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

IN RE DEPAKOTE:	)	
	)	
HAYLEE GRAY, *et al.*,	)	
	)	
Plaintiffs,	)	
	)	
vs.	)	**Case No. 12-CV-1216-NJR-SCW**
	)	
ABBOTT LABORATORIES, INC., and ABBVIE, INC.,	)	**LEAD CONSOLIDATED CASE (Case No. 12-CV-52-NJR-SCW)**
	)	
Defendants.	)	

ORDER

ROSENSTENGEL, District Judge:

On January 19, 2017, Defendants filed several nearly identical motions for summary judgment claiming absolute immunity under the statutory defense established by the Michigan products liability law.[1] *Compare* (Case No. 12-CV-163, Doc. 82) *with* (Case N. 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).

Defendants claim immunity under the statutory defense established by the Michigan products liability law, which states:

[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; Case No. 16-CV-463.

> In a product liability action against a manufacturer or seller, a product that is a drug is not defective or unreasonably dangerous, and the manufacturer is not liable if the drug was approved for safety and efficacy by the United States food and drug administration, and the drug and its labeling were in compliance with the United States food and drug administration's approval at the time the drug left the control of the manufacturer or seller.

MICH. COMP. LAWS ANN. § 600.2946(5).

The Michigan legislature carved out two exceptions, when a 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, 675, 62 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; or (b) make 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).

Defendants claim that Depakote and "its prescribing information" were FDA approved "at all relevant times." (Doc. 52, p. 9). Further, they claim that Depakote does not fall within the immunity exceptions, because the FDA did not order Depakote be taken off the market, the FDA did not withdraw its approval of Depakote, and Abbott did not intentionally withhold or misrepresent information concerning Depakote from the FDA. (Doc. 52, p. 10). Plaintiffs make a number of assertions concerning the inapplicability of Defendants' alleged immunity; however, the assertion relevant to this Order concerns the lack of evidence provided by Defendants.

Immunity under the Michigan statute § 600.2946(5) is an affirmative defense,

which places the burden of proof on the Defendants. *Taylor v. Smithkline Beecham Corp*, 658 N.W.2d 127, 131 (Mich. 2003). Plaintiffs assert that:

> …if a manufacturer fails to prove that its drug was FDA approved ***or*** that the drug and its labeling were in compliance with FDA's approval, the burden does not shift to the claimant to prove a statutory exception to this affirmative defense….While Abbott has asserted, and Plaintiffs do not dispute, that Depakote is FDA approved, Abbott disregards its additional burden to establish that Depakote and its labeling have been in compliance with FDA's approval at all relevant times.

(Doc. 53, at p. 9).

In support of their motion, Defendants provided the Physicians' Deck References ("PDRs") for each label year. (Doc. 53-2; 53-5). The PDRs (along with a letter from the FDA approving the initial Depakote application in the 1980's and a similar letter approving Depakote ER in 1999) form the only evidence supporting the claim of immunity. While the PDRs demonstrate that Depakote received FDA approval for each label, they do not show that the "drug and its labeling were in compliance with the United States food and drug administration's approval **at the time the drug left the control of the manufacturer or seller**." MICH. COMP. LAWS ANN. § 600.2946(5) (emphasis added).

In their response, Plaintiffs imply that because Defendants did not provide the necessary evidence in their primary brief, the motion must be denied by default. (Doc. 53, at pp. 9-10). The Court does not agree. Upon finding that a party has failed to properly support or address a fact, a court may "give an opportunity to properly support or address the fact," FED. R. CIV. P. 56(e)(1), or "issue any other appropriate order." FED. R. CIV. P. 56(e)(4). "Where the reply affidavit merely responds to matters

placed in issue by the opposition brief and does not spring upon the opposing party new reasons for the entry of summary judgment reply papers—both briefs and affidavits—may properly address those issues." *Beck v. Univ. of Wis. Bd. of Regents*, 75 F.3d 1130, 1134 (7th Cir. 1996); *Baugh v. City of Milwaukee*, 823 F. Supp. 1452, 1456-57 (7th Cir. 1993) ("Such a rule would allow the party opposing the motion to gain an unfair advantage by submitting to issues and evidentiary support that were unforeseen at the time the motion was proffered").

Plaintiffs have correctly pointed to an evidentiary hole in Defendants' motion for summary judgment. The gap in evidence was likely caused by an inadvertent oversight or by the mistaken belief that Plaintiffs would not contest such an issue. Regardless of the reasons, the parties will be given a further opportunity to provide briefing in support of this limited issue. The briefing may include additional evidence in support. Defendants shall have until **April 3, 2017** to provide their supplemental briefing. Plaintiffs shall have until **April 10, 2017** to provide their supplemental response. This Order is applicable to all Depakote cases where the Defendants filed a motion for summary judgment concerning immunity under Michigan Law.

IT IS SO ORDERED.

DATED: March 24, 2017

NANCY J. ROSENSTENGEL
United States District Judge