Interoperability in Automated Insulin Delivery (AID) Systems: Products Liability Issues and Strategies

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I. Introduction

A. Purpose and Scope[1]

Recent regulatory innovations and the continuing evolution of technology have brought within reach the goal of what the FDA has called a "vibrant device ecosystem"—in which healthcare providers and patients may customize automated insulin delivery ("AID") systems by choosing among multiple interoperable component devices. Innovations in healthcare require the prudent company to consider the risks of products liability ("PL") personal injury litigation. The primary objective of this paper is to provide non-lawyer decision-makers with a basic understanding of PL litigation in the medical device arena and ways they can proactively mitigate and manage risks associated with it. We also hope this paper will be a resource for in-house and outside litigation attorneys counseling companies about PL risk management as those companies design and develop components of AID systems.

B. Executive Summary

In many ways, PL risk for interoperable AID systems is no different than PL risk for current, closed AID systems (i.e., AID systems with components that communicate only through closed business arrangements). The technical complexities, types of alleged adverse events, and legal theories overlap significantly. Similarly, while there is a new FDA marketing authorization pathway for some interoperable devices that we will analyze for possible PL litigation impact below, many regulatory requirements for these devices—and their impacts in PL litigation—are the same. And to the extent that interoperability presents unique PL challenges, those risks may be evaluated by reference to existing legal precedents, and proactively managed through well-established risk mitigation strategies.

Proactive PL risk mitigation includes evaluating risks, but also the considerable benefits that innovation and a greater range of choices can bring to patients and their families—as demonstrated by their vocal demand for new products. It also includes leveraging to the greatest extent possible the FDA's support for such innovation, as illustrated by its willingness to use a novel pathway to streamline the process of bringing interoperable devices to market while ensuring their safety and effectiveness. Further,

[1] Technology innovations and regulatory requirements will continue to evolve, and this work-product may be updated to account for those changes. The information in this paper is for informational purposes only and not for the purposes of providing legal advice with respect to any particular issue or problem. This paper does not provide legal advice or opinions concerning specific products or manufacturers, regulatory advice or opinions, or a comprehensive guide to risk mitigation plans. We encourage you to consult your own counsel with respect to the issues discussed in this paper.

remaining in the AID component market but not keeping pace with others' innovations may itself have negative implications for PL risk. For example, plaintiffs bringing PL design defect claims may use "new and improved" products to argue that a "safer alternative design" was available.

Of course, it is impossible to prevent all lawsuits. But it is entirely possible to make one's company a less attractive target to the plaintiffs' attorneys who chiefly drive pharmaceutical and medical device litigation in the United States. A key component in successful litigation risk management is thinking ahead—before litigation is on the horizon.

II. Overview of AID Systems—An Important Advance in Diabetes Technology

A. Modern Innovations in Diabetes and its Limits

Type 1 diabetes (T1D) is an autoimmune disease in which the insulin-producing cells in the pancreas are destroyed by the body's immune system. T1D can be diagnosed at any age; its causes are not fully known; and there is currently no cure. People with T1D must take insulin multiple times a day to survive. Given the shortcomings of current treatment, people with T1D typically spend many hours a day with blood sugar too high or too low, which can result in serious complications and medical emergencies.

Today, patients with T1D use a variety of medical devices to monitor and control their blood glucose levels. Self-monitoring blood glucose monitors allow patients to determine their blood glucose level through a fingerstick. Insulin pumps allow for a continuous basal infusion of insulin to be given in addition to larger bolus doses at mealtimes. A continuous glucose monitor (CGM) can constantly measure the amount of glucose in the interstitial fluid, allowing patients to monitor glucose level trends and patterns. A CGM also can provide alerts and alarms when glucose values deviate from specified levels. Some CGMs are designed to replace fingerstick blood glucose testing for treatment decisions. Most recently available to patients, automated insulin delivery (AID)—also known as artificial pancreas (AP)—systems, which consist of an insulin pump, a CGM, and an algorithm, are designed to automatically adjust delivery of insulin based on the CGM sensor glucose values in order to control glucose to a desired target or range.

Despite advances in diabetes care, there is much room for improvement. Less than a third of adults and only twenty percent children in the U.S. meet recommended glycemic targets as measured by HbA1c. This data comes from the clinic-based T1D Exchange, so it is reasonable to assume that those not seen in the specialty clinics are

doing even worse.[2] In addition, rates of severe hypoglycemia and DKA are unacceptably high.[3,4]

The disease burden of T1D can negatively impact a person's quality of life, including finances and careers.[5] In addition, it can add distress to the lives of their family members and caregivers.[6] More safe and effective innovative tools are needed for people with T1D and their families to reduce complications and mitigate the disease burden.

The extent of unmet need and the benefits of innovative diabetes technology are important when evaluating the risk of PL litigation. Whether a product is "defective" is often judged under a risk/benefit calculus.[7] For example, when an underlying health condition can be portrayed by plaintiffs' lawyers as minor (a cosmetic or "lifestyle" issue), a jury is more likely to believe that treating or managing that health condition should involve little to no risk. When, as here, the health condition is serious, life-threatening, and life-long, a jury may view the benefit of novel treatments to outweigh substantially more risk. Highlighting the life-enhancing and life-saving benefits of innovative medical devices is an important strategy in successfully defending PL litigation.

B. Closed Versus Interoperable Systems

1. Three Components of AID Systems

An AID system consists of three components designed to communicate with each other to automate the process of maintaining blood glucose concentrations at or near a specific target or range, thereby increasing time spent at desirable glucose levels and reducing time spent at high and low glucose levels (among other benefits). The three components are:

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2 Kellee M. Miller et al., *Current State of Type 1 Diabetes Treatment in the U.S.: Updated Data from the T1D Exchange Clinic Registry*, DIABETES CARE 2015 Jun; 38(6): 971–78, *avail. at* http://care.diabetesjournals.org/content/38/6/971.

3 Eda Cengiz et al., *Severe Hypoglycemia and Diabetic Ketoacidosis among Youth with Type 1 Diabetes in the T1D Exchange Clinic Registry*, PEDIATR. DIABETES 2013 Sep; 14(6): 447–54, *avail. at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4100244/.

4 Ruth S. Weinstock et al., *Severe Hypoglycemia and Diabetic Ketoacidosis in Adults with Type 1 Diabetes: Results from the T1D Exchange Clinic Registry*, J. CLIN. ENDOCRIN. & METABOL., Vol. 98, Iss. 8, Aug. 1, 2013, 3411–19, *avail. at* https://academic.oup.com/jcem/article/98/8/3411/2834244.

5 Helena B. Nielsen et al., *Type 1 diabetes, quality of life, occupational status and education level – A comparative population-based study*, DIABETES RES. & CLIN. PRACT. 2016 Nov.; Vol. 121, 62–68, *avail. at* https://doi.org/10.1016/j.diabres.2016.08.021.

6 Martha M. Funnell et al., *The Diabetes Attitudes, Wishes and Needs Second Study*, CLIN. DIABETES 2015 Jan; 33(1): 32–36, *avail. at* https://www.ncbi.nlm.nih.gov/pmc/articles/PMC4299747/.

7 Michael J. Toke, *Restatement (Third) of Torts and Design Defectiveness in American Products Liability Law*, 5 CORNELL J.L. & PUB. POL. 239, 279–83, *avail. at* http://scholarship.law.cornell.edu/cjlpp/vol5/iss2/5.

- Continuous glucose monitor (CGM) – a sensor placed under the patient's skin (subcutaneously), which automatically measures glucose levels in the interstitial fluid to determine the blood glucose levels continuously throughout the day and night.

- Control algorithm – a software program that receives information from the CGM and performs a series of mathematical calculations (based on the CGM data, insulin delivery history, and/or other physiological parameters), the result of which is the optimal amount of insulin to deliver the patient. Following these calculations, the algorithm sends dosing commands to the insulin pump.

- Insulin pump – a device that delivers rapid-acting insulin through a cannula placed under a person's skin. Based on the commands sent by the algorithm, the insulin pump adjusts the insulin delivery to the subcutaneous tissue.

2. Current, Closed AID Systems

The original AID system concept was a single, fixed set of the three components that functions and is regulated as one medical device. The components can only communicate and function with each other as a complete, or "closed," system. Such a closed AID system involves a single manufacturer, or two or more manufacturers with business agreements that address regulatory responsibilities and, almost always, the allocation of litigation liability.

The FDA regulates a closed AID system as a single, Class III device requiring an Investigation Device Exemption (IDE) to perform clinical trials and approval of a Premarket Application (PMA) for marketing authorization.[8]

To date, the FDA has approved two closed AID systems: (1) the Medtronic 670G, a system that monitors glucose and automatically adjusts the delivery of insulin based on the user's glucose reading; and (2) the Tandem Basal-IQ, a predictive low-glucose suspend system that predicts whether glucose levels will fall below a predefined threshold and, in that event, suspends insulin delivery. Several other closed AID systems are in various stages of development or regulatory approval.

3. Interoperable AID Systems

An interoperable AID system is one that consists of medical devices, each separately cleared or approved by the FDA, that function as components of the system through seamless wireless communication. A fully "open," interoperable device is designed to interface with any other device meeting established criteria, freely and without restriction. Because the specificity with which the FDA will mandate design features of interoperable devices is not yet clear, the term "criteria," as used in this paper refers to a

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[8] FDA Final Guidance. The Content of IDE and PMA Applications for Artificial Pancreas Device Systems, *avail. at* https://www.fda.gov/downloads/medicaldevices/deviceregulationandguidance/guidancedocuments/ucm259305.pdf (Oct. 9, 2012).

regulatory requirement or Special Control if applicable. Unless otherwise noted, "interoperable" as used in this paper refers to "open" systems, as these introduce elements of innovation raising unique PL risk potential.

An example of an FDA-cleared interoperable AID system component device is the Dexcom G6 CGM. Via a novel regulatory pathway described more fully in section IV.C, below, the FDA has allowed the Dexcom G6 to be marketed as an integrated continuous glucose monitoring (iCGM) system for determining blood glucose levels in children (aged two and older) and adults with diabetes. It is the first CGM system on the market intended to autonomously communicate with digitally connected devices, including as part of an AID system. The Dexcom G6 can be used alone or in conjunction with these digitally connected medical devices.[9]

The FDA's clearance of the Dexcom G6 through a novel regulatory pathway is a game-changer for medical device companies and people with T1D. This new pathway—explicitly chosen to streamline the regulatory process and foster the development of innovative, safe, and effective interoperable AID system devices—is a significant step toward achieving the "vibrant device ecosystem" that the agency supports. Below we discuss the possible impact of the swiftly evolving technological and regulatory landscape on PL risk and identify issues companies should think through on the front-end before PL litigation develops.

III. A Brief Overview of PL Concepts Applicable to Prescription Medical Devices

The law governing products liability claims is set out in statutes and court decisions in all 50 states, the District of Columbia, and United States territories. PL claims may be asserted, depending on the jurisdiction, under several legal theories, including strict liability for product defects, negligence, breach of warranty, and fraud. Claims typically are brought against manufacturers and distributors, though other actors in the chain of distribution may also face liability.

Below, we briefly discuss common elements, standards, and doctrines that are generally applicable to most PL litigation involving medical devices. In section V, below, we address how these concepts raise issues specific to interoperable component devices of AID systems.

A. Types of Defects

Broadly speaking, there are three types of defects theories asserted in PL claims: design, manufacturing, and marketing (which includes labeling and warnings).[10] A defect in design is inherent, causing every device manufactured to the design specifications to be unreasonably dangerous for its intended use. Plaintiffs will frequently allege, for

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[9] FDA Dexcom G6 CGM Decision Letter, *avail. at* https://www.accessdata.fda.gov/cdrh_docs/pdf17/DEN170088.pdf (Mar. 27, 2018). Unless otherwise noted, subsequent references to the FDA's action with respect to the Dexcom G6 CGM are taken from this document.

[10] *E.g.*, RESTATEMENT (THIRD) OF TORTS: PRODUCTS LIABILITY § 2 (1998) ("RESTATEMENT (THIRD): PL").

example, that a manufacturer's choice of materials is inappropriate for the product's expected use, or that the product lacks sufficiently robust safety features, or that certain characteristics of the product make it prone to user error and injury. In many states, plaintiffs must show that the product's risk could have been reduced or avoided through a reasonable alternative design.[11] In some states, certain risks inherent in a product's design cannot be cured through warnings; rather, if there is a feasible design that eliminates or minimizes the risk, the manufacturer must use it.[12]

In contrast, a manufacturing defect occurs during the production of the product through unintended deviations from the product's intended design. In medical device PL cases, plaintiffs often claim that the manufacturing processes did not comply with design specifications or the FDA's current good manufacturing practices, or that the product's materials were adulterated in some way.[13] Sometimes the distinction between manufacturing and design can be subtle. For example, a condition caused by a manufacturing process may be deemed a *design* defect if evidence shows that the choice to use the process (for all devices) caused the condition at issue instead of an unintended deviation that affected only a subset of devices.[14]

Finally, medical device marketing claims are based on the manufacturer's putative failure to provide adequate instructions and warnings concerning the device, or on allegedly misleading or inaccurate promotion of the device to physicians or patients, including, for example, through sales representatives. Plaintiffs commonly allege that the product's warnings fail to describe dangers to specific patient populations, or the product's instructions for use are inadequate to convey how to use the product, or the product's label otherwise fails to describe the product's limitations or the magnitude and frequency of potential adverse events.

B. Key Legal Doctrines and Defenses in Prescription Medical Device Cases

1. Learned Intermediary Doctrine

Under the learned intermediary doctrine (LID), the maker of a prescription medical device generally does not have to provide warnings directly to patients. Rather, it must provide adequate instructions and warnings to prescribing physicians, through the device's "labeling." It is then up to physicians to determine what warnings and instructions

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[11] *E.g.*, *Gomez v. St. Jude Med. Diag. Div. Inc.*, 442 F.3d 919, 930 (5th Cir. 2006) (Louisiana law).

[12] *E.g.*, *Uniroyal Goodrich Tire Co. v. Martinez*, 977 S.W.2d 328, 334, 336–37 (Tex. 1998) (holding that an adequate warning about the risk of injury associated with a size mismatch between a tire and the tire rim did not defeat the plaintiff's claim that the tire maker should have adopted an available, safer alternative design that would prevent mismatches).

[13] *E.g.*, *Bass v. Stryker Corp.*, 669 F.3d 501, 509–10 (5th Cir. 2012) (describing allegations of adulteration and violations of FDA quality regulations).

[14] *E.g.*, *Johannsen v. Zimmer, Inc.*, No. 3:00CV2270 (DJS), 2005 WL 756509, at *5 (D. Conn. Mar. 31, 2005) (holding that the choice of a manufacturing process is "not evidence of a manufacturing defect; rather, it is possible evidence of a design defect.").

are suitable for particular patients.[15] The LID provides a powerful causation defense to device-makers in some circumstances. For example, a physician's independent knowledge of the device's proper use and risks may breach the causal chain between allegedly inadequate instructions for use and the patient's adverse outcome.[16]

Though a large majority of states has adopted the LID, there are recognized exceptions. Some courts have limited or refused to apply the LID to prescription medical devices—like those used in an interoperable AID system—when the device is primarily operated by patients outside a medical setting. Some courts have recognized other exceptions to the LID; *e.g.*, when the manufacturer markets a medical product directly to consumers,[17] or when the court deems that the patient plays a significant role in choosing the product,[18] or when the "prescription" occurs in a setting with insufficient physician oversight.[19] The possible impact of these decisions in evaluating PL risk for interoperable component devices in AID systems is discussed in section 19V.C, below.

The nature of the doctor-patient relationship in the context of interoperable AID systems may lead plaintiffs to argue for an exception to the LID on similar grounds. For example, some AID system users may have as much, or more, knowledge about innovative AID components and their effects on the user's health than their physician. These users actively participate in decision-making about component selection, device settings, and other treatment options. Finally, as it is expected that patient choice will be an important driver of interoperable AID component sales, some products may be advertised directly to the public.

2. Foreseeable Misuse / Product Alteration

Generally, a product manufacturer is not strictly liable for injuries caused by its product unless the product "is expected to and does reach the user or consumer without substantial change in the condition in which it is sold."[20] But PL laws in some states allow manufacturers to be held liable for injuries caused by a product even when a consumer

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[15] In the context of prescription medical devices, warnings issues implicate the FDA's regulatory requirements for "labeling," a term that includes all written warnings and instructions as well as virtually any other written material accompanying a medical device under the Food, Drug, and Cosmetic Act. *See* 21. U.S.C. § 210(k).

[16] *E.g.*, *Small v. Amgen, Inc.*, 134 F. Supp. 3d 1358, 1367 (M.D. Fla. 2015), *aff'd*, 723 F. App'x 722 (11th Cir. 2018) ("[T]the failure of the manufacturer to provide the physician with an adequate warning is not the proximate cause of a patient's injury if the prescribing physician had independent knowledge of the risk that an adequate warning should have communicated." (citations omitted)).

[17] *E.g.*, *Centocor, Inc. v. Hamilton*, 310 S.W.3d 476, 506–08 (Tex. App. 2010); *Perez v Wyeth Labs.*, 734 A.2d 1245 (N.J. 1999).

[18] For example, the LID has been held not to apply to certain contraceptives because patients actively participate in contraceptive decision-making. *E.g.*, *Odgers v Ortho Pharm. Corp.*, 609 F. Supp. 867, 878 (E.D. Mich. 1985).

[19] For example, some courts hold that the LID does not apply to mass immunization programs due to the lack of physician-patient contact. *E.g.*, *Petty v United States*, 740 F.2d 1428, 1440 (8th Cir. 1984).

[20] RESTATEMENT (SECOND) OF TORTS § 402A.

fails to use the product as intended, so long as the consumer shows that the misuse was reasonably foreseeable—that is, the manufacturer knew or should have known of the misuse when it sold the product, and the resulting risks from the misuse rendered the product defective.[21] Further, in some jurisdictions, a manufacturer may be held liable for misuse that was not known when the product was sold but became known (or should have been known) at some point between the time of sale and the alleged injury.[22]

Given the technological prowess of some AID users and the active DIY community, plaintiffs may argue that manufacturers of interoperable AID system components should foresee that consumers will modify their devices in unauthorized ways, as occurred with some older, non-interoperable AP devices. But it is also likely that increased patient choice from newly interoperable AID components will reduce the demand for DIY modifications, resulting in improved treatment outcomes and patient safety. As well, current state-of-the-art protocols and encryption will help interoperable AID systems to be fundamentally more secure—and resistant to misuse—than older combinations of non-interoperable devices.

3. State of the Art

Depending on state law, proof that a product conformed to the state of the art when manufactured may provide an absolute defense,[23] a rebuttable presumption of non-defectiveness,[24] or admissible evidence of non-negligence or the lack of a feasible safer alternative.[25] State-of-the-art arguments are typically supported by showing that the product conformed with industry standards and applicable regulatory design standards.

4. Comparative Fault and Liability Allocation

There can be more than one cause of an injury, and virtually all states allow some form of liability allocation. In the context of prescription products, for example, a jury might apportion some percentage of responsibility for the plaintiff's injury to a defect in the device, some to the malpractice of the physician, and some to the plaintiff's own failure to comply with instructions.

Liability allocation may include apportioning fault among multiple device manufacturers in the same case—a scenario particularly relevant in the context of interoperable AID system components made by different companies. Many states used to apply "joint and several" liability, whereby a defendant assigned even a very low percentage of fault could be forced to pay the entire judgment to the plaintiff and then try

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21 *E.g.*, *Liriano v. Hobart Corp.*, 700 N.E.2d 303, 307 (N.Y. Ct. App. 1998).

22 *E.g.*, *id*. ("Such a duty will generally arise where a defect or danger is revealed by user operation and brought to the attention of the manufacturer …").

23 *E.g.*, NEB. REV. STAT. § 25-21,182 (Nebraska).

24 *E.g.*, IND. CODE § 34-20-5-1(1) (Indiana).

25 *E.g.*, S.D. CODIFIED LAWS § 20-9-10.1 (South Dakota); *Bernier v. Raymark Indus., Inc*., 516 A.2d 534, 540 (Me. 1986).

to recover from liable codefendants based on their percentage allocation. But most have abrogated in whole or in part this harsh rule.[26] As discussed below, advances in creating a secure audit trail—a "black box" recording of exactly what happened—is one way in which technological innovation can ameliorate PL litigation risk.

IV. FDA Regulation of Medical Devices and the Doctrine of Federal Preemption

A. Statutory and Regulatory Classification of Devices

1. The FDA's Mandate

The FDA is responsible for protecting public health by assuring the safety, effectiveness, and security of drugs and medical devices, as well as a host of other products such as veterinary drugs, biological products, foods, cosmetics, and products that emit radiation. The agency's mandate is not just to prevent unsafe medical products from reaching or staying on the market; it is also charged with promoting the public health by facilitating innovations that make medical products safer, more effective, and more affordable.

The federal Food, Drug, and Cosmetic Act (FDCA) contains a detailed definition of "device."[27] For our purposes, a device may be defined as almost any healthcare product that fulfills its intended purpose by physical or mechanical means, rather than through chemical or metabolic activity. The breadth of products that meet the definition of a device is tremendous, ranging from simple tongue depressors, bandages, and gauze to complex implantable cardiac defibrillators, intraocular implants, and DNA probes. Device components and accessories are also devices regulated by the FDA.

The FDA assures that medical devices are safe and effective under the authority granted by the FDCA and in accordance with the implementing regulations found principally in Title 21 of the Code of Federal Regulations ("CFR"), Parts 800 through 1299. Medical devices are regulated by the agency through a classification system. The FDA's approach to assuring safety and effectiveness depends upon the class of the device and varies with the agency's level of concern regarding the adequacy of the available regulatory controls to provide this assurance.

2. Classification of Medical Devices and the Difference Between PMA Approval and 510(k) Clearance

Under the FDCA, devices are categorized as Class I, Class II, or Class III. Class I devices are simple products that usually present minimal potential for harm to the user. These devices are subject to "general controls"—a set of FDA regulations applicable to virtually all devices. General controls include labeling requirements, provisions against

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[26] *E.g.*, Michigan Compiled Laws § 600.2956 (limiting a defendant's liability to its percentage of fault, with certain exceptions); New Mexico Statutes Ann. § 41-3A-1(A) (same); Wisconsin Statutes § 895.045 (abolishing joint and several liability with respect to defendants assigned less than 51 percent of fault).

[27] 21 U.S.C. § 201(h).

adulteration and misbranding, good manufacturing practices ("GMPs"), establishment registration, medical device listing, and medical device reporting. General controls also include premarket notification, or what is commonly referred to as "510(k)" clearance. Since 1997, however, most Class I devices have been exempted from 510(k) requirements.

a. Class II Devices and 510(k) Clearance

In general, Class II devices present more risk than Class I devices, but their safety and effectiveness can be assured through a combination of the general controls and additional "special controls" designed to mitigate device-specific risks. Special controls can include a wide range of requirements such as specific labeling requirements, mandatory performance standards, post-market surveillance, patient registries, guidelines (such as for providing clinical data in 510(k) submissions), or scientific or procedural recommendations. In practice, however, most Class II devices are not subject to these types of special controls because the FDA has not had the resources to create them for many Class II devices.

Under Section 510(k), a Class II device may be marketed if the manufacturer demonstrates that it is substantially equivalent to a predicate device.[28] Often 510(k) devices are cleared within 90 to 180 days of the submission. A Class II device is "cleared" under 510(k), in contrast to Class III devices that are "approved" through the PMA process (see below). In fact, a regulation specifically forbids manufacturers from referring to their 510(k) devices as approved by the FDA.[29] The disparate regulatory treatment of Class II and Class III devices has important legal ramifications, as discussed in subsection B.3, below.

b. Premarket Approval of Class III Devices

Under the FDCA, Class III devices support or sustain human life, are of substantial importance in preventing impairment of human health or present a potential unreasonable risk of illness or injury to patients. They are subject to the highest levels of FDA's regulation, including not just general and special controls, but a rigorous, "device-by-device" review to determine safety and effectiveness. This process is known as premarket approval ("PMA").

In contrast to the relatively speedy 510(k) review, it is not unusual for the PMA process to take 2 to 3 years to complete.

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[28] 21 U.S.C. § 360c(i)(1)(A)(ii).

[29] 21 C.F.R. § 807.97; *see also Medtronic, Inc. v. Lohr*, 518 U.S. 470, 492 (1996) (referencing FDA letter clearing 510(k) device warning manufacturer it did not "denote official FDA approval of your device" and that any "representation that creates an impression of official approval of this device because of compliance with the premarket notification regulations is misleading and constitutes misbranding." (internal quotation marks omitted)).

3. "De Novo" Submissions

A device that would otherwise be classified as Class III may be submitted for regulatory review pursuant to a De Novo request.[30] This is a type of premarket submission seeking to classify the new device as Class I or Class II. In 2012, Congress amended the FDCA to permit direct De Novo requests; previously a request could be submitted only after receiving a "not substantially equivalent" rejection of a 510(k) application. The De Novo option offers a more streamlined regulatory pathway (compared to PMA review) in which the FDA is to reach a decision within 120 days. If granted, the FDA will create a new classification regulation for the new device type. The new device may then be used as the predicate device for 510(k) "substantial equivalence" submissions.

A De Novo request for Class II classification, if granted, results in special controls applicable to the newly classified type of device. As discussed in subsection B.3, below, these special controls implicate the potentially powerful defense of federal preemption and may impact PL litigation in other ways.

B. Overview of Federal Preemption

1. The Concept

The Supremacy Clause of the United States Constitution makes federal law "the supreme Law of the Land[.]" It "was at the core of the Framers' effort to provide a national government with the powers needed to govern the new Republic effectively."[31] By virtue of this constitutional precept, states cannot enforce their own laws if they directly conflict with federal law. "State law" in this context can include both statutes and regulations, as well as state common law developed by courts and "enforced" through jury verdicts, such as a duty to warn about potential adverse events associated with a medical device.[32] "Federal law" in this context includes regulations promulgated pursuant to a federal statute.

To illustrate: Suppose a state's products liability law permits a jury to find a company liable for failing to warn about the risk of a specific adverse event associated with a medical product. But the FDA has taken actions clearly demonstrating its view that there is insufficient scientific evidence to permit such a warning under the applicable federal standard. The company may assert federal preemption to defeat the state law failure-to-warn claim because the company could not simultaneously comply with state law (give the warning) and federal law (don't give the warning).[33] If sufficient evidence is

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[30] FDA De Novo Classification Process (Evaluation of Automatic Class III Designation), *avail. at* https://www.fda.gov/downloads/Training/CDRHLearn/UCM585955.pdf.

[31] U.S. CONST. Art. IV, § 2; *Dolin v. GlaxoSmithKline*, 901 F.3d 803, 811 (7th Cir. 2018).

[32] *Riegel v. Medtronic, Inc.*, 552 U.S. 312, 324 (2008).

[33] *E.g. Dolin*, 901 F.3d at *813–14 (holding that where there was clear evidence of the FDA's repeated rejection of a warning that SSRI prescription antidepressants were associated with an increased risk of non-pediatric suicidality, widow's state law claim based on GSK's failure to include such a warning in

available to establish the conflict at the pretrial stage, the defendant may be able to obtain early dismissal before incurring the expense of working up and trying the case to a jury.

2. Express Versus Implied Preemption

The two types of preemption relevant here are express statutory preemption and implied conflict preemption. In the former, Congress explicitly states its intent to preempt conflicting state law in the text of a federal statute. In the latter, Congress does not include an express preemption clause, but courts nevertheless find implied preemption because complying with state law would violate, or thwart the purposes and objectives of, the statute or its associated regulations. For example, in the case cited at footnote 33, above, the court's ruling was based on implied conflict preemption because the Food, Drug, and Cosmetic Act (FDCA) does not include an express preemption clause applicable to prescription drugs.

3. Express Preemption Under the FDCA

Congress did include an express preemption clause in the FDCA for medical devices. It preempts any state law "requirement" that is "different from, or in addition to, any requirement" under the statute, and that "relates to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under this chapter."[34] The United States Supreme Court has interpreted "requirement" as used in this clause somewhat narrowly. Under its decisions, the general rule is that PMA devices are subject to "requirements" for purposes of express preemption under the FDCA, but 510(k) devices are not.[35]

The reasoning behind this distinction—which, as discussed below, is key to analyzing a potential preemption defense for interoperable AID devices—turns on the degree of control exercised by the FDA. The PMA approval process results in detailed, device-specific requirements governing virtually all aspects of design, manufacture, and labeling. Once a device receives PMA approval, the FDCA and its implementing regulations generally forbid the manufacturer from deviating from these requirements without the prior permission of the FDA.[36] Given these constraints, a state-law claim premised on a failure to design, manufacture, or label a device in a way that differs from its PMA requirements necessarily conflicts with federal law and is preempted. For example, the Supreme Court in *Riegel* affirmed dismissal of claims based on the putative negligence of the device company in designing, manufacturing, and labeling a PMA-

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the label of its SSRI drug Paxil—a failure she asserted caused her husband's suicide—was preempted by federal law).

[34] *Id.* at § 360k(a).

[35] *See Lohr*, 518 U.S. 470; *Riegel*, 552 U.S. 312.

[36] *Riegel*, 552 U.S. at 317-320.

approved and -compliant balloon catheter that ruptured during coronary angioplasty surgery.[37]

In contrast, the Supreme Court has held that clearance under the 510(k) "substantial equivalence" review does not impose sufficiently device-specific requirements to trigger express preemption under the FDCA. It described the 510(k) process as "focused on equivalence, not safety."[38] Clearance under 510(k) often imposes only "general controls," which are not device-specific, and does not require the device "to take any particular form for any particular reason[.]"[39] The maker of a 510(k) device has greater latitude to change aspects of its design, manufacture, and labeling without prior FDA permission. To the extent the company may change how the device is made or labeled without prior FDA permission (*e.g.,* to include new warnings or substitute a different type or grade of material), state law claims premised on its failure to do so are not preempted.

Finally, keep in mind two important caveats. First, express preemption for PMA devices is a powerful defense, but it is subject to a significant exception—so-called "parallel claims." Because the FDCA preempts only state-law requirements that are "different from, or in addition to" federal law, a claim that is both cognizable under state law ***and*** involves violation of a PMA requirement is not preempted.[40] To illustrate: Suppose the plaintiff claims that the device company used a grade of plastic that did not meet specifications for a key component, which broke during normal use and led to her injury. That is a straightforward manufacturing-defect claim cognizable under state tort law. It may also be a non-preempted parallel claim if the PMA approval for the device set the materials specifications that the company allegedly failed to meet.[41]

Second, makers of 510(k) devices are not automatically precluded from asserting a preemption defense in all cases. First, implied conflict preemption—which may arise whenever a plaintiff claims a device company should have done something it could not do under FDA requirements—is a potential defense for any type of medical device. Second, while the Supreme Court has held that 510(k) devices generally are not subject to device-specific "requirements" with preemptive effect under FDCA § 360a(k), the FDA is empowered to impose device-specific requirements on 510(k) devices—or even Class I devices. In some cases, these requirements, like the requirements imposed by PMA

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37 *Id.* at 320–21, 331.

38 *Lohr*, 518 U.S. at 493 (internal quotations and citation omitted).

39 *Id.*

40 *Riegel*, 552 U.S. at 330 ("§ 360k does not prevent a State from providing a damages remedy for claims premised on a violation of FDA regulations; the state duties in such a case 'parallel,' rather than add to, federal requirements." (citing *Lohr*, 518 U.S. at 495)).

41 *See*, *e.g.*, *Waltenburg v. St. Jude Med., Inc.*, 33 F. Supp. 3d 818, 833 (W.D. Ky. 2014) (finding that plaintiffs adequately pled a parallel claim that escaped express preemption where they alleged that the leads in a Class III cardiac defibrillator were defectively manufactured in various ways that also deviated from their PMA approval).

approval, may give rise to a viable express preemption defense.[42] These issues warrant close attention by manufacturers of interoperable AID system components given the FDA's recent clearance of an interoperable CGM and insulin pump under the De Novo regulatory process.[43]

C. Preemption and Potential Litigation Impact of the FDA's Innovative Grant of De Novo Request to Market Dexcom G6® CGM System

On March 27, 2018, the FDA granted a De Novo request by Dexcom, Inc. with respect to its G6 Continuous Glucose Monitoring System.[44] It identified the device (and future substantially equivalent devices) as an integrated continuous glucose monitoring system "(iCGM") that can "autonomously communicate with digitally connected devices, including automated insulin dosing (AID) systems," and may be used alone or in conjunction with such systems.

The FDA's De Novo classification of iCGMs reflects the agency's analysis of the risks of these devices and ways to mitigate those risks. In a new regulation specific to iCGMs, the FDA has imposed seven special controls (some with multiple subparts) with which the devices must comply.[45] It identified five "Identified Risks to Health," and specified which of the seven special controls would mitigate each. The special controls address myriad aspects of the devices' design, manufacture, testing, and labeling, including design verification and validation through clinical data, the necessity of "appropriate measures to ensure that disposable sensors cannot be used beyond its claimed sensor wear," and contents of labeling vis-à-vis sensor performance data observed in the required clinical studies. The FDA's letter to Dexcom permits the company to market the device only "subject to the general control provisions of the FD&C Act ***and the special controls identified in this order***." Any company marketing a non-compliant device faces a risk of being found in violation of federal law.

How then does this De Novo regulatory pathway fit within the Supreme Court's express preemption framework for medical devices? It is not as rigorous and time-consuming as PMA review—by design. The FDA expressly intends for the De Novo process to streamline and shorten the regulatory pathway to market for interoperable AID devices like the Dexcom iCGM.[46] Thus, the De Novo process does not result in the same

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[42] *E.g.*, *Busch v. Ansell Perry, Inc.*, No. Civ. A. 3:01CV126H, 2005 WL 877805, at *2 (W.D. Ky. Mar. 8, 2005) (observing that "premarket approval of a device is not the only way for the FDA to impose a "requirement," and holding that failure-to-warn claim involving Class I latex gloves was preempted because the FDA "requires a specific warning with respect to a specific group of devices to which Defendant's gloves belong.")

[43] FDA Dexcom G6 CGM Decision Letter, *supra* note 9; FDA t:Slim X2 Insulin Pump Decision Letter, *avail. at* https://www.accessdata.fda.gov/cdrh_docs/pdf18/DEN180058.pdf.

[44] FDA Dexcom G6 CGM Decision Letter, *supra* note 9.

[45] 21 C.F.R. § 862.1355 (2018).

[46] FDA News Release (Mar. 27, 2018), *avail. at* https://www.fda.gov/newsevents/newsroom/pressannouncements/ucm602870.htm ("Today's authorization [for the Dexcom G6 iCGM] … classifies this new type of device in Class II and subjects it to certain criteria called special controls. This enables

comprehensive, device-specific PMA requirements for Class III devices that the Supreme Court has determined expressly preempt additional or different state law requirements under FDCA § 360a(k).[47] On the other hand, the special controls adopted by the FDA for Class II iCGMs pursuant to the De Novo process do impose requirements that govern aspects of design, manufacturing, and labeling, and that on their face pertain to safety and effectiveness. Thus, the Dexcom device and future iCGMs subject to the same special controls do have to meet requirements applicable specifically to them—unlike the majority of Class II devices that the Supreme Court has determined do not benefit from express preemption under FDCA § 360a(k).[48]

Of course, we don't yet know how courts will decide these issues. The point here is that the innovative regulatory pathway the FDA has opened for iCGMs and insulin pumps—and may in future open for other devices comprising AID systems—may have potentially significant implications for PL risk and the defenses available to manufacturers. First, the De Novo special controls may be held to have express preemptive effect. Courts already have grappled with the impact of special controls imposed in different contexts, and most at least acknowledge that they may give rise to an express preemption defense.[49] Second, even if express preemption does not apply, implied preemption might. A state tort law claim that effectively would require a device manufacturer to do something contrary to applicable special controls arguably is impliedly preempted and barred.

Finally, not only does De Novo classification implicate preemption; the FDA's analysis of the safety and effectiveness of the devices, as reflected in the special controls, may aid device companies facing litigation in other ways. For example, some courts—echoing the Supreme Court's characterization of 510(k) review as not focused on safety—have refused to permit the jury to hear that a 510(k) device was subject to any review by the FDA.[50] This can leave jurors with the mistaken impression that even a complex device that must be implanted by a surgeon was not regulated at all, and should have had no more risk than an over-the-counter product available at a drugstore. The FDA's plain

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developers of future iCGM systems to bring their products to market in the least burdensome manner possible.")

47 *Riegel*, 552 U.S. 312.

48 *Lohr*, 518 U.S. at 500–01.

49 *E.g.*, *Busch*, 2005 WL 877805, at *2; *see also In re: Bard IVC Filters Prods. Liab. Litig.*, No. MDL 15-92641-PHX DGC, 2017 WL 5625547, at *8 (D. Ariz. Nov. 22, 2017) (observing that *Lohr* does not hold "510(k) clearance can never result in preemption," but holding that an FDA draft guidance document specific to the type of device at issue was insufficiently specific to constitute a "requirement" under § 360k of the FDCA); *James v. Diva Int'l, Inc.*, 803 F. Supp. 2d 945, 952 (S.D. Ind. 2011) ("Ultimately, because Defendant has failed to identify any special controls**,** performance standards, post-market surveillance, or guidelines to date, that are applicable to this *particular device*, Defendant's preemption argument fails." (emphasis in original)); *Oliver v. Johnson & Johnson, Inc.*, 863 F. Supp. 251, 253–54 (W.D. Pa. 1994) (rejecting preemption defense under same reasoning as *James*).

50 *E.g.*, *In re C.R. Bard, Inc., MDL No. 2187, Pelvic Repair System Prods. Liab. Litig.*, 810 F.3d 913, 921 (4th Cir. 2016) ("While some courts have found evidence of compliance with the 510(k) equivalence procedure admissible in product liability cases, the clear weight of persuasive and controlling authority favors a finding that the 50(k) procedure is of little or no evidentiary value.").

attention to safety issues with respect to iCGMs—we would argue—provides a viable argument with which to refute this reasoning as to those devices.

V. Products Liability Considerations and Strategies for Manufacturers of AID Systems and Components

This section addresses the risks and benefits of innovative interoperable AID system devices that impact PL risk, and the issues that manufacturers should consider and analyze with counsel as part of their risk mitigation plans.

A. Benefits of Interoperability Relevant to PL Risk

Products liability defense lawyers naturally focus on the risks posed by medical products that may lead to personal injury litigation. But risk is only half of the equation. Particularly in the context of medical products, it is critical to remember the countervailing consideration of benefit. Benefit is directly relevant to design-defect claims under state laws that direct the jury to evaluate the risk/benefit profile of a product. Some states explicitly require the plaintiff to prove that a safer alternative design exists that does not significantly decrease the product's benefits or drive the price so high as to make the product economically infeasible.[51]

Even when the product's benefits do not directly bear on an element of the plaintiff's cause of action, a good benefit "story" colors the entire case. All medical products involve some degree of risk. Educating the judge and jury about the ways a medical device improves lives and leads to better health outcomes helps put an individual plaintiff's alleged adverse event into the proper perspective.

Interoperable AID systems may provide real, significant, benefits to the T1D community—over and above the benefits of automated, closed systems. Indeed, the FDA has indicated that greater interoperability among AID system components will likely benefit patients. Available data suggests that there is a significant unmet need for better diabetes management,[52] and anecdotally we know that some patients prefer the ability to choose and customize (with the aid of their doctors) devices that best suit individual needs. Providing greater flexibility and a range of options to patients who must daily contend with managing their disease is a benefit unto itself, and furthermore promotes at least two significant goals with both private and public health implications. First, a system of interoperable AID components customized to a patient's needs and preferences may increase patient compliance and the better health outcomes that flow from it. Second, increased flexibility and more choice may also lead more patients to adopt an AID system for the first time, and thereby benefit from the improved management that automation provides; *e.g.*, lower A1c, less DKA, increased time in range, less hypo- and

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51 *E.g.*, *Bullock v. Volkswagen Grp. of Am., Inc.*, 107 F. Supp. 3d 1305, 1315 (M.D. Ga. 2015) (finding there was sufficient evidence to support jury's finding that a safer, economically feasible alternative design existed).

52 Miller et al., *supra* note 2; Cengiz et al., *supra* note 3; Weinstock et al., *supra* note 4.

hyperglycemia, fewer severe hypoglycemic events, and better quality of life, to name a few.

Finally, innovation in developing interoperable devices for AID systems likely will improve transparency in component functionality and accountability—including minimizing the chance that an AID-component device company bears the cost for the failure of another company's defective component device. A secure audit trail also could be a valuable source of data for device makers, patients, and even public health officials, although privacy and intellectual property issues would need to be addressed.

B. Evidence as to Design Issues Specific to Interoperable AID System Components will also be Presented at Trial

1. Design Challenges/Strategies—Interoperability

From a manufacturer's perspective, the greatest difference between current, closed AID systems and new, interoperable AID systems may be the challenge of designing and manufacturing components that perform within their specifications and that meet applicable criteria (as that term was previously defined), while not being designed and manufactured to be part of a specific system. Moving from closed to interoperable is more than a simple line-drawing exercise to separate components. Each new component must provide reliable, baseline functionality in concert with—and independently of—components from other manufacturers. Design questions in PL litigation will likely focus on the specific ways in which these components interoperate and the degree to which certain components "control" the functionality of the system as a whole.

a. Potential for Inter-Device and Human Factors Conflicts

Verifications and validations of interoperability, for example, are common in multi-component PL fault analyses. But by design, interoperable AID components will most likely be tested for compliance only with applicable criteria, but not necessarily with all or even most devices with which they will be used. Criteria allowing for variations that could result in incompatibilities or adverse functionality between disparate components increase potential PL risk. And if any device is capable of performing functions beyond its core AID specifications, those functions must not interfere with the reliability and safety of the component or overall system. Manufacturers may wish to consider advance due diligence of other companies' compliance with standards and broad compatibility testing with other companies' interoperable components. Potential problems identified could then be resolved before someone claims an injury.

Interoperability also inherently raises questions of fault allocation among manufacturers. Plaintiffs have an incentive to implicate as many manufacturers as possible by, for example, having their experts opine that there were multiple overlapping causes of an adverse event. This reinforces the importance of designing devices to create and preserve comprehensive logs of all communications, user inputs, conditions, operations, and device states. In a complex, multi-device adverse event, this "black box" data may be the only objective evidence available to defend the product. The data can

also be valuable when litigating failure-to-warn claims related to human factors issues (user errors such as incorrect inputs or button presses). Data showing good compliance with instructions and warnings in the past can be a compelling defense against allegations that a user was later confused and inadequately warned.

Interoperability also implicates human factors issues because of the potential for conflicting status or error messages or inconsistent feedback regarding user inputs among multiple components. From a PL litigation perspective, it would be helpful to establish and follow standardized models for device-to-user communications and critical user-interface elements (*e.g.*, alerts, warning icons), to help reduce the potential for inter-device conflict or confusion. While each manufacturer may strive to differentiate its products in the competitive field, conforming to the "state of the art" provides advantages in PL litigation for the reasons discussed above.

b. Communications and Security

Interoperability necessarily will require robust design specifications not only to ensure reliable operation through each component's lifetime, but also to prevent unauthorized alteration or use with non-compatible components. Software update functionality must be designed so that urgent patches are timely applied but do not adversely impact functionality or interoperability. This requires consideration of functional variability within the tolerances of the operational standard, as mentioned above. And though cybersecurity risks exist in all networked devices,[53] the nature of interoperable AID components may present special risks, most notably in the inter-device communications that affect dosing operations. Notwithstanding the openness of the communication protocols, the devices should be designed with state-of-the-art protections against interference or hacking for malicious purposes such as data theft or ransom. Strict adherence to industry standard, state-of-the-art protocols is expected to make open, interoperable AID systems as secure as closed systems, and almost certainly will make them more secure than the older, non-interoperable AP devices that some patients are using to create do-it-yourself "interoperability."

c. Risk Management

As interoperable AID innovation creates unique engineering challenges, it may also raise issues with traditional risk-management tools, such as contractual indemnity and liability insurance. In closed systems, risk among manufacturers could be managed through agreements or insurance with clear knowledge of the components at issue and the relative risk profiles of each. But manufacturers and insurers of interoperable AID systems, i.e., systems that are designed to be fully interoperable with any other device that meets applicable criteria, will not have those partnerships or that certainty. Risk management for disparate interoperable products will require a different actuarial analysis.

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[53] These risks also exist in some non-networked devices, including the modified components in DIY AP systems.

2. Challenges/Strategies—Electronic Transmission and Data Storage

Interoperable AID systems will share many of the data security, privacy, and communications challenges present in current, closed AID systems. Data must be secured as it is stored in and communicated between components. Components must fall back to an appropriate baseline of functionality when inter-device communications fail or degrade below performance specifications.

But interoperability raises some unique questions regarding the ownership of data and the reporting of adverse events or security breaches. First, in PL litigation, manufacturers typically must preserve and produce relevant data in their "possession, custody, or control" in response to discovery requests. With closed AID systems, manufacturers will address data-related functions—such as collection, storage, summarization, and archiving—in advance, establishing the control and "ownership" of system data as part of the product's design. But an interoperable AID system component will exchange data with any device that is approved or cleared by the FDA and that meets relevant established criteria. Manufacturers must determine how data received from interoperable components is managed within their devices and, if applicable, in remote, interconnected systems. This analysis should include an assessment of litigation discovery obligations, specifically focusing on the extent to which the data may be deemed to be within the manufacturer's possession, custody, or control.

Second, interoperability raises reporting issues that Plaintiffs may use to their advantage in PL litigation. While the scope of regulatory reporting obligations is beyond the scope of this paper, it is common for PL plaintiffs to argue that a product manufacturer failed to comply with its regulatory obligation to report adverse events, cybersecurity breaches, or similar types of events. Interoperability raises unique issues in this regard. For example, one component of an interoperable AID system may receive data or input from another component that is outside of specifications, potentially suggesting a malfunction or security breach. Manufacturers must determine the extent to which situations like this may give rise to reporting obligations, because failing to comply with such obligations not only may result in regulatory action but may give ammunition to plaintiffs in PL litigation.

C. Labeling (*i.e.*, Warnings) Issues Specific to Interoperable Devices

Most PL lawsuits focus primarily or exclusively on a putative failure to warn, or warn adequately, about an adverse event the plaintiff claims to have experienced. Establishing a design or manufacturing defect with respect to a complex medical device generally requires costly analysis by an expert with sufficient qualifications and technical know-how. By comparison, it is relatively simple to assert that a warning was not "strong enough," or should have included more specific information pertinent to the circumstances of the plaintiff's alleged injury.

For this reason, warnings issues always merit an in-depth review by medical device manufacturers. That is especially true in the context of innovative products with

which physicians and patients may not be familiar. Each design aspect unique to interoperability should be analyzed from the perspective of warnings and instructions. Following are some labeling issues to consider specifically in the context of potential PL litigation involving component devices of interoperable AID systems.

1. The Role of the Learned Intermediary

Most states apply the learned intermediary doctrine which requires a prescription device manufacturer to deliver adequate warning and instruction only to physicians, not patients.[54] The devices at issue, however, like many other prescription medical devices, are only available by prescription yet are operated primarily by patients outside a clinical setting and are accompanied by extensive patient-directed instructions and warnings. Some courts have weakened or declined to apply the learned intermediary doctrine in such circumstances.[55] Others have applied the doctrine, but permitted claims based on the failure to provide adequate operating instructions to patients for home use.[56] In this context, manufacturers may help to persuade a court not to abrogate the learned intermediary doctrine by employing patient-directed warnings emphasizing the importance of working with the prescribing physician to choose and monitor the component devices of an interoperable AID system, and frequently directing patients to consult their physicians with questions or concerns, or in the event problems arise.

In any event, manufacturers should assume that their warnings to physicians and patients will be scrutinized for adequacy in the context of PL litigation, and they should strive to create complementary set of warnings tailored to each audience. Even in an environment characterized by robust patient involvement in treatment decisions involving medical devices primarily operated by the patient, the physician's role must be factored into labeling decisions. In evaluating how best to instruct and warn prescribing physicians in the context of interoperable component devices, some of the considerations include:

Physician Education and Training. Most states do not impose on prescription device manufacturers a duty to train physicians—at least with respect to matters that should fall within the expertise they are presumed to possess already. Going beyond providing adequate written warnings and instructions in device labeling may subject a manufacturer to claims that it "undertook" a duty to train physicians.[57]

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[54] As currently contemplated by the FDA, all component devices making up an interoperable AID system would be either Class II or Class III devices under the FDCA and its implementing regulations.

[55] *See*, *e.g., Bigler-Engler v. Breg, Inc.*, 209 Cal. Rptr. 3d 619 (Cal. App. 4th Dist. 2016) (finding the learned intermediary doctrine inapplicable to a prescription cold therapy device operated by patient outside a medical environment).

[56] *See Friedl v. Airsource, Inc.*, 323 Ill. App. 3d 1039 (2001) (holding that the manufacturer of a prescription portable hyperbaric oxygen chamber could be liable for providing "Incomplete operating instructions, resulting in injuries unrelated to whether the device was properly prescribed").

[57] *See, e.g., Scott v. C.R. Bard, Inc.*, 231 Cal. App. 4th 763, 774 (2014) (holding that a device manufacturer had no duty to train physicians in the use of its devices but could be liable for failing to exercise due care having undertaken to do so).

On the other hand, as interoperable AID systems become more technologically complex, and as the quantity of potential combinations grows (each potentially presenting unique benefits, risks, and health outcomes for different patients), the knowledge required of physicians to conduct risk/benefit analyses will increase dramatically. Eventually, it is likely that questions will be raised in litigation about whether the prescribing physician is in the best position to collect, interpret, and communicate this knowledge to patients. The internet has enabled broad dissemination of tutorials and similar video resources. Manufacturers should consider providing physicians with materials highlighting the key aspects of interoperability that may impact their prescribing decisions and communications with patients.

Rapid Dissemination of Information. Depending on age, education, and socioeconomic status, patients may rely on their physicians as a primary source of information. Typically, manufacturers provide instructions and warnings to physicians in labeling accompanying the product, which can be supplemented over time. But existing channels for providing and supplementing information to physicians may not be optimal for communicating rapidly changing (and highly technical) information about inter-device conflicts.

Prescribing Decisions—Special Populations. Design choices reflect the weighing of risks and benefits, including possibly, ease of use by a layperson-patient. These choices may impact the suitability of a device for certain patient populations (*e.g.*, pediatric or geriatric). Product instructions should enable physicians to take these and similar considerations into account when making prescribing decisions and counseling their patients.

2. Instructing and Warning the Patient

The manufacturer of a prescription medical device to be used primarily outside a medical setting faces the challenge of drafting patient-directed instructions and warnings that are thorough yet understandable to patients and the guardians and caregivers of patients. In evaluating how best to instruct and warn non-physician users of interoperable component devices, some of the considerations include:

Impact of Using Various Smart Devices. If an interoperable component device may be used with smart devices such as phones and tablets that are not prescription medical devices, patients should be informed of any limitations on the types of devices that are suitable, necessary security settings, common issues that may impact functionality, and the like.

Physician Oversight. In drafting patient-directed warnings for interoperable component devices, manufacturers should consider the circumstances in which it may be appropriate to direct patients to consult medical professionals—*e.g.*, if a certain message appears indicating that communication between two devices is compromised.

Prominence of Key Instructions. Warnings and instructions are assessed in PL litigation not only for their content, but also their prominence. For a device that will be

used in a variety of settings outside the home—including by children and adolescents—and that may involve a non-prescription smart device, consideration should be given to which instructions and warnings are most critical and how to maximize their availability in real-life situations.

3. Foreseeable Misuse and Product Alteration

Information is readily, publicly available about the various DIY solutions currently being employed by some diabetes patients. With this background, plaintiffs in PL litigation may argue that unauthorized alterations or combinations of AID components were foreseeable to the manufacturers and should have been warned against. The first line of defense to such claims is design; *i.e.*, robust technological features that minimize the chances a user (or malicious hacker) can alter the device or connect it to another non-compliant device. Since no design is failproof, however, manufacturers should also consider addressing misuse and product alteration through warnings.

Be aware, however, that altering medical devices or using them outside the approved or cleared indications in the label is considered "off-label" under the FDA's regulatory scheme.[58] Off-label use presents complex issues in the PL context, but the basic rule is that physicians are free to prescribe drugs and devices for uses outside the labeling, but manufacturers may not promote off-label uses. The circumstances in which manufacturers may or must warn about off-label use implicates FDA regulations. Manufacturers who become aware of off-label use of their devices—especially if such use has been associated with adverse outcomes—should consult a regulatory expert and/or the FDA to determine the appropriate action vis-à-vis product warnings.[59]

D. Allocation of Fault Among Device Companies in PL Litigation

The concept of interoperable AID system component devices necessarily raises fault-allocation issues in litigation. How much control manufacturers can exercise on the front end depends to some extent on how "open" the system components are. When manufacturers of devices designed to be used together have a business relationship, they can agree beforehand on the circumstances in which one will have to indemnify the other in litigation. Truly open, interoperable AID systems would not involve such preexisting business relationships and similar opportunities to make fault-allocation contracts in advance.

The same technology that permits such an open system, however, provides a way to mitigate the fault-allocation problem. Devices featuring a secure audit trail provide the means to determine which, if any, of two or more interconnected devices malfunctioned. This type of "black box" may simplify proving that user error was at fault. Of course, a black box is a double-edged sword—if a device did malfunction and cause the adverse

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[58] *See* FDA "Off-Label" and Investigational Use of Marketed Drugs, Biologics, and Medical Devices, *avail. at* https://www.fda.gov/RegulatoryInformation/Guidances/ucm126486.htm (July 12, 2018).

[59] *See* 21 C.F.R. § 801.4. (addressing the meaning of "intended uses" as that phrase is used in certain regulations).

event, the audit trial may prove the plaintiff's case for her. Judging from PL litigation in other contexts, however, technology that permits an accurate recreation of events generally benefits the defendant by providing the means to refute self-serving testimony by an injured and sympathetic plaintiff about what supposedly happened.

VI. Best Practices for Proactive PL Risk Management

A. In General

This section discusses proactive steps manufacturers, working with their lawyers, can take now to reduce PL risk generally and specifically with respect to innovative new products like interoperable AID devices. PL risk is a fact of life for medical product manufacturers in the United States, but all manufacturers can and should take steps to address and minimize common vulnerabilities.

The key is to *start early.* With the passage of time, the reasons for key design, manufacturing, or labeling decisions likely will fade from employees' memories or become difficult to recreate when they leave the company. From the outset of product development, employees create documents, including emails, that may be used against the corporation if not properly written. Proactive steps can help manufacturers document, in the form of evidence admissible in court, their reasonableness and diligence and how seriously they consider patient safety.

In discovery, plaintiffs' attorneys will request (and manufacturers must produce) design history files, risk analyses, testing, communications, regulatory files, post-market surveillance and customer complaints. Work with your lawyers to educate employees now that those documents impact the risk of products liability cases and their involvement in it. The AID system's open protocol is unique. Document the challenges of designing components that will communicate with products manufactured by others. Show in your documents why design alternatives—especially those that plaintiffs' experts may seize on as purportedly superior designs—actually decrease effectiveness or utility or introduce different and more serious risks.

Involve the legal department and the entire product team. Employees' communications with each other will be read by products liability attorneys, and they will not be gentle with their criticisms. Employees who are not key players in the design but who write emails that suggest a lack of care become the targets of deposition notices. Develop email policies with the help of your counsel and regularly instruct employees on these policies and why they are important. It pays to remind people who email day-in and day-out that what they say in a moment of frustration or in jest may look very different to a jury when the email becomes an exhibit in a case against the company.

The goal is to ensure that the employees' documents and communications accurately reflect the vigor the manufacturer put into developing safe, interoperable components in this important emerging market. Carelessness turns relatively unimportant documents into plaintiffs' attorneys' featured exhibits at trial. By training employees about potential litigation pitfalls, manufacturers and their lawyers will force plaintiffs' attorneys

to focus on science and data instead of inadequate documentation and careless communications. Following are some specific issues to consider in implementing an effective risk mitigation program.

1. Industry and Company Standards

Compliance with applicable industry standards generally is not, of itself, a complete defense to PL claims, but it can be helpful evidence. Conversely, non-compliance with industry standards may significantly aid a PL plaintiff seeking to establish negligence or product defect. In this context, "industry standards" doesn't refer to standards governing interoperability, but more general guidelines for "best practices" that are commonly accepted in an industry. Being familiar with potentially applicable industry standards and guidelines—and complying with them where appropriate—is part of good litigation risk management.

It is perhaps even more important to ensure compliance with one's own standards, whether they govern technical specifications or ethical issues such as the proper scope of interactions with physicians. A plaintiff who can make a credible case that the company violated its own "rules" gains a significant litigation advantage. If you have company standards or guidance, make sure you regularly update and communicate them to your employees and, if necessary, train employees on how they apply in specific situations.

2. Litigation Holds

Once sued, your lawyers will take steps to ensure that unique, relevant data is preserved for the duration of the litigation. Failing to do so (or *arguably* failing to do so) may hand PL plaintiffs a powerful litigation weapon—a claim of "spoliation" of evidence. Spoliation can result in significant sanctions, up to and including a judgment against the manufacturer by "default" (*i.e.*, without the plaintiffs having to prove their case). To help protect against the loss of potentially relevant evidence, ensure in advance that systems are in place to control the disposition of documents and data, especially where retention policies provide for automatic destruction.

In 2014, a jury awarded $6 billion in punitive damages against a Japanese pharmaceutical company in a case where the plaintiffs persuaded the judge that spoliation of evidence had occurred.[60] This alleged spoliation played a significant role at trial because the judge instructed jurors they could make negative inferences about the absent evidence, harming the company's defense as a result.

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[60] *See* S. Sundar, *Doc Destruction Likely Fired Up Jury Behind $6B Actos Verdict*, Law360, *avail. at* http://www.law360.com/articles/526181/doc-destruction-likely-fired-up-jury-behind-6b-actos-verdict (Apr. 8, 2014); *see also* C. Stueben, *Takeda Part Two: Destroy Evidence, Pay the Price—Eli Lilly and Takeda Pharmaceutical Co. Get Hit for $9 Billion Punitive Damages Verdict*, Gibbons E-Discovery Law Alert, *avail. at* http://www.ediscoverylawalert.com/2014/04/articles/legal-decisions-court-rules/takeda-part-two-destroy-evidence-get-hammered-eli-lily-and-takeda-pharmaceutical-co-get-hit-for-9-billion-punitive-damages-verdict/ (Apr. 16, 2014). The district court reduced the verdict to $36.8 million. Compensatory damages were approximately $1.3 million.

In addition to formal litigation holds and periodic reminders to custodians, in-house and outside legal counsel establish and oversee protocols to identify sources and custodians with potentially discoverable information and documents. This typically requires counsel to participate in and supervise custodial interviews and document collections. It is not sufficient to rely on non-attorney employees to implement holds and collections: "Counsel must oversee compliance with the litigation hold, monitoring the party's efforts to retain and produce the relevant documents."[61]

Turning the focus away from the merits of the case to alleged spoliation by the corporate defendant is a favorite tactic of plaintiffs' attorneys pursuing weak cases, and this tactic can make all cases more challenging to defend. As many manufacturer defendants can attest, the tactic of questioning a defendant's fulfillment of its discovery obligations can be very successful if the defendant does not take prompt and reasonable steps to preserve potentially relevant information.[62] Plaintiffs' attorneys engage in these tactics because of the significant sanctions attendant to even inadvertent failures to preserve potentially responsive documents.

Working with your lawyers now you can proactively familiarize yourself with, and take steps to improve where necessary, the structure of stored company data. Have your attorneys identify the steps IT takes upon employee departures. Before litigation strikes, identify what data may be at risk because of retention schedules that may automatically destroy data even though it may be subject to litigation hold.

This preparedness would empower your lawyers to work effectively and quickly once a lawsuit is served. They could avoid the time-consuming challenge of having to learn about your data, where it is located, how long it lives, and how it can be successfully preserved and collected after the company has been named a defendant in a product liability lawsuit.

3. Interoperable AID Systems—Who Owns the Data and Where Does It Reside?

The interoperable AID system raises new data ownership issues with significant litigation implications: who owns the data that is generated and shared among the devices, where does that data reside, and for how long? A person or company with "possession, custody, or control" of potentially relevant data is responsible for ensuring preservation once litigation is on the horizon.[63] Does the data reside on the patients' (the likely plaintiff's) mobile device? Does the manufacturer have access to it? Do the other component manufacturers have access to it?

The person or entity who owns, possesses, or controls the data will be obligated to preserve and produce it in the litigation. But if the manufacturer merely has access to

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61 *Zubulake v. UBS Warburg LLC*, 229 F.R.D. 422, 432 (S.D.N.Y. 2004).

62 *See In re Actos Prods. Liab. Litig.*, MDL 6:11-md-2299, 2014 U.S. Dist. LEXIS 86101 (W.D. La. June 23, 2014).

63 FED. R. CIV. P. 34(a).

the data but does not own or control it, preservation may be impossible. Yet, the manufacturer could be criticized (and potentially sanctioned) for not ensuring that it retained ownership, custody, or control of potentially relevant device data.

Consider working with your attorneys now to prepare for this unique litigation issue. Identify where data is retained by the interoperable components and prepare a plan for data preservation and collection upon receiving notice of a lawsuit. If the data resides on a patient's mobile device and is controlled only by the patient, manufacturers' counsel may wish to promptly send a letter to the plaintiffs' attorney demanding that it be preserved. If the data resides with and is controlled by a different component maker, your counsel may want to consider sending a demand that it be preserved to that manufacturer's counsel. If such notices are not sent and relevant data is lost, a manufacturer may lose potential opportunities to strike claims due to spoliation.

On the other hand, if *the manufacturer* owns, possesses or controls the patient's data, it is even more important to act promptly upon notice of a lawsuit to preserve it. Manufacturers will receive demands to preserve and produce it. And it is critical to devise a plan to ensure that it can be preserved in a timely fashion without losing the data or any of its associated metadata. This will require collaboration between your attorneys and the company's internal information technology group or the outside vendor that supports the data.

4. Document Retention Policies

Plaintiffs' attorneys frequently demand that manufacturers produce their document retention policies and courts often allow that discovery. They use these policies as a fertile source of questions for company witnesses: How is the policy used? Is it followed? Were you aware of it? A failure to follow retention policies presents an opportunity for plaintiffs to argue that important documents were improperly discarded, and that the company's non-compliance reveals carelessness and risks patient safety.

To minimize the chance of facing these types of contentions in litigation, manufacturers should adopt and follow meaningful document retention policies. The retention periods of documents should match their applicable regulatory document retention requirements. Employees should be trained and periodically refreshed on how to comply with the terms of the policy and the consequences of failures. By creating an environment where this compliance is the norm, manufacturers may help to avoid costly discovery battles and the unnecessary production of certain difficult-to-explain documents and information to plaintiffs' attorneys.

5. Internal Communications

Manufacturers should educate regulatory, engineering, marketing, and sales employees that their electronic communications may be requested by plaintiffs' lawyers in product liability lawsuits. Careless emails increase the possibility of sitting for a deposition in future litigation across from an aggressive and well-prepared plaintiffs' lawyer. Employees should be taught that emails expressing frustration with others, or with

ordinary product development issues, can be taken out of context to harm the company and embarrass the author. Training should address the manner in which employees communicate about problems they are trying to solve or difficulties they are having, including the value of using business-appropriate language and pausing before pushing "send" to distribute a poorly worded email that may be misinterpreted. Proactive management of employee conflicts can be the difference between trying to explain an impetuous email exchange at trial and an early, favorable resolution of the case.

Employees should be taught the value of in-person meetings, and it is helpful if they understand that emails are used by plaintiffs' lawyers as evidence in products liability cases. That knowledge decreases the likelihood they will be asked to testify about what they meant in emails discussing the pros and cons of various solutions to product development issues being considered. Ideally, disagreements regarding design decisions will be documented carefully and formally showing a thorough evaluation of the issues, not casually in frustrated employees' emails back and forth.

Employees should:

- Conduct personal meetings on complex issues, rather than engaging in long and confusing email strings.

- Understand that business communications are not casual.

- Comply with the company's code of conduct—both verbally and in writing, inside and outside of the company.

- Pursuant to company policies developed with the input of counsel, manufacturers should regularly dispose of documents, personal files, and emails that are not subject to litigation holds and are no longer needed. But documents should always be discarded in accordance with company policies, even in the absence of a litigation hold, to ensure the defensibility of records management decisions.

B. Documented Compliance with Regulatory Requirements

Plaintiffs' attorneys will focus on regulatory requirements at several levels. They will want to learn about pre-market clinical trials and to examine whether the company deviated from study requirements provided to the FDA. They will analyze regulatory submissions, including back-and-forth communications between the FDA and the company's regulatory representatives, looking for any possible failures to disclose information. Post-market surveillance files will be examined for possible failures to report. If the manufacturer asserts a preemption defense, the plaintiff likely will seek to examine FDA communications in hopes of finding a regulatory violation with which to defeat that defense.

The point is this: assume that communications with the FDA and documents reflecting compliance (or non-compliance) with regulatory requirements will become

evidence in PL litigation. Compliance alone may not be enough. Manufacturers, working with their attorneys, may wish to create guidelines or standards for documenting regulatory compliance and interacting with the FDA, and then train employees to help ensure they are followed.

Manufacturers should pay especially close attention to their post-market surveillance and adverse event reporting documents. These files are often produced in product liability cases whether events were reported to the FDA or not. Plaintiffs' attorneys use them to develop a claim that the manufacturer under-reported adverse events and thereby understated the product's risk. They will claim that post-market surveillance demonstrated trends in safety-related data that the manufacturer missed or intentionally ignored. Finally, they will claim that, had the trends been identified earlier, the plaintiff's injuries could have been prevented.

Manufacturers should verify that post-market surveillance documentation complies with all FDA guidelines and ensure that employees' decisions not to report events to the FDA are well-documented and correctly made. It bears repeating that regulatory employees (and all employees) should receive rigorous training on the products liability implications of their work *before* litigation begins. Document prompt and reasonable action in response to new post-market surveillance data.

Finally, manufacturers must remember that proper documentation and retention of communications with the FDA are critical for a viable preemption defense. In consultation with counsel, regulatory management should strive to create a clear record of any communication from the FDA directing the company to do or not do something—such as a communication rejecting a proposed change in design, manufacture, or labeling.

C. Documented Risk Profile Analysis

Product development, design history files, failure modes and effects analysis (FMEA), and product testing are requested and produced in product liability cases. Employees are examined about them during depositions and trial.

Creating a detailed documentary record of thorough risk analysis and decision-making may provide crucial evidence to help win the case. The focus today—before litigation—should be on documenting the known risks and steps taken to avoid or mitigate them. Such evidence refutes plaintiffs' arguments that an alleged injury was foreseeable but missed by the company, and it strengthens the argument that different testing or different warnings would not have prevented the injury at issue.

D. Structured Databases

There are several considerations related to how manufacturers structure databases containing product information. One is access—judges may presume that databases can interact with each other to produce information responsive to discovery requests even though the databases may not have that capability. Another is expense—both in maintaining the data and in retrieving it for litigation purposes—what appears to be easy and inexpensive for locating, collecting, and producing data often isn't.

A third area of concern is automation—because of the demand on electronic storage systems, electronic processes are set up to archive and purge active data without human input. When a manufacturer receives notice of a lawsuit (or potential claim), a manufacturer defendant may be required to show that, from that point forward, neither its potentially relevant product data, nor the ease of accessing it, has been altered.

Before litigation, in order to prepare for the rigors of discovery and the company's compliance with judicial expectations for producing information, manufacturers should consider adopting a formal litigation-hold policy that assigns responsibility for accessing and preserving structured data to a competent employee with relevant subject-matter expertise. That person should ensure that the company's Information Technology group is aware of the obligations during litigation to preserve data—including structured data—and the ease of access to it.

E. Sales Representatives

Sales representatives can be excellent witnesses for a company in PL litigation, but if improperly trained and prepared they can unwittingly provide evidence that bolsters the ubiquitous "profits over safety" theme employed by PL plaintiffs. It is critical to train sales representatives, whether employees or agents of independent distributors, that marketing, selling, and servicing the product must comply with all regulatory and ethical standards. Just as with other employees, sales representatives should be instructed and frequently reminded that their communications with physicians are discoverable in litigation and may subject them to depositions.

VII. Conclusion

The need for interoperable AID components that better serve the unmet needs of the T1D public is compelling—as demonstrated by the FDA's unprecedented willingness to work with industry to foster innovation in this area. Such components may become a target for PL litigation, but the risk of PL litigation is ubiquitous for U.S. medical product manufacturers generally. It has not kept American companies from developing some of the world's most innovative new products that save and improve lives.

We hope this paper has brought home the lesson that advance planning and good risk mitigation strategies are the keys to managing PL risk, including the unique issues raised by interoperability.