of comparative negligence.

[59] Peggy Bui & Yuan Liu, Using AI to Help Find Answers to Common Skin Conditions, *Google, The Keyword* (2021), https://blog.google/technology/health/ai-dermatology-preview-io-2021/.

[60] Oral communication between David A. Simon and Peter Small (January 20, 2022).

[61] Resmed, *Devices* (May 19, 2022), www.resmed.com/en-us/healthcare-professional/products-and-support/devices/.

[62] Medtronic, *Virtual Care Solutions: Care Management Services* (May 10, 2022), www.medtronic.com/us-en/healthcare-professionals/services/medtronic-care-management-services/our-solutions/care-management-services.html.

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Finally, third parties, like those who are "emergency contacts" alerted by a seizure detection device like the Embrace2, may have their phones turned off or may not respond to the patient in time to treat them. If their failure to respond causes harm to the patient, they could face liability, potentially reducing the liability of other actors. But if the third party's inaction is caused by the patient's failure to inform the third party that they would be notified, how they would be notified, or what they were expected to do when notified, then the patient may be responsible for the harm.

In short, the more patients can control what goes into the RPM, the more likely both the manufacturer and prescribing physician are to argue that any injury was caused not by them, but by the patient. To reduce the probability of patient-caused injury, manufacturers and physicians should carefully instruct patients on how, when, and for what purposes they should use RPM devices, and they should emphasize the limitations of the devices.

IV CONCLUSION

RPM devices may help patients self-manage conditions with fewer complications and at lower cost than traditional clinical care. But they also raise liability issues in tort law. While the doctrines used to assess these claims are quite old, their application to this new and changing area of medicine is unsettled. In this chapter, we have provided a framework for understanding these tort claims and how courts are likely to assess them based on a series of factors, including how the device reaches the market, the type of device, the type of claim, where it is brought, how it reaches the market and consumer, who uses it, and how they do so.

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