IN THE UNITED STATES DISTRICT COURT
FOR THE SOUTHERN DISTRICT OF ILLINOIS

IN RE DEPAKOTE:	)	
	)	
RHEALYN ALEXANDER, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**Case No. 12-CV-52-NJR-SCW**
	)	
ABBOTT LABORATORIES, INC., and ABBVIE, INC.,	)	**LEAD CONSOLIDATED CASE**
	)	
	)	
Defendants.	)	

MEMORANDUM AND ORDER

ROSENSTENGEL, District Judge:

On January 19, 2017, Defendants filed several identical motions for summary judgment claiming absolute immunity under the statutory defense established by Michigan products liability law.[1] *Compare* (Case No. 12-CV-163, Doc. 82) *with* (Case No. 14-CV-1069, Doc. 13). The applicable Plaintiffs filed uniform responses to the motions on February 2, 2017. *See e.g.*, (Case No. 14-CV-1069, Doc. 14); (Case No. 13-CV-414, Doc. 15). On February 9, 2017, Defendants filed uniform replies to Plaintiffs' responses. *See e.g.*, (Case No. 14-CV-1069, Doc. 15); (Case No. 14-CV-414, Doc. 16). The motions, responses, and replies are all substantively identical; thus, the Court issues one omnibus Order addressing the issue. References to the docket in this Memorandum and Order will be to Case No. 12-CV-1216, unless otherwise specified.

[1] The summary judgment motions were filed in the following cases: Case No. 12-CV-54; Case No. 12-CV-57; Case No. 12-CV-163; Case No. 12-CV-1091; Case No. 12-CV-1216; Case No. 13-CV-134; Case No. 13-CV-414; Case No. 13-CV-443; Case No. 13-CV-622; Case No. 13-CV-758; Case No. 13-CV-890; Case No. 13-CV-1115; Case No. 13-CV-1157; Case No. 13-CV-1312; Case No. 14-CV-1069; Case No. 15-CV-102; Case No. 15-CV-472; and Case No. 16-CV-463.

The individual claims subject to the instant motion include: (1) Karin Townsend, individually as parent and next friend of T.M.O., a minor; (2) Ana J. Jimenez, individually as parent and next friend of K.R., a minor; (3) Mary Hobbins, individually and as parent and next friend of B.H., a minor; (4) De'Wanda O'Neil, individually and as parent and next friend of I.O., a minor; (4) Catherine Harries, individually as parent and next friend of G.H., a minor; (5) Christine Nelson, individually as parent and next friend of D.N., a minor; (6) Amanda Castle individually and as next of friend of B.C., a minor; (7) Tiffany Burroughs, individually as parent and next friend of T.B-L., a minor; (8) Jamie Bailey, individually as parent and next friend of G.L., a minor; (9) Stacy L. Rowland, individually and as next friend of C.R., a minor; (10) Laresa Vance, individually and as next friend of T.V., a minor; (11) Mary Massi-Lee, individually and as next friend of H.L., a minor; (12) Jennifer Klaasen, individually and as next friend of K.H., a minor; (13) Ashley M. Price, individually and as next friend of A.P., a minor; (14) Ronald Cimini, individually as parent of A.C., a minor; (15) Lisa Marentette, individually and as next friend of C.M., decedent; (16) Jennifer Robinson, individually and as next friend of B.R., a minor; (17) Tawanna Simmons, individually and as next friend of Z.S., a minor; (18) Jody Ladoux, individually and as next friend of C.H., (19) Shellee Grochowski, as parent and natural guardian of K.C., a minor; (20) Lori Pickering, individually and as parent and next friend of D.P.; (21) Francine Adams, individually as next friend and legal guardian of C.A., a minor; and (22) Christina Simpson, individually as parent of A.S., a minor.

Plaintiffs in this mass action allege that they suffered serious birth defects as a direct result of exposure to Depakote.[2] The exposure for each Plaintiff is alleged to have occurred

[2] "Depakote" refers to Abbott's group of prescription drugs with the basic active ingredient valproic acid. Depakote is also sometimes referred to by the chemical names "valproic acid," "valproate," or "divalproex

in utero after his or her biological mother ingested Depakote during pregnancy. Plaintiffs contended that Defendants failed to warn Plaintiffs' biological mothers of the real risk of birth defects, even though Defendants knew or reasonably should have known of the true risks.

The Court has jurisdiction over the Depakote mass action and all of the individual claims via diversity jurisdiction, including expanded diversity jurisdiction under 28 U.S.C. § 1332(d)(11)(B)(i), also known as the Class Action Fairness Act ("CAFA"). *See* (Case No. 12-CV-52, Doc. 667) (dismissing several Plaintiffs for lack of subject matter jurisdiction, as they failed to properly plead typical diversity jurisdiction or invoke CAFA). There is no dispute that under Illinois choice of law principles, Michigan law applies to the claims of these Plaintiffs. (Doc. 52, p. 3); *See* (Doc. 53, p. 4). Instead, the only dispute is whether Defendants are entitled to full immunity under the applicable Michigan statute.

SUMMARY JUDGMENT STANDARD

Summary judgment is only appropriate "if the movant shows that there is no genuine dispute as to any material fact and the movant is entitled to judgment as a matter of law." *Spurling v. C & M Fine Pack, Inc.*, 739 F.3d 1055, 1060 (7th Cir. 2014) (*quoting* FED. R. CIV. P. 56(a)). Once the moving party has set forth the basis for summary judgment, the burden then shifts to the nonmoving party who must go beyond mere allegations and offer specific facts showing that there is a genuine issue of fact for trial. FED. R. CIV. P. 56(e); *see Celotex Corp. v. Catrett*, 477 U.S. 317, 232-24 (1986). The nonmoving party must offer more than "[c]onclusory allegations, unsupported by specific facts," to establish a genuine issue of material fact. *Payne v. Pauley*, 337 F.3d 767, 773 (7th Cir. 2003) (*citing Lujan v. Nat'l Wildlife*

sodium." Depakote is an anti-epilepsy drug ("AED") that has been marketed by Abbott in the United States in some form since 1978.

Fed'n, 497 U.S. 871, 888 (1990)). In determining whether a genuine issue of fact exists, the Court must view the evidence and draw all reasonable inferences in favor of the party opposing the motion. *Bennington v. Caterpillar Inc.*, 275 F.3d 654, 658 (7th Cir. 2001); *see also Anderson v. Liberty Lobby, Inc.*, 477 U.S. 242, 255 (1986). A "court may not assess the credibility of witnesses, choose between competing inferences or balance the relative weight of conflicting evidence . . . ." *Reid v. Neighborhood Assistance Corp. of America*, 749 F.3d 581, 586 (7th Cir. 2014) (*quoting Abdullahi v. City of Madison*, 423 F.3d 763, 769 (7th Cir. 2005)).

DISCUSSION

Michigan law creates almost total immunity for drug manufacturers and sellers. Simply put, "[a] manufacturer or seller of a drug that has been approved by the FDA [United States Food and Drug Administration] has an absolute defense to a products liability claim if the drug and its labeling were in compliance with the FDA's approval at the time the drug left the control of the manufacturer or seller." *Taylor v. Smithkline Beecham Corp*, 658 N.W.2d 127, 131 (Mich. 2003); *See* MICH. COMP. LAWS ANN. § 600.2946(5). The Michigan legislature carved out two exceptions to the affirmative defense for circumstances in which the drug manufacturer or seller:

> (a) Intentionally withholds from or misrepresents to the United States food and drug administration information concerning the drug that is required to be submitted under the federal food, drug, and cosmetic act, chapter 675, 52 Stat. 1040, 21 U.S.C. 301 to 321, 331 to 343-2, 344 to 346a, 347, 348 to 353, 355 to 360, 360b to 376, and 378 to 395, and the drug would not have been approved, or the United States food and drug administration would have withdrawn approval for the drug if the information were accurately submitted.
>
> (b) Makes an illegal payment to an official or employee of the United States food and drug administration for the purpose of securing or maintaining approval of the drug.

MICH. COMP. LAWS ANN. § 600.2946(5)(a), (b).

The Michigan statute's broad grant of immunity in product liability actions is evidenced by its definition of products liability. Per the statutory definition, a "[p]roduct liability action" refers to harm "caused by or resulting from the production of a product." MICH. COMP. LAWS ANN. § 600.2945(h). A "'product' includes any and all components to the product." MICH. COMP. LAWS ANN. § 600.2945(g). Further, "'[p]roduction means manufacture, construction, design, formulation, development of standards, preparation, processing, assembly, inspection, testing, listing, certifying, warning, instructing, marketing, selling, advertising, packaging, or labeling." MICH. COMP. LAWS ANN. § 600.2945(i). Therefore, a finding of immunity effectively extinguishes all claims resulting from manufacturing and selling drugs.

Defendants claim they are entitled to summary judgment because the Michigan statute bars Plaintiffs' claims, and the exceptions to the Michigan statute do not apply to these cases. (Doc. 52, pg. 6, 9). Defendants argue that "Depakote and its prescribing information have been, and remain, FDA-approved at all relevant times, not even Plaintiffs' oft-made allegations of off-label promotion are actionable under the Michigan Statute." (Doc. 52, p. 8). Finally, Defendants state that fraud-on-the-FDA claims are preempted by the Supremacy Clause. *Buckman Co. v. Plaintiff's Legal Comm.*, 531 U.S. 347 (2001).

Plaintiffs assert that the Michigan statute is an affirmative defense, and Defendants have not met their burden to assert immunity because they failed to show that Depakote was FDA-approved when the drug left Abbott's[3] control. (Doc. 53, pg. 3). To support this position, Plaintiffs assert that the off-label promotions by Abbott eviscerated the FDA

[3] In 2013, Defendant Abbott Laboratories Inc. split off part of its business, including the rights to Depakote, into a separate publicly traded company, Abbvie, Inc. Accordingly, Plaintiffs filing claims after 2013 have included both Abbott and Abbvie as defendants in the litigation.

approval. (Doc. 53, p. 3). Additionally, they argue that granting summary judgment in favor of Defendants based in part on preemption "would render the statute inoperable." (Doc. 53, p. 4). Defendants' reply asserts that they have met their burden to establish immunity under the Michigan statute and that the settlements for non-FDA-approved uses of Depakote are not applicable to the present claims because Plaintiffs used Depakote for FDA-approved indications.[4]

On March 24, 2017, the Court issued an Order affording Defendants the opportunity to provide supplemental briefing noting that, "Plaintiffs have correctly pointed to an evidentiary hole in Defendants' motion for summary judgment." (Case No. 12-CV-52, Doc. 891). In addition to providing all of the applicable labels and communications between the FDA concerning their approval of these labels, Defendants assert that "Plaintiffs' allegations, experts, and attorneys consistently acknowledged that FDA-approved warnings accompanied Depakote and Depakote ER at all relevant times." (Case 12-CV-52, Doc. 901, p. 3-4). Plaintiffs filed a response to the Court's request for supplemental briefing on April 10, 2017. (Case No. 12-CV-52, Doc. 905). In that response, Plaintiffs reiterate the assertion that the conduct of Abbott in its off-label marketing for elderly dementia and schizophrenia caused the entire label to "not comply with the terms of the FDA's approval." (Case No. 12-CV-52, Doc. 905, p. 3). Alternatively, they argue that the evidence presented by Plaintiffs creates a genuine issue of fact to be resolved by the jury. (Case No. 12-CV-52, Doc. 905, p. 3).[5]

The confusion on this issue stems from the Court's misinterpretation of Plaintiffs' primary argument concerning Depakote's FDA approval. Upon initial review, the Court

[4] There is no dispute that Plaintiffs in the instant cases were prescribed Depakote for "on-label" uses.

[5] On April 14, 2017, Defendants filed a Motion for Leave to File a Reply to Plaintiffs' Supplemental Brief. (Case No. 12-CV-52, Doc. 916). Nothing in Plaintiffs' response presents an exceptional circumstance to warrant the filing of a reply brief by Defendants. Accordingly, Defendant's motion is denied. (Case No. 12-CV-52, Doc. 916). The denial applies to all of the identical motions filed by Defendants in the component cases.

interpreted Plaintiffs response as an attack based on a technical deficiency in the evidence provided by Defendants. The subsequent briefing makes it clear, however, that they do not challenge the general FDA approval status of the drug when it left the manufacturer; instead, they assert that the off-label promotions for elderly dementia and schizophrenia eviscerate the FDA approval in whole—and by extension—the absolute immunity under Michigan law.

As explained below, the Court finds Defendants have met their burden and are entitled to immunity under Michigan law. Further, the Court finds the Michigan Plaintiffs do not fall into any of the statutory exceptions necessary to survive summary judgment.

ANALYSIS

As noted above, Michigan law grants absolute immunity to a drug manufacturer or seller unless the drug manufacturer or seller misrepresented information to the FDA about the drug and the drug would not have been put on the market if the information had been accurately represented, MICH. COMP. LAWS ANN. § 600.2946(5)(a), or an official bribed a member of the FDA to get the drug on the market. MICH. COMP. LAWS ANN. § 600.2946(5)(b). As an initial matter, there is no dispute that Depakote continually received FDA approval for the labeling throughout the relevant period, *i.e.*, 1983-2016. The main disagreement concerns whether Abbott's conduct in off-label marketing rendered the FDA approval void.

Plaintiffs attack both the threshold determination of whether Abbott qualified for immunity, and whether, notwithstanding the initial determination, an exception to the immunity applies. (Doc. 53, p. 3-4). Each theory is based upon the same conduct, *i.e.*, Defendants' illegal off-label marketing of Depakote. *Id.* First, Plaintiffs assert that Defendants failed to establish that Depakote was in compliance with the FDA's approval at

the time it left the companies control, because the warning letters provided and the 2012 criminal conviction affirmatively demonstrate that Depakote and its labeling were not in compliance during the relevant period. (Doc. 53, p. 3) ("Abbott's own undisputed [criminal guilty plea] establishes that Depakote—the very drug for which Abbott now seeks immunity in this case—was misbranded and therefore, by definition, was not in compliance with FDA's approval at the time it left Abbott's control.")

The Sixth Circuit addressed a similar issue when analyzing the Michigan immunity statute in *Marsh v. Genentech, Inc.*, 693 F.3d 546, 548 (6th Cir. 2012). In *Marsh*, the appellate court rejected the plaintiffs' assertion that the drug manufacturer's post approval conduct caused the drug to be in non-compliance with the original approval. *Id.* at 552-553. The operative complaint in *Marsh* alleged that the manufacturer "intentionally and negligently failed to update statement of contraindications, warnings, precautions, and adverse reactions that Defendant affirmatively knew about and intentionally and negligently failed to comply with various but not limited to, 21 CFR 201, 21 CFR 202, 21 CFR 314.80, and 21 CFR 314.81." *Id.* at 522 (internal quotations omitted). The Court reasoned that even if true, the plaintiffs' allegations did not touch upon the core of substantive compliance (as opposed to procedure compliance with the FDA approval). *Id.* at 552; *see also id.* at 552-553 ("Marsh does not allege that the dose of [the drug] she received was adulterated *or that its label varied from the label that the FDA approved.*" (emphasis added)). Ultimately, the Sixth Circuit concluded that the allegations made by the plaintiffs concerning defendants' post-approval

conduct were not of the nature or category of claims that would thwart the product liability immunity. *Id.* at 555.[6] The same conclusion applies to the Michigan Plaintiffs in this case.

Here, Defendants have demonstrated that the drug received FDA approval and was in compliance when it left Abbott's control. The alleged deficiencies asserted by Plaintiffs, similar to *Marsh*, do not allege that the doses of Depakote they received were adulterated or "that its label varied from the label that the FDA approved." *Id.* at 553. While the presence of a criminal conviction by Abbott and the nature of the off-label promotions in general may first appear to distinguish *Marsh* from the claims here, upon closer review it is clear that the conduct in question does not salvage Plaintiffs' arguments.

Plaintiffs have not cited, and the Court cannot find, any legal authority indicating that the Michigan statute's "compliance" provision is eviscerated when a company is convicted of misconduct completely unrelated to the instant tortious allegations. Other courts analyzing the Michigan immunity statute in the face of "unlawful marketing scheme[s]" have held the same. *See e.g.*, *White v. SmithKline Beecham Corp.*, 538 F. Supp. 2d 1023 (W.D. Mich. 2008); *Short v. Janssen Pharm., Inc.*, No. 1:14–CV–1025, 2015 WL 2201713, at *6 (W.D. Mich. May 11, 2015) ("There is no allegation in this case that any information relating to [the off-label marketing scheme] would have affected the on-label usage that the FDA approved, and so the immunity applies."); *Blair v. Genentech, Inc.*, No. 1:11–CV–482, 2011 WL 5088969, at *6 (W.D. Mich. Oct. 26, 2011) (post FDA approval conduct insufficient to invalidate immunity.)

Indeed, after a detailed analysis of the Michigan statute, the Court in *White v. SmithKline*, provided the following rationale:

[6] The Sixth Circuit also held that the plaintiffs' claims, to the extent any raised the exception of "fraud upon the FDA," were barred by federal preemption. *Marsh v. Genentech, Inc.*, 693 F.3d 546, 554 (6th Cir. 2012). The applicability of federal preemption is addressed below.

> The Michigan Legislature provided immunity for drug manufacturers for products approved by the FDA, so long as the product and its labeling meet the FDA standards. Through the definition of "production," the statute extends the protection from suits broadly to a myriad of activities a manufacturer might perform related to the product. The statute does not limit the protection to situations when the drug is used for its approved purposes. Should the Legislature wish to limit the protection available to "off-label" uses of the drug, it may do so. Until such an amendment is enacted, this Court must interpret the statute as it is written.

White v. SmithKline Beecham Corp., 538 F. Supp. 2d 1023, 1030 (W.D. Mich. 2008).

Plaintiffs attempt to distinguish the facts of these cases from their claims here further fails because the post FDA approval misconduct in these authorities was at least linked to the plaintiffs' underlying claims. Even assuming that off-label marketing could cause a label to be out of FDA compliance, the tenuous connection between the wrongful conduct and the current claims nevertheless undermines Plaintiffs' position. First, there is no dispute that Plaintiffs' mothers were prescribed Depakote for "on-label" FDA approved purposes. Second, there is no evidence or assertion that the labels accompanying the Depakote sent to Plaintiffs varied in the slightest way from the FDA approved label. And third, there is no evidence that Plaintiffs in this case ever received or observed any of the off-label marketing material. Stated another way, at the time the actual Depakote in question left the manufacturer to reach the biological mothers, the drug's label and marketing relating to epilepsy, bi-polar, and migraines were in compliance with the FDA approved label. Accordingly, Defendants have demonstrated that Depakote was FDA approved and its labeling was in compliance with the FDA approval at the time it left Abbott's control.

Turning to the statute's two immunity exceptions, the Court notes that there has never been an allegation in this mass action that Defendants "[made] an illegal payment to an official or employee of the United States food and drug administration for the purpose of

securing or maintaining approval of the drug." MICH. COMP. LAWS ANN. § 600.2946(5)(b). Accordingly, the Court focuses exclusively on the first exception, *i.e.*, whether Abbott committed fraud upon the FDA. MICH. COMP. LAWS ANN. § 600.2946(5)(a).

Defendants assert that without a finding of fraud by the FDA, they are entitled to immunity under the Michigan statute. Plaintiffs respond by asserting that the statute is not preempted, and even if it is, a finding of federal preemption causes the entire immunity statute to be "inoperable." (Doc. 53, p. 12). The genesis of the disagreement between the parties comes from the structure the Michigan legislature chose for assessing "reasonable care" in product liability cases.

When the legislature enacted § 600.2946(5), it set determinations of fraud by the FDA as the measure of "reasonable care" in Michigan product liability cases. *Taylor*, 658 N.W.2d at 134. Stated another way,

> [The Michigan immunity statute] delegates nothing to the FDA; rather, it uses independently significant decisions of the FDA as a measuring device to set the standard of care for manufacturers and sellers of prescription drugs in Michigan. It represents a legislative determination as a matter of law of when a manufacturer or seller of a prescription drug has acted sufficiently reasonably, solely for the purpose of defining the limits of a cognizable products liability claim under Michigan law.

Id. at 137; *see also Garcia v. Wyeth-Ayerst Laboratories*, 385 F.3d 961, 966 (6th Cir. 2004) (finding that the Michigan legislature decided to "incorporate a federal standard into its law of torts.")

The seminal case concerning fraud on the FDA and preemption is *Buckman*, where the Supreme Court held that "[s]tate-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Agency's judgment and objectives." *Buckman*, 531 U.S. at 350. Following *Buckman* and *Taylor*, the Sixth Circuit in

Garcia noted that the concept of preemption applies in certain situations concerning the Michigan immunity statute, but not in all situations. *Garcia,* 385 F.3d at 966. The Court concluded that Plaintiffs' claims are preempted only if they assert that the manufacturer committed "fraud-on-the-FDA" without the FDA itself finding fraud occurred. *Id.*

Plaintiffs did not presented evidence of an FDA determination that Abbott committed fraud to secure any relevant label. Instead, Plaintiffs direct the Court to consider other courts' holdings on the Michigan immunity statute, most notably the Second Circuit's opinion of *Desiano v. Warner-Lambert & Co*. 467 F.3d 85, 94 (2nd Cir. 2006). In *Desiano*, the Second Circuit rejected the *Garcia* Court's interpretation of *Buckman* on the grounds that the *Buckman* plaintiffs brought a single claim of fraud on the FDA in a state court proceeding and not "claims that sound in traditional state tort law." *Id.* The underlying claims in *Desiano* included "breach of implied and express warranties, negligence, negligent misrepresentation, negligence per se, fraud, defective design, defective manufacturing, and loss of consortium." *Id*. at 88. The Second Circuit rationalized that these types of claims could not "reasonably be characterized as a state's attempt to police fraud against the FDA" because the legislative goal was "to regulate and restrict when victims could continue to recover under preexisting state products liability law." *Id.* at 94. Ultimately, the Second Circuit held that the Michigan exception was not preempted by federal law. *Id.* at 98. Notably, however, both the Fifth and Sixth Circuit have rejected the Second Circuit's holding in *Desiano*. *See Lofton v. McNeil Consumer & Specialty Pharm.*, 672 F.3d 372, 380 (5th Cir. 2012); *see also Marsh v. Genentech, Inc*., 693 F.3d 546, 551, n. 6 (6th Cir. 2012).

In 2012, the Fifth Circuit rejected the Second Circuit's interpretation in *Desiano*, finding it a strained reading of *Buckman. Lofton v. McNeil Consumer & Specialty Pharm.*, 672

F.3d 372, 380 (5th Cir. 2012). Interpreting a Texas statute similar to Michigan's product liability immunity provision, the Fifth Circuit noted that statutes like the one in question are not "an expression of traditional state common law." *Id*. at 379. By linking the FDA standards into their tort recovery provisions, the Fifth Circuit reasoned that liability for a failure to warn claim would necessarily involve proof of the same conduct the FDA was empowered to punish and deter, thereby bringing the case directly under *Buckman's* preemption provisions. *Id.* at 379.

Similarly, the Sixth Circuit rejected *Desiano* in *Marsh v. Genentech, Inc*., 693 F.3d 546, 551, n. 6 (6th Cir. 2012)[7] In *Marsh*, the Court held that even framing the claim as non-compliance or failure to warn did not save the plaintiffs' claims from preemption. *Id.* at 555. ("Even characterized as non-compliance, Marsh's "claim" that Genentech is not entitled to immunity under the Act triggers the same concerns that animated *Buckman* and *Garcia*—it is premised on violation of federal law, implicates the relationship between a federal agency and the entity it regulates, and asks the court to assume a role usually held by the FDA—and is thus preempted.")

The Court disagrees with the Second Circuit's analysis, and instead finds the Fifth and Sixth Circuits interpretation of Michigan law to be persuasive. The decision by the Michigan legislature to link their reasonableness standard to the FDA's conclusions regarding the safety and efficacy of a drug places the statute directly in line with the concerns annunciated in *Buckman*. Contrary to the Second Circuit's analysis, Michigan has independently decided to incorporate FDA findings of independent significance as both their floor and ceiling. *Taylor*, 658 N.W.2d at 134. The only way to circumvent the protection

[7] The claims in *Marsh* included claims that the drug company knew of dangerous side effects and concealed them from the public, and that the company intentionally and negligently failed to update the label's warnings. *Marsh v. Genentech, Inc*., 693 F.3d 546, 548 (6th Cir. 2012)

afford by Michigan is to demonstrate fraud was committed on the FDA. "[T]he plaintiff necessarily re-treads the FDA's administrative ground both to conduct discovery and persuade a jury." *Lofton*, 672 F.3d at 380. Accordingly, without a federal determination of fraud, Plaintiffs' claims are preempted.

Finally, Plaintiffs claim that a determination of federal preemption renders the entire statute "inoperable." (Doc. 53, p. 2). Plaintiffs' assertion rests upon a flawed understanding of the statute's mechanics. Plaintiffs assert "the plain text chosen by Michigan's legislature to describe the exceptions to immunity does not include limitations to circumstances where FDA or the Federal Government has previously found fraud or bribery. As instructed by the Michigan Supreme Court, this Court must not read such limitations into the statute." (Doc. 53, p. 15). Contrary to Plaintiffs' position, the Michigan Supreme Court expressly held in *Taylor* that the legislature tied the "rebuttal mechanism" to the determinations of the FDA. Further, it is not that the entire exception is invalidated by preemption; rather, findings by the FDA serve as an evidentiary feature, or measuring stick, in assessing the reasonableness of a manufacturer's actions. *See Taylor*, 658 N.W.2d at 134. The Sixth Circuit addressed Plaintiffs' inoperability charge in *Garcia. Garcia*, 385 F.3d at 966-967 (Noting the presence of Michigan's general severability clause and then concluding that the preemption of Plaintiffs' claims did not rendered the entire statute inoperable.) This Court finds no reason to deviate from the rationale in *Garcia.* For these reasons, Abbott's Motions for Summary Judgment are granted.

JUDGMENT UNDER RULE 54(B)

Under Federal Rule of Civil Procedure 54(b), a district court "may direct entry of a final judgment as to one or more, but fewer than all, claims or parties only if the court

expressly determines that there is no just reason for delay." FED. R. CIV. P. 54(b). *see also Gelboim v. Bank of America Corp.*, 135 S. Ct. 897, 902 (2015) (Rule 54(b) permits district courts to authorize immediate appeal "[w]hen an action presents more than one claim for relief… or when multiple parties are involved, the court may direct entry of a final judgment as to one or more, but fewer than all, claims or parties if the court expressly determines that there is no just reason for delay."); *In re MTBE Products Liab. Litig.*, Nos. 00 MDL 1898(SAS), 04 CIV. 3417(SAS), 2010 WL 1328249, at *4 (S.D. N.Y. Apr. 5, 2010) ("the role of this trial as a bellwether for an entire MDL makes this the type of 'exceptional' case where entry of final judgment pursuant to Rule 54(b) is appropriate").

The Court finds that there is no just reason to delay entering a judgment in these cases. The claims of any one Plaintiff in the mass action—even those Plaintiffs who brought their claims in one unified complaint—are not dependent upon one another to be resolved on the merits.[8] While the Court previously found certain cases sufficiently similar to warrant joint trials, entering judgment on an individual Plaintiff's claim would not trigger the type of "piecemeal appeal" the Supreme Court cautioned against in *Sears, Roebuck, & Co. v. Mackey*, 351 U.S. 427, 438 (1956).

Here, summary judgment was granted because Defendants are entitled to immunity under the Michigan product liability statute. This is a discrete issue that is completely independent from other cases within the mass action. There is no risk that any change to the remaining cases would alter the analysis related to these specific Plaintiffs. Finally, there are approximately six hundred cases remaining on the Court's docket, which will likely take

[8] The exception to this general principal is for parents who bring claims on behalf of their minor children *and* a claim in their own individual capacity. It is difficult to conceive of a circumstance where the Court would allow a parent's individual claim to be tried separately from the minor child's claim; however, this is the only circumstance where the factual overlap would prohibit entry of judgment until the conclusion of both claims.

years to adjudicate. If the Court does not enter judgment under Rule 54(b), these Plaintiffs could potentially wait a decade or more before all of the associated claims in their original complaints were resolved. To allow for the continued maturation of the mass action and to prevent an injustice on all the parties, the Court finds that judgment shall be entered under Rule 54(b). The Clerk is directed to file a copy of this Order and the Judgment in: Case No. 12-CV-54; Case No. 12-CV-57; Case No. 12-CV-163; Case No. 12-CV-1091; Case No. 12-CV-1216; Case No. 13-CV-134; Case No. 13-CV-414; Case No. 13-CV-443; Case No. 13-CV-622; Case No. 13-CV-758; Case No. 13-CV-890; Case No. 13-CV-1115; Case No. 13-CV-1157; Case No. 13-CV-1312; Case No. 15-CV-102; Case No. 15-CV-472; Case No. 16-CV-463. Judgment shall be entered without regard to Rule 54(b) in Case No. 14-CV-1069, as granting of summary judgment in this case leaves no remaining claims or Plaintiffs.

IT IS SO ORDERED.

DATED: September 25, 2017

NANCY J. ROSENSTENGEL
United States District Judge