

UNITED STATES DISTRICT COURT
 SOUTHERN DISTRICT OF INDIANA
 INDIANAPOLIS DIVISION

WILLIAM L. GRIFFIN, SR,)	
REGINALD JACKSON, JR,)	
)	
Plaintiffs,)	
)	
v.)	No. 1:17-cv-03292-JMS-MJD
)	
MEDTRONIC INC.,)	
MEDTRONIC MINIMED, INC.,)	
)	
Defendants.)	

ORDER

The co-administrators of Arleen Griffin’s estate (the “Estate”) allege that Ms. Griffin’s death on March 13, 2013 was caused by a malfunctioning insulin pump. Four years later, the Estate brought suit against the companies that manufactured the insulin pump, Medtronic, Inc. and Medtronic Minimed, Inc., (collectively, “Defendants”). [[Filing No. 1.](#)] On December 8, 2017, Defendants filed a Motion to Dismiss, [[Filing No. 19](#)], along with a Declaration from counsel and four exhibits, [[Filing No. 21](#)]. A month later, the Estate filed a Motion to Strike Defendants’ Declaration and exhibits, or otherwise treat Defendants’ Motion to Dismiss as a Motion for Summary Judgment. [[Filing No. 26.](#)] The Estate’s Motion to Strike is now fully briefed and is ripe for the Court’s consideration.

**I.
 BACKGROUND**

In this suit, the Estate alleges that on March 13, 2013, a Medtronic Insulin Pump failed to consistently deliver insulin to Arleen Griffin, resulting in her death. [[Filing No. 1 at 3.](#)] On September 15, 2017, the Estate filed suit against Defendants, claiming eleven causes of action

arising out of Ms. Griffin's death, including: (1) strict liability, (2) negligence, (3) failure to warn, (4) design defect, (5) manufacturing defect, (6) breach of express warranty, (7) breach of implied warranty of fitness for a particular purpose, (8) breach of implied warranty of merchantability, (9) punitive damages, (10) unjust enrichment, and (11) loss of consortium. [[Filing No. 1 at 4-16.](#)]

On December 8, 2017, Defendants filed a Motion to Dismiss the Estate's Complaint, alleging that it pleads claims that "are not recognized under Indiana law, are inadequately pleaded, and are expressly and/or impliedly preempted in their entirety by the Medical Device Amendments ("MDA") to the federal Food, Drug, and Cosmetic Act. . . ." [[Filing No. 19 at 1.](#)]

Contemporaneously with filing their Motion to Dismiss, Defendants filed four exhibits in support thereof, along with a declaration. [[Filing No. 21.](#)] Three of Defendants' supporting documents involve premarket approval ("PMA") from the U.S. Food and Drug Administration ("FDA"):

1. the FDA PMA database listing for the Medtronic MiniMed Continuous Glucose Monitoring System, [[Filing No. 21-1](#)];
2. a June 15, 1999 FDA Approval Letter for the Medtronic MiniMed Continuous Glucose Monitoring System's PMA, [[Filing No. 21-2](#)]; and
3. the FDA PMA database listing for the Paradigm Real-Time Insulin Infusino (sic) Pumps, [[Filing No. 21-3](#)],

(collectively, the "PMA Documents").

Defendants cite the PMA Documents in the memorandum in support of their Motion to Dismiss for the proposition that "the FDA originally granted premarket approval to the MiniMed Continuous Glucose Monitoring System on June 15, 1999, under PMA No. 980022, and has since approved numerous supplements." [[Filing No. 20 at 4-5.](#)] The PMA Documents specifically relate

to Defendants' argument that the Estate's claims are preempted by federal law. [[Filing No. 20 at 23.](#)]

In addition to the PMA Documents, Defendants also filed a summary of probate documents related to the Estate, [[Filing No. 21-3](#)], which Defendants cite in support of their contention that "court records reveal that Plaintiffs opened Ms. Griffin's estate for the 'sole purpose of collecting damages for wrongful death,' with no mention of any loss of consortium claim." [[Filing No. 20 at 38.](#)]

In lieu of responding to Defendants' Motion to Dismiss, the Estate filed a Motion to Strike Defendants' Declaration and exhibits, or otherwise treat Defendants' Motion to Dismiss as a Motion for Summary Judgment. [[Filing No. 26.](#)]

II. DISCUSSION

In their Motion to Strike, the Estate argues that the Declaration and exhibits that Defendants filed in support of their Motion to Dismiss are matters outside the pleadings, and that "pursuant to Rule 12(d), the Court should either strike the Declaration and exhibits or treat the Defendants' Motion as one for summary judgment under Rule 56." [[Filing No. 26 at 2.](#)]

In response, Defendants argue that the Court should not strike the PMA Documents and may take judicial notice of the same because "they are government records maintained on the FDA's public database, and are therefore not subject to reasonable dispute." [[Filing No. 27 at 2.](#)]

In addition, Defendants argue that the Court should not convert the Motion to Dismiss to a motion for summary judgment because "[s]uch a result would be unfair and unsupported in the law." [[Filing No. 27 at 2.](#)]

With respect to the summary of probate documents, Defendants argue that the Court may take judicial notice of such documents and that "simply providing the Court with publicly-available court records that the Court is otherwise permitted to take judicial notice of on

a Rule 12(b)(6) motion should not result in the conversion of a Rule 12(b)(6) motion to a Rule 56 motion for summary judgment.” [\[Filing No. 27 at 4.\]](#)

In its reply brief, the Estate argues that “judicial notice can be taken as to the existence” of the PMA Documents, “but not as to the contents of the documents—even if the documents are available as public records on the FDA’s website.” [\[Filing No. 32 at 3 \(emphasis in original\).\]](#)

[Federal Rule of Civil Procedure 12\(f\)](#) provides that the court “may strike from a pleading an insufficient defense or any redundant, immaterial, impertinent, or scandalous matter.” The court may either strike on its own or on a motion by a party and has “considerable discretion” in striking any redundant, immaterial, impertinent, or scandalous matter. [Delta Consulting Grp., Inc. v. R. Randle Const., Inc., 554 F.3d 1133, 1141 \(7th Cir. 2009\).](#)

The Court finds significant the fact that the PMA Documents are, by Defendants’ own admission, related only to Defendants’ preemption argument. [\[Filing No. 27 at 4.\]](#) The substance of that argument is that the Estate’s Complaint fails to allege that the design of the product at issue differed from federal requirements. [\[Filing No. 20 at 16; Filing No. 20 at 17.\]](#) However, in a decision issued two days before Defendants filed their Motion to Dismiss, this Court held that “[t]his argument asks more of [the plaintiff] than what is required at the pleading stage.” [Bailey v. Medtronic, Inc., 2017 WL 6035329, at *7 \(S.D. Ind. Dec. 6, 2017\)](#) (quoting [Fisk v. Medtronic, Inc., 2017 WL 4247983, at *5 \(N.D. Ind. Sept. 25, 2017\)](#)). This Court’s prior adoption of the holding in *Fisk* renders the PMA Documents immaterial at this stage in the litigation. Specifically, in *Bailey*, this Court quoted at length from *Fisk*’s finding that:

In order to ultimately prevail on this claim, [the plaintiff] will have to prove that Medtronic violated a federal requirement in manufacturing the device and that she suffered an injury as a result of a defect caused by that violation. But preemption is an affirmative defense, and complaints need not address or plead around affirmative defenses . . . If a complaint need not plead such a violation in the first place, it follows that a complaint need not trace the injury to such a violation in particular.

[Bailey, 2017 WL 6035329](#), at *7 (quoting [Fisk, 2017 WL 4247983](#), at *5 (citations omitted)). The same logic applies to the Court’s consideration of the pending Motion to Strike: if a complaint need not plead around preemption, then the Court need not consider PMA Documents relating only to a preemption argument in connection with a Motion to Dismiss. Such documents are, therefore, immaterial to the Court’s consideration of the Motion to Dismiss and will be stricken.

The Court notes, however, that the Estate appears to concede that the Court may take judicial notice of the existence of the PMA Documents, just not the contents. [[Filing No. 32 at 3.](#)] Accordingly, if in considering Defendants’ Motion to Dismiss or any subsequent motion, the Court finds it appropriate to take judicial notice of the existence of the PMA Documents, it will do so at that time.

The same applies to the summary of probate documents related to the Estate. See [United States v. Wood, 925 F.2d 1580, 1582 \(7th Cir. 1991\)](#) (“[t]he district court may also take judicial notice of matters of public record”). If necessary, the Court may take judicial notice of the summary of probate documents related to the Estate at an appropriate time.

III. CONCLUSION

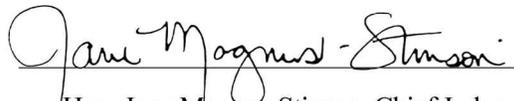
For the foregoing reasons, the Estate’s Motion to Strike, [26], is **GRANTED** and Defendants’ Declaration and supporting exhibits, [[Filing No. 21](#)], are stricken. However, nothing in this Order shall preclude the Court from taking judicial notice of any documents in the future, consistent with the law of this Circuit.

The Estate is **GRANTED** fourteen (14) days from the date of this Order in which to respond to Defendants’ Motion to Dismiss. In the alternative, the Estate is reminded that, pursuant to [Federal Rule of Civil Procedure 15\(a\)\(1\)\(B\)](#), a plaintiff may amend its complaint once as a matter of course in response to a motion to dismiss. [Mitchell v. Muncie Cmty. Sch., 2016 WL](#)

[3031084](#), at *8 n.3 (S.D. Ind. May 27, 2016). The 2009 notes to Rule 15 emphasize that this “will force the pleader to consider carefully and promptly the wisdom of amending to meet the arguments in the motion. A responsive amendment may avoid the need to decide the motion or reduce the number of issues to be decided, and will expedite determination of issues that otherwise might be raised seriatim.” Accordingly, should the Estate opt to amend its Complaint, it is **GRANTED** fourteen (14) days from the date of this Order in which to do so. In doing so, the Estate may find it provident to tailor its claims to those recognized by the Indiana Product Liability Act, consistent with this Court’s holding in [Bailey, 2017 WL 6035329](#).

Regardless of whether the Estate responds to the Motion to Dismiss or amends its Complaint in response thereto, the Court believes its analysis in [Bailey, 2017 WL 6035329](#) will inform its resolution of this matter. The parties are therefore advised that any subsequent briefs should specifically address the pleadings in this case in light of such analysis.

Date: 2/8/2018


Hon. Jane Magnus-Stinson, Chief Judge
United States District Court
Southern District of Indiana

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