UNITED STATES DISTRICT COURT
NORTHERN DISTRICT OF NEW YORK

SHAQUIL BYRD,

Plaintiff,

v.

1:14-CV-0820
(GTS/DJS)

JANSSEN PHARM., INC.; and JOHNSON & JOHNSON,

Defendants.

APPEARANCES:

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JEFFREY J. HUGHES, ESQ.

GLENN T. SUDDABY, Chief United States District Judge

DECISION and ORDER

Currently before the Court, in this products liability action filed by Shaquil Byrd ("Plaintiff") against Janssen Pharmaceuticals, Inc. ("Janssen"), and Johnson & Johnson ("Defendants"), is Defendants' motion for judgment as a matter of law pursuant to Fed. R. Civ. P. 50 or, in the alternative, for a new trial pursuant to Fed. R. Civ. P. 59. (Dkt. No. 199.) For the reasons set forth below, Defendants' motion is granted.

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I. RELEVANT BACKGROUND

A. Relevant Procedural History

Generally, following the issuance of the Court's Decision and Order of March 7, 2017, two claims of Plaintiff's Amended Complaint survived Defendants' motion for summary judgment: (1) Plaintiff's claim that Defendants were negligent in designing, manufacturing, and selling Risperdal as well as in failing to properly warn the general public of the risks and dangers of Risperdal; and (2) Plaintiff's claim that Defendants are strictly liable for the injuries caused by (a) Risperdal's defective condition, (b) the failure to give appropriate warnings regarding the drug's dangers and adverse effects, and (c) their misleading representations regarding the risk of gynecomastia and hyperprolactinemia in adolescent patients. (Dkt. No. 108, at 70.)

The trial on these two claims commenced on September 18, 2017. (Dkt. No. 163.) At the conclusion of the trial on September 27, 2017, the jury reached a verdict against Plaintiff with regard to his negligent design claim but in favor of him with regard to his failure-to-work claim, awardeding him $500,000 for past and/or present pain and suffering and $500,000 in future pain and suffering; and Judgment was entered accordingly. (Dkt. Nos. 179, 180.) On October 25, 2017, Defendants filed the current motion for judgment a matter of law pursuant to Fed. R. Civ. P. 50 or, in the alternative, for a new trial pursuant to Fed. R. Civ. P. 59. (Dkt. No. 199.) Plaintiff has opposed this motion. (Dkt. No. 204, 205.)

Because this Decision and Order is intended primarily for the review of the parties, who have (in their memoranda of law) demonstrated an accurate understanding of the remainder of the relevant procedural history of this action, the Court will not summarize the remainder of that procedural history in detail in this Decision and Order.

B. Parties' Briefing on Defendants' Motion Generally

Generally, in their motion, Defendants assert the following arguments: (1) as a threshold matter, Defendant Janssen is entitled to judgment as a matter of law because (a) Plaintiff's failure-to-warn claim is preempted by federal law, (b) Plaintiff failed to introduce sufficient evidence of proximate and medical causation, and (c) Plaintiff cannot establish that Defendant Johnson & Johnson is liable; and (2) in the alternative, Defendant Janssen is entitled to a new trial because (a) the jury's verdict is against the weight of the evidence, (b) the conduct of Plaintiff's counsel warrants a new trial, and (c) Plaintiff's award is excessive (warranting either remittitur or a new trial). (Dkt. No. 199, Attach. 1.)

Generally, in opposition to Defendants' motion, Plaintiff asserts the following arguments: (1) Defendants are not entitled to judgment as a matter of law because (a) their preemption arguments are meritless, unavailing and frivolous, (b) their arguments regarding causation are similarly unavailing and (c) Defendant Johnson & Johnson is liable just as Defendant Janssen is liable; and (2) there is no legal basis warranting a new trial because (a) the verdict is supported by compelling evidence, (b) there is no evidence of prejudice against Defendants created by the actions of Plaintiff's counsel, and (c) Plaintiff's award is not excessive but is comparable to awards in identical cases. (Dkt. No. 205.)

Generally, in reply, Defendants repeat the arguments asserted in their memorandum of law-in chief, albeit modified to reply to Plaintiff's responses. (Dkt. No. 206.)

II. GOVERNING LEGAL STANDARDS

A. Legal Standard Governing Motions for Judgment Notwithstanding the Verdict Pursuant to Fed. R. Civ. P. 50(b)

Rule 50(b) of the Federal Rules of Civil Procedure provides as follows, in pertinent part:

> If the court does not grant a motion for judgment as a matter of law made under Rule 50(a), the court is considered to have submitted the action to the jury subject to the court's later deciding the legal questions raised by the motion. No later than 28 days after the entry of judgment—or if the motion addresses a jury issue not decided by a verdict, no later than 28 days after the jury was discharged—the movant may file a *renewed* motion for judgment as a matter of law and may include an alternative or joint request for a new trial under Rule 59.

Fed. R. Civ. P. 50(b) (emphasis added).

As a result, a prerequisite for a motion for a post-trial motion for a judgment as a matter of law (also known as a motion for judgment notwithstanding the verdict) is a pre-verdict motion for judgment as a matter of law. *See* Fed. R. Civ. P. 50 Advisory Committee Note (1963) ("A motion for judgment notwithstanding the verdict will not lie unless it was preceded by a motion for a judgment as a matter of law made at the close of all the evidence.") (emphasis added); Fed. R. Civ. P. 50 Advisory Committee Note (1991) ("A post-trial motion for judgment can be granted only on grounds advanced in the pre-verdict motion."); *Exxon Shipping Co. v. Baker*, 554 U.S. 471, 486, n.5, 128 S. Ct. 2605 (2008) ("A motion under Rule 50(b) is not allowed unless the movant sought relief on similar grounds under Rule 50(a) before the case was submitted to the jury.").

Such a post-trial motion may be granted by a district court where doing so is necessary to prevent "manifest injustice." *Kirsch v. Fleet Street, Ltd.*, 148 F.3d 149, 164 (2d Cir. 1998) ("As to any issue on which proper Rule 50 motions were not made, [a judgment as a matter of law]

may not properly be granted by the district court, or upheld on appeal, or ordered by the appellate court unless that action is required in order to prevent manifest injustice."); *accord, Lore v. City of Syracuse*, 670 F.3d 127, 153 (2d Cir. 2012); *Cordius Trust v. Kummerfeld*, 331 F. App'x 810, 811 (2d Cir. 2009). "[M]anifest justice" exists only when a jury's verdict is "wholly without legal support." *Pahuta v. Massey-Ferguson, Inc.*, 170 F.3d 125, 129 (2d Cir. 1999) ("We may overlook such a default in order to 'prevent a manifest injustice' in cases where a jury's verdict is wholly without legal support.") (internal quotation marks omitted); *accord, U.S. S.E.C. v. Stamoulis*, 350 F. App'x 499, 500 (2d Cir. 2009); *Clergeau v. Local 1181, Amalgamated Transit Union, AFL-CIO*, 162 F. App'x 32, 34 (2d Cir. 2005); *Rothstein v. Carriere*, 373 F.3d 275, 291 (2nd Cir. 2004).

B. Legal Standard Governing Motions for a New Trial Pursuant to Fed. R. Civ. P. 59(a)

Rule 59(a) of the Federal Rules of Civil Procedure provides, in pertinent part, that "[t]he court may, on motion, grant a new trial on all or some of the issues–and to any party– . . . after a jury trial, for any reason for which a new trial has heretofore been granted in an action at law in federal court . . . ." Fed. R. Civ. P. 59(a)(1)(A). The Second Circuit has interpreted this standard to permit the granting of new trials when, "in the opinion of the district court, the jury has reached a seriously erroneous result or the verdict is a miscarriage of justice." *DLC Mgmt. Corp. v. Town of Hyde Park*, 163 F.3d 124, 133 (2d Cir. 1998) (internal quotation marks omitted); *Lightfoot v. Union Carbide Corp.*, 110 F.3d 898, 911 (2d Cir. 1997). Examples of such a serious error or a miscarriage of justice include when "the verdict is against the weight of the evidence," or when "for the reasons stated the trial was not fair to the moving party." *Mallis v. Bankers Trust Co.*, 717 F.2d 683, 691 (2d Cir. 1983). However, "the court should only grant a motion for

a new trial when the jury's verdict is 'egregious.'" *DLC Mgmt. Corp.*, 163 F.3d at 134 (internal quotation marks omitted); *Dunlap-McCuller v. Riese Org.*, 980 F.2d 153, 158 (2d Cir. 1992), *cert. denied*, 510 U.S. 908, 114 S. Ct. 290 (1993).

C. Legal Standards Governing Grounds Asserted by Defendants

For ease of analysis, the legal standards governing the grounds asserted by Defendants will be set forth below in Part III of this Decision and Order.

III. ANALYSIS

A. Whether Defendants Are Entitled to Judgment as a Matter of Law Because Plaintiff's Failure-to-Warn Claim Is Preempted by Federal Law

1. Parties' Briefing of This Issue

a. Defendants' Memorandum of Law-in Chief

In their memorandum of law-in chief, Defendants assert three arguments on the subject of preemption: (1) an argument that 21 C.F.R. § 201.57(e) (2004) (which governed the content of the "Warnings" section on Risperdal's label because it was the regulation in effect at the time Plaintiff started taking Risperdal) should be interpreted to mean that Defendants were precluded from using the "Changes Being Effected" (or "CBE") process to update Risperdal's warning label; (2) an argument that, in any event, there is "clear evidence" that the FDA would not have approved the proposed labeling during the relevant time period; and (3) an argument that contrary arguments by Plaintiff are unavailing. (Dkt. No. 199, Attach. 1.)

More specifically, Defendants' first argument can be broken down into the following three parts: (a) while 21 C.F.R. § 314.70(c)(2)(i) permits a manufacturer to "add or strengthen a . . . warning" without prior FDA approval, during the time in question the content of that warning

was governed by 21 C.F.R. § 201.57(e) (2004), which stated that "[a] specific warning relating to . . . [an off-label use] may be required by the [FDA] if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with serious risk or hazard," and which thus prohibited Defendants from unilaterally updating Risperdal's label regarding pediatric use; (b) this common-sense interpretation of 21 C.F.R. § 201.57(e) (2004) (as conferring on the FDA the sole authority to add safety information regarding an off-label use of a medication) is supported by the structure of the FDA's regulations, which treat labels as containing adequate directions for intended use (i.e., the use for which the medication had been approved), which is why in 1996 the FDA rejected as promotional Defendants' request for permission to add safety information to the Risperdal label regarding use in children and adolescents; and (c) this interpretation is also supported by the FDA's interpretation of identical language in 21 C.F.R. § 201.57(e) (2004)–regarding boxed warnings–which (according to the FDA's statement during the regulation's notice-and-comment period in 1979) permits a boxed warning in labeling only when specifically required by the FDA, and which should be interpreted in the same manner as the language regarding off-label uses. (*Id*.)

Moreover, Defendants' second argument can be broken down into the following two parts: (a) in any event, there is "clear evidence" that FDA would not have approved the proposed labeling during the relevant time period, because (i) despite the fact that Defendant Janssen asked the FDA to include safety information regarding pediatric dosing on Risperdal's label, and the fact that the FDA knew that Risperdal was being used off-label in pediatric patients, the FDA denied Defendant Janssen's request because it believed that adding dosing information for an

unapproved population would encourage use of Risperdal for off-label purposes, and (ii) subsequently the FDA repeatedly approved Risperdal's label without requesting any changes regarding pediatric use until October 2006; and (b) rather, a manufacturer of prescription medication may update a label without prior FDA approval only if it acquires *new* information regarding *serious* hazards associated with the medication, and here the relationship between antipsychotics and hyperprolactinemia was not *new* information because it had been discussed in basic psychiatry textbooks for decades, and the FDA does not consider gynecomastia a *serious* adverse event. (*Id*.)

Finally, Defendants' third argument can be broken down into the following three parts: (a) the FDA's statement in the 1979 Federal Register (that a manufacturer of prescription medicine may add warnings to labeling) is merely a general statement paralleling the language of 21 C.F.R. § 201.57(e), which again, *inter alia*, requires a *serious* adverse reaction; (b) 21 C.F.R. § 201.57(f)(9)(vi) did not allow Defendants to unilaterally add to the Risperdal labeling information regarding Risperdal use in children because the section required a hazard to be described in the Precautions subsection of the labeling only if it was specific to children and gynecomastia was not specific to children; and (c) the *ipse dixit* conclusion of Plaintiff's regulatory expert, Dr. Laura M. Plunkett, Ph.D., that manufacturers of prescription medicine can unilaterally add safety information regarding off-label is contrary to both the plain language of the regulations and her own concession that Defendants could not unilaterally add safety information relative to unapproved populations. (*Id*.)

b. Plaintiff's Opposition Memorandum of Law

In his opposition memorandum of law, Plaintiff asserts the following four arguments on the subject of preemption: (1) Defendants' first argument (regarding 21 C.F.R. § 201.57[e]

[2004]) has been considered, and rejected, by state courts in Pennsylvania and California,[1] which have ruled that there was no FDA regulation that would have precluded Defendants from adding new *safety* (as opposed the efficacy) information regarding the frequency of gynecomastia in child and/or adolescent Risperdal patients during the relevant time period (which is why, for example, Viagra contains safety information regarding its use by pregnant women even though women are not the population for which the drug is indicated); (2) Defendants' second and fourth arguments (regarding their 1996 request) improperly rely on their 1996 request because that request regarded *efficacy* (not safety) information for the pediatric population (specifically pediatric dosing), which was why the request was denied as promotional; (3) Defendants' first argument (regarding the FDA's 2014 response to a Citizen Petition) and third argument (regarding the FDA's 1979 statement regarding boxed warnings) are unpersuasive because the FDA's statements should be viewed as merely informative (given that they were given in response to a request) and not applicable (given that Plaintiff has never advocated the use of a black box warning); and (4) Defendants' fifth argument is unpersuasive because the relationship between Risperdal and hyperprolactinemia was, during the time in question, both "new" (or "recently-learned") and "danger[ous]." (Dkt. No. 205.)

[1] *See Risperdal & Invega Product Liability Cases*, Judicial Council Coordination Proceeding No. 4775, Case Nos. BC562887 and BC568282, at 4-13 (Cal. Super. Ct., Los Angeles Cnty., June 22, 2016) (Highberger, J.); *Stange v. Janssen Pharm. Inc.*, Case No. 1304011984, at 11-14 (Pa Ct. of Common Pleas, 1st Judicial Dist.. May 23, 2016) (Powell, J.).

c. Defendants' Reply Memorandum of Law

In their reply memorandum of law, Defendants assert the following six arguments on the subject of preemption: (1) that portion of Plaintiff's first argument regarding the preclusive effect to be attributed to the state court decisions from Pennsylvania and California is unpersuasive, because (a) Plaintiff fails to meet his threshold burden of demonstrating how the doctrine of collateral estoppel applies, and (b) the issues in this case (which regard whether 21 C.F.R. § 201.57[e] preempts New York law, and whether a manufacturer can unilaterally add safety information regarding an off-label use with respect to a condition that the FDA does not consider a serious adverse event) are not identical to those addressed in the referenced state court decisions (and non-mutual offensive collateral estoppel should not apply to pure questions of law); (2) the remaining portion of Plaintiff's first argument (regarding Viagra) is unpersuasive, because (a) Viagra does not contain a warning regarding its use by pregnant women as Plaintiff suggests, (b) 21 C.F.R. § 201.57(c)(9) requires the information that appears on the Viagra label about usage during pregnancy, and (c) Plaintiff did not introduce evidence that Viagra's manufacturer added this information to its label without prior approval by the FDA; (3) Plaintiff's second argument (regarding Defendants' 1996 request) is unpersuasive because the fact that the FDA denied as promotional Defendant Janssen's proposed addition of pediatric dosing information before October 2006 actually supports the conclusion that safety information regarding an off-label use would not be permitted because the FDA's denial suggests an unapproved intended use of the medicine; (4) Plaintiff's fourth argument (regarding the requirement of *new* information and *serious* hazards) is unpersuasive because Plaintiff does not sufficiently dispute that the relationship between antipsychotics and hyperprolactinemia was not

new information in that it had been discussed in basic psychiatry textbooks for decades, and the FDA does not consider gynecomastia a *serious* adverse event; (5) Plaintiff's own regulatory expert (Dr. Plunkett) conceded that (a) Janssen submitted a supplemental new drug application ("sNDA") in December of 2003 to obtain an indication for a pediatric population, (b) a manufacturer of prescription medicine cannot update labeling information with respect to an unapproved indication that is subject of a pending sNDA, (c) the FDA did not approve this sNDA until October of 2006, and (d) 21 C.F.R. § 201.57(e) provided the FDA with control over the addition of safety information related to off-label uses; and (6) Plaintiff takes out of context the testimony of Defendants' regulatory expert Dr. Janet B. Arrowsmith, M.D., (that "[21 C.F.R. §] 314.70 offers options for adding safety information to a label without prior approval"), ignoring her next statement that, "if you're submitting an sNDA or particularly a CBE, that that is information relevant *to the approved indication*." (Dkt. No. 206.)

2. Legal Standard Governing This Issue

"Impossibility pre[]emption is a demanding defense." *Wyeth v. Levine*, 555 U.S. 555, 573 (2009). "In the context of claims against drug manufacturers for allegedly inadequate warnings, a drug manufacturer may show preemption in two ways: (1) by showing that it was prohibited by federal law from modifying the FDA-approved labeling; or (2) by presenting clear evidence that the FDA would not have approved a change to the drug's label." *Amos v. Biogen Idec Inc.*, 249 F. Supp. 3d 690, 699 (W.D.N.Y. 2017) (citing two Supreme Court cases).

Expressed differently, "[p]ost-FDA approval preemption analysis proceeds in two stages." *Utts v. Bristol-Myers Squibb Co.*, 251 F. Supp. 3d 644, 661 (S.D.N.Y. 2017). First, the plaintiff must show that "the defendants could unilaterally change the label . . . without FDA

approval," such as through the "change being effected" (or "CBE") regulation. *Utts*, 251 F. Supp. 3d at 661. Second, "[b]ecause the FDA 'retains the authority to reject labeling changes,' a manufacturer may still . . . establish an impossibility preemption defense through 'clear evidence that the FDA would not have approved a change' to the label." *Id*. "In sum, if the plaintiff can point to the existence . . . to support a labeling change under the CBE regulation, the burden then shifts to the manufacturer to show by 'clear evidence' that the FDA would not have approved the labeling change made on the basis of this newly acquired information." *Id*.

With regard to the second stage, the Third Circuit has explained that the "term 'clear evidence' . . . does not refer directly to the type of facts that a manufacturer must show, or to the circumstances in which preemption will be appropriate." *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d 268, 285 (3d Cir. 2017). Rather, the term "specifies how difficult it will be for the manufacturer to convince the factfinder that the FDA would have rejected a proposed label change. The manufacturer must prove that the FDA would have rejected a warning not simply by a preponderance of the evidence, as in most civil cases, but by 'clear evidence.'" *In re Fosamax (Alendronate Sodium) Prods. Liab. Litig.*, 852 F.3d at 285. The Third Circuit noted that "clear evidence" is "synonymous with 'clear and convincing evidence'" and that, in order "for a defendant to establish a preemption defense under *Wyeth*, the factfinder must conclude that it is highly probable that the FDA would not have approved a change to the drug's label." *Id*. at 285-86.

3. Analysis of This Issue

After carefully considering the matter, the Court answers the above-described question (i.e., whether Plaintiff's failure-to-warn claim is preempted by federal law) in the affirmative for

the reasons stated by Defendants in their memoranda of law. To those reasons, the Court adds the following analysis.

The Court is especially persuaded by the second and third of Defendants' three general arguments described above in Part III.A.1.a. of this Decision and Order (i.e., that clear evidence exists that the FDA would not have approved a change to the drug's label, and that contrary arguments are unavailing). In particular, the Court is persuaded by not only the arguments primarily relied on by Defendants in their memorandum of law-in chief and their reply memorandum of law but an argument more-obliquely relied on by Defendants: that the updated warning must have regarded a hazard that was *serious*.

While the relevant regulations during the time in question permitted Defendants to "add or strengthen a . . . warning" without prior FDA approval,[2] the Court construes those regulations as requiring, as a threshold matter, that the new warning regard a hazard that was "serious."[3] The parties' regulatory experts appear to have agreed on this interpretation of the relevant regulations.[4]

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[2] *See* 21 C.F.R. § 314.70(c)(2)(i) (2002, 2003, 2004) (permitting a manufacturer to "add or strengthen a . . . warning" without prior FDA approval); 21 C.F.R. § 314.70(c)(6)(iii)(A) (2005, 2006) (permitting a manufacturer to "add or strengthen a . . . warning" without prior FDA approval).

[3] *See* 21 C.F.R. § 201.57(e) (2002, 2003, 2004, 2005, 2006) ("Under this section heading, the labeling shall describe *serious* adverse reactions and potential safety hazards, limitations in use imposed by them, and steps that should be taken if they occur. The labeling shall be revised to include a warning as soon as there is reasonable evidence of an association of a *serious* hazard with a drug . . . . A specific warning relating to . . . [an off-label use] may be required by the [FDA] if the drug is commonly prescribed for a disease or condition, and there is lack of substantial evidence of effectiveness for that disease or condition, and such usage is associated with *serious* risk or hazard.") [emphasis added].

[4] (*See, e.g.*, Dkt. No. 183, at 18 [attaching page "328" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Plunkett, in which she answers, "Serious adverse

Rather, Plaintiff spent much time at trial adducing the testimony of experts that, in their opinion, gynecomastia is a "serious" adverse event, which Defendant attempted to rebut.[5] However, the issue is not whether, at the time of trial in September 2017 (or even at the time of Plaintiff's surgery in June 2014), an expert viewed gynecomastia as a "serious" adverse event. Rather, the issue is whether, between February or March of 2002 (when Plaintiff started taking Risperdal) and August 2006 (when Plaintiff stopped taking Risperdal), gynecomastia was a "serious" adverse event under the then-governing law: i.e., that it, *inter alia*, either (1) *resulted* in *inpatient* hospitalization or (2) *required* surgical intervention to *prevent* inpatient hospitalization.[6] Again, regulatory experts appear to have agreed on this definition of

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reactions, yes," to the question, "Now, the first line of Exhibit C [containing 21 C.F.R. § 201.57(e)], in the warnings section, the label shall describe serious adverse events, correct?"]; Dkt. No. 199, Attach. 3, at 101, 102 [attaching pages "911" and "914" of Trial Transcript, containing testimony of Defendant's expert Dr. Arrowsmith, in which she states that, "in terms of warnings and so forth, it's only serious adverse events that get into certain parts of the label"].)

[5] (*Compare* Dkt. No. 184, at 70 [attaching page "486" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Tucker that gynecomastia can require surgical correction] *and* Dkt. No. 185, at 71-72 [attaching pages "615" and "616" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Matthew Leinung that Plaintiff's gynecomastia would not have resolved itself without surgery] *and* Dkt. No. 189, at 129-30 [attaching pages "1164" and "1165" of Trial Transcript, containing testimony of Plaintiff that he needed to have surgery] *with* Dkt. No. 188, at 126-28 [attaching pages "1026" through "1028" of Trial Transcript, containing testimony of Defendant's expert Dr. Arrowsmith that surgery for Plaintiff's gynecomastia was not absolutely indicated but was a choice].)

[6] *See* 21 C.F.R. § 314.80 (2002, 2003, 2004, 2005, 2006) (2002, 2003, 2004, 2005, 2006) (defining "[s]erious adverse drug experience" as "[a]ny adverse drug experience occurring at any dose that *results* in any of the following outcomes: Death, a life-threatening adverse drug experience, *inpatient hospitalization* or prolongation of existing hospitalization, a persistent or significant disability/incapacity, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered a serious adverse drug experience when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may *require* medical or *surgical intervention* to *prevent* one of the outcomes listed in this definition.") [emphasis added], *accord*, 21 C.F.R. § 312.32(a).

seriousness.[7]

After scouring the record, the Court has found insufficient evidence upon which a jury could rationally answer that question in the affirmative. For the sake of brevity, the Court will not linger on the fact that there appears to be a dearth of evidence that, when Plaintiff underwent surgery on June 24, 2014, he received *inpatient* hospitalization at Ellis Hospital. The Court will also set aside the fact that any inpatient hospitalization (at a psychiatric facility) that Plaintiff may still need due to his gynecomastia has (by definition) not been prevented by his 2014 surgery,[8] making it impossible to conclude that gynecomastia has *required* surgical intervention to *prevent* inpatient hospitalization under 21 C.F.R. § 312.32(a) (2002, 2003, 2004, 2005, 2006).

More important is the fact that, while a November 2014 letter from a FDA senior official (stating that "Gynecomastia is a common clinical manifestation of hyperprolactinemia, regardless or cause, and does not represent a serious adverse event as defined in 21 CFR 3l2.32(a)") was not admitted into evidence because of Fed. R. Evid. 403,[9] the parties' regulatory experts both agreed (one readily and the other begrudgingly) that, according to the FDA's own

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[7] (*See, e.g.*, Dkt. No. 183, at 26 [attaching page "336" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Plunkett, in which she states, "I agree with that . . . specific limitation [of seriousness] to that definition [contained in 21 C.F.R. 312.32[a] . . ."]; Dkt. No. 188, at 123 [attaching page "1023" of Trial Transcript, containing testimony of Defendant's expert Dr. Arrowsmith, in which she states that, "under the regulations a serious adverse reaction is . . . [written] in 314.80" . . . "[a]nd . . . in 312.32"].)

[8] (Dkt. No. 187, at 63-64 [attaching pages "859" and "860" of Trial Transcript, containing testimony of Plaintiff's expert Dr. George Glass that, as a result of gynecomastia, and despite his surgery, Plaintiff may still need six months of inpatient care at a structured long-term psychiatric facility].)

[9] (Dkt. No. 183, at 23, 24 [attaching pages "333" and "334" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Plunkett]; Dkt. No. 152, at 18; Dkt. No. 142, at 33.)

regulations, gynecomastia would not be a serious adverse event.[10] This concession by Plaintiff's regulatory expert (Dr. Plunkett) makes sense given the strictures of 21 C.F.R. § 312.32(a) (2002, 2003, 2004, 2005, 2006).

Granted, Dr. Plunkett hastened to add that she personally disagrees with the FDA because hospitalization and/or surgery *sometimes* result from gynecomastia.[11] However, her current personal disagreement with the FDA is not relevant to whether, between February or March of 2002 and August 2006, gynecomastia was a "serious" adverse event under the *then-governing FDA regulations*. Even if Dr. Plunkett's current personal disagreement were relevant, she did not go so far as to testify that her personal opinion was so free of qualifications that it rose to one that gynecomastia "*results* in . . . *inpatient* hospitalization" or "require[s] . . . surgical intervention to *prevent* [inpatient hospitalization]."[12] Nor did she even testify that she held any such a view between 2002 and 2006, or that her current view regarded the period of 2002 to 2006.[13]

Dr. Plunkett certainly did not testify that the "investigators" or "sponsors"[14] of the

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[10] (*See, e.g.*, Dkt. No. 199, Attach. 3, at 100-01 [attaching pages "911" and "100" of Trial Transcript, containing testimony of Defendant's expert Dr. Arrowsmith]; Dkt. No. 183, at 20, 21, 82 [attaching pages "330," "331," and "392" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Plunkett, stating that "I agree that as it's defined in 21 CFR 312.32(a) gynecomastia would not be a regulatory defined [sic] serious adverse event"].)

[11] (Dkt. No. 199, Attach. 3, at 23-26, 82-83 [attaching pages "326" through "331," and pages "392" and "393," of Trial Transcript, containing testimony of Plaintiff's expert Dr. Plunkett].)

[12] (*See generally* Dkt. Nos. 181-183 [containing Dr. Plunket's trial testimony].)

[13] (*Id.*)

[14] *See* 21 C.F.R. § 812.3(i) ("Investigator means an individual who actually conducts a clinical investigation, i.e., under whose immediate direction the test article is administered or dispensed to, or used involving, a subject, or, in the event of an investigation conducted by a team of individuals, is the responsible leader of that team."); 21 C.F.R. §

clinical studies on which she relied (whose views control the *current* definition of seriousness)[15] held such a view before 2006.[16] To the contrary, she testified that, before 2006, two investigators (Dr. Robert L. Findling and Dr. Jan Croonenberghs) and a sponsor (Johnson & Johnson)[17] of RIS-INT 41 and RIS-INT 70 held the contrary view. For example, Dr. Plunkett testified that, in an article summarizing the RIS-INT 41 and RIS-INT 70 clinical studies, an investigator of those studies (Dr. Findling) expressed a view (specifically, that "[t]here was no direct correlation between prolactin elevation and [side effects hypothetically attributable to

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812.3(n) ("Sponsor means a person who initiates, but who does not actually conduct, the investigation, that is, the investigational device is administered, dispensed, or used under the immediate direction of another individual. A person other than an individual that uses one or more of its own employees to conduct an investigation that it has initiated is a sponsor, not a sponsor-investigator, and the employees are investigators."); *Burgos v. Satiety, Inc.*, 10-CV-2680, 2011 WL 1327684, at *3, n.6 (E.D.N.Y. Apr. 5, 2011) ("Satiety, as the manufacturer of the TOGA device . . . , is a sponsor and not an investigator."). (*See also* Dkt. No. 188, at 86 [attaching page "986" of Trial Transcript, containing testimony of Defendant's expert Dr. Arrowsmith that "[a sponsor is] the manufacturer or the person who has been responsible for the development of a new drug"].)

[15] *See* 21 C.F.R. § 312.32(a) (2017) ("An adverse event . . . is considered 'serious' if, *in the view of either the investigator or sponsor*, it results in any of the following outcomes: Death, a life-threatening adverse event, inpatient hospitalization or prolongation of existing hospitalization, a persistent or significant incapacity or substantial disruption of the ability to conduct normal life functions, or a congenital anomaly/birth defect. Important medical events that may not result in death, be life-threatening, or require hospitalization may be considered serious when, based upon appropriate medical judgment, they may jeopardize the patient or subject and may require medical or surgical intervention to prevent one of the outcomes listed in this definition.") [emphasis added].

[16] (*See generally* Dkt. Nos. 181-192 [containing Trial Transcript].)

[17] (*See, e.g.*, Dkt. No. 181, at 86, 87, 89, 93, 106, 107, 109, 114-15 [attaching pages "156," "157," "159," "163," "176," "177," "179," "184," and "185" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Plunkett]; Dkt. No. 182, at 2 [attaching page "201" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Plunkett].)

prolactin]") with which she disagreed.[18] Similarly, Dr. Plunkett testified that, in abstracts of articles regarding the RIS-INT 41 and RIS-INT 70 clinical studies, an investigator (Dr. Croonenberghs) and an employee of Johnson & Johnson (Dr. Reyes) did not even reference gynecomastia but concluded that Risperdal was safe and effective for use in children with conduct disorder over two years.[19] Again, this testimony by Dr. Plunkett makes sense given that the RIS-INT 41 and RIS-INT 70 clinical studies nowhere contain a view by an investigator or sponsor that gynecomastia either resulted in inpatient hospitalization or required surgical intervention to prevent inpatient hospitalization before 2006.

In short, because it is undisputed that gynecomastia was not a "serious" hazard pursuant to the regulations in existence during the time in question, the Court finds that Defendants could not have unilaterally warned of gynecomastia pursuant to those regulations: even if Defendants had tried to do so, Plaintiff's regulatory expert conceded (as described above) that the FDA would not have approved the proposed change. *See, supra,* note 10 of this Decision and Order. This admission constitutes the sort of "clear evidence" required under the governing legal standard. *See Risperdal & Invega Product Liability Cases*, No. BC599531, 2017 WL 4100102, at *10 (Cal. Super. Ct., Los Angeles Cnty., March 16, 2017) (Highberger, J.) (granting defendants' motion for summary judgment regarding all claims on preemption grounds because, *inter alia*, "[t]he denial of the Citizen Petition [through the FDA's November 2014 letter] . . .

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[18] (*See, e.g.*, Dkt. No. 181, at 120, 121, 122, 123, 124, 128 [attaching pages "190," "191," "192," "193," "194," and "198" of Trial Transcript, containing testimony of Dr. Plunkett].)

[19] (Dkt. No. 182, at 2-8 [attaching pages "201" through "207" of Trial Transcript, containing testimony of Plaintiff's expert Dr. Plunkett].)

alone serves to provide 'clear evidence' that the FDA was satisfied with the current Risperdal label insofar as pediatric usage is concerned and would not have adopted Plaintiffs' proposed change") [emphasis added].[20]

For all of these reasons, the Court grants Defendants' motion for judgment a matter of law. The Court notes that, while granting a summary judgment motion based on preemption might have been appropriate, Defendants' motion for summary judgment did not present the issue. (*See generally* Dkt. No. 92, Attach. 1.) Furthermore, while one of Plaintiff's pre-trial motions *in limine* and Defendants' response thereto presented the issue (Dkt. No. 142, at 27-29; Dkt. No. 147, at 16-17), the Court found it necessary to receive evidence, and hear additional argument, regarding the issue (Dkt. No. 152, at 17). Having now done so, the Court finds that the issue of preemption has been clarified.

The Court notes also that, in rendering the above-described findings, it does not accept any argument that Defendants could have warned of the risks of gynecomastia on the pre-2006 labeling through other means (such as sales force communications, medical education, "Dear

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[20] While the Court need not rely on the FDA's November 2014 letter from a senior FDA senior official given the above-referenced concession by Plaintiff's regulatory expert, the Court may in fact rely on that letter (despite its decision to preclude the admission of the letter into evidence due to the letter's substantial likelihood of confusing the issues and misleading the jury under Fed. R. Evid. 403) because the particular preemption issue at hand presents a question of law reserved for the Court. *See, e.g., In re MTBE Prods. Liability Lit.*, 725 F.3d 65, 99 (2d Cir. 2013) (affirming decision of district court which found that, absent certain factual issues, impossibility preemption presented question of law for court); *Risperdal & Invega Product Liability Cases*, No. BC599531, 2017 WL 4100102, at *7-8 (Cal. Super. Ct., Los Angeles Cnty., March 16, 2017) (Highberger, J.) (concluding that the "application of 'impossibility preemption' under *Wyeth v. Levine* is a question of law reserved for the judiciary").

Doctor" letters, regional advisory committee meetings, its website, or medical literature),[21] because (even assuming that the above-discussed regulations did not also govern those communications)[22] Plaintiff adduced no argument (or admissible evidence) in support of such a theory of liability at trial. Nor does the Court accept any argument that, if Defendants were precluded from warning of gynecomastia, then they should not have permitted or encouraged its off-label use at all, because, again, Plaintiff adduced no argument (or admissible evidence) in support of such a theory of liability at trial. Nor does the Court consider any argument that Defendants somehow defrauded the FDA by not disclosing certain information to it, because such an theory of liability is futile in that it is preempted by federal law.[23]

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[21] *Stange v. Janssen Pharm. Inc.*, Case No. 1304011984, at 14 (Pa Ct. of Common Pleas, 1st Judicial Dist.. May 23, 2016) (Powell, J.).

[22] *See, e.g.*, *Pliva, Inc. v. Mensing*, 131 S. Ct. 2567, 2576 (2011) ("A Dear Doctor letter that contained substantial new warning information would not be consistent with the drug's approved labeling.").

[23] *See Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341, 350 (2001) ("State-law fraud-on-the-FDA claims inevitably conflict with the FDA's responsibility to police fraud consistently with the Administration's judgment and objectives . . . [while also] caus[ing] applicants to fear that their disclosures to the FDA, although deemed appropriate by the Administration, will later be judged insufficient in state court."); *Bruno v. Zimmer, Inc.*, 15-CV-6129, 2017 WL 8793242, at *8, n.3 (E.D.N.Y. Aug. 11, 2017) ("To the extent Plaintiffs are attempting to assert fraud premised on the theory that Defendants defrauded the FDA, such a claim in futile since it is preempted by federal law."); *Utts v. Bristol-Myers Squibb Co.*, 16-CV-5668, 2017 WL 1906875, at *26 (S.D.N.Y. May 8, 2017) (finding fraud-on-the-FDA claim preempted by federal law).

B. Whether Defendants Are Entitled to Judgment as a Matter of Law for the Alternative Reason that Plaintiff Failed to Introduce Sufficient Evidence of Proximate and Medical Causation

1. Parties' Briefing of This Issue

a. Defendants' Memorandum of Law-in Chief

In their memorandum of law-in chief, Defendants assert two arguments on the subject of causation: (1) no alternative warning would have affected the prescribing decisions of Plaintiff's treating doctors, because (a) no alternative label would have affected the prescribing decisions of Plaintiff's expert Dr. Suguna C. Reddy, M.D. (b) no alternative label would have affected the prescribing decisions of Plaintiff's expert Dr. Robertson B. Tucker, M.D., and (c) no alternative warning would have affected the prescribing decisions of Plaintiff's other prescribing physicians; and (2) Plaintiff has not established that his alleged gynecomastia is causally related to Risperdal as a matter of law, because (a) Plaintiff has failed to put forward a prima facie case of general or specific causation (given that [i] Plaintiff's general causation expert Dr. Plunkett conceded she is not an expert regarding causation, and the fact that her opinion is contradicted by the literature she cited, [ii] Plaintiff's expert Dr. Matthew Leinung, M.D., merely assumed that general causation had been proven, [iii] Dr. Leinung failed to properly rule out obesity as a potential cause of Plaintiff's gynecomastia, [iv] Dr. Leinung also failed to properly rule out marijuana and puberty as potential causes of Plaintiff's gynecomastia, and [v] there is undisputed testimony that elevated prolactin levels related to Risperdal cannot cause gynecomastia prior to puberty), and (b) Plaintiff has failed to demonstrate that any psychological suffering is linked to his use of Risperdal. (Dkt. No. 199, Attach. 1.)

b. Plaintiff's Opposition Memorandum of Law

In his opposition memorandum of law, Plaintiff asserts the following two arguments on the subject of causation: (1) Plaintiff put forward more than sufficient evidence that Defendants' failure to adequately warn of the frequency of the risk of gynecomastia in children/adolescents proximately caused Plaintiff's injuries, because (a) Plaintiff's prescribing physician Dr. Reddy testified that she would have disclosed any frequent risks (e.g., those of gynecomastia) had they been contained in the *Physicians' Desk Reference*, (b) Plaintiff's prescribing physician Dr. Tucker testified that he would have disclosed gynecomastia as a risk of Risperdal if the manufacturers had shared information indicating that it was a frequent risk during the relevant time period, and (c) Plaintiff's mother testified that she never would have consented to Plaintiff taking Risperdal had she been told during the relevant time period that there was even a chance he could develop gynecomastia; and (2) Plaintiff put forward more than sufficient evidence for a reasonable jury to conclude that Defendants' failure to warn proximately caused Plaintiff's injuries, because (a) Dr. Plunkett testified within a reasonable degree of medical/scientific certainty that Risperdal can cause gynecomastia, (b) Dr. Leinung testified within a reasonable degree of medical/scientific certainty that Risperdal caused Plaintiff's bilateral gynecomastia; and (c) Plaintiff's expert Dr. George S. Glass, M.D., Plaintiff's mother and Plaintiff's sister all testified in a manner that gave the jury more than sufficient evidence from which to reasonably find that Risperdal was a substantial factor in causing/exacerbating Plaintiff's psychological suffering. (Dkt. No. 205.)

c. Defendants' Reply Memorandum of Law

In their reply memorandum of law, Defendants assert the following two arguments on the subject of causation: (1) Plaintiff has not shown how an alternative label would have affected the prescribing decisions of Plaintiff's treating physicians because (a) Plaintiff does not address Defendants' argument that Plaintiff failed to introduce any evidence that an alternative warning would have affected the prescribing decisions of Plaintiff's physicians who did not testify at trial, (b) Plaintiff's reliance on Dr. Reddy's testimony is insufficient given that, in fact, she testified that she warned Plaintiff and his mother of the risk of gynecomastia, and (c) Plaintiff's reliance on Dr. Tucker's testimony is insufficient given that he testified (and Plaintiff's counsel conceded) that, even with an alternative warning, he would have prescribed Risperdal for Plaintiff; and (2) in his response, Plaintiff addresses none of the numerous flaws identified by Defendants in Plaintiff's arguments regarding the relationship between Risperdal and Plaintiff's injuries, such as (a) the fact that Dr. Plunkett conceded that she was not a causation expert and the fact that her opinion was contradicted by the literature she cited, (b) the fact that Dr. Leinung offered insufficient support for his general causation opinion and filed to properly rule out other likely causes of Plaintiff's gynecomastia, and (c) the fact that undisputed testimony demonstrated that elevated prolactin levels related to Risperdal cannot cause gynecomastia prior to puberty. (Dkt. No. 206.)

2. Legal Standards Governing This Issue

To prevail on a failure-to-warn claim involving prescription medications under New York law where the warnings are directed to prescribing physicians, a plaintiff must prove that, "had a different, more accurate warnings been given, his physician would not have prescribed

the drug in the same manner." *Alston v. Caraco Pharm., Inc.*, 670 F. Supp. 2d 279, 285 (S.D.N.Y. 2009), *accord, Chandler v. Janssen Pharm., Inc.*, 15-CV-3106, 2018 WL 3212422, at *10 (E.D.N.Y. June 29, 2018); *see also Krasnopolsky v. Warner-Lambert Co.*, 799 F. Supp. 1342, 1347-1348 (E.D.N.Y. 1992) (granting manufacturer's motion for summary judgment where treating medical care provider testified that he would have followed the same course of treatment had the warnings been different); *Mulhall v. Hannafin*, 841 N.Y.S.2d 282, 287 (N.Y. App. Div., 1st Dep't 2007) ("[P]laintiffs had to show that[,] had the warning been different, Dr. Hannafin would have departed from her normal practice and used another device.").

Moreover, with regard to the element of causation, a plaintiff must prove both general causation and specific causation. *See DeVito v. Smithkline Beecham Corp.*, 02-CV-0745, 2004 U.S. Dist. LEXIS 27374, at *5-6 (N.D.N.Y. Nov. 29, 2004); *see also In re Rezulin Prods. Liab. Litig.*, 441 F. Supp. 2d 567, 575 (S.D.N.Y. 2006). "General causation is established by demonstrating . . . that exposure to a substance can cause a particular disease . . . . Specific, or individual, causation, however, is established by demonstrating that a given exposure is the cause of an individual's disease . . . ." *In re Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 402 (S.D.N.Y. 2005) (citation and internal quotations omitted). "Plaintiff must first demonstrate general causation because without general causation, there can be no specific causation." *Norris v. Baxter Healthcare Corp.*, 397 F.3d 878, 881 (10th Cir. 2005). "[E]xpert testimony about general causation is sufficiently admissible under Rule 702 if (1) the testimony is based upon sufficient facts or data, (2) the testimony is the product of reliable principles and methods, and (3) the witness has applied the principles and methods reliably to the facts of the case." *In re Ephedra Prods. Liab. Litig.*, 393 F. Supp. 2d 181, 186 (S.D.N.Y. 2005).

3. Analysis of This Issue

After carefully considering the matter, the Court answers the above-described question (i.e., whether Plaintiff failed to introduce sufficient evidence of proximate and medical causation) in the affirmative for the reasons stated by Defendants in their memoranda of law. To those reasons, the Court adds the following analysis.

The Court is especially persuaded that Plaintiff has failed to establish general causation for the second reason described above in Part III.B.1.a. of this Decision and Order (that, as a threshold matter, Dr. Plunkett admitted to not being a causation expert, that, in any event, her opinion is unsupported by the literature she cited, and that Dr. Leinung's opinion was unreliable in that it only assumed general causation).

With regard to the testimony of Dr. Plunkett, in response to the question, "[H]ave you come here today to offer opinion to this jury with respect to whether or not Risperdal can cause gynecomastia?" Dr. Plunkett responded as follows:

> I'm not a causation expert, as a physician but certainly as a pharmacologist and a toxicologist, yes, I have done a review of the scientific information, the clinical information and come to an opinion that indeed Risperdal can cause gynecomastia.

(Dkt. No. 181, at 59 [attaching page "129" of Trial Transcript].) Given the importance of causation in light of the facts of this case, Defendants' reliance on Dr. Plunkett's admission to not being a causation expert is well placed.[24]

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[24] *See, e.g., In re: Mirena IUD Prods. Liab. Litig.*, 169 F. Supp. 3d 396, 477 (S.D.N.Y. 2016) ("Dr. Parisian will not be allowed to opine on foreign regulatory issues. Dr. Parisian is admittedly not an expert in the laws of foreign jurisdictions, and therefore is not qualified to testify on those subjects."); *In re: Rezulin Prods. Liab. Litig.*, 309 F. Supp. 2d 531, 559-60 (S.D.N.Y. 2004) (excluding doctor's testimony regarding the efficacy of prescription diabetes medication based, in part, on fact that doctor admitted that he is not an expert on diabetes).

In any event, even if the Court were to look past this significant admission to the review of literature on which Dr. Plunkett's opinion is based, the fact remains that, while scientific literature may certainly constitute the sort of "sufficient facts or date" required by Fed. R. Evid. 702(b), the purported expert must demonstrate that the literature in question sufficiently supports her opinion.[25] Dr. Plunkett did not do so.

Dr. Plunkett specifically identified only three pieces of scientific literature as the bases for her opinion: (1) Dr. Robert L. Findling's 2003 paper "Prolactin Levels During Long-Term Risperidone Treatment in Children and Adolescents"; (2) Dr. Jan Croonenberghs' 2005 paper "Risperidone in Children With Disruptive Behavior Disorders and Subaverage Intelligence"; and (3) Dr. Magali Reyes' 2006 paper "Long-Term Use of Risperidone in Children with Disruptive Behavior Disorders and Subaverage Intelligence."[26]

The first piece of literature stated, *inter alia*, that, although gynecomastia reported in some of the 592 children and adolescents studied, "[n]o correlation was found between [symptoms hypothetically attributable to prolactin] and prolactin levels, even when male gynecomastia during puberty was included." (Dkt. No. 199, Attach. 7, at 8.) The reason that the

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[25] *See, e.g., Hall v. United Ins. Co. of Am.*, 367 F.3d 1255, 1261-62 (11th Cir. 2004) ("Petrella's 'expert' opinion was based on his review of several documents related to Bobby's mental health, including statements made by Bobby's attending psychiatrist. While Bobby's medical doctor concluded that he was competent, Petrella came to the opposite conclusion, with no explanation offered in his affidavit for this contrary result. The district court concluded that Hall '[had] not demonstrated that the information Petrella reviewed contained sufficient facts or data upon which to base [his] opinion' . . . .").

[26] (*See, e.g.*, Dkt. No. 181, at 59-60, 112, 113, 115, 123 [attaching pages "129," "130," "182," "183," "185" and "193" of Trial Transcript, containing testimony of Dr. Plunkett]; Dkt. No. 182, at 2 [attaching pages "201," "205" and "206" of Trial Transcript, containing testimony of Dr. Plunkett].)

underlying study did not support such a correlation is that "[o]ne of the deficiencies of this analysis is that there was no long-term control group to show the incidences of gynecomastia, galactorrhea, or menstrual irregularities that may occur normally in such a population." (*Id*.)[27] In other words, while "[e]levated prolactin has . . . been associated with gynecomastia . . ." (*id*. at 2), an observed association between Risperdal and gynecomastia is, without more, insufficient to support an opinion that Risperdal is capable of causing gynecomastia. *See, e.g., Beyer v. Anchor Insulation Co.*, 238 F. Supp. 3d 270, 281 (D. Conn. 2017) ("To prove general causation, scientists frequently rely on epidemiological data to first establish an association between a chemical and a disease or set of symptoms *which they then probe to determine if the association warrants being described as cause-effect relationship*.") (emphasis added).

The second piece of literature stated, *inter alia*, that, although gynecomastia reported in some of the 504 children and adolescents studied, "[g]ynecomastia . . . is often observed in normal pubertal boys . . . and girls . . . , so it is not possible to assess the contribution of risperidone without a placebo control group." (Dkt. No. 199, Attach. 8, at 6, 8.)[28] As in the first piece of the literature, this lack of a control group was expressly acknowledged as a "limitation" of the study. (*Id*. at 8.)

The third piece of literature stated, *inter alia*, that, although gynecomastia reported in some of the 48 children and adolescents studied, "occurrence of gynecomastia was not related to

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[27] Indeed, the paper stated, "It is considered normal for males to have gynecomastia at some point in the evolution of puberty, with the frequency estimated as high as 50%." (Dkt. No. 199, Attach. 7, at 4.)

[28] Indeed, the paper acknowledged that eight of the cases "resolved during the study without intervention." (Dkt. No. 199, Attach. 8, at 6.)

increases in serum prolactin levels." (Dkt. No. 199, Attach. 9, at 8; *cf. id.* at 11 ["Importantly, elevated prolactin levels were not correlated with the 3 cases of gynecomastia."].) This is because, "[a]lthough there were several potentially prolactin-related [adverse events], it should be noted that some of these, such as gynecomastia in boys over the age of 10 years, often also present as a normal part of puberty." (*Id*. at 4.) As in the first and second pieces of the literature, this lack of a control group was expressly acknowledged as a "limitation[]" of the study. (*Id*. at 12; *see also id*. ["Because of its open-label nature, this study could not distinguish between improvements related directly to risperidone therapy or other factors, such as environment, better behavioral control, or simply normal development over the course of the study."].)

Moreover, while Dr. Plunkett relied on other data (e.g., a 1992 study, the RIS-INT 41 study, the RIS-INT 70 study, the 2002 label for Risperdal, and internal company documents), that reliance suffers from the same logical defect as do the above-discusses pieces of scientific literature: a disregard for the difference between an association between two things and a causal relationship between those two things. (*See, e.g.*, Dkt. No. 181, at 59, 61, 63, 71, 87 [attaching pages "129," "131," "132," "141" and "157" of Trial Transcript, containing testimony of Dr. Plunkett]; Dkt. No. 183, at 40 [attaching page "350" of Trial Transcript, containing testimony of Dr. Plunkett].)

The closest Dr. Plunkett came to basing her opinion on sufficient facts or data under under Fed. R. Evid. 702(b) was when she relied on data referenced in an unpublished draft of the first piece of scientific literature (i.e., the paper by Dr. Findling). (Dkt. No. 182, at 18-20 [attaching pages "217" through "219" of Trial Transcript, containing testimony of Dr. Plunkett].)

More specifically, Dr. Plunkett relied on data that she characterized as finding a statistically significant association between prolactin levels and adverse events related to prolactin during weeks eight to twelve of the study (which portion she states was omitted from the published paper). (*Id*.) Admittedly, this reliance presents a close question for the Court. However, several problems plague this reliance: (1) Dr. Plunkett did not actually rely on data that was published in a peer-reviewed article but on a *table* that was not admitted into evidence and that was prepared not by the author of the paper but by a third-party company;[29] (2) Dr. Plunkett myopically viewed the data, considering it in a vacuum (e.g., without considering other data showing that prolactin levels subsequently declined to within, or very close to, normal range);[30] and (3) Dr. Plunkett relied on the data almost exclusively to draw a conclusion (i.e., an intent by Defendants to mislead physicians) that was within the exclusive province of the jury to decide.[31] Most importantly, Dr. Plunkett failed to *explain* how the (unadmitted) data purportedly showed a correlation between Risperdal and gynecomastia: as explained above, even when data showing an association is considered, a correlation between Risperdal and gynecomastia cannot be drawn without a control group. The jury was essentially left with her bare assertion.

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[29] (Dkt. No. 182, at 11-17 [attaching pages "210" through "216" of Trial Transcript].)

[30] (*See, e.g.*, Dkt. No. 199, Attach. 7, at 1 ["With long-term resperidone treatment in children and adolescents, serum prolactin levels tended to rise and peak within the first 1 to 2 months and then steadily decline to values within or very close to the normal range by 3 to 5 months."].)

[31] *See Nimely v. City of New York*, 414 F.3d 381, 397 (2d Cir. 2005) ("Expert testimony that usurp[s] . . . the role of the jury in applying that law to the facts before it, by definition does not aid the jury in making a decision; rather, it undertakes to tell the jury what result to reach,' and this attempts to substitute the expert's judgment for the jury's.") (internal quotation marks omitted).

Simply stated, there is so great an analytical gap between the facts and/or data relied on and the general-causation opinion proffered by Dr. Plunkett as to render her opinion not "based" on them under Fed. R. Evid. 702(b). *See Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (U.S. 1997) ("[N]othing in either *Daubert* or the Federal Rules of Evidence requires a district court to admit opinion evidence that is connected to existing data only by the ipse dixit of the expert. A court may conclude that there is simply too great an analytical gap between the data and the opinion proffered."); *see, e.g., Pugliano v. United States*, 315 F. Supp. 2d 197, 200 (D. Conn. 2004) (excluding opinion based on three pieces of scientific literature because the opinion was tied to the literature by only the ipse dixit of the expert); *In re Human Tissue Prods. Liab. Litig.*, 582 F. Supp. 2d 644, 679-680 (D.N.J. 2008) (rejecting physician-expert opinion that "has no basis in any specific medical literature and is merely based upon his belief").

Turning to the testimony of Dr. Leinung, Defendants argue that Dr. Leinung identified insufficient facts or data on which his opinion of general causation was based, citing pages "625" and "626" of the trial transcript. Those pages indeed reflect no such identification by Dr. Leinung. (Dkt. No. 185, at 81-82 [attaching pages "625" and "626" of Trial Transcript, containing testimony of Dr. Leinung].)

In response, Plaintiff relies on page "617" of the trial transcript, wherein Dr. Leinung testified that he previously diagnosed Plaintiff with bilateral gynecomastia "secondary at least in part to prolonged use of Risperdal." However, that page and the prior page of the transcript show that Dr. Leinung merely *assumed* that the cause of the gynecomastia was Risperdal. (Dkt. No. 185, at 72-73 [attaching pages "616" and "617" of Trial Transcript, containing testimony of Dr. Leinung].)

Plaintiff also relies on pages "672" and "673" of the trial transcript, wherein Dr. Leinung testified that Risperdal caused Plaintiff's bilateral gynecomastia. However, those pages of the transcript show only that Dr. Leinung's opinion of causation is based on (1) a differential diagnosis (discussed in the following paragraph), and (2) a "review of the literature," the "preponderance of [which]" he asserts "show[s] that Risperdal has a higher association with gynecomastia." (Dkt. No. 186, at 15-16 [attaching page "672" and "673" of Trial Transcript, containing testimony of Dr. Leinung].) Setting aside the lack of any specificity as to what "literature" Dr. Leinung relied on, to the extent he was relying on the literature and/or studies discussed above, that reliance was misplaced: it is insufficient to conclude the existence of causation from evidence of mere association, for the reasons discussed above in this Decision and Order.

Finally, Defendants argue that Dr. Leinung's opinion of general causation actually relied on a differential diagnosis.[32] Based on a careful review of Dr. Leinung's trial testimony, the Court finds that Defendants are correct that his general-causation opinion relied on a differential diagnosis. (*See, e.g.*, Dkt. No. 185, at 72 [attaching page "616" of Trial Transcript, containing testimony of Dr. Leinung, stating that, in determining how Plaintiff's gynecomastia had "developed," Dr. Leinung reasoned that, although the condition "corresponded" with pubertal development, he "did not believe that this could be solely attributed to typical pubertal gynecomastia that persisted"]; Dkt. No. 185, at 73, 107 [attaching pages "617" and "651" of

[32] "A differential diagnosis is a patient-specific process of elimination that medical practitioners use to identify the most likely cause of a set of signs and symptoms from a list of possible causes." *Ruggiero v. Warner-Lambert Co.*, 424 F.3d 249, 254 (2d Cir. 2005) (internal quotation marks omitted).

Trial Transcript, containing testimony of Dr. Leinung, defining "differential diagnosis," and performing excluding Plaintiff's marijuana use from the differential diagnosis]; Dkt. No. 186, at 5, 8 [attaching pages "662" and "665" of Trial Transcript, containing testimony of Dr. Leinung, continuing differential diagnosis]; *see also* Dkt. No. 90, Attach. 4, at 8 [attaching page "7" of Dr. Leinung's Expert Report, discussing a "differential diagnosis for gynecomastia"].) Defendants are also correct that a differential diagnoses assumes that general causation has been proven, and therefore generally does not prove general causation (except perhaps in rare cases due to the rigor of differential diagnosis performed, the expert's training and experience, the type of illness or injury at issue, or some other case-specific circumstance). *See Ruggiero v. Warner-Lamber Co.*, 424 F.3d 249, 254 (2d Cir. 2005); *see, e.g., In re: Fosamax Prods. Liab. Litig.*, 645 F. Supp. 2d 164, 178 (S.D.N.Y. 2009) ("[A] differential diagnoses generally is insufficient by itself to support an opinion on general causation . . . ."); *In re: Rezulin Prods. Liab. Litig.*, 369 F. Supp. 2d 398, 436 (S.D.N.Y. 2005) ("[A] differential diagnosis . . . does not speak to the issue of general causation. [It] assumes that general causation has been proven . . . ."). The Court finds no exceptional circumstances with regard to Dr. Leinung that warrant a deviation from the application of the above-described general rule.

For all of these reasons, the Court grants Defendants' motion for judgment a matter of law on this alternative ground.

C. Whether, in the Alternative, Defendants Are Entitled to a New Trial Because of the Conduct of Plaintiff's Counsel

1. Parties' Briefing of This Issue

a. Defendants' Memorandum of Law-in Chief

In their memorandum of law-in chief, Defendants assert two arguments on the subject of attorney misconduct: (1) an argument that Plaintiff's counsel engaged in improper conduct by (a) eliciting the jury's sympathy through (i) constantly making personal remarks in both his arguments and questions (referring to his lack of professional skills and/or experience, the number of doctors in his family, and the fact that he was bullied as a child, despite the Court's directives not to do so) and (ii) recklessly or intentionally necessitating frequent admonishment from the Court (through disregarding the Court's directives), which placed the Court, in the eyes of the jury, in what amounted to an adversarial position, and (b) continually asserting the truth of Plaintiff's case, vouching for his witnesses (and seeking his witnesses to vouch for each other), offering his personal opinions about the evidence, testifying when he could not otherwise introduce evidence, and seeking to introduce evidence or elicit testimony after sustained objections; and (2) an argument that the cumulative impact of all of this improper conduct prejudiced Defendants in that it resulted an award of damages ($500,000 for past pain and suffering and $500,000 for future pain and suffering) that is excessive as compared to the awards typically given based on mere teasing and lowered self-esteem (especially when the plaintiff would have experienced those things anyway, to a certain extent, given his obesity and separately caused mental health issues). (Dkt. No. 199, Attach. 1.)

b. Plaintiff's Opposition Memorandum of Law

In his opposition memorandum of law, Plaintiff asserts the following two arguments on the subject of attorney misconduct: (1) at most, the conduct of Plaintiff's attorney amounted to zealous advocacy as required by the relevant ethical rules; and (2) when viewed in the context of the entire trial, any such misconduct did not cause unfair prejudice to Defendants because (a) the vast majority of purported misconduct occurred sidebars (when music was playing to ensure that the jury could not hear the content of the discussions), (b) with regard to the purported conduct occurring outside of sidebars, Defendants met the misconduct with frequent objections, which were sustained, (c) on one occasion, the Court gave a curative instruction to the jury, and (d) indeed, an affidavit of one of the jurors confirms that the verdict was based on the evidence, not the conduct of Plaintiff's counsel. (Dkt. No. 205.)

c. Defendants' Reply Memorandum of Law

In their reply memorandum of law, Defendants assert the following four arguments on the subject of attorney misconduct: (1) the misconduct of Plaintiff's counsel was so repeated that it rose above the level of *de minimis* misconduct; (2) Plaintiff's attempt to distinguish the current case from those cited by Defendants fails because, as do the cases cited by Defendants, the current case involves attorney misrepresentations of evidence; (3) Plaintiff's reliance on verdicts from other cases is inappropriate given that those cases do not apply New York law; and (4) the Court must strike the jury affidavit submitted by Plaintiff because, pursuant to Fed. R. Evid. 606(b)(1), "a juror may not testify about . . . the effect of anything on that juror's or another juror's vote . . . or any juror's mental processes concerning the verdict" (and, here, Plaintiff introduced a juror affidavit specifically to describe the mental processes of the jury and the motivating forces animating each juror's vote). (Dkt. No. 206.)

2. Legal Standard Governing This Issue

A court may order a new trial on the basis of attorney misconduct when, *inter alia*, "the conduct of counsel in argument causes prejudice to the opposing party and unfairly influences a jury's verdict." *Pappas v. Middle Earth Condo. Ass'n*, 963 F.2d 534, 540 (2d Cir. 1992). For example, a new trial is warranted where (1) the attorney improperly arouses the sympathy of the jury and thereby causes unfair prejudice to the opposing party and unfairly influences the jury's verdict;[33] or (2) the attorney refers to his or her personal opinions regarding the evidence in the case, the truthfulness of the witnesses or the liability of a party, and thereby causes unfair prejudice to the opposing party and unfairly influences the jury's verdict.[34]

"[I]n evaluating a motion for a new trial based on counsel's alleged misconduct, the court must consider such a claim in the context of the trial as a whole, examining, among other things, the totality of the circumstances, including the nature of the comments, their frequency, their possible relevancy to the real issues before the jury, and the manner in which the parties and the court treated the comments." *Graham v. City of New York*, 128 F. Supp. 3d 681, 698 (E.D.N.Y. 2015) (internal citations and quotation marks omitted).

"Determining if counsel's conduct was so improper as to warrant a new trial is committed to the sound discretion of the trial judge." *Graham*, 128 F. Supp. 3d at 698. As the Second Circuit has recognized, the trial court holds a "superior vantage point when evaluating the possible impact of the alleged prejudicial conduct" as "[a] printed record is unable to replicate in

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[33] *See, e.g., Levitant v. City of N.Y. Human Res. Admin.*, 914 F. Supp. 2d 281, 311-12 (E.D.N.Y. 2012).

[34] *See, e.g., Fineman v. Armstrong World Indus.*, 774 F. Supp. 266, 270 (D. N.J. 1991), *aff'd*, 980 F.2d 171 (3d Cir. 1992).

full all the circumstances–for example, tones of voices, demeanor of witnesses and jurors and the like–that occur in the course of an unfolding trial." *Pappas*, 963 F.2d at 540.

3. Analysis of This Issue

After carefully considering the matter, the Court answers the above-described question (i.e., whether, in the alternative, the conduct of Plaintiff's counsel warrants a new trial) in the affirmative for the reasons stated by Defendants in their memoranda of law. To those reasons, the Court adds the following analysis.

Contrary to Plaintiff's suggestion on page 18 of his opposition memorandum of law, each of the 23 acts of misconduct listed by Defendants on pages 21 through 23 of their memorandum of law-in chief occurred *within* the presence of the jury (not during a sidebar). (*Compare* Dkt. No. 199, Attach. 1, at 28-30 [attaching pages "21" through "23" of Defs.' Memo. of Law] *with* Dkt. No. 199, Attach. 3 [attaching relevant portions of Trial Transcripts].)

Furthermore, only 12 of those 23 acts met with objections by Defendants. (Dkt. No. 199, Attach. 3, at 18-19, 30-31, 29, 72, 81, 93, 126, 127, 129 [attaching pages "252," "253," "373," "394," "395," "671," "712," "856," "1298," "1313," and "1313" of Trial Transcript]; Dkt. No. 182, at 96-97 [attaching pages "295" and "296" of Trial Transcript]; Dkt. No. 188, at 63-64 [attaching pages "963" and "964" of Trial Transcript]; Dkt. No. 189, at 94-95 [attaching pages "1129" and "1130" of Trial Transcript].)

The Court notes that, in addition to relying on the transcript of Plaintiff's counsel's comments, the Court relies on (1) Plaintiff's counsel's self-deprecating tone of voice and posture when referring to his lack of professional skills and/or experience, (2) his helpless tone of voice and posture when referring to the fact that he was bullied as a child, (3) his alternating innocent

and defensive tones of voice in response to an admonishment by the Court, (4) the sympathetic facial expressions of the jurors following the aforementioned acts and/or accompanying comments, (5) the credulous facial expressions of the jurors following Plaintiff's counsel's acts of asserting of the truth of Plaintiff's case and/or vouching for his witnesses, and (6) the jurors' reactions following Plaintiff's counsel's acts of offering his personal opinions about the evidence and/or testifying when he could not otherwise introduce evidence. (*Cf.* Dkt. No. 186, at 55 [attaching page "712" of Trial Transcript, referencing Plaintiff's counsel's "puzzled" facial expressions after objections by defense counsel].)

Moreover, contrary to Plaintiff's suggestion that the comments and practices in question regarded immaterial issues before the jury, the Court finds that the majority of the above-referenced comments and practices primarily concerned highly relevant issues before the jury: for example, (1) the credibility of Plaintiff's expert witnesses, (2) the competency and credibility as a witness of Plaintiff's counsel himself, (3) whether the verdict should be based on evidence or sympathy, and (4) whether Dr. Findling's decision to (purportedly) omit from final draft of his paper certain data from weeks eight to twelve of the study evidences an intent by Defendants to mislead physicians. (Dkt. No. 199, Attach. 1, at 28-30 [attaching pages "21" through "23" of Defs.' Memo. of Law]; Dkt. No. 199, Attach. 3 [attaching relevant portions of Trial Transcripts].)

Although Plaintiff argues that any errors by his counsel were ameliorated by the curative instruction given by the Court, the instruction to which he apparently refers was given only once (Dkt. No. 204, Attach. 1, at 66-67 [attaching pages "66" and "67" of Trial Transcript]), and it clearly did not curb his counsel's misconduct (given the misconduct's continuation).

Simply stated, the Court is convinced that, absent the inappropriate conduct of Plaintiff's counsel, the ultimate outcome of the trial would have been different.

Finally, the Court finds that Defendants are correct when they argue that the juror affidavit adduced by Plaintiff may not be considered by the Court. The affidavit violated Fed. R. Evid. 606(b)(1) in the following three ways: (1) it contained testimony about a statement that had been made and/or an incident that had occurred during the jury's deliberations (Dkt. No. 204, Attach. 16, at ¶ 10; *cf. id.* at ¶¶ 4, 9); (2) it contained testimony about the effect of a thing or things on the affiant's vote (*id.* at ¶¶ 9, 10, 11); and (3) it contained testimony about a juror's or multiple jurors' mental processes concerning the verdict (*id.* at ¶¶ 9, 10).

Even if the affidavit were admissible, the Court would give it little weight because (1) it unreliably testifies to other jurors' mental processes concerning the verdict (Dkt. No. 204, Attach. 16, at ¶¶ 9, 10), and (2) it admits to having been prepared with the assistance of Plaintiff's counsel (*id.* at ¶ 14). *See Munafo v. Metro. Transp. Auth.*, 381 F.3d 99, 107-08 (2d Cir. 2004) (finding that district court did not abuse its discretion in giving little weight to affidavits of two jurors asserting that special verdict form miscommunicated jury's finding because [1] the two jurors were not competent to testify to other jurors' alleged mistake, and [2] the two jurors prepared their affidavits with the assistance of plaintiff's counsel). Indeed, the affidavit actually supports Defendants' argument that the jurors were driven by feelings of sympathy due to the efforts to Plaintiff's counsel. (*See, e.g.*, Dkt. No. 204, Attach. 16, at ¶¶ 11, 13.)

For all of these reasons, the Court finds that, even if alternative grounds did not exist to grant Defendants' motion for judgment a matter of law, grounds exist to, at the very least, grant Defendants' motion for a new trial.

D. Three Remaining Issues (I.e., Whether Plaintiff Cannot Establish that Defendant Johnson & Johnson Is Liable as a Matter of Law, Whether the Jury Verdict Is Against the Weight of the Evidence, and Whether Plaintiff's Award Is Excessive)

Because the Court answers the three previously addressed issues in the affirmative, the Court need not, and thus does not, analyze these three remaining issues, except to note generally that the Court finds them to be the weaker of Defendants' arguments generally for the reasons stated in Plaintiff's opposition memorandum of law.

ACCORDINGLY, it is

ORDERED that Defendants' motion for judgment a matter of law pursuant to Fed. R. Civ. P. 50 or, in the alternative, for a new trial pursuant to Fed. R. Civ. P. 59 (Dkt. No. 199) is **GRANTED**; and it is further

ORDERED that both the Jury Verdict (Dkt. No. 179) and Judgment for Plaintiff (Dkt. No. 180) are **VACATED**; and it is further

ORDERED that the Clerk of the Court shall enter Judgment for Defendants and close this action.

Date: September 21, 2018
Syracuse, NY

Hon. Glenn T. Suddaby
Chief U.S. District Judge