IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF IOWA
WESTERN DIVISION

DENNIS and MELISSA EGGERLING, both individually and as parents and guardians of A.E., their daughter and a minor,

Plaintiffs,

vs.

ADVANCED BIONICS, L.L.C.,

Defendant.

No. C 11-4104-MWB

MEMORANDUM OPINION AND ORDER REGARDING DEFENDANT'S MOTION FOR SUMMARY JUDGMENT

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I. INTRODUCTION

This is another in a series of product liability cases against defendant Advanced Bionics, L.L.C., (AB) concerning an allegedly defective cochlear implant, called the HiRes 90k, with an AstroSeal feed-thru assembly, which was intended to allow some profoundly deaf people to hear. This case arises from the failure and replacement of the cochlear implant received by the minor daughter of plaintiffs Dennis and Melissa Eggerling. In this case, as in several similar cases in other jurisdictions, AB has filed a Motion For Summary Judgment (docket no. 41) on the ground that the Eggerlings' claims are expressly or impliedly preempted by the Medical Device Amendments (MDA) to the Federal Food Drug and Cosmetic Act (FDCA), pursuant to *Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); 21 U.S.C. § 360k(a); *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001); and 21 U.S.C. § 337(a).

The Eggerlings counter that their claims are not preempted, because AB is collaterally estopped to assert its preemption defense by contrary determinations in a prior case against it over the same cochlear implant; because the specific cochlear implant that they allege caused their damage was not FDA-approved, where AB had made an unapproved substitution of a critical component, the AstroSeal feed-thru assembly, instead of a Pacific Aerospace and Electronics (PA & E) feed-thru assembly on which pre-market approval (PMA) by the FDA had been based; and because, even if AB might otherwise be able to assert preemption, their negligence and strict liability product liability claims are valid "parallel" claims that are not preempted.[1] In order to simplify the trial, however, the Eggerlings "withdraw" their claims of breach of warranty, fraud, and intentional infliction of emotional distress.

[1] Notwithstanding their collateral estoppel argument, the Eggerlings have not cross-moved for summary judgment on AB's preemption defense or on any part of AB's defense of compliance with applicable law and regulations.

II. LEGAL ANALYSIS

A. Summary Judgment Standards

Summary judgment is only appropriate when "the pleadings, depositions, answers to interrogatories, and admissions on file, together with affidavits, if any, show that there is no genuine issue of material fact and that the moving party is entitled to a judgment as a matter of law." FED. R. CIV. P. 56(c) (emphasis added); *see Woods v. DaimlerChrysler Corp.*, 409 F.3d 984, 990 (8th Cir. 2005) ("Summary judgment is appropriate if viewing the record in the light most favorable to the nonmoving party, there are no genuine issues of material fact and the moving party is entitled to judgment as a matter of law."); *see generally Celotex Corp. v. Catrett*, 477 U.S. 317, 323-24 (1986). "The nonmovant 'must do more than simply show that there is some metaphysical doubt as to the material facts,' and must come forward with 'specific facts showing that there is a genuine issue for trial.'" *Torgerson v. City of Rochester*, 643 F.3d 1031, 1042-43 (8th Cir. 2011) (*en banc*) (quoting *Matsushita Elec. Indus. Co. v. Zenith Radio Corp.*, 475 U.S. 574, 586–87 (1986)). Summary judgment is particularly appropriate when only questions of law are involved, rather than factual issues that may or may not be subject to genuine dispute. *See, e.g., Cremona v. R.S. Bacon Veneer Co.*, 433 F.3d 617, 620 (8th Cir. 2006). For instance, "issue preclusion," which is central to the Eggerlings' resistance, is appropriately adjudicated by summary judgment, because whether or not the elements of issue preclusion are satisfied is a question of law. *See Employers Mut. Cas. Co. v. Van Haaften*, 815 N.W.2d 17, 22 (Iowa 2012).

B. Bars To Preemption

I note, from the outset, that all of the courts to consider AB's preemption arguments on summary judgment have held that at least some parts of the claims of the plaintiffs in those cases were not preempted. Similarly, I conclude that at least some of the claims presented here also survive AB's Motion For Summary Judgment based on preemption. Notwithstanding the parties' substantial briefing and the Eggerlings' lengthy statement of additional facts, only the Eggerlings' last argument, that they have asserted non-preempted "parallel" state law claims, presents any significant question on AB's Motion For Summary Judgment.

1. Issue preclusion

First, the form of "collateral estoppel" at issue here, "issue preclusion," presents no bar to AB's assertion of preemption. As the Eighth Circuit Court of Appeals has explained,

> [Courts] look to state law in determining whether to apply issue preclusion. *See Royal Ins. Co. of Am. v. Kirksville Coll. of Osteopathic Med., Inc.*, 304 F.3d 804, 807 (8th Cir. 2002). "This rule applies [even] when the original judgment is that of another federal court sitting in diversity." *Follette v. Wal–Mart Stores, Inc.*, 41 F.3d 1234, 1237 (8th Cir. 1994) (citations omitted), *cert. denied*, 516 U.S. 814, 116 S.Ct. 66, 133 L.Ed.2d 28 (1995).

Liberty Mut. Ins. Co. v. FAG Bearing Corp., 335 F.3d 752, 758 (8th Cir. 2003). Under Iowa law, the state law applicable to the product liability and tort claims at issue in this diversity action, "[i]ssue preclusion prevents parties '"from relitigating in a subsequent action issues raised and resolved in [a] previous action."'" *Employers Mut. Cas. Co.*, 815 N.W.2d at 22 (quoting *Soults Farms, Inc. v. Schafer*, 797 N.W.2d 92, 103 (Iowa 2011), in turn quoting *Hunter v. City of Des Moines*, 300 N.W.2d 121, 123 (Iowa 1981)). More specifically,

> The party invoking issue preclusion must establish four elements:
>
> > "(1) the issue in the present case must be identical, (2) the issue must have been raised and litigated in the prior action, (3) the issue must have been material and relevant to the disposition of the prior case, and (4) the determination of the issue in the prior action must have been essential to the resulting judgment."
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> [*Soults Farms, Inc.*, 797 N.W.2d at 104] (quoting *Fischer v. City of Sioux City*, 654 N.W.2d 544, 547 (Iowa 2002)); *accord Hunter*, 300 N.W.2d at 123.

Employers Mut. Cas. Co., 815 N.W.2d at 22. Issue preclusion applies "[w]hen an issue of fact or law is actually litigated" in the prior action, "can be used defensively or offensively,"[2] and "applies irrespective of the parties' mutuality or privity." *Soults*

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[2] As the Iowa Supreme Court has explained,

> Defensive use of the doctrine is when "a stranger to the judgment, ordinarily the defendant in the second action, relies upon a former judgment as conclusively establishing in his favor an issue which he must prove as an element of his defense." [*Hunter v. City of Des Moines*, 300 N.W.2d 121, 123 (Iowa 1981)]. Offensive use of the doctrine is when "a stranger to the judgment, ordinarily the plaintiff in the second action, relies upon a former judgment as conclusively establishing in his favor an issue which he must prove as an essential element of his cause of action or claim." *Id*.

Comes v. Microsoft, 709 N.W.2d 114, 118 (Iowa 2006). Thus, the doctrine is available defensively when "the party against whom it is invoked was 'so connected with the former action as to have had a full and fair opportunity to litigate the claim or issue and be properly bound by its resolution.'" *Dettmann v. Kruckenberg*, 613 N.W.2d 238, 244 (Iowa 2000) (quoting *Brown v. Kassouf*, 558 N.W.2d 161, 163-64 (Iowa 1997)).

Farms, Inc., 797 N.W.2d at 104. Decisions may be given preclusive effect even during the pendency of an appeal. *Employers Mut. Cas. Co.*, 815 N.W.2d at 25.

Nevertheless "issue preclusion" is not limitless. As the Iowa Supreme Court has also explained, "Even when the requirements of the general issue preclusion rule are present, courts are required to consider if special circumstances exist that make it inequitable or inappropriate to prevent relitigation of the issue previously determined in the prior action." *Hunter v. City of Des Moines Mun. Housing Auth.*, 742 N.W.2d 578, 584 (Iowa 2007). Several exceptions are summarized in RESTATEMENT (SECOND) OF JUDGMENTS § 28 (1982). *Id.* at 585. One such exception is that "'[t]he issue is one of law and . . . the two actions involve claims that are substantially unrelated.'" *Id.* (quoting RESTATEMENT (SECOND) OF JUDGMENTS § 28(2)(a)). The Iowa Supreme Court (and the RESTATEMENT) have recognized that, when claims between the same parties are closely related, preclusion applies, because it is unfair to the winning party and an unnecessary burden on the courts to allow relitigation of a legal issue, but if the two actions are substantially unrelated, it would be unfair to preclude relitigation of a legal issue by one party, when other litigants would be free to urge that the legal rule should be rejected. *Id.* at 586 (citing RESTATEMENT (SECOND) OF JUDGMENTS § 28, cmt. *b*).

The Eggerlings cannot satisfy the first requirement for issue preclusion under Iowa law, because no court has yet considered whether any product liability or tort claims *under Iowa law* are preempted by the MDA, or even *under the RESTATEMENT (THIRD) OF TORTS, PRODUCT LIABILITY (RESTATEMENT (THIRD))*, as adopted by the Iowa courts. *See Scott v. Dutton-Lainson Co.*, 774 N.W.2d 501, 504 (Iowa 2009) (explaining that the Iowa Supreme Court adopted the RESTATEMENT (THIRD) in *Wright v. Brooke Group Ltd.*, 652 N.W.2d 159 (Iowa 2002)). Certainly, that was not so in *Sadler v. Advanced Bionics, Inc.*, Civil Action No. 3:11–CV–00450–H (W.D. Ky.), on

which the Eggerlings expressly rely for issue preclusion in this case. Thus, no court has considered the *identical* issue presented in this case. *Employers Mut. Cas. Co.*, 815 N.W.2d at 22.[3]

Perhaps more importantly, even if the Eggerlings could satisfy the requirements for issue preclusion, it is inappropriate to apply issue preclusion to the preemption issue in this case. *See Hunter*, 742 N.W.2d at 585 (explaining that, even when the requirements for issue preclusion are met, the court must still consider whether it is inequitable or inappropriate to apply issue preclusion). Because the Eggerlings seek to use issue preclusion defensively to preclude relitigation by AB of a *legal* issue, concerning preemption of claims by the MDA, in an unrelated case involving a different person's injuries from an allegedly defective medical device, it is patently inequitable to preclude AB from challenging a prior determination of the scope of MDA preemption, when other litigants would be free to urge that the rule from the prior litigation should be rejected. *See Hunter*, 742 N.W.2d at 585-86. The Eggerlings and other persons with claims against AB arising from cochlear implants should not remain free to challenge parts of a prior preemption ruling that they did not like, while asserting that AB is precluded from challenging parts of a prior preemption ruling that it did not like. Indeed, this is plainly a circumstance in which AB should retain the right to assert that the law is otherwise than a different court in an unrelated case has determined it to be. *Id.* at 587.

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[3] This is true, whether the decision in *Sadler* that the Eggerlings contend is entitled to preclusive effect is the jury's verdict on the ultimate questions in the case or the district court's summary judgment ruling on preemption, made "final" by the jury's verdict. Indeed, as AB points out, the jury's "general" verdict in *Sadler* is not sufficiently clear about the basis for the jury's decision to identify clearly what specific issues with regard to violations of the MDA the jury decided, such as whether the AstroSeal HiRes 90k lacked pre-market approval.

In short, issue preclusion does not bar AB's reassertion of MDA preemption in this case.

2. FDA approval as a prerequisite to preemption

Second, the Eggerlings argue that their claims are not preempted by the MDA, because the specific cochlear implant that they allege caused their damage was not FDA-approved, where AB had made an unapproved substitution of an AstroSeal feed-thru assembly for the approved PA & E feed-thru assembly. This argument also fails.

Analysis of this argument begins and ends with the scope of MDA preemption. The parties agree that 21 U.S.C. § 360k(a) of the MDA provides for express preemption of certain claims "with respect to a device intended for human use," specifically, any claim "which is different from, or in addition to, any requirement applicable under this chapter to the device," and any claim "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); *see also Riegel v. Medtronic, Inc.*, 552 U.S. 312 (2008); *In re Medtronic, Inc. v. Sprint Fidelis Leads Prods. Liab. Litig.*, 623 F.3d 1200, 1204 (8th Cir. 2010). They also agree that, in *Buckman v. Plaintiffs' Legal Committee*, 531 U.S. 341 (2001), the Supreme Court recognized that 21 U.S.C. § 337(a) impliedly preempts private claims that directly enforce FDCA provisions against a manufacturer. *See also In re Medtronic*, 623 F.3d at 1204. Neither *Riegel* nor *Buckman* stands for the proposition that preemption—either express or implied—only applies to devices with a PMA under the MDA, the Eggerlings have cited no case that stands for such a proposition, and I have found none.

Indeed, in a decision on which the Eggerlings otherwise rely, Judge John G. Heyburn II, of the Western District of Kentucky, rejected the argument that a PMA for the specific medical device in question is a prerequisite for express preemption under § 360k(a) to apply, as follows:

> As an initial matter, Plaintiffs assert that because Advanced Bionics never obtained a PMA Supplement for the Vendor B [AstroSeal] HiRes 90k, it is not a PMA-approved device, and the preemption provisions of the MDA, and specifically § 360k, are inapplicable to this case. However, § 360k preempts claims "with respect to a device intended for human use." 21 U.S.C. § 360k(a). Under the FDCA, a device need not be PMA-approved to satisfy the definition of device. 21 U.S.C. § 321(h) [(defining "device")]. Therefore, § 360k preemption applies to a medical device regardless of its status as PMA-approved or not. Moreover, Advanced Bionics did obtain supplemental approval for the HiRes 90k itself. Therefore, this argument fails, and the Court finds that the MDA preemption provisions apply to the Vendor B HiRes 90k.

Sadler v. Advanced Bionics, Inc., ___ F. Supp. 2d ___, ___, 2013 WL 898152, *7 (W.D. Ky. March 8, 2013).

While it might make some sense for MDA preemption to apply only to "approved" medical devices, that simply is not the law. There is no requirement that a medical device be FDA-approved for preemption by the MDA to apply, and the Eggerlings' argument to the contrary fails.[4]

3. "Parallel" state law claims

Because the issue of MDA preemption of the Eggerlings' Iowa tort claims is not collaterally estopped or precluded, because it has been raised and resolved in other litigation, nor inapplicable, because the device at issue was allegedly not "FDA-approved," the remaining question is whether or what parts, if any, of the Eggerlings' remaining negligence and strict liability product liability claims are preempted. That

[4] Thus, whether or not the AstroSeal HiRes 90k was "FDA-approved"—a determination purportedly made in the negative in *Sadler*, which the Eggerlings argue has preclusive effect—is ultimately irrelevant to the preemption issue, because preemption is not contingent on a PMA or FDA approval for the specific device in question.

question turns on whether, or to what extent, the Eggerlings have asserted "parallel" state law claims.

a. The scope of MDA preemption

As the Eighth Circuit Court of Appeals has explained,

> Read together—
>
> > *Riegel* and *Buckman* create a narrow gap through which a plaintiff's state-law claim must fit if it is to escape express or implied preemption. 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*).
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> *Riley v. Cordis Corp.*, 625 F.Supp.2d 769, 777 (D. Minn. 2009).

In re Medtronic, 623 F.3d at 1204 (emphasis in the original). As the district court explained in *Riley*, "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." 625 F. Supp. 2d at 777. Such claims are non-preempted "parallel" state law claims.

b. Claims based on non-compliance with general CGMPs

The Eggerlings assert, *inter alia*, that their negligence and strict liability claims are based on violations of numerous Current Good Manufacturing Practices (CGMPs), set forth in FDA regulations.[5] I conclude, however, that claims based on alleged non-compliance with CGMPs are preempted, with limited exceptions identified below. As the court noted in *Sadler*, "Most of these CGMPs impose only administrative standards

[5] The Eggerlings have summarized these assertions in a chart, on pages 4 and 5 of their Response (docket no. 46), showing which claims are based on violations of which regulations.

or flexible guidelines rather than mandate manufacturing requirements" and that "[o]ther CGMPs cited in the Complaint are too general to impose a federal requirement on medical device manufacturers, such that enforcing a state law claim based on violations of those CGMPs would impose an additional requirement on manufacturers, which is preempted under 21 U.S.C. § 360k." ___ F. Supp. 2d at ___, 2013 WL 898152 at *11. To put it somewhat more specifically, I conclude that attempting to define the general requirements in CGMPs in the device-specific manner required for state tort liability to attach would necessarily impose obligations "different from, or in addition to, any requirement applicable under [the MDA] to the device," or would "relate[ ] to the safety or effectiveness of the device or to any other matter included in a requirement applicable to the device under [the MDA]." 21 U.S.C. § 360k(a). Thus, with the exceptions noted below, to the extent that the Eggerlings' negligence and strict liability claims rely on design, testing, or manufacturing requirements set forth in CGMPs, those claims are preempted.

c. Claims based on non-compliance with the PMA and specific CGMPs

My conclusion is much different as to the Eggerlings' claims based on non-compliance with the PMA for the HiRes 90k cochlear implant, because the PMA is necessarily device-specific. My conclusion is also different as to claims based on non-compliance with certain CGMPs that are sufficiently specific. I turn, therefore, to what design, manufacturing, and testing claims I conclude are *not* preempted, because they are based on non-compliance with the PMA for the HiRes 90k cochlear implant or CGMPs that are sufficiently specific.

i. Design defect claims

The Eighth Circuit Court of Appeals has stated that, as to design defect claims, "Absent concrete allegations that the product sold by [the manufacturer] was not the

product design approved in the PMA Supplement," claims that a product was designed "in a dangerous and defective condition" and "in a manner violative of the [MDA]" are not parallel claims and, consequently, are preempted. *In re Medtronic*, 623 F.3d at 1206. Here, however, the Eggerlings *have* made the appropriate allegations that the cochlear implant that their daughter received was not the product design approved in AB's PMA Supplement, so that their design defect claims are non-preempted "parallel" state-law claims. Specifically, in their "negligence" claim, the Eggerlings allege, *inter alia*, that the "[d]efendant breached its duty of reasonable care to Plaintiff by incorporating a defect in the design of the Device that was not approved by the FDA." Complaint (docket no. 1) at ¶ 199. Similarly, in their "strict liability" claim, alleging "design defects," the Eggerlings allege, *inter alia*, that "[t]he devices were designed . . . in a manner that violates the [FDCA] and applicable FDA regulations." *Id*. at ¶ 207; *see also id*. at ¶ 205 (incorporating by reference all preceding paragraphs of the Complaint).

These allegations would give rise to recovery under Iowa law, even in the absence of the FDCA, where the Eggerlings have alleged, and generated genuine issues of material fact, that the substitution of the AstroSeal feed-thru not only violated the MDA, but was what made the cochlear implant that their daughter received defectively designed within the meaning of Iowa law. *See Riley*, 625 F. Supp. 2d at 777 (the second requirement for a non-preempted "parallel" state law claim is that the defect alleged would give rise to a recovery under state law, even in the absence of the FDCA). Iowa products liability law for design defects, as defined by the RESTATEMENT (THIRD) § 2(b), is not cast in terms of a product that is "in a dangerous and defective condition," *compare In re Medtronic*, 623 F.3d at 1206, but in terms of whether "the foreseeable risks of harm posed by the product could have been reduced or avoided by the adoption of a reasonable alternative design by the [manufacturer], and

the omission of the alternative design renders the product not reasonably safe." *See* RESTATEMENT (THIRD) § 2(b); *see also Estate of Thompson v. Kawasaki Heavy Indus., Inc.*, ___ F. Supp. 2d ___, ___ 2013 WL 1248677, *19 (N.D. Iowa Feb. 25, 2013); *Nationwide Agribusiness Ins. Co. v. SMA Elevator Constr., Inc.*, 816 F. Supp. 2d 631, 657-58 (N.D. Iowa 2011). Here, the Eggerlings have alleged that it is AB's violation of the MDA, and specifically, AB's failure to use the design approved in the PMA, that renders the design of the cochlear implant that their daughter received not reasonably safe. Furthermore, to the extent that success on a "design defect" claim under Iowa law, that is under the RESTATEMENT (THIRD) § 2(b), requires proof of the existence of a reasonable alternative design that would have reduced the foreseeability of the harm posed by the product, *see Thompson*, ___ F. Supp. 2d at ___ 2013 WL 1248677 at *19; *Nationwide Agribusiness Ins. Co., Inc.*, 816 F. Supp. 2d at 657-58, the Eggerlings have pointed to the HiRes 90k with the PA & E feed-thru, for which there was indisputably a PMA under the MDA, as the reasonable alternative design.

Thus, the Eggerlings' negligent design and strict liability design defect claims are not preempted by the MDA to the extent those claims allege that the PMA was violated by substituting the AstroSeal feed-thru assembly.

ii. Manufacturing defect claims

Turning to manufacturing defect claims, the Eighth Circuit Court of Appeals also suggested in *In re Medtronics, Inc.*, that such claims cannot survive preemption unless they also rely on failure to manufacture the device in question in the manner approved in the PMA Supplement. *See* 623 F.3d at 1206-07 (explaining that the plaintiffs had not identified specific federal requirements in the PMA that were not satisfied and that formed the basis for a manufacturing defect that harmed the plaintiff, and holding that the plaintiffs' contention that they did not have access to the PMA to make such an allegation came too late). The Eggerlings *have* made the appropriate allegations that

the cochlear implant that their daughter received was not manufactured in compliance with AB's PMA Supplement, and they have alleged and generated genuine issues of material fact that such manufacturing defects caused their harm. Thus, they have alleged a manufacturing defect within the meaning of Iowa law, and their manufacturing defect claims are, to this extent, non-preempted "parallel" state-law claims. Specifically, the alleged manufacturing defect is a departure from the intended (and FDA approved) design of the cochlear implant that their daughter received, in that it included the AstroSeal feed-thru assembly, rather than the PA & E feed-thru assembly. *See Nationwide Agribusiness Ins. Co.*, 816 F. Supp. 2d at 663 (explaining the requirements for a manufacturing defect claim under Iowa law, as established by RESTATEMENT (THIRD) § 2(a), as departure from the intended design); *see also* 21 U.S.C. § 351(f)(1) (defining a class III medical device as "adulterated" if it does not have a PMA in effect). The Eggerlings specifically allege, and have generated genuine issues of material fact, that the cochlear implant that their daughter received was not manufactured in compliance with the FDA approved design in the PMA and that this failure rendered the device defective. *See* Complaint, Count I (Negligence), ¶ 201(a); Count II (Strict Liability), ¶ 207.

Thus, manufacturing defect claims based on allegations that the HiRes 90k cochlear implant that the Eggerlings' daughter received did not comply with the PMA, because it contained an unapproved AstroSeal feed-thru assembly, rather than the PA & E feed-thru assembly, are not preempted. As noted above, however, manufacturing defect claims based on allegations that AB failed to comply with GCMPs in the manufacturing process are preempted.

iii. Negligent and inadequate testing claims

The Eggerlings also assert claims based on negligent and inadequate testing—specifically, failure to subject the device to FDA approved or required testing—in their

negligence claim. *See* Complaint, Count I (Negligence), ¶¶ 200, 201(c), 203(q). RESTATEMENT (THIRD) § 2, which is recognized as the basis for Iowa product liability law, recognizes that inadequate testing, that is, testing that is not undertaken or that is performed in an inadequate manner, that results in a defect that causes harm can be the basis for liability. RESTATEMENT (THIRD) § 2, cmt. m; *id.* at cmt. n ("In connection with a claim under §§ 1 and 2 and related provisions of this Restatement, the evidence that the defendant did or did not conduct adequately reasonable research or testing before marketing the product may be admissible (but is not necessarily required) regardless of whether the claim is based on negligence, strict liability, or implied warranty of merchantability.").

Like the court in *Sadler*, I conclude that the CGMP requirement in 21 C.F.R. § 820.30(g), which requires AB to test products "under actual or simulated use conditions," is specific enough to support a parallel claim, because it "'impose[s] a concrete requirement on a manufacturer that embodies a standard of care related to the safety and effectiveness of the device.'" *See* ___ F. Supp. 2d at ___, 2013 WL 898152 at *11 (quoting *Purchase v. Advanced Bionics, L.L.C.*, 896 F. Supp. 2d 694, 698 (W.D. Tenn. 2011)). On the other hand, like the court in *Sadler*, I find that the plaintiffs here have not cited any federal regulations that require "life-cycle testing," so that imposing such a requirement would constitute imposing an additional duty pursuant to state law, which is expressly preempted by § 360k. *Id.* at *14. Here, the Eggerlings have leaped from FDA requests to see the results of "accelerated life-cycle testing" to some regulatory requirement for such testing, without citing any regulatory authority for the FDA's request or any requirement under the MDA for such testing. To the extent that the Eggerlings rely on language in 21 C.F.R. § 820.30(g) stating, "Design validation shall ensure that devices conform to defined user needs and intended uses," as requiring "life-cycle testing," that language is too general to support the specific

requirement of "life-cycle testing," and nowhere does that regulation define "conform[ing] to defined user needs" for cochlear implants as specifically including "life-cycle testing."

Thus, to the extent that the Eggerlings assert a negligent testing claim based on failure to test the AstroSeal HiRes 90k "under actual or simulated use conditions," that claim is not preempted by the MDA. On the other hand, to the extent that the Eggerlings assert a negligent testing claim based on failure to preform "life-cycle testing" on the AstroSeal HiRes 90k, that claim is preempted by the MDA.

III. CONCLUSION

Upon the foregoing, the Eggerlings' arguments that none of their claims are subject to MDA preemption, because of issue preclusion or lack of FDA approval for the cochlear implant that their daughter received, both fail. Although the Eggerlings have asserted some "parallel" claims that survive MDA preemption, they have also asserted claims that are expressly preempted by § 360k(a), or that are impliedly preempted, in light of § 337, because they are "backdoor" attempts at private enforcement of FDA regulations.

THEREFORE, AB's May 31, 2013, Motion For Summary Judgment (docket no. 41) is **granted in part and denied in part,** as follows:

1. The Motion is **granted** as to the Eggerlings' claims of breach of warranty, fraud, and intentional infliction of emotional distress, which the Eggerlings have "withdrawn" in response to AB's Motion;

2. The Motion is **granted** as to the Eggerlings' claims of violations of numerous Current Good Manufacturing Practices (CGMPs), set forth in FDA regulations, with exceptions identified below;

3. The Motion is **denied** as to the Eggerlings' negligent design and strict liability design defect claims, to the extent those claims allege that the PMA was violated by substituting the AstroSeal feed-thru assembly;

4. The Motion is **denied** as to the Eggerlings' manufacturing defect claims based on allegations that the HiRes 90k cochlear implant that the Eggerlings' daughter received did not comply with the PMA, because it contained an unapproved AstroSeal feed-thru assembly, rather than the PA & E feed-thru assembly; and

5. The Motion is

a. **denied** as to the Eggerlings' negligent testing claim based on failure to test the AstroSeal HiRes 90k "under actual or simulated use conditions," but

b. **granted** as to the Eggerlings' negligent testing claim based on failure to perform "life-cycle testing" on the AstroSeal HiRes 90k.

IT IS SO ORDERED.

DATED this 24th day of July, 2013.

Mark W. Bennett

MARK W. BENNETT
U.S. DISTRICT COURT JUDGE
NORTHERN DISTRICT OF IOWA