

STATE OF NORTH DAKOTA

IN DISTRICT COURT

COUNTY OF BURLEIGH

SOUTH CENTRAL JUDICIAL DISTRICT

State of North Dakota Ex Rel. Wayne
Stenehjem, Attorney General,

Plaintiff,

v.

Purdue Pharma L.P.; Purdue Pharma, Inc.,
The Purdue Frederick Company, Inc., and
Does 1 through 100, inclusive,

Defendants.

Case No. 08-2018-CV-01300

**ORDER DENYING PLAINTIFF'S
RULE 60(b) MOTION FOR RELIEF
FROM JUDGMENT**

INTRODUCTION

[¶1] This matter is before the Court on the Plaintiff's, the State of North Dakota ex rel. Wayne Stenehjem, Attorney General (the State), Motion for Rule 60(b) Relief from Judgment ("State"). [DE 66-69] In its Motion, the State seeks relief from this Court's Judgment [DE 61] and the *Order Granting Defendants' Motion to Dismiss* [DE 56] on the grounds that a subsequent opinion from the United States Supreme Court warrants relief from this Court's Order.

[¶2] Specifically, the State argues the case of *Merck Sharp & Dohme Corp. v. Albrecht*, 139 S.Ct. 1668 (2019), ("*Merck Court*") clarifies impossibility preemption in cases involving prescription drugs, and establishes the Defendants did not meet their burden of establishing impossibility preemption in this case. The Defendants (collectively, "Purdue") resist the Motion. [DE 70]

LEGAL STANDARD

[¶3] Rule 60(b) of the North Dakota Rules of Civil Procedure provides that:

On motion and just terms, the court may relieve a party or its legal representative from a final judgment, order, or proceeding for the following reasons:

- (1) mistake, inadvertence, surprise, or excusable neglect;
- (2) newly discovered evidence that, with reasonable diligence, could not have been discovered in time to move for a new trial under Rule 59(b);
- (3) fraud (whether previously called intrinsic or extrinsic), misrepresentation, or misconduct by an opposing party;
- (4) the judgment is void;
- (5) the judgment has been satisfied, released, or discharged; it is based on an earlier judgment that has been reversed or vacated; or applying it prospectively is no longer equitable; or
- (6) any other reason that justifies relief.

N.D.R.Civ.P. 60(b).

[¶4] Subsection(6) of Rule 60(b) is a catch-all provision that allows a district court to grant relief from judgment for “any other reason that justifies relief.” *Olander Contracting Co. v. Gail Wachter Invs.*, 2003 ND 100, ¶ 9, 663 N.W.2d 204. “The catch-all clause in N.D.R.Civ.P. 60(b)(vi) gives the court ‘a grand reservoir of equitable power to do justice in a particular case.’” *Olander Contracting Co. v. Gail Wachter Investments*, 2003 ND 100, ¶ 9, 663 N.W.2d 204 (quoting *Compton v. Alton Steamship Co., Inc.*, 608 F.2d 96, 106 (4th Cir. 1979)).

[¶5] Rule 60(b)(6) “attempts to strike a proper balance between the conflicting principles that litigation must be brought to an end and that justice should be done, and accordingly . . . should be invoked only when extraordinary circumstances are present.”

Kopp v. Kopp, 2001 ND 41, ¶ 9, 622 N.W.2d 726. A court is vested with discretion in ruling on a motion for relief from a judgment under Rule 60(b)(6). *Meier v. Meier*, 2014 ND 127, ¶ 7, 848 N.W.2d 253.

ANALYSIS

[¶6] In response to the State's Rule 60(b)(6) Motion, Purdue first argues the motion should be denied because the State has failed to satisfy the heavy burden imposed to justify relief under the rule. Both parties cite to several cases supporting their respective positions on whether or not an alleged "clarification" in the law justifies Rule 60(b)(6) relief.

[¶7] This Court, and most certainly the parties, are all well aware that an appeal in this case is forthcoming to the North Dakota Supreme Court. The Court understands and appreciates the State's motivation for bringing the present Motion, as any subsequent appeal will involve arguments regarding the United States Supreme Court's decision in *Merck*. It would be difficult for the State to fairly set forth its arguments under *Merck* on appeal when that issue was never raised or addressed by this Court.

[¶8] And the Court was well aware at the time of the Order on Purdue's Motion to Dismiss that the parties were awaiting a decision in *Merck*. The arguments subsequent to *Merck* have been fully briefed by both parties. [DE 67,70 and 72] Therefore, this Court will address the merits of the State's Motion. The primary conclusions of this Court are outlined in the Order Granting Defendants' Motion to Dismiss. [DE 56]. Any additional findings in this Order are meant to be read in conjunction with the Court's previous Order, and it is hereby incorporated by reference.

[¶9] In *Merck*, the United States Supreme Court elaborated on the “clear evidence” standard set forth in its prior *Wyeth* decision, as this Court detailed in its Order on Purdue’s Motion to Dismiss. The *Merck* Court held that “clear evidence is evidence that shows the court that the drug manufacturer fully informed the FDA of the justifications for the warning required by state law and that the FDA, in turn, informed the drug manufacturer that the FDA would not approve a change to the drug’s label to include that warning.” *Merck*, 139 S.Ct. at 1672. However, the question of what other methods constitute “clear evidence,” or fully informing the FDA, was not addressed by the *Merck* Court.

[¶10] The error corrected in *Merck* was not the “clear evidence” standard; rather, it was the 3rd Circuit’s erroneous holding that “whether the FDA would have rejected a proposed label change is a question of fact that must be answered by a jury.” *Merck*, 139 S.Ct. at 1676. The *Merck* Court vacated the 3rd Circuit’s ruling and held that the question of agency disapproval and preemption is one for the judge to decide, not a jury. *Id.* This was the “determinative” question decided by the Court in *Merck*. *Id.* at 1679.

[¶11] The State argues that, under *Merck*, the FDA’s decision not to change a medication’s labeling triggers *Wyeth* preemption only if the manufacturer itself proposed the change, and that the FDA’s own labeling decisions cannot preempt the State’s claims.

[¶12] This Court does not read *Merck* so narrowly. The State’s argument ignores the *Merck* Court’s explicit warning that “[t]he question of disapproval ‘method’ is not now before us.” *Id.* at 1679. The *Merck* Court noted only that the FDA’s actions must “lie

within the scope of the authority Congress has lawfully delegated.” *Id.* *Merck* did not involve agency “actions” or “methods” similar to this case, and the *Merck* Court did not even decide whether the facts before it preempted state law claims. The *Merck* Court certainly did not decide whether other agency actions, such as the denial of a Citizen Petition, would be sufficient.

[¶13] Moreover, this Court finds the State’s narrow interpretations of *Wyeth* and *Merck* to be nonsensical. Where the FDA has already rejected a proposed label or warning change, as it did in this case, there is no reason why the “impossibility” of a subsequent change would depend on whether the earlier change was proposed by the manufacturer as opposed to a third party or the FDA itself. Regardless of who submitted the proposed warning or labeling change, the FDA has already decided that the relevant evidence and policies do not meet the standard to justify a change.

[¶14] Contrary to the State’s assertions, the *Merck* Court did not hold that *Wyeth* preemption applies only where the FDA rejects a change proposed by the manufacturer. It appears that the *Merck* Court clearly held that such a situation, i.e. where the FDA rejects a change proposed by the manufacturer, would constitute clear evidence, but the *Merck* Court did not hold that this was the only method which could constitute such evidence. In fact, the *Merck* Court very clearly stated it was not deciding the question of disapproval method. *Id.* at 1679.

[¶15] This Court concludes that under *Merck*, *Wyeth* preemption applies anytime the applicable statutes, regulations, or constitutionally permitted actions of the FDA show that the FDA would not have approved a change to a pharmaceutical manufacturer’s labeling or advertising. This Court concluded as much in its previous Order. [DE 56].

[¶16] The FDA has considered and rejected prior requests to change OxyContin's labeling in the manner demanded by the State. The FDA's response to the 2008 and 2012 Petitions, repeated approval of Purdue's branded marketing materials, and continuing decision not to change OxyContin's labeling or REMS to this day – all in the face of the State's evidence and the FDA's duty to change the labeling and warnings if appropriate – conclusively show that the FDA does not yet believe the state of the data supports additional warnings or altered labeling when presented with the issues asserted by the State. Based on the evidence submitted to this Court, for years the FDA was aware of the issues asserted by the State, studied all relevant available information, and instructed that no labeling or warning change was yet warranted.

[¶17] The marketing practices of Purdue that the State claims are improper were consistent with the FDA-approved product labeling. The Complaint contains no new allegations of newly acquired information that could provide a basis for Purdue to change its labeling, warnings, or marketing without prior FDA approval. *Merck*, does not change this Court's conclusions. Instead, consistent with the United States Supreme Court's decisions in *Wyeth* and *Merck*, there is "clear evidence" that the FDA would not have approved changes to Purdue's labels, marketing, or warnings to comport with the State's claims.

[¶18] Because Purdue has met its burden under *Wyeth* and *Merck*, this Court concludes the state law claims asserted by the State are preempted in this matter by federal law. The current Judgment stands as entered, and the State's Motion for Rule 60(b) Relief from Judgment is denied.

[¶19] This Court notes that preemption was not the only basis for dismissal of the State's claims in this matter. This Court's previous rulings on the State's consumer fraud law claims and nuisance claims also stand for all the reasons detailed in the *Order Granting Defendants' Motion to Dismiss*. [DE 56]

CONCLUSION

[¶20] For all the reasons stated above, the State's Rule 60(b) Motion for Relief from Judgment is, in all respects, hereby **DENIED**.

IT IS SO ORDERED.

Dated this 22nd day of July, 2019.

BY THE COURT:

A handwritten signature in black ink, reading "James S. Hill". The signature is written in a cursive, slightly stylized font. The first name "James" is written in a larger, more prominent script, followed by "S." and "Hill".

James S. Hill, District Judge
South Central Judicial District

cc: