2017 PA Super 375

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
MA.J.L. AND M.L.	:	
	:	
Appellants	:	
	:	
	:	
v.	:	
	:	No. 577 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): August Term, 2013, No. 2596
March 2010 No. 296

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
A.H., JR. AND A.H.	:	
	:	
Appellants	:	
	:	
	:	
v.	:	
	:	No. 578 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, ABD JANSSEN REESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): April Term 2013, No. 1995
March 2010 No. 296

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
DANIEL BREWER	:	
	:	

Appellant	:	
	:	
	:	
v.	:	
	:	No. 579 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): March 2010 No. 296
October Term 2013, No. 3604

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
D.A. AND B.A.	:	
	:	
Appellants	:	
	:	
	:	
v.	:	
	:	No. 580 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): March 2010 No. 296
November Term 2013, No. 2990

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
K.S., AND SARAH LABADIE	:	
	:	
Appellants	:	
	:	
	:	
v.	:	
	:	No. 581 EDA 2015

JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, JANSSEN RESEARCH AND DEVELOPMENT LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): March 2010, No. 296
September Term, 2013, No. 1341

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
MATTHEW LANTHIER	:	
Appellant	:	
v.	:	
	:	No. 582 EDA 2015
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, JANSSEN RESEACH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): January Term 2014, No. 989
March 2010 No. 296

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF PENNSYLVANIA
MITCHELL LINDBERG	:	
Appellant	:	
v.	:	
	:	No. 583 EDA 2015
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): August Term 2013, No. 2624
March 2010 No. 296

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
MI.J.L. AND M.L.	:	
	:	
Appellants	:	
	:	
	:	
v.	:	
	:	No. 584 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEACH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): August Term 2013, No. 2611
March 2010 No. 296

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
ERIK RIGGS	:	
	:	
Appellant	:	
	:	
	:	
v.	:	
	:	No. 585 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): July Term 2013, No. 3223
March 2010 No. 296

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
SCOTT WISNIEWSKI	:	
	:	
Appellant	:	
	:	
	:	
v.	:	
	:	No. 586 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): August Term 2013, No. 473
March 2010 No. 296

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
NATHAN ZACHAR	:	
	:	
Appellant	:	
	:	
	:	
v.	:	
	:	No. 587 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): August Term 2013, No. 1909
March 2010 No. 296

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
DANNY WOODCOCK	:	
	:	
Appellant	:	

	:	
	:	
v.	:	
	:	No. 588 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): March 2010 No. 296
September Term 2013, No. 2986

IN RE: RISPERDAL LITIGATION	:	IN THE SUPERIOR COURT OF
	:	PENNSYLVANIA
CORTEZ MULLEN	:	
	:	
Appellant	:	
	:	
	:	
v.	:	
	:	No. 589 EDA 2015
	:	
JANSSEN PHARMACEUTICALS, INC., JOHNSON & JOHNSON COMPANY, AND JANSSEN RESEARCH AND DEVELOPMENT, LLC.	:	

Appeal from the Judgment Entered January 27, 2015
In the Court of Common Pleas of Philadelphia County
Civil Division at No(s): July Term 2013, No. 1440
March 2010 No. 296

BEFORE: PANELLA, J., RANSOM, J., and FITZGERALD*, J.

OPINION BY PANELLA, J. **FILED NOVEMBER 28, 2017**

---

* Former Justice specially assigned to the Superior Court.

In these consolidated appeals, Appellants, Ma.J.L. and M.L., A.H., Jr. and A.H., Daniel Brewer, D.A. and B.A., K.S. and Sarah LaBadie, Matthew Lanthier, Mitchell Lindberg, Mi.J.L. and M.L., Erik Riggs, Scott Wisniewski, Nathan Zachar, Danny Woodcock, and Cortez Mullen, appeal from the judgments entered in the Philadelphia County Court of Common Pleas, following the entry of summary judgment in favor of Appellees, Janssen Pharmaceuticals, Inc., Johnson & Johnson Company, and Janssen Research and Development, LLC.[1] Appellants contend the trial court erred in determining the Michigan Product Liability Act barred their claims. We affirm.

Appellees developed risperidone, an atypical antipsychotic, for the treatment of schizophrenia in adult patients. The Food and Drug Administration ("FDA") approved risperidone for this use in December 1993. Subsequently, in 1994, Appellees brought this product to market under the brand name Risperdal. Risperdal was later approved for the short-term treatment of manic episodes associated with bipolar disorder I in adults in December 2003; for the treatment of irritability associated with autistic disorder in children aged five to sixteen in October 2006; for the treatment

---

[1] The caption in the notice of appeal listed Johnson & Johnson Pharmaceutical Research and Development, LLC, Excerpta Medica, Inc., and Elsevier, Inc., as Appellees. ***See*** Notices of Appeal, 2/25/15. However, Janssen Pharmaceuticals, Inc., Johnson & Johnson Company and Janssen Research and Development, LLC appear to be the correct, and only, Appellees to the instant appeal. ***See*** Appellants' Brief; Appellees' Brief; Stipulation to Discontinue, 1/27/15. We have corrected the caption accordingly.

of schizophrenia in adolescents in August 2007; and for the treatment of manic episodes associated with bipolar I disorder in children aged ten to seventeen in August 2007.

Four years prior to Risperdal's approval for use in juvenile populations, Appellees began to study the safety and efficacy of Risperdal in children and adolescents through clinical trials. The data from these trials indicated a potential link between the ingestion of Risperdal and the development of gynecomastia.[2] In October 2006, when Risperdal was first approved for use in juvenile patients, the Risperdal label was updated to include warnings of this link.

Appellants in this mass action are young men[3] who allege that they suffered weight gain and developed gynecomastia as a direct result of the ingestion of Risperdal. Appellants were residents of Michigan when they were prescribed and ingested Risperdal. With the exception of Appellant K.S., Appellants were prescribed Risperdal prior to the FDA approval for the treatment of their individual conditions.[4]

---

[2] Merriam-Webster's online dictionary defines gynecomastia as "excessive development of the breast in the male." Available at http://merriam-webster.com/dictionary/gynecomastia (last visited October 20, 2017).

[3] In certain cases, where Appellant was under eighteen when suit was filed, Appellant's parent is also listed as an Appellant on behalf of his or her minor child.

[4] ***See*** U.S. Food & Drug Administration, *Understanding Unapproved Use of Approved Drugs "Off Label,"* available at

(Footnote Continued Next Page)

Between April 12, 2013 and January 13, 2014, Appellants commenced their actions by filing complaints. All thirteen complaints were filed in the Philadelphia County Court of Common Pleas as part of the ***In re Risperdal*** mass tort program, and incorporated allegations found in the master complaint.[5] Appellants contended that Appellees initially concealed, and subsequently failed to warn, Appellants of the exact risk and prevalence of developing gynecomastia. Based upon these allegations, Appellants raised identical claims against Appellees of (I) negligence; (II) negligent design defect; (III) fraud; (IV) strict liability failure to warn; (V) strict liability design defect; (VI) breach of express warranty; (VII) breach of implied warranty; (VIII) violation of Pennsylvania's Unfair Trade Practices and Consumer Protection Law ("UTPCPL"), 73 P.S. § 201, *et. seq*.; (IX) violation of Michigan's Consumer Protection Act ("MCPA"), Mich. Comp. Laws. § 445.901 *et. seq*. (IX) unfair and deceptive trade practices; (X) conspiracy; (XI) punitive damages; and (XII) medical expenses incurred by parent.[6] Appellees denied Appellants' allegations and asserted all applicable defenses.

(Footnote Continued) ———————————

https://www.fda.gov/forpatients/other/offlabel/default.htm (last visited August 24, 2017).

[5] The ***In Re Risperdal® Litigation*** mass tort program was formed on May 26, 2010, as a depository for the filings of pleadings, motions, orders, and other documents common to all Risperdal cases in the Philadelphia County Court of Common Pleas. ***See*** Case Management Order 1, 5/26/10, ***In Re Risperdal® Litigation***, March Term 2010 No. 296.

[6] Appellants A.H., Jr. and A.H. also raised a claim for loss of consortium.

Appellees later filed a motion for partial summary judgment on the master docket disputing the validity of the punitive damages claim. The trial court granted Appellees' motion and dismissed all plaintiffs' claims for punitive damages. The trial court then denied reconsideration.

On June 16, 2014, Appellees filed motions for summary judgment in each of Appellants' cases claiming immunity from suit. Appellees argued that because Appellants were all residents of Michigan when they were prescribed and ingested Risperdal, Michigan law governs the claims in Appellants' complaints. ***See*** Appellees' Motion for Summary Judgment, 6/16/14, at 3-6. Therefore, because Appellees' claims constituted product liability claims under two provisions of Michigan's Product Liability Act ("MPLA") §§ 600.2945 and 600.2946, and because Appellees had complied with the conditions for protection under that law, Appellees asserted that they had statutory immunity from Appellants' common law claims. ***See id***., at 6-13.

Appellants responded, asserting that Pennsylvania law, not Michigan law, applied to Appellants' claims. ***See*** Appellants' Response to Motion for Summary Judgment, 7/7/14, at 8-14. Further, even assuming that Michigan substantive law governed their claims, Appellants contended that because Appellees withheld or misrepresented evidence to the FDA, the MPLA's affirmative defense was not available to Appellees. ***See id***., at 22-38. Moreover, Appellants argued the MPLA's protections should not be available to Appellees, as Risperdal was prescribed to Appellants off-label. ***See id***., at 14-22.

Following oral argument on the motion, the trial court determined the application of Michigan law, specifically §§ 600.2945 – 600.2949(b) of the MPLA, barred Appellants' common law claims against Appellees.[7] ***See*** Trial Court Order, 11/4/14. Further, the trial court found that Appellants' UTPCPL and MCPA claims failed as a matter of law. ***See id***., at ¶¶ 2-3. Therefore, the court granted Appellees' motions in all thirteen cases.

The parties later stipulated to the dismissal of Appellants' claims against Excerpta Medica, Inc., and Elsevier, Inc.[8] Appellants filed timely

---

[7] The trial court's application of the law in its order granting summary judgment differs from its application of the law in its Rule 1925(a) opinion. In its November 2014 order granting summary judgment, the trial court determined that Appellees' common law claims fail as a matter of law due to the application of the MPLA. ***See*** Trial Court Order, 11/4/14, at ¶ 1. However, in its Rule 1925(a) opinion, following a conflict of law analysis, the trial court determined that while the MPLA bars Appellants' negligence, negligent design defect, fraud, breach of express warranty, and unfair and deceptive trade practices claims, Pennsylvania law bars Appellants' strict liability – failure to warn, strict liability – design defect, and breach of implied warranty claims. ***See*** Trial Court Rule 1925(a) Opinion, 10/1/15 at 13-17.

While this lack of consistency is apparent, it does not impact our analysis. In both the November 2014 order and the Rule 1925(a) opinion, the trial court determined Michigan law applied after a choice of law analysis. However, it appears the trial court dismissed the strict liability and breach of implied warrant claims pursuant to Pennsylvania law in its Rule 1925(a) opinion only after determining that both Pennsylvania and Michigan law would bar the claims. Thus, because the trial court determined Michigan law would bar all claims, we will restrict our analysis to the application of Michigan law.

[8] The parties filed praecipes, on each individual docket, to discontinue the action against Excerpta Medica, Inc. and Elsevier, Inc. on January 27, 2015. *(Footnote Continued Next Page)*

notices of appeal as to the remaining parties. This Court consolidated all thirteen cases.

On appeal, Appellants argue the trial court erred in granting Appellees' summary judgment motions and dismissing Appellants' claims based upon the application of Michigan law.[9] ***See*** Appellants' Brief, at 3. While Appellants do not dispute the trial court's determination that Michigan substantive law governs their claims, Appellants argue the MPLA does not apply to indemnify Appellees in this specific case because Risperdal was not "approved" for these Appellants at the time they ingested the medicine. ***See*** Appellants' Brief, at 3 ¶ 1. Further, in the event the MPLA does govern the viability of

(Footnote Continued) ———————————

On February 13, 2015, the trial court entered individual judgments to that effect, approving the stipulation to discontinue. However, in situations where the praecipe to discontinue resolves all claims against the parties, the praecipe itself constitutes a final judgment. ***See Levitt v. Patrick***, 976 A.2d 581, 587-588 (Pa. Super. 2009). Therefore, final judgment was entered on January 27, 2015. The trial court's subsequent entry of judgment on February 13, 2015 is a nullity.

[9] In its November 4, 2014 order, the trial court dismissed a majority of Appellants' claims based upon the application of Michigan law and the MPLA. ***See*** Trial Court Order, 11/4/14, at ¶ 1. However, the trial court separately determined that Appellants' statutory claims pursuant to the Pennsylvania Unfair Trade Practices and Consumer Protection Law and the Michigan Consumer Protection Act fail as a matter of law. ***See id***., at ¶¶ 2-3. Appellants do not appear to challenge this aspect of the trial court's summary judgment orders; in fact, Appellants focus their appellate brief solely on the alleged error the trial court committed when it dismissed their claims pursuant to the MPLA. ***See*** Appellants' Brief, at 3. Therefore, we will not address the trial court's decision to dismiss Appellants' claims of violation of the UTPCPL and violation of the MCPA.

Appellants' claims, Appellants insist they presented substantial evidence that the fraud exception to the MPLA defeated Appellees' claimed immunity from suit. ***See id***., at 3 ¶ 2. Therefore, Appellants maintain the trial court usurped a jury's role by determining these genuine issues of material fact related to the application of the exception to the MPLA.[10] ***See id***.

We review a challenge to the entry of summary judgment as follows:

> [We] may disturb the order of the trial court only where it is established that the court committed an error of law or abused its discretion. As with all questions of law, our review is plenary.
>
> In evaluating the trial court's decision to enter summary judgment, we focus on the legal standard articulated in the

---

[10] Through their respective notices of appeal, Appellants purport to appeal all previously non-final orders that merged into and were made appealable by the entry of the final judgment. ***See*** Notice of Appeal (Ma.J.L. and M.L), 2/23/15, at 2 (unpaginated); Notice of Appeal (A.H., Jr. and A.H.), 2/23/15, at 2 (unpaginated); Notice of Appeal (Brewer), 2/23/15, at 2 (unpaginated); Notice of Appeal (D.A. and B.A.), 2/23/15, at 2 (unpaginated); Notice of Appeal (K.S. and Labadie), 2/23/15, at 2 (unpaginated); Notice of Appeal (Lanthier), 2/23/15, at 2 (unpaginated); Notice of Appeal (Lindberg), 2/23/15, at 2 (unpaginated); Notice of Appeal (Mi.J.L. and M.L.), 2/23/15, at 2 (unpaginated); Notice of Appeal (Riggs), 2/23/15, at 2 (unpaginated); Notice of Appeal (Wisniewski), 2/23/15, at 2 (unpaginated); Notice of Appeal (Zachar), 2/23/15, at 2 (unpaginated); Notice of Appeal (Woodcock), 2/23/15, at 2 (unpaginated); Notice of Appeal (Mullen), 2/23/15, at 2 (unpaginated).

These orders include the order of May 2, 2014 entering partial summary judgment for Appellees, the order entered July 18, 2014, denying Appellants' motion for reconsideration, and the order entered November 4, 2014 entering summary judgment on the rest of Appellants' claims. However, through their appellate brief, Appellants only challenge the entry of summary judgment on November 4, 2014. Thus, we restrict our review accordingly.

> summary judgment rule. ***See*** Pa.R.C.P. Rule 1035.2. The rule states that where there is no genuine issue of material fact and the moving party is entitled to relief as a matter of law, summary judgment may be entered. Where the nonmoving party bears the burden of proof on an issue, he may not merely rely on his pleadings or answers in order to survive summary judgment. Failure of a non-moving party to adduce sufficient evidence on an issue essential to his case and on which he bears the burden of proof establishes the entitlement of the moving party to judgment as a matter of law. Lastly, we review the record in the light most favorable to the nonmoving party, and all doubts as to the existence of a genuine issue of material fact must be resolved against the moving party.

E.R. Linde Const. Corp. v. Goodwin, 68 A.3d 346, 349 (Pa. Super. 2013) (citation omitted; brackets in original).

Here, the trial court granted summary judgment after determining Appellants' claims were barred due to the application of Michigan law, specifically the MPLA. Unlike the law in Pennsylvania, Michigan has enacted a statute which "limits the liability of drug manufacturers and sellers where the drug at issue was approved for safety and efficacy by the United States Food and Drug Administration and labeled in compliance with FDA standards." ***Taylor v. SmithKline Beecham Corp***., 658 N.W.2d 127, 129-130 (Mich. 2003) (footnote omitted).

Specifically, MPLA provides:

> (5) 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 or seller 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. However, this subsection does not apply to a drug that is sold in the United States after the

> effective date of an order of the United States food and drug administration to remove the drug from the market or to withdraw its approval. This subsection does not apply if the defendant at any time before the event that allegedly caused the injury does any of the following:
>
> (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, cosmetic act, chapter 675, 52 Stat 1040, 21 USC 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 § 600.2946(5).

Further, the Michigan Legislature has defined a "product liability action" as an "action based on a legal or equitable theory of liability brought for the death of a person or for injury to a person or damage to property caused by or resulting from the production of a product." Mich. Comp. Laws § 600.2945(h). "Production" is defined as "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 § 600.2945(i).

Appellants do not dispute the trial court's determination that their claims constituted a product liability action or that the MPLA governs

Michigan product liability actions. Instead, Appellants base both of their claims of error on the trial court's application of the MPLA to their specific claims. ***See*** Appellants' Brief, at 3.

Appellants first contend the trial court misconstrued the parameters of the MPLA in granting summary judgment. ***See*** Appellants' Brief, at 19-30. Specifically, Appellants argue the MPLA does not apply to immunize Appellees in this situation because Risperdal was prescribed to Appellants "off-label" and thus not "approved" by the FDA relative to these specific Appellants. ***See id***., at 23-27. Conversely, Appellees argue that approval for *any* population by the FDA implicates the MPLA, and bars Appellants' suits. ***See*** Appellees' Brief, at 8-16.

Protection under the MPLA is broad. The Michigan Supreme Court has explained that

> [p]ursuant to this statute, unless the fraud exception in subsection a or the bribery exception in subsection b applies …., a manufacturer or seller of a drug that has been approved by the FDA 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. Thus, the Legislature has determined that a drug manufacturer or seller that has properly obtained FDA approval of a drug product has acted sufficiently prudently so that no tort liability may lie.

Taylor, 685 N.W.2d at 131.

Unfortunately, at this juncture, no Michigan state court has encountered a claim that the MPLA does not provide protection for drug

manufacturers when the FDA approval they received is for a different population than those adversely affected by the drug.

However, Michigan federal courts have already dismissed several cases based upon Appellants' argument. For instance, in ***Griffus v. Novartis Pharmaceuticals Corp***., the plaintiff sued a drug manufacturer after participating in a clinical trial testing the efficacy of a drug, Trileptal, for treatment of pain associated with diabetic neuropathy. ***See*** 2006 WL 2583129, at *1 (E.D. Mich. 2006). Plaintiff claimed the MPLA did not apply to bar her product liability claims against the drug manufacturer because when she was prescribed the drug, it had only received FDA approval for the treatment of seizures caused by epilepsy. ***See id***. The district court rejected plaintiff's argument, reasoning the Michigan legislature was "certainly aware" that a drug could be used for purposes other than what it received FDA approval for, but that a clear reading of the statute provided the legislature chose to offer blanket immunity to drug manufacturers once it received any type of FDA approval. ***Id***., at *2.

Additionally, in ***White v. SmithKline Beecham Corp***., a plaintiff sued a drug manufacturer for failing to warn of the associated risk between adolescent use of Paxil and an increased risk of suicidality. ***See*** 538 F.Supp.2d 1023, 1025 (W.D. Mich. 2008). While the plaintiff admitted Paxil had FDA approval for adults and was labeled in accordance with the FDA requirements, plaintiff alleged that the fact the drug was prescribed "off-

label" to the adolescent in question placed the case outside of the parameters of the MPLA. ***Id***., at 1029-1030.

However, the Michigan district court rejected this argument, finding

> [t]he 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 [c]ourt must interpret the statute as it is written. Under Michigan law, the actions of Defendant GSK alleged in the complaint are protected from a lawsuit because Defendant has complied with FDA regulations.

Id., at 1030.

Conversely, we were unable to find *any* state or federal cases supporting Appellants' reading of the statute.

After reviewing these cases within the context of the plain language of the statute, we are inclined to agree with the federal courts' determination that the FDA "approval" required to trigger the application of immunity under the MPLA does not need to be specific to the population utilizing the approved drug.[11] There is no language within the confines of the MPLA which

---

[11] We recognize that with the exception of the United States Supreme Court, we are not bound by a federal court decision. ***See NASDAQ OMX PHLX, Inc. v. PennMont Secs***., 52 A.3d 296, 303 (Pa. Super. 2012). However, such decisions can be instructive in areas such as this where Pennsylvania courts have not interpreted an out-of-state statute.

suggests the Michigan legislature intended to limit this protection to drug manufacturers when patients are prescribed the drug for its indicated uses.

Further, all of the Michigan case law that does refer to FDA approval refers to the FDA approval of *the drug*, rather than FDA approval of a drug for use in a specific population. ***See Taylor***, 658 N.W.2d at 131 ("[A] manufacturer or seller of a drug that has been approved by the FDA has an absolute defense to a products liability claim….") Thus, we conclude that as long as a drug has received FDA approval, and its label is compliant with FDA regulations, the MPLA applies to bar any product liability claim, despite the drug's indicated uses.

Through their complaints, Appellants concede Risperdal was initially approved by the FDA in 1993. And, though Appellants dispute the accuracy of Risperdal's label, they do not dispute that the drug was labeled at all times in compliance with the FDA regulations. Thus, Appellants' contention that the MPLA does not apply to their claims because Risperdal was not "approved" for Appellants, fails.

Next, assuming the trial court correctly determined the MPLA applies to these suits, Appellants maintain the trial court erred in granting summary judgment due to genuine issues of material fact concerning the application of the "fraud exception" to the MPLA's blanket immunity for manufacturers. Appellants' Brief, at 30. Appellants assert the factual record contains issues of material fact as to "(1) whether [Appellees] intentionally withheld or

misrepresented information relating to the risk of gynecomastia associated with Risperdal; and (2) whether the information was such that the drug would not have been approved for pediatric use in October 2006." ***Id***., at 30-31.

Conversely, Appellees argue that because Appellants have not presented evidence of an FDA finding of fraud, the "fraud-on-the-FDA" exception to the MPLA has been preempted by federal law pursuant to the Sixth Circuit's decision in ***Garcia v. Wyeth-Ayerst Laboratories***, 385 F.3d 961 (6th Cir. 2004). ***See*** Appellees' Brief, at 17-22. In response to Appellees' claim, Appellants point, in their reply brief, to a conflicting case from the Second Circuit, ***Desiano v. Warner-Lambert & Co.***, 467 F.3d 85 (2d Cir. 2006), in which that court determined this particular exception is not preempted by federal law. Appellees counter the Fifth Circuit in ***Lofton v. McNeil Consumer & Specialty Pharmaceuticals***, 672 F.3d 372, 380 (5th Cir. 2012), found the Sixth's Circuit's preemption finding for the fraud exception to the MPLA a more "faithful" reading of United States Supreme Court precedent, while squarely rejecting the Second Circuit's approach to federal preemption in ***Desiano***.

Once again, there is no guidance from the Michigan state courts concerning the validity and application of this particular exception to the MPLA. Further, we recognize the existence of a circuit split in relation to the issue of federal preemption regarding this exception to the MPLA. However,

we need not determine which circuit's rationale and ultimate conclusion is in line with Pennsylvania law because we agree with the trial court's cogent analysis on the application of the exception.

The trial court determined that

> [f]or the purposes [] of this matter before th[e trial court], it is immaterial whether Garcia or Desiano is applied, the result is the same.[] Applying the law according to Garcia, the exception contained within § 600.2946(5)(a) does not apply for two reasons. First, there has not been a federal finding of fraud.[] Second, even if there was a federal finding of fraud, [Appellants] still have not produced any facts to satisfy their burden under § 600.2946(5)(a). Section 600.2946(5)(a) requires a plaintiff to prove both intentional misrepresentation to the FDA and that "the drug would not have been approved, or the [FDA] would have withdrawn approval for the drug if the information were accurately submitted." Mich. Comp. Laws § 600.2946(5)(a). [Appellants] have not produced any evidence to show the FDA would not have approved Risperdal in 1993, or would have withdrawn Risperdal from the market, if the information was accurately submitted. Indeed, in response to a citizen's petition, the FDA recently declined to withdraw Risperdal from the market, stating "based on review of clinical data submitted by the sponsor, published literature, and postmarketing surveillance, there is no evidence… that would warrant revocation of the pediatric indication of [Risperdal]." FDA Citizen Petition Docket No. FDA-2012-P-0857, Partial Petition Approval and Denial Response Letter dated November 25, 2014 at p. 5. If th[e trial court] applied the law according to Desiano, a federal finding of fraud of the FDA is not required; however, [Appellants] must still show that the FDA would not have approved, or would have withdrawn approval for, Risperdal if the information was accurately submitted. As discussed above, [Appellants] have not provided any evidence to show Risperdal would not have been approved in 1993, or the FDA would have withdrawn approval for Risperdal, if the information was accurately submitted.

Trial Court Rule 1925(a) Opinion, 10/1/15, at 12-13.

A review of the record reveals Appellants' allegations of facts and presentation of data to support their assertion that Appellees fraudulently obtained FDA approval for Risperdal in relation to its approvals for adolescents and children in 2006 and 2007. There is, however, an absence in the record of any facts, or even argument, that Appellees fraudulently obtained FDA approval for the first time in 1993.

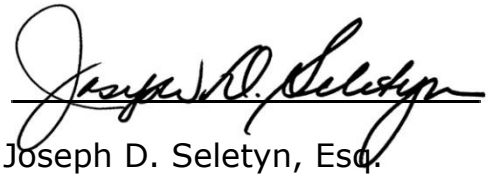
As discussed previously, the MPLA indemnifies a drug manufacturer once a drug had been approved by the FDA for any use, as long as the label is compliant with FDA regulations. Thus, the proof of fraud a plaintiff is required to present in order to receive the benefit of the fraud exception must relate to the initial FDA approval. Further, as highlighted by the trial court, Appellants cannot prove that the FDA, in receipt of the information concerning the Risperdal/gynecomastia link, would have withdrawn it from the market as the FDA had already explicitly declined to withdraw Risperdal from the market for this reason.

Therefore, we cannot find any record support for Appellants' assertion there was a genuine issue of material fact relating to the application of this exception.

Accordingly, the trial court did not abuse its discretion in determining the fraud exception to the MPLA did not apply, leaving Appellees immune from suit, and granting Appellees' motion for summary judgment. Appellants' final issue merits no relief.

Judgments affirmed.

Judgment Entered.



Joseph D. Seletyn, Esq.
Prothonotary

Date: 11/28/2017