IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF OHIO
EASTERN DIVISION

CHRISTOPHER HAWKINS,	
Plaintiff,	**Case No. 2:11-cv-1037**
v.	**Judge Peter C. Economus**
MEDTRONIC, INC., *et al.*	**MEMORANDUM OPINION AND ORDER**
Defendants.	

Plaintiff Christopher Hawkins filed this action claiming that he was injured by a medical device made by Defendant Medtronic, Inc. In his Amended Complaint, Plaintiff alleges that the device, a Medtronic Implantable Pulse Generator, Model #7425 (hereinafter "IPG"), was defective and had to be replaced due to Defendant's failure to satisfy its obligations under the Federal Food, Drug, and Cosmetic Act, as amended by the Medical Device Amendments of 1976, 21 U.S.C. § 301 *et seq*. (Am. Compl. ¶ 39.) Plaintiff filed this action asserting various causes of action under Ohio law. This matter is before the Court for consideration of Defendant's Motion to Dismiss. (Dkt. 16.) For the reasons set forth below, the Court hereby **GRANTS IN PART** and **DENIES IN PART** Defendant's Motion.

I. Background

Plaintiff asserts the following facts. On October 15, 2009, the IPG was surgically implanted into Plaintiff's back. The IPG is designed to send electrical pulses to the spinal cord in order to interfere with the transmission of pain signals and replace them with a tingling sensation called parasthesia. (Am. Compl. ¶ 9.) For a few months, the IPG worked as expected. (*Id.* at ¶ 12.) However, in late December 2009 or early January 2010, Plaintiff began experiencing painful shocks at the implant site, even when he occasionally turned off the device in an attempt to alleviate the shocks. (*Id.* at ¶¶ 13–14.) On numerous occasions, Plaintiffs'

doctors, with the assistance of a Medtronic agent, unsuccessfully attempted to fix the IPG. (*Id.* at ¶¶ 15–16.) On March 22, 2010, Plaintiff's doctor, after consulting with a Medtronic agent, determined that the IPG needed to be replaced. (*Id.* at ¶ 17.) On March 31, 2010, the IPG was excised and replaced by a new model. (*Id.* at ¶ 18.)

II. Preemption Under The Medical Device Amendments

Congress enacted the Medical Device Amendments of 1976 ("MDA") "to provide for the safety and effectiveness of medical devices intended for human use." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 474 (1996) (quoting 90 Stat. 539). The MDA "classifies medical devices in three categories based on the risk that they pose to the public." *Id.* at 477. Class I devices present no unreasonable risk of illness or injury and are subject to minimal regulation. *Id.* at 477–78 (citing 21 U.S.C. § 360c(a)(1)(A)). Class II devices are potentially more harmful and must comply with increased regulation but may be marketed without advance approval. *Id.* at 478 (citing 21 U.S.C. § 360c(a)(1)(B)). Class III devices either "present[] a potential unreasonable risk of illness or injury" or are "purported or represented to be for a use in supporting or sustaining human life or for a use which is of substantial importance in preventing impairment of human health." *Id.* at 478 (citing § 360c(a)(1)(C). Before a manufacturer may introduce a new Class III device to the market, the manufacturer must provide the FDA with a "reasonable assurance" that the device is safe and effective through a rigorous process known as "premarket approval" or "PMA." *Id.* at 478 (citing 21 U.S.C. § 360e(d)(2)).

At issue in this case is the preemption provision of the MDA, contained in 21 U.S.C. § 360k(a), which provides generally[1] that:

> . . . no State . . . may establish or continue in effect with respect to a device intended for human use any requirement—

[1] Section 360k(b) provides that exemptions may be granted to states under certain circumstances.

> (1) which is different from, or in addition to, any requirement applicable under this Act 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 Act.

The Supreme Court has held that this provision "simply was not intended to pre-empt most, let alone all, general common-law duties enforced by damages actions." *Medtronic, Inc. v. Lohr*, 518 U.S. 470, 491 (1996).[2] Rather,

> [s]tate requirements are pre-empted under the MDA only to the extent that they are "different from, or in addition to" the requirements imposed by federal law. Thus, § 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.

Riegel v. Medtronic, Inc., 552 U.S. 312, 330 (2008) (citing § 360k(a)(1); *Lohr*, 518 U.S. at 495). In fact, the Supreme Court has noted that "[t]he presence of a damages remedy does not amount to [an] additional or different 'requirement' . . . ; rather, it merely provides another reason for manufacturers to comply with identical existing 'requirements' under federal law." *Lohr*, 518 U.S. at 495.

To determine whether a state requirement is pre-empted, the Court first "must determine whether the Federal Government has established requirements applicable to" the device in question. *Riegel*, 552 U.S. 312, 321 (2008) (quoting § 360k(a)). The Supreme Court has interpreted § 360k(a) "in a manner 'substantially informed' by the FDA regulation set forth at 21 CFR § 808.1(d)," which regulation states that "state requirements are pre-empted 'only when the Food and Drug Administration has established specific counterpart regulations or there are other

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[2] In *Lohr*, Medtronic "argue[d] that the plain language of the statute pre-empts any and all common-law claims brought by an injured plaintiff against a manufacturer of medical devices." *Lohr*, 518 U.S. at 486. The Court found that, under Medtronic's view of the statute, "Congress would have barred most, if not all, relief for persons injured by defective medical devices," with the "perverse effect of granting complete immunity from design defect liability to an entire industry that, in the judgment of Congress, needed more stringent regulation." *Id.* at 487.

specific requirements applicable to a particular device." *Riegel*, 552 U.S. at 322 (citing *Lohr*, 518 U.S. at 495, 500–01); 21 CFR § 808.1(d).

Defendant correctly points out that "[c]laims involving a PMA-approved device automatically satisfy [this] first condition of the preemption test." (Dkt. 16-1 at 4.) In *Riegel*, the Supreme Court held that PMA "imposes 'requirements' under the MDA as [that Court] interpreted it in *Lohr*" because, "[u]nlike general labeling duties, [PMA] is specific to individual devices." *Riegel*, 552 U.S. at 322–23.

If the federal requirements satisfy the first condition of the preemption test, the Court "must then 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." *Riegel*, 552 U.S. at 321–22 (quoting § 360k(a)). "[R]eference to a State's 'requirements' includes its common-law duties," including, for example, common-law causes of action for negligence and strict liability. *Riegel*, 552 U.S. at 323–24 (citing *Lohr*, 518 U.S. at 512). As noted above, because "[s]tate requirements are pre-empted under the MDA only to the extent that they are 'different from, or in addition to' the [federal] requirements." *Riegel*, 552 U.S. at 330 (citing § 360k(a)(1); *Lohr*, 518 U.S. at 495).

Where the preemption issue is decided on the pleadings, and the complaint has not defined "the precise contours of [the plaintiff's] theory of recovery," but "it is clear that the . . . allegations may include claims that [the defendant] has, to the extent that they exist, violated FDA regulations," the Supreme Court has held that these claims "can be maintained without being pre-empted by § 360k." *Lohr*, 518 U.S. at 495.

III. Standard of Review

Defendant seeks dismissal under Federal Rule of Civil Procedure 12(b)(6), which requires dismissal if the complaint fails to state a claim upon which relief can be granted. While Rule 8(a)(2) requires a pleading to contain a "short and plain statement of the claim showing that the pleader is entitled to relief," in order "[t]o survive a motion to dismiss, a complaint must contain sufficient factual matter, accepted as true, to 'state a claim to relief that is plausible on its face.'" *Ashcroft v. Iqbal*, 129 S. Ct. 1937, 1949 (2009) (quoting *Bell Atl. Corp. v. Twombly*, 550 U.S. 544, 570 (2007)). Furthermore, "[a]lthough for the purposes of a motion to dismiss [a court] must take all of the factual allegations in the complaint as true, [it] [is] not bound to accept as true a legal conclusion couched as a factual allegation." *Id.*, 129 S. Ct. at 1949–50 (quoting *Twombly*, 550 U.S. at 555) (internal quotations omitted).

The context of MDA preemption affects the application of this standard, as explained by the Western District of Kentucky:

> In the context of MDA preemption, *Twombly* and *Iqbal* make a plaintiff's job more difficult than it would be in a typical product liability case. When facing MDA preemption, a plausible cause of action requires, among other things, a showing that the alleged violation of state law parallels a violation of federal law. This additional step requires some greater specificity in the pleadings. However, our appellate courts have been unable to agree upon the precise level of that specificity. Nonetheless, . . . a plaintiff must provide "more than labels and conclusions, and a formulaic recitation of the elements of a cause of action will not do."

White v. Stryker Corp., 818 F. Supp. 2d 1032, 1037 (W.D. Ky. March 25, 2011) (quoting *Twombly*, 550 U.S. at 555) (emphasis added). However, as noted above, the Supreme Court has held that, to avoid preemption, the complaint need not define "the precise contours of [the plaintiff's] theory of recovery," if it alleges that the defendant has violated FDA regulations. *Lohr*, 518 U.S. at 495.

IV. Plaintiffs' Claims

Because Plaintiff's claims involve a PMA-approved device and therefore satisfy the first condition of preemption, the Court moves on to determine whether each claim against Defendant Medtronic is based on a parallel state requirement or one that is "different from, or in additional to" the federal requirements.

A. Count One: Design and Manufacturing Defects

In Count One, Plaintiff alleges that Defendant "designed, manufactured, distributed and sold the IPG [], an unreasonably dangerous, malfunctioning, and defective product to Ohio consumers, including Plaintiff Hawkins." (Am. Compl. 41.) Plaintiff alleges that the IPG "contained a design and/or manufacturing defect, was adulterated, failed to comply with Pre-Market Approval specifications, was not safe and/or effective, was non-conforming, and/or violated performance standards." (*Id.* at 43.) Plaintiff alleges that this "defect rendered [the IPG] more dangerous than an ordinary consumer would expect when used in an intended or reasonably foreseeable manner." (*Id.*) Plaintiff alleges that Defendant has therefore violated the statutes and regulations listed below and is strictly liable for the resulting injuries (*id.* at 43, 44):

i. The following sections of the Ohio Revised Code:

   a. Section 2307.74, which provides that "[a] product is defective in manufacture or construction if, when it left the control of its manufacturer, it deviated in a material way from the design specifications, formula, or performance standards of the manufacturer, or from otherwise identical units manufactured to the same design specifications, formula, or performance standards."

   b. Section 2307.75, which provides generally that "a product is defective in design or formulation if, at the time it left the control of its manufacturer, the foreseeable risks associated with its design or formulation . . . exceeded the benefits associated with that design or formulation."

ii. The MDA, including but not limited to the following sections of Title 21 of the U.S. Code:

a. Section 351, which describes the circumstances under which a "device shall be deemed to be adulterated."

b. Section 360(e), by which the Court assumes Plaintiff meant § 360e, which sets forth the rules regarding the PMA process.

c. Section 360(d), by which the Court assumes Plaintiff meant § 360d, which sets forth the rules regarding performance standards.

d. Section 360(h), by which the Court assumes Plaintiff meant § 360h, which sets forth the rules regarding the FDA's authority to issue notifications regarding unsafe devices and provide other remedies.

iii. The following sections of Title 21 of the Code of Federal Regulations:

a. Section 820.1, which sets forth the scope of the FDA's quality system regulation.

b. Section 820.5, which requires medical device manufacturers to establish and maintain a quality system.

c. Section 820.20, which provides for management responsibility.

d. Section 820.22, which requires quality audits.

e. Section 820.25, which sets qualification requirements for manufacturer personnel.

f. Section 820.30, which provides that manufacturers must "establish and maintain procedures to control the design of the device in order to ensure that specified design requirements are met."

g. Section 820.70, which sets forth rules regarding production and process controls.

h. Section 820.72, which sets forth rules regarding inspection, measuring, and test equipment.

i. Section 820.75, which sets forth rules regarding process validation.

j. Section 820.80, which requires manufacturers to "establish and maintain procedures for acceptance activities . . . includ[ing] inspections, tests, or other verification activities.

k. Section 820.86, which requires manufacturers to identify the "conformance or nonconformance of product with acceptance criteria . . . throughout manufacturing, packaging, labeling, installation, and servicing of the product to ensure that only product which has passed the required acceptance activities

is distributed, used, or installed."

l. Section 820.90, which requires manufacturers to "establish and maintain procedures to control product that does not conform to specified requirements."

m. Section 820.100, which requires manufacturers to "establish and maintain procedures for implementing corrective and preventive action" to address nonconforming product.

1. Design Defect

Defendant incorrectly argues that design defect claims are automatically preempted under the MDA. "[W]here the FDA has specifically approved of the design of the device for investigational purposes, the Sixth Circuit has held that "[t]o allow a cause of action for design defect . . . would thwart the goals of safety and innovation." *Martin v. Telectronics Pacing Sys.*, 105 F.3d 1090, 1099 (6th Cir. 1997) (emphasis added). The same analysis does not apply to a non-investigational device approved through the PMA process; however. *See Kemp v. Medtronic, Inc.*, 1999 U.S. Dist. Lexis 22470, *26–27 (S.D. Oh. Jan. 12, 1999) (holding that the same analysis applies, dismissing design defect claims), *overruled, Kemp v. Medtronic*, 231 F.3d 216, 226 (6th Cir. Ohio 2000) (affirming on different grounds after determining that the purported state requirements exceeded the specific design requirements imposed through the PMA process).

In *Kemp*, which was decided on summary judgment, "[t]he essence of plaintiffs' [state law design defect claim was] that Medtronic failed to coat the lead" to a pacemaker to a uniform thickness. *Kemp*, 231 F.3d at 229. Because the Sixth Circuit found that the specific federal requirements established through the PMA process did "not include a requirement as to the thickness" of the coating, that Court concluded that the plaintiff's state law claim "would . . . impose a requirement different from and in addition to those established by the FDA." *Id.* at 230. The state law claim was therefore preempted. *Id.*

As in *Kemp*, the state law design requirements must not exceed the specific design requirements imposed through the PMA process. Because the preemption issue here must be decided on the pleadings, and the complaint has not defined "the precise contours of [the plaintiff's] theory of recovery," the Court can not engage in a detailed comparison of the specific state and federal requirements at issue. However, because "it is clear that the . . . allegations . . . include claims that [Defendant] has . . . violated FDA regulations," these claims "can be maintained without being pre-empted by § 360k." *See Lohr*, 518 U.S. at 495. The Court therefore **DENIES** Defendant's motion as to Plaintiff's design defect claim.

2. Manufacturing Defect

Defendant asserts simply that "[a] manufacturing defect claim is undeniably preempted," quoting *Riegel* for the proposition that "the MDA preempt[s] a negligent manufacturing claim insofar as it [is] not premised on the theory that [the defendant] violated federal law." (Dkt. 16-1 at 7–8 (quoting *Riegel*, 552 U.S. at 320). While Defendant's quotation from *Riegel* is taken out of context, the Supreme Court did hold that the MDA "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." *Riegel*, 552 U.S. at 330 (emphasis added) (citing *Lohr*, 518 U.S. at 495).

While the complaint has not defined "the precise contours of [the plaintiff's] theory of recovery," and the Court cannot engage in a detailed comparison of the specific state and federal requirements at issue, it is clear from the allegations that Plaintiff's claim is in fact premised on the theory that Defendant violated federal law. The Court therefore **DENIES** Defendant's motion as to Plaintiff's manufacturing defect claim. *See Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495.

The Court notes that if, following the completion of discovery, it appears that Plaintiff

cannot sustain a claim under state requirements that parallel federal requirements, Defendant would be free to file a motion for summary judgment.

B. Count Two: Failure to Warn

In Count Two, Plaintiff alleges that Defendant "knew or should have known of the potential for and/or actual presence of the defect," and, "[h]aving such knowledge, Defendant failed to provide adequate warnings and/or instructions, both at the time of marketing and afterwards." (Am. Compl. ¶ 49.) Plaintiff alleges that Defendant thus violated the following statutes and regulations (*id.* at 49–50):

i. Ohio Revised Code §§ 2307.76 and 2307.80, which provide a cause of action for product liability against a manufacturer which knows or should have known about a risk and fails to provide reasonable warning or instruction regarding the risk.

ii. 21 U.S.C. § 360(h), by which the Court assumes Plaintiff meant § 360h, which sets forth the rules regarding the FDA's authority to issue notifications regarding unsafe devices and provide other remedies.

iii. 21 U.S.C. § 360(i), by which the Court assumes Plaintiff meant § 360i, which requires manufacturers to establish and maintain records, make reports, and provide information to assure that devices are not adulterated or misbranded and to otherwise assure safety and effectiveness.

iv. 21 C.F.R. §§ 803.50 and 803.52, which describe reporting requirements.

v. 21 C.F.R. § 814.82, which describes allowable post-PMA requirements.

Defendant argues that Plaintiff's failure to warn claim is preempted, citing *In re Medtronic Inc.*, 592 F. Supp. 2d 1147, 1159 (D. Minn. 2009), in which that court held that "[m]andating that a manufacturer provide warnings beyond those on the device label would impose requirements 'different from, or in addition to' those approved by the FDA, and are thus preempted."

To the extent that Plaintiffs allege that Defendants' FDA-approved warnings "were inadequate under Ohio law," such claims would be preempted. *Kemp*, 231 F.3d at 237.

However, to the extent that Plaintiff alleges "a claim for breach of [Medtronic's] duty under state law to warn . . . of potential risks . . . based on information obtained subsequent to FDA approval of the device," it is not clear whether such a claim would be preempted. *Id.* (not reaching the question).

As with Count One, the complaint has not defined "the precise contours of [the plaintiff's] theory of recovery," and the Court cannot engage in a detailed comparison of the specific state and federal requirements at issue. It is clear from the allegations, however, that Plaintiff's claim is premised on the theory that Defendant violated federal law. The Court therefore **DENIES** Defendant's motion as to Count Two. *See Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495.

The Court notes that if, following the completion of discovery, it appears that Plaintiff cannot sustain a claim under state requirements that parallel federal requirements, Defendant would be free to file a motion for summary judgment.

C. Count Three: Negligent Handling

In Count Three, Plaintiff alleges that Defendant "failed to establish and/or maintain adequate distribution, installation, handling, and/or inspection instructions and/or procedures" in violation of the MDA and 21 C.F.R. §§ 820.140, 820.150, 820.160, and 820.170. (Am. Compl. ¶ 54.)

Because Plaintiff does not identify a cause of action under Ohio law, and the MDA provides none, *Lohr*, 518 U.S. at 487, Count Three is **DISMISSED**.

D. Count Four: Breach of Express and Implied Warranties

In Count Four, Plaintiff alleges that "Defendant breached its expressed and implied warranties regarding the safety and utility of its defective IPG []." (Am. Compl. ¶ 58.)

1. Express Warranty

Defendant argues that Plaintiff's claim of breach of express warranty is preempted, citing the Fifth Circuit's decision in *Gomez v. St. Judge Med. Diag Div., Inc.*, 442 F.3d 919, 932 (2006). (Dkt. 16-1 at 10.) In *Gomez*, the Fifth Circuit stated that, according to all but one of the appellate courts which had considered the issue, a district court must "look through the general duties imposed by the state-law causes of action and consider the effect a successful lawsuit . . . would have and determine whether they threaten the federal PMA process requirements." *Gomez*, 442 F.3d at 929–30. The Fifth Circuit held that the plaintiff's claim for breach of express warranty under Louisiana law was preempted because it would rely on a factual finding that the defendant's representations regarding the medical device were untrue. "Because those representations—including the label, warnings, and [instructions for use]—were approved by the FDA through the PMA process, the duties arising under [state law] relate to, and are potentially inconsistent with, the federal regulatory scheme." *Gomez*, 442 F.3d at 932.

Here, however, a claim for breach of express warranty does not require a finding that the representations are untrue. The elements of such a claim under Ohio law are as follows:

> (1) the manufacturer of the product, through advertising, makes representations regarding the quality and merit of its product,
>
> (2) the representations are aimed directly at the ultimate consumer, urging the consumer to purchase the product,
>
> (3) the consumer, relying on the manufacturer's representations, does purchase the product, and
>
> (4) the consumer suffers harm as a result of that reliance.

Wagner v. Roche Lab., 709 N.E.2d 162, 166 (Ohio 1999) (citing *Rogers v. Toni Home Permanent Co.*, 167 Ohio St. 244 (1958)). Because an Ohio claim for breach of express warranty does not require a finding that the manufacturer's representations are untrue, the Court

finds that a successful lawsuit would not "threaten the federal PMA process requirements." *See Gomez*, 442 F.3d at 929–30.

Defendant develops no other arguments as to this claim, and its motion is **DENIED** as to Plaintiff's claim for breach of express warranty.

2. Implied Warranty

The elements of an Ohio claim for breach of implied warranty claim are:

> (1) the existence of a defect in the product manufactured and sold by the defendant,
>
> (2) the defect existed when the product left the hands of the defendant, and
>
> (3) the defect was the direct and proximate cause of the plaintiff's injuries.

Tompkin v. Philip Morris USA, Inc., 362 F.3d 882, 903 (6th Cir. 2004) (citing *White v. DePuy, Inc.*, 129 Ohio App. 3d 472, 718 N.E.2d 450, 455–56 (Ohio Ct. App. 1998)). While Plaintiff does not identify the federal violations that correspond to this claim, his other claims clearly identify such violations.

According to Defendant, the *Riegel* Court held that "the MDA pre-empt[s] claims of . . . breach of implied warranty." (Dkt. 16-1 at 10 (quoting *Riegel*, 552 U.S. at 320–21).) Defendant again takes a quote out of context; the *Riegel* Court was merely stating the lower court's ruling. The *Riegel* Court in fact held that the state law "duties underlying negligence, strict-liability, and implied-warranty claims" were requirements subject to potential preemption. *Riegel*, 552 U.S. at 327–28. However, the Court did not address whether such requirements in that case were "different from, or in addition to" the federal requirements, and therefore preempted, because the plaintiffs had not argued below that the state requirements were parallel to the federal requirements. *Id.* at 330.

While the complaint has not defined "the precise contours of [the plaintiff's] theory of

recovery," and the Court cannot engage in a detailed comparison of the specific state and federal requirements at issue, it is clear from the allegations that Plaintiff's claim is in fact premised on the theory that Defendant violated federal law. The Court therefore **DENIES** Defendant's motion as to Plaintiff's implied warranty claim. *See Riegel*, 552 U.S. at 330; *Lohr*, 518 U.S. at 495.

The Court notes that if, following the completion of discovery, it appears that Plaintiff cannot sustain a claim under state requirements that parallel federal requirements, Defendant would be free to file a motion for summary judgment.

E. Count Five: Negligent and Fraudulent Misrepresentation

In Count Five, Plaintiff alleges that "Defendant provided a defective product which failed to conform to [Defendant's] representations," and that Defendant "negligently and/or fraudulently misrepresented the safety and utility of" the IPG, in violation of Ohio Revised Code § 2307.77 and 21 C.F.R. § 801.6. (Am. Compl. ¶ 63.)

The Sixth Circuit has held that, in the context of investigational devices, claims under Ohio Revised Code § 2307.77 are preempted by the MDA. *Martin v. Telectronics Pacing Sys.*, 105 F.3d 1090, 1100 (6th Cir. 1997) (citing *Martin v. Telectronics Pacing Sys.*, 70 F.3d 39, 42 (6th Cir. 1995)). Finding no reason to distinguish representations made regarding investigational devices from representations made regarding non-investigational devices, the Court **GRANTS** Defendant's motion as to Count Five.

F. Count Six: Failure to Report

In Count Six, Plaintiff alleges that Defendant "fail[ed] to adequately and accurately record and/or report a malfunction, adverse event, reportable event, and/or product problem associated with [the IPG]," in violation of 21 U.S.C. § 360(i) and 21 C.F.R. §§ 803.1, 803.10, 803.50, 803.52, 814.82, 820.65, 820.90, 820.184, 820.186, 820.198, 820.200, and 821.25. (Am.

Compl. ¶ 68.) Plaintiff alleges that Defendant "failed to have a system to identify defective products, to maintain a quality system record, [and] to maintain a device history record[;] and failed to properly investigate and/or report a complaint or service a device." (*Id.*)

The MDA provides no private cause of action, *Lohr*, 518 U.S. at 487, and Plaintiff identifies no cause of action under Ohio law. Even assuming that Ohio law provides a cause of action for Claim Six, such a claim would be preempted by the MDA. The Supreme Court has held that a "state-law fraud-on-the-FDA claim[] [would] conflict with, and [is] therefore impliedly pre-empted by federal law." *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 348 (2001). The *Buckman* Court explained that the FDA is amply empowered to punish and deter fraud against it, and the agency uses this authority "to achieve a somewhat delicate balance of statutory objectives" that "can be skewed by allowing fraud-on-the-FDA claims under state tort law." *Buckman*, 531 U.S. at 348. Claim Six therefore fails to state a claim upon which relief can be granted and is hereby **DISMISSED**.

V. Conclusion

For the reasons discussed above, Defendant's Motion is **GRANTED** as to Counts Three, Five, and Six and **DENIED** as to Counts One, Two, and Four. (Dkt. 16.) **COUNTS THREE, FIVE,** and **SIX** are hereby **DISMISSED**.

IT IS SO ORDERED.

/s/ Peter C. Economus - September 24, 2012
UNITED STATES DISTRICT JUDGE