STATE OF MINNESOTA
IN COURT OF APPEALS
A18-1462

Donna Delfino,
Appellant,

vs.

Medtronic, Inc.,
Respondent.

Filed June 10, 2019
Affirmed
Florey, Judge

Anoka County District Court
File No. 02-CV-12-1786

Timothy J. Becker, Michael K. Johnson, Johnson Becker, P.L.L.C., St. Paul, Minnesota (for appellant)

Andrew E. Tauber (pro hac vice), Mayer Brown, L.L.P., Washington, D.C.; and

Benjamin W. Hulse, Charmaine K. Harris, Blackwell Burke, P.A., Minneapolis, Minnesota (for respondent)

Considered and decided by Florey, Presiding Judge; Connolly, Judge; and Bjorkman, Judge.

U N P U B L I S H E D O P I N I O N

FLOREY, Judge

On appeal from summary judgment, appellant Donna Delfino argues that the district court erred by concluding that (1) her state-law claims relating to an implantable

cardioverter defibrillator (ICD) manufactured by respondent Medtronic, Inc., were preempted by the federal Medical Device Amendments (MDA) and (2) the report and testimony of her expert witness were inadmissible. We affirm.

FACTS

In December 2006, a Virtuoso ICD Model D154AWG, designed and manufactured by Medtronic, was implanted in appellant. An ICD treats abnormal heart rhythms by shocking the heart back into normal rhythm with an electrical pulse delivered to the patient's heart through an insulated wire. ICDs are Class III medical devices, and their design, manufacturing method, and labeling are subject to premarket approval (PMA) by the United States Food and Drug Administration (FDA).[1]

The ICD implanted in appellant was subject to a limited warranty and general warning. The limited warranty provided that, if the ICD failed to operate within the first five years after implantation, Medtronic would either provide a replacement device or issue a credit to the purchaser of the replacement device. The limited warranty expressly stated: "THIS LIMITED WARRANTY IS NOT A REPRESENTATION THAT THE BATTERY OF THIS DEVICE WILL LAST THE ENTIRE FIVE (5) YEAR WARRANTY PERIOD." Further, Medtronic's general warning provided:

> Medtronic devices are implanted in the extremely hostile environment of the human body. This environment places severe limitations on the design and function of the device and lead. These limitations unavoidably reduce the potential

[1] In October 1998, the FDA approved Medtronic's original PMA application for the Virtuoso ICD. Medtronic submitted to the FDA a PMA supplement in November 2005. On May 12, 2006, the FDA approved the PMA supplement for the Virtuoso ICD Model D154AWG.

> performance and longevity of the device and lead despite the exercise of due care in design, component selection, manufacture, and testing prior to sale.

In August 2009, Medtronic completed a Field Product Impact Report following the return of several Concerto and Virtuoso devices[2] due to premature battery depletion. The report found that the premature depletion was caused by "[current] leakage through the X5R battery filter capacitors."[3] The report found "an estimated 8,900 affected device[s] were distributed to the field," that "all of the premature depletions as of 22 July 2009 were made with capacitors in which the end terminations were made with copper from a particular supplier," Supplier A, and that the copper from Supplier A was "more porous, which ma[de] it more susceptible to the migration of hydrogen ions." The report recommended that Medtronic notify its customers of the issue.

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[2] As stated in appellant's brief, "[t]he Virtuoso and Concerto are, in effect, the same device albeit with different brand names," and thus, "[f]or purposes of this appeal, they are treated identically."

[3] As articulated by a federal district court:

> [C]apacitors are one of the most basic functional units in electronic circuits. While they can vary considerably in specific application, capacitors generally operate to store energy on a short-term basis, like a temporary battery, and smooth out the flow of energy to avoid surges and deficits. Capacitors are classified as "passive" components, which means they do not generate power but store and condition it. At heart, a capacitor consists of two electrical plates, one positively and one negatively charged, that are sandwiched together with a non-conductive insulator called a dielectric between them. They are used universally in circuits. As the result, virtually every electronic device we use, from toasters to cellphones, has capacitors in it.

In re Capacitors Antitrust Litig., 106 F. Supp. 3d 1051, 1058 (N.D. Cal. 2015).

In September 2009, Medtronic issued "Dear Doctor" and "Dear Patient" letters informing doctors and patients of the device defect. The letters to doctors informed them that certain ICDs "may not meet expected device longevity due to gradually increasing current drain caused by low voltage capacitor degradation," that Medtronic had not received any reports of death or injury attributed to the issue, and the letters offered recommendations for patients with devices in the affected subset. The letters to patients advised them to contact their doctors for more information.

Consequently, on November 16, 2009, appellant's ICD was removed. Medtronic's analysis of appellant's returned ICD concluded that "the cause of the high current drain" condition was "current leakage in the battery filter capacitors." "Longevity calculations showed the device lasted 36 [percent] of its projected longevity. Electrical analysis found the cause of the shortened device longevity to be high current drain caused by current leakage in a capacitor." Medtronic issued a credit in the amount of $13,720 towards the purchase of a Medtronic replacement device for appellant.

In September 2011, appellant commenced suit against Medtronic. Appellant's complaint included seven counts: (1) strict liability for manufacturing defect; (2) strict liability for design defect; (3) strict liability for failure to warn; (4) breach of express warranty; (5) breach of implied warranty; (6) negligence; and (7) negligent infliction of emotional distress. Medtronic moved to dismiss the action on preemption grounds.[4]

[4] As of January 2018, appellant's action was one of 44 individual claims against Medtronic alleging premature battery depletion of the Concerto and Virtuoso devices. However, because appellant and Medtronic agreed to litigate "the threshold issue of federal

Appellant opposed Medtronic's motion to dismiss and filed an expert report, prepared by Dr. Suzanne Parisian, in support. Dr. Parisian concluded that (1) Medtronic's September 2009 advisory, concerning a "specific subset of devices, rather than the whole product line," was "related to a manufacturing defect rather than a design defect" and (2) the manufacturing defect "represent[ed] a violation of the [PMA] and the FDA's approval of the device." Thereafter, in July 2012, appellant filed a motion to amend the original complaint "in order to plead with more particularity her cause of action." The district court granted Medtronic's motion to dismiss and appellant's unopposed motion to amend the original complaint.

Appellant filed an amended complaint on September 5, 2012. The amended complaint included five counts: (1) strict liability for manufacturing defect; (2) breach of express warranty; (3) breach of implied warranty; (4) negligence; and (5) negligent infliction of emotional distress. Medtronic filed an answer, asserting a collection of defenses, including federal preemption.

In the fall of 2012, appellant moved to compel discovery, and on November 9, 2012, appellant filed an affidavit of expert witness, David Schreiber, in support of her motion. The credentials of Schreiber, a retired engineer, included: a B.S. in electrical engineering; "[e]xpertise in manufacturing, electrical test and failure analysis of implantable cardiac pacemakers and implantable cardioverter defibrillators"; and over thirty years' experience

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preemption" through appellant's case individually, appellant's case was the only action that was filed.

in the medical-device field, including employment as an engineer with the FDA, Cardiac Pacemakers, Inc., Guidant Corporation, and Boston Scientific.

Medtronic opposed appellant's motion to compel discovery and argued that, because appellant "improperly introduce[d] expert opinion testimony on a purely legal question," the district court should disregard Schreiber's affidavit. Appellant disputed Medtronic's characterization of the issue as a legal question. She argued that Schreiber's affidavit "simply states [his] opinion, relying on his extensive experience in the field, to detail which documents will be necessary for [appellant] to ascertain which requirements, if any, were not followed." In February 2013, the district court issued a discovery order negotiated and agreed upon by the parties. The deadline for discovery relating to the federal preemption issue was scheduled for September 1, 2017.

On October 6, 2017, Medtronic filed a motion for summary judgment on preemption grounds. Medtronic argued that count one (strict liability for manufacturing defect), count two (breach of express warranty), count three (breach of implied warranty), and count four (negligence) were expressly preempted; that appellant also failed to show that Medtronic breached the limited warranty; that count two (breach of express warranty) and count three (breach of implied warranty) were also impliedly preempted; and that count five (negligent infliction of emotional distress) was preempted.

Appellant opposed Medtronic's summary-judgment motion. Appellant alleged that Medtronic violated the PMA by (1) using copper in the ICDs' capacitors, which was not an FDA-approved material; (2) failing to meet the battery-leakage requirements set out in the PMA; and (3) failing to meet the projected longevity set out in the PMA. Appellant

argued that genuine issues of material fact regarding the three alleged violations precluded summary judgment.

In support of her opposition to Medtronic's summary-judgment motion, appellant filed another report by expert witness Schreiber. Schreiber's report, dated December 6, 2017, concluded that "Medtronic violated their PMA." The report found:

> First, [Medtronic] failed to comply with Specification 0114546 by using an X5R capacitor with end terminations that were not "plated tin over nickel" as required by the specification. Second, the leaky capacitors failed to meet PMA specifications for capacitor leakage. This was a PMA violation, leading to: a) premature battery depletion, and b) failure to satisfy the minimum longevity requirements. These failures independently amount to PMA violations.

Medtronic moved to exclude Schreiber's report and testimony as inadmissible under Minnesota Rule of Evidence 702. Medtronic argued that Schreiber's curriculum vitae (CV) did "not indicate that he has any experience or qualification in interpreting federal requirements for medical devices," and that "[t]he major factual errors and faulty legal premises in his report demonstrate his lack of qualification." A hearing on Medtronic's motions was held.

In May 2018, the district court issued an order granting Medtronic's motions for summary judgment and to exclude testimony of Schreiber. The district court concluded that appellant failed to show that Medtronic violated a federal requirement during the device's manufacture, and, therefore, appellant's state-law claims were preempted by federal law; that appellant's breach of warranty claims were both barred by implied preemption as well as by the express terms of Medtronic's limited warranty; that the

opinions of Schreiber were disclosed in an untimely manner, and, were, nevertheless, inadmissible under rule 702; and that there were no genuine issues of material fact precluding summary judgment. This appeal followed.

D E C I S I O N

I. The district court did not err by determining that appellant's state-law claims were preempted by the federal MDA.

Appellant argues that the district court erred by granting Medtronic's motion for summary judgment and concluding that her claims were barred by federal preemption. The district court shall grant a summary-judgment motion "if the movant shows that there is no genuine issue as to any material fact and the movant is entitled to judgment as a matter of law." Minn. R. Civ. P. 56.01. "A party need not show substantial evidence to withstand summary judgment." *Carlson v. SALA Architects, Inc.*, 732 N.W.2d 324, 327 (Minn. App. 2007) (quotation omitted), *review denied* (Minn. Aug. 21, 2007). Rather, to defeat a summary-judgment motion, the nonmoving party must present sufficient evidence to allow reasonable persons to find in its favor. *Id.* On a motion for summary judgment, the district court must not weigh the evidence or make factual determinations. *DLH, Inc. v. Russ*, 566 N.W.2d 60, 70 (Minn. 1997).

On appeal, we review de novo both whether there is any genuine issue of material fact and whether the district court erred in its application of the law. *STAR Ctrs., Inc. v. Faegre & Benson, L.L.P.*, 644 N.W.2d 72, 76-77 (Minn. 2002). In doing so, we must view the evidence in the light most favorable to the party against whom judgment was granted.

Id. Whether federal law preempts state law is also an issue that we review de novo. *Angeles v. Medtronic, Inc.*, 863 N.W.2d 404, 409 (Minn. App. 2015).

A. MDA of 1976 and Federal Oversight

In 1976, Congress enacted the MDA to the Food, Drug, and Cosmetic Act (FDCA) "to provide for the safety and effectiveness of medical devices intended for human use." *Lamere v. St. Jude Med., Inc.*, 827 N.W.2d 782, 789 (Minn. App. 2013) (quoting *Medtronic v. Lohr*, 518 U.S. 470, 474, 116 S. Ct. 2240, 2245 (1996)); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312, 315, 128 S. Ct. 999, 1002 (2008). Before the enactment of the MDA, "the introduction of new medical devices was left largely for the States to supervise as they saw fit." *Riegel*, 552 U.S. at 315, 128 S. Ct. at 1002.

The passage of the MDA "imposed a regime of detailed federal oversight," including "various levels of oversight for medical devices, depending on the risks they present." *Id.* at 316, 128 S. Ct. at 1003; *see also* 21 U.S.C. § 360c (2012 & Supp. 2017). "Devices that pose the least risk are designated as Class I, devices that pose a more harmful risk are designated Class II, and devices that present a potential unreasonable risk of illness or injury are designated Class III." *Lamere*, 827 N.W.2d at 789 (quotations omitted). Class III devices are subject to the FDA's "strictest regulation." *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 341, 344, 121 S. Ct. 1012, 1015 (2001); *see* 21 U.S.C. § 360c(a)(1)(C). Appellant's Virtuoso ICD is a Class III medical device.

Before Class III devices may be marketed, they must undergo a thorough review process with the FDA. *Buckman*, 531 U.S. at 344, 121 S. Ct. at 1015; *see generally* 21 U.S.C. § 360e (2012 & Supp. 2017). The PMA process "requires the applicant to

demonstrate a reasonable assurance that the device is both safe and effective under the conditions of use prescribed, recommended, or suggested in the proposed labeling thereof." *Buckman*, 531 U.S. at 344, 121 S. Ct. at 1015 (quotations omitted).

The PMA process "is a rigorous one." *Medtronic*, 518 U.S. at 477, 116 S. Ct. at 2247. "A manufacturer must submit what is typically a multivolume application." *Riegel*, 552 U.S. at 317, 128 S. Ct. at 1004. The application must include, among other things, "a full statement of the device's components, ingredients, and properties," the device's proposed labeling, and other information about the device's manufacturing processes and performance standards. *Id.* at 318, 128 S. Ct. at 1004 (quotations omitted).

The FDA spends an average of 1,200 hours on each submission. *Buckman*, 531 U.S. at 345, 121 S. Ct. at 1015. The FDA must "weig[h] any probable benefit to health from the use of the device against any probable risk of injury or illness from such use." *Riegel*, 552 U.S. at 318, 128 S. Ct. at 1004 (quoting 21 U.S.C. § 360c(a)(2)(C)). "It may thus approve devices that present great risks if they nonetheless offer great benefits in light of available alternatives." *Id.*

If the FDA approves the PMA application, the manufacturer is prohibited from "mak[ing], without FDA permission, changes in design specifications, manufacturing processes, labeling, or any other attribute, that would affect safety or effectiveness." *Id.* at 319, 128 S. Ct. at 1005. If a manufacturer wishes to make such changes, it must submit an application for supplemental premarket approval (a PMA supplement), which the FDA evaluates under the same rigorous standards of review as an initial application. *Id.*

B. Federal preemption

Regulating medical devices is an enormously complicated task. In order to create uniform standards across the country, Congress used its power under the Supremacy Clause to preempt, or override, certain state or local laws. *See* U.S. Const. art. VI, cl. 2. Congress added what is known as an express preemption provision to the MDA that states:

> [N]o State or political subdivision of a State may establish or continue in effect with respect to a device intended for human use any requirement—
>
> (1) which is different from, or in addition to, any requirement applicable under this chapter to the device, and
>
> (2) which 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.

21 U.S.C. § 360k(a) (2012); *see also Brandt v. Marshall Animal Clinic*, 540 N.W.2d 870, 878 n.4 (Minn. App. 1995) ("Express preemption occurs where Congress' intent to preempt is explicitly stated in the statute's purpose."), *review denied* (Minn. Feb. 9, 1996).

Determining whether claims are expressly preempted involves a two-step process. First, this court "must determine whether the [f]ederal [g]overnment has established requirements applicable to" the specific device at issue. *Riegel*, 552 U.S. at 321-22, 128 S. Ct. at 1006. Second, this court must "determine whether the [plaintiff's] common-law claims are based upon [state] requirements with respect to the device that are 'different from, or in addition to,' the federal ones, and that relate to safety and effectiveness." *Id.* (quoting section 360k(a)).

The Supreme Court in *Riegel* held that the PMA process imposes federal requirements specific to the particular device under review. *Id.* at 322-23, 128 S. Ct. at

1007; *see also In re Medtronic, Inc., Implantable Defibrillators Litigation*, 465 F. Supp. 2d 886, 894 (D. Minn. 2006) ("[T]hrough the PMA process, the FDA has established specific federal requirements for the . . . devices' design, testing, intended use, manufacturing methods, performance standards, and labeling."). There is no dispute that appellant's Virtuoso ICD underwent a rigorous PMA process. Thus, this court's focus is on the second inquiry of the two-step test. To satisfy the second inquiry and survive express preemption under section 360k(a), appellant must show that her state common-law claims "parallel" the requirements under federal law. *See Lamere*, 827 N.W.2d at 790.

In other words, appellant must show that her state-law claims "are equal to, or substantially identical to" federal requirements. *Id.* (quotation omitted). State-law claims premised on a violation of FDA regulations survive express preemption. *See Riegel*, 552 U.S. at 330, 128 S. Ct. at 1011 ("[Section] 360k does not prevent a [s]tate 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."); *see also Lohr*, 518 U.S. at 513, 116 S. Ct. at 2264 (O'Connor, J., concurring in part and dissenting in part) ("Section 360k does not preclude [s]tates from imposing different or additional *remedies*, but only different or additional *requirements*.)."

Surviving express preemption by showing a state-law claim merely parallels, rather than adds to, a federal requirement is not enough. In addition to being expressly preempted, a state-law claim may be impliedly preempted. The Supreme Court held in *Buckman* that the FDCA does not provide a private right of action. 531 U.S. at 349 n.4, 121 S. Ct. at 1018 n.4. Section 337(a) of the FDCA provides: "all such proceedings for the enforcement,

or to restrain violations, of this chapter shall be by and in the name of the United States." 21 U.S.C. § 337(a) (2012). "[T]o avoid being impliedly preempted under *Buckman*, a claim must 'rely[] on traditional state tort law which had predated the federal enactments in question[].'" *Riley v. Cordis Corp.*, 625 F. Supp. 2d 769, 777 (D. Minn. 2009) (quoting *Buckman*, 531 U.S. at 353, 121 S. Ct. at 1012). Otherwise, "the plaintiff is effectively suing for a violation of the FDCA (no matter how the plaintiff labels the claim), and the plaintiff's claim is thus impliedly preempted under *Buckman*." *Id.*

Consequently, under *Riegel* and *Buckman*, the gap through which a state-law claim must fit in order to survive express or implied preemption is narrow. *Id.*

> The plaintiff must be suing for conduct that *violates* the FDCA (or else his claim is expressly preempted by § 360k(a)), but the plaintiff must not be suing *because* the conduct violates the FDCA (such a claim would be impliedly preempted under *Buckman*). For a state-law claim to survive, then, the claim must be premised on conduct that both (1) violates the FDCA and (2) would give rise to a recovery under state law even in the absence of the FDCA.

Id. (emphasis in original).

Appellant argues that "Medtronic violated a 'parallel requirement' by failing to comply with three mandatory PMA obligations." First, appellant contends that Medtronic failed to comply with Specification No. 0114546, which, appellant alleges, is an FDA-approved manufacturing specification that was part of the PMA.[5] Specification 0114546

[5] Appellant's belief that Specification 0114546 was part of the PMA supplement is based on the following, as articulated in her appellate brief:

> The PMA supplement for the Virtuoso included a Product Qualification Report for the CRM-C Hybrid used in

provides that "[t]he end terminations shall consist of plated tin over a nickel barrier layer." Appellant argues that, "[n]otwithstanding this clear directive," Supplier A "manufactured the end terminations using a plated tin over nickel barrier with an intermediate porous copper alloy"—the use of which "was never discussed with FDA, let alone approved for use." She contends that Medtronic's Director of Quality and Reliability, Nancy Willems, agreed in her deposition that the specification required a tin-over-nickel configuration, and that copper was not listed in the capacitor's description.[6]

Second, appellant argues that her Virtuoso ICD failed to satisfy the battery-leakage requirements set forth in the PMA "due directly to the use of the unapproved porous copper." She argues that Medtronic's tests of the returned ICD "concluded that [a]ppellant's capacitor was leaking at a rate *thirty-seven to forty times higher* than allowed under the PMA." Pointing to other jurisdictions, appellant argues that "[c]ourts

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> the Virtuoso, which was assigned part number A00263. *See* Doc 31. The Product Qualification Report stated the component parts of the A00263 Hybrid are set forth in Specification Number 0414492 Revision B, titled Bill of Materials for the A00263 Hybrid, dated August 18, 2005. *Id.* at 1. Specification 0114546-002, in turn, was identified in Specification 0414492 Revision B, as the "Component Specifications" (i.e., the manufacturing requirements) for the capacitors that failed in Appellant's device. *See* Doc. 33 at MDT-ConVirt-0009293.

[6] Willems also testified in her deposition that "Medtronic [is] not the subject matter expert[] on how to manufacture ceramic capacitors." Willems testified that Medtronic relies on its suppliers, such as Supplier A, to be subject-matter experts on what Medtronic is procuring from them.

considering this issue have overwhelmingly found performance standards are part of the PMA."

Third, appellant contends that the capacitor failed to comply with the mandatory longevity and aging requirements set out in the PMA. She contends that, although "[t]he PMA directed that the device was to last *at least* 5.1 years," her ICD "lasted 34.5 months—more than 25 months *less* than that required by the PMA." Pointing to Willems's deposition testimony, appellant argues that Medtronic "readily acknowledged that the PMA imposed a binding longevity requirement" when Willems stated: "[T]he early battery depletion devices are not acceptable, because they don't meet the longevity requirements that are set out in our PMA." Appellant argues that, "where FDA imposes longevity requirements, the failure to satisfy those requirements is a PMA violation."[7] She further argues that, despite the district court's failure to address the following in its order, "Medtronic manufactured a product that failed to comply with the capacitor aging requirements," set forth in section 4.6 of the specification, thereby constituting another PMA violation.

[7] Appellant also argues that Medtronic did not present any evidence that the longevity requirement was a mere estimate until it submitted its reply brief in support of its motion to exclude Schreiber's testimony. She contends that the district court's order "was predicated upon a document that was not supplied in connection with Medtronic's Rule 56 motion," and that the court's "reliance on this document was clear error given Medtronic did not raise the issue in its Motion for Summary Judgment." Appellant does not cite any caselaw in support of this proposition. Nevertheless, our review of the record establishes that Medtronic did represent in its motion for summary judgment that the expected longevity of the device was a mere estimate. In its memorandum in support of its summary-judgment motion, Medtronic quoted language from the limited warranty and stated, "The Limited Warranty makes clear that Medtronic does not warrant that the Virtuoso ICD will, in fact, operate normally for five years."

In the alternative, appellant argues that there are genuine fact issues precluding summary judgment. Appellant alleges that the parties dispute whether Medtronic used copper, whether the use of copper was part of the end terminations' construction, and whether Medtronic admitted that the PMA included certain performance standards. Consequently, according to appellant, the district court's dismissal of her claims was error.

We conclude that the district court did not err by determining that appellant's state-law claims were preempted by the federal MDA. Under the narrow exception to express and implied preemption, appellant must show that her state-law claims are premised on conduct that both (1) violates federal requirements and (2) would give rise to recovery under traditional state tort law. *See Riley*, 625 F. Supp. 2d at 777. Appellant has not met her burden.

1. Violation of federal requirements

Appellant's claims are not premised on conduct that violates federal requirements. As the district court determined, appellant presented insufficient evidence that Medtronic violated any federal requirement in the manufacture of her Virtuoso ICD. Indeed, the affidavit and deposition testimony of Willems—testimony that appellant cites in support of her argument—actually demonstrates that Medtronic's manufacture of the ICD complied with its requirements under the MDA. Willems testified that, when the hybrid contained in appellant's ICD was shipped from Medtronic, "it met all product requirements and specifications," and "all the design and manufacturing requirements." A copy of the test results was included with Willems's affidavit.

Willems's deposition testimony also established that the copper material in the capacitor was a separate, distinct component from the "end terminations" requiring tin and nickel. She explained, copper is the "base material" that "is the underlying material underneath those end terminations." She explained that Medtronic's supplier, Supplier A, which is an "expert[] on ceramic capacitor manufacturing," would have made the decision to use copper, based on the specifications supplied by Medtronic. She further testified that it was not copper generally, but porous copper that ultimately caused the premature battery depletion. And, although Willems testified that Medtronic's internal specifications are "indirectly" approved by the FDA, and that "longevity requirements" are "set out in our PMA," she also testified, several times, to her limited knowledge about the PMA process. She testified that she had limited knowledge about what PMA submissions entail and that she was not involved in the preparation of the Virtuoso ICD's PMA application.

The undisputed affidavit and deposition testimony of another Medtronic employee also established that appellant's ICD was manufactured in compliance with FDA-approved requirements. Franky Santiago Rivera, a senior quality systems manager at Medtronic, testified that Medtronic has additional, "more stringent procedures," that go beyond requirements mandated by the FDA. Rivera attested that, at the time appellant's ICD left Medtronic's manufacturing facility, it "was free from any deviation from the applicable FDA-approved requirements as well as any internal Medtronic requirements."

Appellant also presented insufficient evidence, as the district court determined, that copper was incorporated with the plated tin and nickel as part of the capacitor's end terminations. Specification 0114546 provides: "The end terminations shall consist of

plated tin over a nickel barrier layer."[8] As the district court articulated in its order, "Figure 2 in Specification 0114546 shows that the X5R capacitor consisted of a ceramic body with 'metalization' at ends." The district court determined that Supplier A's schematic of the capacitor demonstrated that copper was part of the metalization, not the end terminations, and that copper "s[at] in between the ceramic body of [the] capacitor and [the] plated tin and nickel at the end termination of the capacitor." The district court determined that Willems's testimony, establishing that copper was used as a "base material," separate from the tin and nickel material comprising the end termination, confirmed that metalization and end termination "are not the same." In reviewing the evidence in the light most favorable to appellant, we conclude that she failed to present sufficient evidence to allow reasonable persons to find that copper was part of the capacitor's end terminations.

Appellant also presented insufficient evidence, as the district court determined, that the use of copper generally was prohibited. Citing to Medtronic's investigative report, the district court concluded that "copper *per se* was not the cause of the problem; rather, the specific type of copper from Supplier A (used in about 4 percent of the devices) was susceptible to greater porosity." The district court reasoned, "[I]t was Supplier A's copper, which was more porous and permeable—not copper generally—that caused [appellant's]

[8] Appellant appears to concede in her appellate brief that Specification 0114546 was never *directly* submitted to the FDA. Rather, as appellant articulates, Specification 0114546 was referenced as a component specification in the Bill of Materials for the A00263 Hybrid, which was referenced in the Product Qualification Report submitted with the PMA supplement.

device to deplete prematurely," and appellant failed to present any evidence "that the PMA specified the porosity or permeability of copper to be used in X5R capacitors." We agree.

While Specification 0114546 includes a rather detailed list of prohibitions, the use of copper is not among them. Furthermore, appellant failed to explain how the capacitors could function if her interpretation of Specification 0114546 was correct. Citing to Medtronic's explanation, the district court determined that "without the electrodes between the ceramic body and the end terminations, there is no capacitor—and therefore no way to meet the performance requirements of Specification 0114546." Thus, even if Specification 0114546 was part of the PMA supplement, making it a federal requirement, appellant presented insufficient evidence that the mere use of copper would constitute a federal violation.

We are also not persuaded that there are any material disputed fact issues regarding the use of copper. Citing to the Third Circuit's decision in *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268 (3d Cir. 2017), *vacated and remanded sub nom. Merck Sharp & Dohme Corp. v. Albrecht*, No. 17-290, 2019 WL 2166393 (U.S. May 20, 2019), appellant argues that there are factual disputes concerning whether Medtronic believed it had to comply with Specification 0114546. Appellant contends that, although *In re Fosamax* "arises in the context of pharmaceutical regulations under the FDCA, it is relevant here in that its clear holding is that factual disputes regarding the manufacturer's preemption defense are reserved for the jury."

The Third Circuit, in *In re Fosamax*, held that the question of whether the FDA would have approved a change to a prescription drug's label was a question of fact for the

jury to decide, rather than a question of law for the court. *Id.* at 289, 293. Accordingly, the Third Circuit concluded, "A state-law failure-to-warn claim will only be preempted if a jury concludes it is highly probable that the FDA would not have approved a label change." *Id.* at 293. Because the Third Circuit determined that a reasonable juror could find it less than highly probable that the FDA would not have approved the label change, it concluded that the drug's manufacturer was not entitled to summary judgment on its preemption defense. *Id.* at 300.

Pending our decision in the matter before us, the United States Supreme Court effectively reversed the Third Circuit's holding. *Albrecht*, 2019 WL 2166393, at *9. The Supreme Court held that issues concerning the nature and scope of FDA determinations are questions of law to be decided by a judge. *Id.* Indeed, explained the Court, "sometimes contested brute facts will prove relevant to a court's legal determination about the meaning and effect of an agency decision." *Id.* Including, for example, that "the litigants may dispute whether the drug manufacturer submitted all material information to the FDA." *Id.* However, the Court held:

> [W]e consider these factual questions to be subsumed within an already tightly circumscribed legal analysis. And we do not believe that they warrant submission alone or together with the larger pre-emption question to a jury. Rather, in those contexts where we have determined that the question is "for the judge and not the jury," we have also held that "courts may have to resolve subsidiary factual disputes" that are part and parcel of the broader legal question.

Id. (quoting *Teva Pharm. USA, Inc. v. Sandoz, Inc.*, 135 S. Ct. 831, 838 (2015)).

Thus, contrary to appellant's position, we conclude that the issue of whether Specification 0114546 constituted a federal requirement is a question of law to be decided by a judge. *See id*; *see also S. Pine Helicopters, Inc. v. Phoenix Aviation Managers, Inc.*, 320 F.3d 838, 841 (8th Cir. 2003) (indicating that what constitutes a violation of federal regulations is a matter of law); *Denelsbeck v. Wells Fargo & Co.*, 666 N.W.2d 339, 347 (Minn. 2003) (stating that "determining compliance with a regulation . . . is a question of law"). And, if Specification 0114546 constituted a federal requirement, Medtronic would be required to follow it, regardless of its subjective belief. We, therefore, reject appellant's contention that there are factual disputes concerning whether Medtronic believed Specification 0114546 constituted a federal requirement with which it had to comply.

Appellant's claims that the capacitors failed to meet battery leakage and longevity requirements, as allegedly set forth in the PMA, are also without merit. As the record indicates, appellant's ICD underwent several different tests before it was sold to ensure the device functioned properly. "PMA Supplement approval only constitutes approval of the [device's] design, testing, intended use, manufacturing methods, performance standards and labeling—not the device's success rate." *Hughes v. Cook*, 452 F. Supp. 2d 832, 842 (W.D. Tenn. 2006). "The PMA process does not guarantee that every device is safe." *Lamere*, 827 N.W.2d at 792. "In fact, every case in which a court has held that § 360k(a) of the MDA preempts state common law tort claims has involved a malfunctioning Class III device." *Hughes*, 452 F. Supp. 2d at 842 n.7.

Due to the inherent risks, unpredictable progression, and invasive nature of Class III devices, Medtronic had in place express warnings advising its customers of the device's

"severe limitations." Medtronic's general warning explained that the human body "places severe limitations on the design and function of the device" that "unavoidably reduce the *potential* performance and longevity of the device . . . despite the exercise of due care in design, component selection, manufacture, and testing prior to sale." (Emphasis added.) Accordingly, Medtronic's limited warranty expressly stated that it was, just that, a limited warranty, and that Medtronic did not guarantee the device would last the entire five-year warranty period. Furthermore, the Virtuoso ICD's reference manual—which was submitted as part of the PMA application—expressly used the terms, "projected service life" and "estimate" throughout.

In sum, we conclude that, based on our review of the evidence in the light most favorable to appellant, there is no genuine fact dispute that precluded the district court from granting Medtronic's motion for summary judgment. *What* constitutes a federal regulation and, in turn, what constitutes a violation of that regulation are matters of law properly determined by the court. *See Albrecht*, 2019 WL 2166393, at *9. And, while the issue of *whether* a federal regulation has been violated may present a question of fact for the jury, appellant presented insufficient evidence to allow a reasonable person to find that Medtronic violated an FDA-approved regulation by using copper in the manufacture of her Virtuoso ICD.

2. Recovery under traditional state tort law

Even if appellant had presented sufficient evidence to demonstrate a federal violation, her claims would not give rise to recovery under traditional state tort law. Minnesota requires a plaintiff to show that "(1) the product was in a defective condition

unreasonably dangerous to the user, (2) the defect existed when it left the manufacturer's control, and (3) the defect was the proximate cause of the injury sustained." *Drager by Gutzman v. Aluminum Indus. Corp.*, 495 N.W.2d 879, 882 (Minn. App. 1993), *review denied* (Minn. Apr. 20, 1993). The undisputed affidavits and testimony of Willems and Rivera establish, as the district court determined, that the device was not in a defective condition when it left the manufacturer's control. Indeed, as Willems attested, "several tests or inspections were conducted during the manufacturing process to confirm that the particular components and device as a whole functioned properly and met relevant specifications." Because appellant presented insufficient evidence to show that her claims are premised on conduct that both violates federal requirements and would give rise to traditional state tort recovery, the district court did not err by determining that her state-law claims were preempted by the federal MDA, and, thus, subject to summary judgment.[9] *See Riley*, 625 F. Supp. 2d at 777.

II. The district court did not abuse its discretion by determining that the report and testimony of appellant's expert witness were inadmissible.

Appellant argues that the district court abused its discretion by granting Medtronic's motion to exclude the report and testimony of her expert witness, Schreiber. We review a district court's ruling on the admissibility of expert testimony for an abuse of discretion.

[9] Appellant's breach of warranty, negligence, and negligent infliction of emotional distress claims are derivative claims that depend on the outcome of her primary claim of strict liability for a manufacturing defect. Because her primary claim is preempted, so too are her derivative claims. *See Lamere*, 827 N.W.2d at 785, 791-92 (declining to address plaintiff's derivative claims, including breach of express and implied warranty and negligence, where plaintiff's primary claim of strict liability for a manufacturing defect was held to be preempted by federal law).

Hayes v. Comm'r of Pub. Safety, 773 N.W.2d 134, 136-37 (Minn. App. 2009). Absent a clear abuse of discretion, this court will not reverse a district court's evidentiary ruling. *Benson v. N. Gopher Enters., Inc.*, 455 N.W.2d 444, 445-46 (Minn. 1990). "Even if evidence has probative value, it is still within the district court's discretion to exclude the testimony because it is a very deferential standard." *Hayes*, 773 N.W.2d at 137 (quotation omitted).

Minnesota Rule of Evidence 702 provides that a district court "may" admit expert testimony if the expert's "scientific, technical, or other specialized knowledge will assist the trier of fact to understand the evidence or to determine a fact in issue." "The proponent of scientific evidence has the burden to establish the proper foundation for [its] admissibility." *Goeb v. Tharaldson*, 615 N.W.2d 800, 816 (Minn. 2000).

Opinion testimony "involving a legal analysis or mixed questions of law and fact . . . are not deemed to be of any use to the trier of fact." Minn. R. Evid. 704 1977 comm. cmt; *see Behlke v. Conwed Corp.*, 474 N.W.2d 351, 359 (Minn. App. 1991) ("Legal analysis by an expert is ordinarily inadmissible." (quotation omitted)), *review denied* (Minn. Oct. 11, 1991); *see also S. Pine Helicopters*, 320 F.3d at 841 ("[E]xpert testimony on legal matters is not admissible.").

Appellant challenges the district court's determinations that (1) the disclosure of Schreiber's report was untimely and (2) Schreiber was not qualified to testify under rule 702. First, she contends that the district court's order finding that the report was untimely was error because she "disclosed Schreiber as an expert in 2012, more than 5 years before

Medtronic moved for summary judgment." Further, argues appellant, the district court's scheduling order did not contain a deadline for expert reports.

Second, appellant contends that the district court erroneously determined that Schreiber was unqualified to testify. She argues that the bulk of Schreiber's report "dealt with interpretation and discussion of technical terms"—terms that he was qualified to interpret pursuant to his three decades' experience as an electrical engineer in the medical-device industry. She argues that the report was disclosed "to provide technical clarification on the engineering terms subsumed within this case," and, at the least, Schreiber should have been permitted to testify "about basic electrical engineering principals." Appellant argues that Schreiber's CV "clearly established" that his testimony would help the trier of fact evaluate the evidence or resolve factual issues, as required under rule 702.

We conclude that the district court did not abuse its discretion by determining that Schreiber's report and testimony were inadmissible. First, as an initial matter, the district court did not abuse its discretion by finding that appellant's disclosure of the report was untimely. The district court's scheduling order provided that "[d]iscovery relating to the threshold issue of federal preemption" was to "be completed by September 1, 2017." Despite this clear directive, appellant did not disclose Schreiber's report, which specifically focused on the issue of whether Medtronic violated its PMA mandates, until December 6, 2017. Whether Medtronic committed PMA violations directly relates to the threshold issue of federal preemption. Accordingly, appellant was ordered to disclose Schreiber's report by September 1, 2017. *See* Minn. R. Civ. P. 26.01(b)(4) (requiring a party to disclose expert testimony "at the times and in the sequence that the court orders").

Second, the district court correctly concluded that Schreiber's report, primarily comprised of legal conclusions, rather than statements of fact or opinion, was inadmissible under rule 702. *See* Minn. R. Evid. 704 1977 comm. cmt. In his report, Schreiber states, Specification 0114546 "is both the floor and the ceiling for construction of the end terminations for the capacitors. . . . Because the capacitors did not comply with the design specification[,] . . . the product as manufactured, violated the PMA." As we explained in the preceding section, "determining compliance with a regulation . . . is a question of law." *Denelsbeck*, 666 N.W.2d at 347; *see also Albrecht*, 2019 WL 2166393, at *9. And expert opinion as to a legal matter is generally inadmissible. *Behlke*, 474 N.W.2d at 359; *see S. Pine Helicopters*, 320 F.3d at 841. As such, the district court did not abuse its discretion by prohibiting Schreiber from opining on a legal question.

Affirmed.