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DRINKER BIDDLE & REATH LLP
A Delaware Limited Liability Partnership
500 Campus Drive
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(973) 549-7000
Attorneys for Defendants
Johnson & Johnson and
Janssen Pharmaceuticals, Inc.
(f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.,
f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	:	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	:	CIVIL ACTION
Docket No. MID-L-6820-06	:	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	:	
Docket No. MID-L-6720-06	:	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF RISPERDAL®'S ALLEGED ADVERSE EFFECTS UNRELATED TO PLAINTIFFS' INJURIES AND PLAINTIFFS' ASSOCIATED ALLEGATIONS

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers, ~~and the arguments of counsel~~, and good cause having been shown; *

IT IS on this 16th day of December, 2011,

ORDERED that Defendants' Motion *In Limine* To Exclude Evidence of, and/or argument about, Risperdal®'s Alleged Adverse Effects Unrelated to Plaintiffs' Injuries and Plaintiffs' Associated Allegations is hereby GRANTED;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs'~~ posted on line ~~counsel~~ within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision.

FP01/ 6664413.1

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of adverse effects unrelated to Plaintiffs' alleged injuries.

Defendants' motion *in limine* to exclude evidence of alleged adverse effects attributable to Risperdal® that are different than those allegedly suffered by Plaintiffs.

Plaintiffs do not intend to offer evidence of alleged adverse effects attributable to Risperdal® that are different than those allegedly suffered by Plaintiffs. If Plaintiffs seek to introduce evidence on this topic, the court will determine, based upon trial testimony, if the evidence is relevant and the proper foundation has been established so as to be admissible. Therefore, this motion is **GRANTED**.

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IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
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ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF RISPERDAL®'S ALLEGED ADVERSE EFFECTS UNRELATED TO PLAINTIFFS' INJURIES AND PLAINTIFFS' ASSOCIATED ALLEGATIONS

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having heard

~~and~~ considered the moving papers, ~~any~~ opposition papers, ~~and the arguments of counsel~~, and good cause having been shown; *

IT IS on this 10th day of December, 2011,

ORDERED that Defendants' Motion *In Limine* To Exclude Evidence of, and/or argument about, Risperdal®'s Alleged Adverse Effects Unrelated to Plaintiffs' Injuries and Plaintiffs' Associated Allegations is hereby GRANTED;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs~~ posted on line ~~counsel~~ within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision.

FP01/ 6664413.1

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of adverse effects unrelated to Plaintiffs' alleged injuries.

Defendants' motion *in limine* to exclude evidence of alleged adverse effects attributable to Risperdal® that are different than those allegedly suffered by Plaintiffs.

Plaintiffs do not intend to offer evidence of alleged adverse effects attributable to Risperdal® that are different than those allegedly suffered by Plaintiffs. If Plaintiffs seek to introduce evidence on this topic, the court will determine, based upon trial testimony, if the evidence is relevant and the proper foundation has been established so as to be admissible. Therefore, this motion is **GRANTED**.

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#0051

DRINKER BIDDLE & REATH LLP
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500 Campus Drive
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Janssen Pharmaceuticals, Inc.
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f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
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Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	
Docket No. MID-L-6720-06	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE IRRELEVANT AND PREJUDICIAL EVIDENCE OF ALLEGED OFF-LABEL PROMOTION OF RISPERDAL®

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers, ~~and the arguments of counsel~~, and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that Defendants' Motion *In Limine* to Exclude Irrelevant and Prejudicial Evidence, and/or argument about, of Alleged Off-Label Promotion and Use, is hereby granted;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs'~~ posted on line counsel within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision

FP01/ 6665633.1

Memorandum of Decision on Defendants' motions *in limine* to exclude irrelevant and prejudicial evidence, including evidence of off-label promotion, marketing materials that were not relied upon by Plaintiffs or Plaintiffs' prescribing healthcare providers, and foreign regulatory activities.

Defendants' motion *in limine* to exclude irrelevant and prejudicial evidence of, and/or argument about, alleged off-label promotion and use of Risperdal®

Defendants argue that evidence of Janssen's alleged off-label marketing of Risperdal® should be excluded as irrelevant and unduly prejudicial. Under N.J.R.E. 402, all relevant evidence is admissible unless excluded by law. Relevant evidence is defined as "evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. "In determining whether evidence is relevant, the inquiry should focus upon the logical connection between the proffered evidence and a fact in issue. If the evidence offered renders the desired inference more probable than it would be without the evidence, it is relevant." State v. Swint, 328 N.J. Super. 236, 252 (App. Div.), certif. denied, 165 N.J. 492 (2000) (citation omitted); see also Furst v. Einstein Moomju, Inc., 182 N.J. 1, 15 (2004). However, under Rule 403, the trial judge may exclude relevant evidence "if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury or (b) undue delay, waste of time, or needless presentation of cumulative evidence." N.J.R.E. 403. "The trial court is granted broad discretion in determining both the relevance of the evidence to be presented and whether its probative value is substantially outweighed by its prejudicial nature." Green v. N.J. Mfrs. Ins. Co., 160 N.J. 480, 492 (1999).

The parties do not contend that either Plaintiff was prescribed Risperdal® for an off-label use. Therefore, Defendants assert that Janssen's alleged off-label marketing of Risperdal® is irrelevant in either of the bellwether cases. Furthermore, Defendants argue that the prejudicial effect of such evidsence requires its exclusion under the Rule 403. Moreover, Defendants allege that while an off-label use "is both accepted medical practice and legally permissible," the term "seems to suggest uses that are dubious, untested or dangerous." Defendants Brief in support of the motion *in limine* ("Def. Br.") at 2. Additionally, if evidence of off-label use is admitted, Defendants maintain that they will be required to defend against the allegations of off-label promotion, thereby wasting the time and resources of the court and the parties. See Def. Br. at 5. Defendants conclude that, in the absences of any connection between Plaintiffs' claims and Janssen's alleged marketing of off-label uses for Risperdal®, the risk of such evidence causing undue prejudice and undue delay substantially outweighs its probative value. See Def. Br. at 4.

In response, Plaintiffs argue that this court permitted testimony regarding off-label promotion or marketing in a litigation involving another antipsychotic medication. However, in Baker v. AstraZeneca Pharmaceuticals LP, Docket No. L-1099-07, the plaintiff alleged that he was prescribed Seroquel® off-label to treat post-traumatic stress disorder ("PTSD"). Further, plaintiff's experts in that case offered opinions regarding the

off-label promotion of Risperdal® for the treatment of PTSD. In contrast, no claim for off-label use is alleged by Plaintiffs or Plaintiffs' experts in these bellwether cases.

As neither Plaintiff alleges off-label use of Risperdal®, such evidence is irrelevant. The court further finds that such testimony in these bellwether cases is substantially outweighed by the potential to cause undue prejudice and delay. Therefore, this motion is **GRANTED**.

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f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	CIVIL ACTION
Docket No. MID-L-6820-06	
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Docket No. MID-L-6720-06	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE IRRELEVANT AND PREJUDICIAL EVIDENCE OF ALLEGED OFF-LABEL PROMOTION OF RISPERDAL®

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers, ~~and the arguments of counsel~~, and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that Defendants' Motion *In Limine* to Exclude Irrelevant and Prejudicial Evidence, and/or argument about, of Alleged Off-Label Promotion and Use, is hereby granted;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs'~~ posted on line counsel within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision

FP01/6665633.1

Memorandum of Decision on Defendants' motions *in limine* to exclude irrelevant and prejudicial evidence, including evidence of off-label promotion, marketing materials that were not relied upon by Plaintiffs or Plaintiffs' prescribing healthcare providers, and foreign regulatory activities.

Defendants' motion *in limine* to exclude irrelevant and prejudicial evidence of, and/or argument about, alleged off-label promotion and use of Risperdal®

Defendants argue that evidence of Janssen's alleged off-label marketing of Risperdal® should be excluded as irrelevant and unduly prejudicial. Under N.J.R.E. 402, all relevant evidence is admissible unless excluded by law. Relevant evidence is defined as "evidence having a tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. "In determining whether evidence is relevant, the inquiry should focus upon the logical connection between the proffered evidence and a fact in issue. If the evidence offered renders the desired inference more probable than it would be without the evidence, it is relevant." State v. Swint, 328 N.J. Super. 236, 252 (App. Div.), certif. denied, 165 N.J. 492 (2000) (citation omitted); see also Furst v. Einstein Moomju, Inc., 182 N.J. 1, 15 (2004). However, under Rule 403, the trial judge may exclude relevant evidence "if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury or (b) undue delay, waste of time, or needless presentation of cumulative evidence." N.J.R.E. 403. "The trial court is granted broad discretion in determining both the relevance of the evidence to be presented and whether its probative value is substantially outweighed by its prejudicial nature." Green v. N.J. Mfrs. Ins. Co., 160 N.J. 480, 492 (1999).

The parties do not contend that either Plaintiff was prescribed Risperdal® for an off-label use. Therefore, Defendants assert that Janssen's alleged off-label marketing of Risperdal® is irrelevant in either of the bellwether cases. Furthermore, Defendants argue that the prejudicial effect of such evidsence requires its exclusion under the Rule 403. Moreover, Defendants allege that while an off-label use "is both accepted medical practice and legally permissible," the term "seems to suggest uses that are dubious, untested or dangerous." Defendants Brief in support of the motion *in limine* ("Def. Br.") at 2. Additionally, if evidence of off-label use is admitted, Defendants maintain that they will be required to defend against the allegations of off-label promotion, thereby wasting the time and resources of the court and the parties. See Def. Br. at 5. Defendants conclude that, in the absences of any connection between Plaintiffs' claims and Janssen's alleged marketing of off-label uses for Risperdal®, the risk of such evidence causing undue prejudice and undue delay substantially outweighs its probative value. See Def. Br. at 4.

In response, Plaintiffs argue that this court permitted testimony regarding off-label promotion or marketing in a litigation involving another antipsychotic medication. However, in Baker v. AstraZeneca Pharmaceuticals LP, Docket No. L-1099-07, the plaintiff alleged that he was prescribed Seroquel® off-label to treat post-traumatic stress disorder ("PTSD"). Further, plaintiff's experts in that case offered opinions regarding the

off-label promotion of Risperdal® for the treatment of PTSD. In contrast, no claim for off-label use is alleged by Plaintiffs or Plaintiffs' experts in these bellwether cases.

As neither Plaintiff alleges off-label use of Risperdal®, such evidence is irrelevant. The court further finds that such testimony in these bellwether cases is substantially outweighed by the potential to cause undue prejudice and delay. Therefore, this motion is **GRANTED**.

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Attorneys for Defendants
Johnson & Johnson and
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(f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.,
f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	CIVIL ACTION
Docket No. MID-L-6820-06	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	
Docket No. MID-L-6720-06	

ORDER ON DEFENDANTS' MOTION *IN LIMINE*
TO EXCLUDE EVIDENCE OF OTHER MATTERS REGARDING RISPERDAL®
AND OTHER PRODUCTS MANUFACTURED, MARKETED
OR DISTRIBUTED BY ANY JOHNSON & JOHNSON COMPANY

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers~~, any reply papers, and the arguments~~ of ~~counsel~~, and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that Defendants' Motion *In Limine* to Exclude Evidence of Other Matters Regarding Risperdal® and Other Products Manufactured, Marketed or Distributed by any Johnson & Johnson Company is ~~hereby granted~~ granted as follows:

1. Plaintiffs are precluded from offering evidence related to other alleged Risperdal® incidents, claims, reports, complaints, lawsuits, government investigations or actions and verdicts; – Denied

2. Plaintiffs are precluded from offering evidence related to recalls, alleged improper promotion, incidents, claims, reports, complaints, lawsuits, government investigations or actions, and verdicts in connection with other products manufactured, marketed or distributed by any Johnson & Johnson company or affiliate. – Granted

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs~~ noted on line ~~counsel~~ within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memoranda of decision

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of other matters regarding Risperdal® and other Johnson & Johnson Products.

Defendants' motion *in limine* to preclude Plaintiffs from offering evidence related to other alleged Risperdal® incidents, claims, reports, complaints, lawsuits, government investigations or actions and verdicts.

Janssen argues that evidence of "other matters" involving Risperdal® is irrelevant and inadmissible. See Defendants' Brief in support of Motion *In Limine* ("Def. Br.") at 1. In response, Plaintiffs contend that they "do not presently intend to offer evidence of claims, lawsuits, government investigations or actions, or verdicts concerning Risperdal® or any other J & J product." Plaintiffs' Brief in opposition to Motion *In Limine* ("Pl. Opp.") at 1. However, Plaintiffs argue that evidence of Risperdal® incidents and reports involving patients who developed diabetes or hyperglycemia or gained weight while taking Risperdal® is relevant to notice and failure to warn issues. Id.

Under the New Jersey evidentiary rules, evidence is relevant if it has "any tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. In evaluating the probative value of evidence, the court must focus on "the logical connection between the proffered evidence and a fact in issue." Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004) (quoting State v. Hutchins, 241 N.J. Super. 353, 358 (App. Div. 1990)). However, the evidence need not by itself support or prove the fact in issue. See State v. Swint, 328 N.J. Super. 236, 252 (App. Div.) certif. denied, 165 N.J. 492 (2000). Rather, "[i]f the evidence offered renders the desired inference more probable than it would be without the evidence, it is relevant." Ibid.

It is well established in New Jersey that evidence of similar incidents and injuries may be relevant and admissible under certain circumstances. Wymbs v. Tp. of Wayne, 163 N.J. 523, 533-537 (2000); see also Harris v. GMC, No. A-6138-03T3, 2007 N.J. Super. Unpub. LEXIS 396, at *25-26 (App. Div. Mar. 2, 2007). A trial court has the discretion to admit evidence of "substantially similar" prior incidents "to establish circumstantially that a condition or a product is dangerous." Wymbs, supra, 163 N.J. at 534. Decisions to admit such evidence should be made on a case-by-case basis, since "the requirement of substantial similarity is more stringent when the prior-accident evidence is offered to prove the existence of a dangerous condition than when offered to prove notice." Id. at 536; see also Dresdner v. Meehan, Nos. A-4787-03T1, A-6274-03T1, 2006 N.J. Super. Unpub. LEXIS 48, at *5-6 (App. Div. Apr. 11, 2006).

Thus, this court will consider evidence of other similar incidents on a case-by-case basis. As the court has not been presented with evidence that Plaintiffs intend to proffer, the court is unable to rule at this time and must await the testimony at trial. Therefore, this motion is **DENIED.**

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of other matters regarding Risperdal® and other Johnson & Johnson Products.

Defendants' motion *in limine* to preclude Plaintiffs from offering evidence related to recalls, alleged improper promotion, incidents, claims, reports, complaints, lawsuits, government investigations or actions, and verdicts in connection with other products manufactured, marketed or distributed by any Johnson & Johnson affiliate.

Neither party anticipates offering any evidence related to recalls, alleged improper promotion, incidents, claims, reports, complaints, lawsuits, government investigations or actions, or verdicts in connection with other products manufactured, marketed or distributed by Johnson & Johnson or its affiliates. Unless and until either party asserts allegations that render such evidence relevant, this evidence shall be excluded. The court may revisit this issue should such allegations be raised. Therefore, this motion is **GRANTED.**

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Attorneys for Defendants
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(f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.,
f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	:	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	:	CIVIL ACTION
Docket No. MID-L-6820-06	:	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	:	
Docket No. MID-L-6720-06	:	

ORDER ON DEFENDANTS' MOTION *IN LIMINE*
TO EXCLUDE EVIDENCE OF OTHER MATTERS REGARDING RISPERDAL®
AND OTHER PRODUCTS MANUFACTURED, MARKETED
OR DISTRIBUTED BY ANY JOHNSON & JOHNSON COMPANY

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers, ~~any reply papers, and the arguments of counsel,~~ and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that Defendants' Motion *In Limine* to Exclude Evidence of Other Matters Regarding Risperdal® and Other Products Manufactured, Marketed or Distributed by any Johnson & Johnson Company is ~~hereby granted~~ Denied as follows:

1. Plaintiffs are precluded from offering evidence related to other alleged Risperdal® incidents, claims, reports, complaints, lawsuits, government investigations or actions and verdicts; - Denied

2. Plaintiffs are precluded from offering evidence related to recalls, alleged improper promotion, incidents, claims, reports, complaints, lawsuits, government investigations or actions, and verdicts in connection with other products manufactured, marketed or distributed by any Johnson & Johnson company or affiliate. - Granted

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs'~~ posted on line counsel within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memoranda of decision.

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of other matters regarding Risperdal® and other Johnson & Johnson Products.

Defendants' motion *in limine* to preclude Plaintiffs from offering evidence related to other alleged Risperdal® incidents, claims, reports, complaints, lawsuits, government investigations or actions and verdicts.

Janssen argues that evidence of "other matters" involving Risperdal® is irrelevant and inadmissible. See Defendants' Brief in support of Motion *In Limine* ("Def. Br.") at 1. In response, Plaintiffs contend that they "do not presently intend to offer evidence of claims, lawsuits, government investigations or actions, or verdicts concerning Risperdal® or any other J & J product." Plaintiffs' Brief in opposition to Motion *In Limine* ("Pl. Opp.") at 1. However, Plaintiffs argue that evidence of Risperdal® incidents and reports involving patients who developed diabetes or hyperglycemia or gained weight while taking Risperdal® is relevant to notice and failure to warn issues. Id.

Under the New Jersey evidentiary rules, evidence is relevant if it has "any tendency in reason to prove or disprove any fact of consequence to the determination of the action." N.J.R.E. 401. In evaluating the probative value of evidence, the court must focus on "the logical connection between the proffered evidence and a fact in issue." Furst v. Einstein Moomjy, Inc., 182 N.J. 1, 15 (2004) (quoting State v. Hutchins, 241 N.J. Super. 353, 358 (App. Div. 1990)). However, the evidence need not by itself support or prove the fact in issue. See State v. Swint, 328 N.J. Super. 236, 252 (App. Div.) certif. denied, 165 N.J. 492 (2000). Rather, "[i]f the evidence offered renders the desired inference more probable than it would be without the evidence, it is relevant." Ibid.

It is well established in New Jersey that evidence of similar incidents and injuries may be relevant and admissible under certain circumstances. Wymbs v. Tp. of Wayne, 163 N.J. 523, 533-537 (2000); see also Harris v. GMC, No. A-6138-03T3, 2007 N.J. Super. Unpub. LEXIS 396, at *25-26 (App. Div. Mar. 2, 2007). A trial court has the discretion to admit evidence of "substantially similar" prior incidents "to establish circumstantially that a condition or a product is dangerous." Wymbs, supra, 163 N.J. at 534. Decisions to admit such evidence should be made on a case-by-case basis, since "the requirement of substantial similarity is more stringent when the prior-accident evidence is offered to prove the existence of a dangerous condition than when offered to prove notice." Id. at 536; see also Dresdner v. Meehan, Nos. A-4787-03T1, A-6274-03T1, 2006 N.J. Super. Unpub. LEXIS 48, at *5-6 (App. Div. Apr. 11, 2006).

Thus, this court will consider evidence of other similar incidents on a case-by-case basis. As the court has not been presented with evidence that Plaintiffs intend to proffer, the court is unable to rule at this time and must await the testimony at trial. Therefore, this motion is **DENIED.**

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of other matters regarding Risperdal® and other Johnson & Johnson Products.

Defendants' motion *in limine* to preclude Plaintiffs from offering evidence related to recalls, alleged improper promotion, incidents, claims, reports, complaints, lawsuits, government investigations or actions, and verdicts in connection with other products manufactured, marketed or distributed by any Johnson & Johnson affiliate.

Neither party anticipates offering any evidence related to recalls, alleged improper promotion, incidents, claims, reports, complaints, lawsuits, government investigations or actions, or verdicts in connection with other products manufactured, marketed or distributed by Johnson & Johnson or its affiliates. Unless and until either party asserts allegations that render such evidence relevant, this evidence shall be excluded. The court may revisit this issue should such allegations be raised. Therefore, this motion is **GRANTED.**

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#0055

DRINKER BIDDLE & REATH LLP
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500 Campus Drive
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Attorneys for Defendants
Johnson & Johnson and
Janssen Pharmaceuticals, Inc.
(f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.,
f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	CIVIL ACTION
Docket No. MID-L-6820-06	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	
Docket No. MID-L-6720-06	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE PLAINTIFFS FROM INTRODUCING EVIDENCE OF SUBSEQUENT REMEDIAL MEASURES, INCLUDING REVISIONS TO RISPERDAL®'S PACKAGE INSERT

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers, ~~and the arguments of counsel~~, and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that defendants' motion *in limine* to preclude Plaintiffs from introducing evidence of subsequent remedial measures, including revisions to Risperdal®'s package insert, is hereby granted; in part;

IT IS FURTHER ORDERED that a copy of this Order shall be served on counsel of record ~~served upon plaintiffs' counsel~~ within seven (7) days of the date of this Order.

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision

FP01/6664400.1

Memorandum of Decision on Defendants' motion *in limine* to preclude Plaintiffs from introducing evidence of subsequent remedial measures, including revisions to the Risperdal® package insert and warnings.

In October of 2003, the Food and Drug Administration ("FDA") issued a labeling change for all atypical antipsychotics medications, including Risperdal®. Defendants move to exclude evidence of this labeling change and other remedial measure undertaken subsequent to Plaintiffs' injuries under N.J.R.E. 407.

Rule 407 provides that "[e]vidence of remedial measures taken after an event is not admissible to prove that the event was caused by negligence or culpable conduct. However, evidence of such subsequent remedial conduct may be admitted as to other issues." As the Appellate Division explained in Harris v. Peridot Chem. (N.J.) Inc., 313 N.J. Super. 257 (App. Div. 1998), evidence of subsequent remedial measures is excluded on public policy grounds:

> not because it lacks relevancy, but because admission of said testimony might discourage corrective action and induce perpetuation of the damage and condition that gave rise to the lawsuit. . . .The theory behind the Rule is that a person should not be penalized for correcting a potentially deleterious situation.
>
> [Id. at 292-293 (citations and internal quotation marks omitted)]

There are exceptions regarding the inadmissibility of evidence of subsequent remedial measures. Evidence of involuntary remedial measures, such as those directed by or at the instance of a governing authority, would not violate the policy underlying the Rule and may therefore be admissible. See id. ("If, as defendant contends, its decision to install fence line monitors, increase the stack heights, and create contingency plans in the event of an inadvertent release of sulfur dioxide was not a voluntary action, but rather was mandated by the DEP, admission of the evidence would not violate the policy underlying the Rule."); see also Schedin v. Ortho-McNeil-Janssen Pharms., Inc., No. 08-5743 (JRT), 2011 U.S. Dist. LEXIS 96837, at *25-27 (D. Minn. Aug. 26, 2011)(evidence of post-2005 labeling of Levaquin® admissible under Fed. R. Evid. 407 since "[a]n exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority," and any potential prejudice was mitigated by the trial judge's limiting instruction) (citation omitted)).

Also, evidence of subsequent remedial measures offered for purposes other than to prove negligence or culpable conduct is admissible. See N.J.R.E. 407. See also Harris, supra, 313 N.J. Super at 292-293 (evidence of remedial measures may be admitted "to show control," "to demonstrate feasibility and practicality of repair," "to impeach the credibility of a witness," and "to prove the condition existing at the time of the accident."). Evidence of subsequent remedial action may be admitted for a variety of other purposes, including "where the evidence is offered to establish control over the injuring instrumentality; to prove the condition existing at the time of the accident; to affect the credibility of a witness; or to show a different method was feasible for avoiding the danger." Hansson v. Catalytic Constr. Co., 43 N.J. Super. 23, 27 (App. Div. 1956) (citation omitted); see also Harris, supra, 313 N.J. Super. at 292-293; Kane v. Hartz Mountain Indus., Inc., 278 N.J. Super. 129, 147-148 (App. Div.) aff'd, 143 N.J. 141 (1996).

In Harris, evidence of a subsequent corrective measures was admitted "to prove 'the condition existing at the time of the accident,'" including whether the condition was defective. Harris, supra, 313 N.J. Super. at 293 (citation omitted). The Harris court held that "wholly apart from the fact that defendant's remedial conduct was not voluntary but rather mandated by statute and an administrative order entered by the DEP . . . [the] evidence was admissible to prove that . . . the gaseous fumes . . . were in fact released from the MgO unit." Id. at 295. In addition, the trial court in Harris specifically instructed the jury that the evidence of remedial measures was not admissible to prove defendant's negligence. The trial court stated:

> So I'm instructing you that the evidence that you're about to hear about any subsequent remedial measures, any actions taken after one or the other of these alleged incidents, is not evidence of negligence of Peridot on the indicated dates that they are charged with negligence.
>
> You may consider the testimony regarding other issues that may be established in the case. If you hear testimony regarding such things as them having notice of a problem, the feasibility of a different way of avoiding a particular type of danger; the exercise of control over property; credibility; actions that can be construed as maintaining their property; then you can consider it in line with those type of issues, but not as to the question of negligence on--at the times that they are charged with being negligent.
>
> [Id. at 291]

Thus, the purpose for the evidence admitted in Harris was not to prove the defendants' negligence or culpability, but rather to prove that the unit was defective.

Upon appellate review of Harris, the court considered the purpose for which the trial court admitted the evidence, whether the trial court properly provided limiting instructions to the jury, and whether the defendants were unduly prejudiced by the evidence. Unlike the Appellate Division in Harris, this court does not have the benefit of knowing the purpose[s] for which evidence of a subsequent remedial measure may be offered. Nor does this court have a suggested limiting instruction to be given to the jury before allowing such evidence. Since this court is unable to identify the nature of the evidence Plaintiffs might introduce and the purpose for Plaintiffs would seek to introduce it, the court will not permit evidence of subsequent remedial measures at this time. The court must await the testimony at trial to determine whether the evidence is admissible under an exception to Rule 407.

However, even if the proffered evidence of subsequent remedial measures is admissible under an exception to the general rule, it may nonetheless be excluded under Rule 403 as unduly prejudicial or confusing. See N.J.R.E. 403; see also Molino v. B.F. Goodrich Co., 261 N.J. Super. 85, 103 (App. Div.), certif. denied, 134 N.J. 482 (1992) (a trial court has the authority to exclude otherwise admissible evidence of subsequent remedial measures if the prejudicial effect outweighs the probative value). In accordance with Rule 403, a trial judge exercising discretion

may exclude otherwise relevant and admissible evidence "if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury or (b) undue delay, waste of time, or needless presentation of cumulative evidence." N.J.R.E. 403; see also Green v. N.J. Mfrs. Ins. Co., 160 N.J. 480, 492 (1999).

In this case, even if evidence of a subsequent remedial measure were to be admissible under Rule 407, under Rule 403, the court would have to consider the prejudice to Defendants of such evidence. For example, if Plaintiffs introduce evidence of the class labeling change for all atypical antipsychotics to prove Defendants' failure to provide adequate warnings, a jury might erroneously conclude that the revised labels confirmed the inadequacy of the prior warnings. See McCarrell v. Hoffman La Roche, Inc., 2009 N.J. Super. Unpub. LEXIS 558 (App. Div. March 12, 2009) (slip op. at 7-8), certif. denied, 199 N.J. 518 (2009) (the revised Accutane® label excluded by the trial court under the subsequent remedial measure rule); and see Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 271 n.10 (5th Cir.) certif. denied, 537 U.S. 824 (2002) (evidence of an updated package insert sought to be admitted for the purpose of proving that prior warnings were inadequate was excluded). Furthermore, the "apparent 'official' nature" of "reports promulgated by agencies of the United States government is likely to cause a jury to give the evidence inordinate weight," exacerbating the danger of unfair prejudice and confusion of the issues. Adelman v. Lupo, 291 N.J. Super. 207, 220 (App. Div.) certif. denied, 147 N.J. 259 (1996) (quoting Fowler v. Firestone Tire & Rubber Co., 92 F.R.D. 1, 2 (N.D. Miss. 1980)).

Courts in other jurisdictions have addressed this issue specifically in the context of pharmaceutical product liability suits. For example, in Baroldy v. Ortho Pharmaceutical Corp., 157 Ariz. 574, 585 (App. Div. 1988), the Arizona Court of Appeals upheld the trial court's decision to admit evidence of subsequent remedial measures (including the manufacturer's revision of its Patient Information Book) only for purposes other than to prove culpability. Id. The Arizona trial court granted the pharmaceutical company's *in limine* motion to preclude evidence of subsequent remedial measures, but qualified its ruling as follows:

> However, if the Defendant denies or contests that its diaphragm caused Plaintiff's injuries, claims that precautionary measures, such as changes in the literature warnings, were not feasible or necessary, then the Plaintiff may, pursuant to the "for another purpose" clause of Rule 407, offer evidence of Defendant's revisions of its [Patient] Information Booklet and literature in July, 1982 and May, 1983, the "Dear Doctor" letter sent to physicians in July, 1983, and other TSS studies and developments subsequent to 7/10/82 to impeach such claims. . . . If such evidence is admitted, the Court, if requested and tendered an instruction, will give an instruction limiting the purpose for which the jury can consider this evidence.
>
> [Id.]

Because the pharmaceutical company in the Arizona case disputed that its diaphragm caused plaintiff's injuries, the trial court admitted evidence of the subsequent remedial measures. By way of a limiting instruction given to the jury in the Arizona case, the trial court told the jury, "This evidence has been admitted and should be considered by you only on the issue of whether

it contradicts or impeaches [the pharmaceutical company's] claim that its diaphragm was not a cause of [plaintiff's] injuries." Id.

In this case, the court shall exclude evidence of subsequent remedial measures offered to show Defendants' culpability and failure to warn. If Plaintiffs seek to introduce evidence of the class label change for some purpose other than culpability or failure to warn, for example to show "control," "feasibility," "existing conditions," or "affect credibility", then the court shall consider the admission of such evidence with an appropriate limiting instruction to be given to the jury. In that event, the court requests that counsel confer and offer a suggested limiting instruction.

Defendants' *in limine* motion to preclude Plaintiffs from introducing evidence of subsequent remedial measures, including revisions to the Risperdal® package insert and warning label, is **GRANTED IN PART**. Plaintiffs are precluded from offering evidence of subsequent remedial measures for the purpose of demonstrating Defendants' culpability and failure to warn.

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f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	:	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	:	CIVIL ACTION
Docket No. MID-L-6820-06	:	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	:	
Docket No. MID-L-6720-06	:	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO PRECLUDE PLAINTIFFS FROM INTRODUCING EVIDENCE OF SUBSEQUENT REMEDIAL MEASURES, INCLUDING REVISIONS TO RISPERDAL®'S PACKAGE INSERT

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers, and ~~the arguments of counsel~~, and good cause having been shown;

IT IS on this 16th day of December, 2011, A

ORDERED that defendants' motion *in limine* to preclude Plaintiffs from introducing evidence of subsequent remedial measures, including revisions to Risperdal®'s package insert, is hereby granted; in part;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs'~~ posted on line counsel within seven (7) days of the date of this Order.

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision.

FP01/6664400.1

Memorandum of Decision on Defendants' motion *in limine* to preclude Plaintiffs from introducing evidence of subsequent remedial measures, including revisions to the Risperdal® package insert and warnings.

In October of 2003, the Food and Drug Administration ("FDA") issued a labeling change for all atypical antipsychotics medications, including Risperdal®. Defendants move to exclude evidence of this labeling change and other remedial measure undertaken subsequent to Plaintiffs' injuries under N.J.R.E. 407.

Rule 407 provides that "[e]vidence of remedial measures taken after an event is not admissible to prove that the event was caused by negligence or culpable conduct. However, evidence of such subsequent remedial conduct may be admitted as to other issues." As the Appellate Division explained in Harris v. Peridot Chem. (N.J.) Inc., 313 N.J. Super. 257 (App. Div. 1998), evidence of subsequent remedial measures is excluded on public policy grounds:

> not because it lacks relevancy, but because admission of said testimony might discourage corrective action and induce perpetuation of the damage and condition that gave rise to the lawsuit. . . .The theory behind the Rule is that a person should not be penalized for correcting a potentially deleterious situation.
>
> [Id. at 292-293 (citations and internal quotation marks omitted)]

There are exceptions regarding the inadmissibility of evidence of subsequent remedial measures. Evidence of involuntary remedial measures, such as those directed by or at the instance of a governing authority, would not violate the policy underlying the Rule and may therefore be admissible. See id. ("If, as defendant contends, its decision to install fence line monitors, increase the stack heights, and create contingency plans in the event of an inadvertent release of sulfur dioxide was not a voluntary action, but rather was mandated by the DEP, admission of the evidence would not violate the policy underlying the Rule."); see also Schedin v. Ortho-McNeil-Janssen Pharms., Inc., No. 08-5743 (JRT), 2011 U.S. Dist. LEXIS 96837, at *25-27 (D. Minn. Aug. 26, 2011)(evidence of post-2005 labeling of Levaquin® admissible under Fed. R. Evid. 407 since "[a]n exception to Rule 407 is recognized for evidence of remedial action mandated by superior governmental authority," and any potential prejudice was mitigated by the trial judge's limiting instruction) (citation omitted)).

Also, evidence of subsequent remedial measures offered for purposes other than to prove negligence or culpable conduct is admissible. See N.J.R.E. 407. See also Harris, supra, 313 N.J. Super at 292-293 (evidence of remedial measures may be admitted "to show control," "to demonstrate feasibility and practicality of repair," "to impeach the credibility of a witness," and "to prove the condition existing at the time of the accident."). Evidence of subsequent remedial action may be admitted for a variety of other purposes, including "where the evidence is offered to establish control over the injuring instrumentality; to prove the condition existing at the time of the accident; to affect the credibility of a witness; or to show a different method was feasible for avoiding the danger." Hansson v. Catalytic Constr. Co., 43 N.J. Super. 23, 27 (App. Div. 1956) (citation omitted); see also Harris, supra, 313 N.J. Super. at 292-293; Kane v. Hartz Mountain Indus., Inc., 278 N.J. Super. 129, 147-148 (App. Div.) aff'd, 143 N.J. 141 (1996).

In Harris, evidence of a subsequent corrective measures was admitted "to prove 'the condition existing at the time of the accident,'" including whether the condition was defective. Harris, supra, 313 N.J. Super. at 293 (citation omitted). The Harris court held that "wholly apart from the fact that defendant's remedial conduct was not voluntary but rather mandated by statute and an administrative order entered by the DEP . . . [the] evidence was admissible to prove that . . . the gaseous fumes . . . were in fact released from the MgO unit." Id. at 295. In addition, the trial court in Harris specifically instructed the jury that the evidence of remedial measures was not admissible to prove defendant's negligence. The trial court stated:

> So I'm instructing you that the evidence that you're about to hear about any subsequent remedial measures, any actions taken after one or the other of these alleged incidents, is not evidence of negligence of Peridot on the indicated dates that they are charged with negligence.
>
> You may consider the testimony regarding other issues that may be established in the case. If you hear testimony regarding such things as them having notice of a problem, the feasibility of a different way of avoiding a particular type of danger; the exercise of control over property; credibility; actions that can be construed as maintaining their property; then you can consider it in line with those type of issues, but not as to the question of negligence on--at the times that they are charged with being negligent.
>
> [Id. at 291]

Thus, the purpose for the evidence admitted in Harris was not to prove the defendants' negligence or culpability, but rather to prove that the unit was defective.

Upon appellate review of Harris, the court considered the purpose for which the trial court admitted the evidence, whether the trial court properly provided limiting instructions to the jury, and whether the defendants were unduly prejudiced by the evidence. Unlike the Appellate Division in Harris, this court does not have the benefit of knowing the purpose[s] for which evidence of a subsequent remedial measure may be offered. Nor does this court have a suggested limiting instruction to be given to the jury before allowing such evidence. Since this court is unable to identify the nature of the evidence Plaintiffs might introduce and the purpose for Plaintiffs would seek to introduce it, the court will not permit evidence of subsequent remedial measures at this time. The court must await the testimony at trial to determine whether the evidence is admissible under an exception to Rule 407.

However, even if the proffered evidence of subsequent remedial measures is admissible under an exception to the general rule, it may nonetheless be excluded under Rule 403 as unduly prejudicial or confusing. See N.J.R.E. 403; see also Molino v. B.F. Goodrich Co., 261 N.J. Super. 85, 103 (App. Div.), certif. denied, 134 N.J. 482 (1992) (a trial court has the authority to exclude otherwise admissible evidence of subsequent remedial measures if the prejudicial effect outweighs the probative value). In accordance with Rule 403, a trial judge exercising discretion

may exclude otherwise relevant and admissible evidence "if its probative value is substantially outweighed by the risk of (a) undue prejudice, confusion of issues, or misleading the jury or (b) undue delay, waste of time, or needless presentation of cumulative evidence." N.J.R.E. 403; see also Green v. N.J. Mfrs. Ins. Co., 160 N.J. 480, 492 (1999).

In this case, even if evidence of a subsequent remedial measure were to be admissible under Rule 407, under Rule 403, the court would have to consider the prejudice to Defendants of such evidence. For example, if Plaintiffs introduce evidence of the class labeling change for all atypical antipsychotics to prove Defendants' failure to provide adequate warnings, a jury might erroneously conclude that the revised labels confirmed the inadequacy of the prior warnings. See McCarrell v. Hoffman La Roche, Inc., 2009 N.J. Super. Unpub. LEXIS 558 (App. Div. March 12, 2009) (slip op. at 7-8), certif. denied, 199 N.J. 518 (2009) (the revised Accutane® label excluded by the trial court under the subsequent remedial measure rule); and see Stahl v. Novartis Pharms. Corp., 283 F.3d 254, 271 n.10 (5th Cir.) certif. denied, 537 U.S. 824 (2002) (evidence of an updated package insert sought to be admitted for the purpose of proving that prior warnings were inadequate was excluded). Furthermore, the "apparent 'official' nature" of "reports promulgated by agencies of the United States government is likely to cause a jury to give the evidence inordinate weight," exacerbating the danger of unfair prejudice and confusion of the issues. Adelman v. Lupo, 291 N.J. Super. 207, 220 (App. Div.) certif. denied, 147 N.J. 259 (1996) (quoting Fowler v. Firestone Tire & Rubber Co., 92 F.R.D. 1, 2 (N.D. Miss. 1980)).

Courts in other jurisdictions have addressed this issue specifically in the context of pharmaceutical product liability suits. For example, in Baroldy v. Ortho Pharmaceutical Corp., 157 Ariz. 574, 585 (App. Div. 1988), the Arizona Court of Appeals upheld the trial court's decision to admit evidence of subsequent remedial measures (including the manufacturer's revision of its Patient Information Book) only for purposes other than to prove culpability. Id. The Arizona trial court granted the pharmaceutical company's *in limine* motion to preclude evidence of subsequent remedial measures, but qualified its ruling as follows:

> However, if the Defendant denies or contests that its diaphragm caused Plaintiff's injuries, claims that precautionary measures, such as changes in the literature warnings, were not feasible or necessary, then the Plaintiff may, pursuant to the "for another purpose" clause of Rule 407, offer evidence of Defendant's revisions of its [Patient] Information Booklet and literature in July, 1982 and May, 1983, the "Dear Doctor" letter sent to physicians in July, 1983, and other TSS studies and developments subsequent to 7/10/82 to impeach such claims. . . . If such evidence is admitted, the Court, if requested and tendered an instruction, will give an instruction limiting the purpose for which the jury can consider this evidence.
>
> [Id.]

Because the pharmaceutical company in the Arizona case disputed that its diaphragm caused plaintiff's injuries, the trial court admitted evidence of the subsequent remedial measures. By way of a limiting instruction given to the jury in the Arizona case, the trial court told the jury, "This evidence has been admitted and should be considered by you only on the issue of whether

it contradicts or impeaches [the pharmaceutical company's] claim that its diaphragm was not a cause of [plaintiff's] injuries." Id.

In this case, the court shall exclude evidence of subsequent remedial measures offered to show Defendants' culpability and failure to warn. If Plaintiffs seek to introduce evidence of the class label change for some purpose other than culpability or failure to warn, for example to show "control," "feasibility," "existing conditions," or "affect credibility", then the court shall consider the admission of such evidence with an appropriate limiting instruction to be given to the jury. In that event, the court requests that counsel confer and offer a suggested limiting instruction.

Defendants' *in limine* motion to preclude Plaintiffs from introducing evidence of subsequent remedial measures, including revisions to the Risperdal® package insert and warning label, is **GRANTED IN PART**. Plaintiffs are precluded from offering evidence of subsequent remedial measures for the purpose of demonstrating Defendants' culpability and failure to warn.

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Attorneys for Defendants Johnson & Johnson
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(f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.,
f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	CIVIL ACTION
Docket No. MID-L-6820-06	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	
Docket No. MID-L-6720-06	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF THE JANUARY 5, 1999 AND APRIL 19, 2004 DDMAC LETTERS AND ALL RELATED MATERIALS AND COMMUNICATIONS

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, counsel for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.), for an Order to exclude evidence of the January 5, 1999 and April 19, 2004 DDMAC letters and all related materials and

communications. and the Court having considered the submissions of the parties and for good cause shown,

IT IS on this 16th day of December, 2011,

ORDERED that the motion to exclude evidence of, and/or argument about, the January 5, 1999 and April 19, 2004 DDMAC letters and all related materials and communications is hereby GRANTED.

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs~~ posted on line ~~counsel~~ within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

___ Unopposed

* The parties having consented to adjournment of the motion on the papers and for the reasons set forth in the attached memorandum.

FP01/ 6664398.1

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of DDMAC letters and related materials.

Defendants' motion *in limine* to exclude evidence of the January 5, 1999 Untitled Letter from DDMAC.

DDMAC defines Untitled Letters as letters that "cite violations that do not meet the threshold of regulatory significance for a Warning Letter." FDA Regulatory Procedures Manual, Ch. 4 Advisory Action (March 2010), http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176871.htm (last visited December 14, 2011). This type of letter can be issued by "any appropriate agency compliance official" and "does not include a warning statement that failure to take prompt correction may result in enforcement action." Ibid.

The 1999 Untitled Letter sent to Janssen by DDMAC addressed promotional activities directed at the geriatric patient population. As neither Plaintiff falls within the geriatric population, the 1999 Untitled Letter provides no relevant evidence in these bellwether cases. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of DDMAC letters and related materials.

Defendants' motion *in limine* to exclude evidence of the November 10, 2003 "Dear Healthcare Provider" letter from Janssen and the April 19, 2004 Warning Letter from DDMAC.

Under N.J.R.E. 401, relevant evidence must have the tendency "to prove or disprove any fact of consequence to the determination of the action." Plaintiff Skala was first diagnosed with diabetes mellitus in July of 2002. See Defendants' brief to exclude evidence of DDMAC letters and related materials at 3. Plaintiff Laissen was first diagnosed with diabetes mellitus in May of 2000. Ibid. Plaintiffs do not dispute the diagnosis dates in their opposition to Defendants' *in limine* motion. See Plaintiffs' opposition brief in response to defendants' brief to exclude evidence of DDMAC letters and related materials. Thus, Plaintiffs were diagnosed with diabetes prior to the November 10, 2003 "Dear Healthcare Provider" letter from Janssen and the subsequent April 19, 2004 Warning Letter from DDMAC. It is not relevant to the facts of the bellwether cases that a misleading letter may have been sent to healthcare providers in 2003. As of November 2003, Plaintiffs' prescribing physicians made the decision to treat Plaintiffs with Risperdal® and Plaintiffs already suffered their alleged resulting injury. Therefore, this motion is **GRANTED**.

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IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
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Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	
Docket No. MID-L-6720-06	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE EVIDENCE OF THE JANUARY 5, 1999 AND APRIL 19, 2004 DDMAC LETTERS AND ALL RELATED MATERIALS AND COMMUNICATIONS

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, counsel for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.), for an Order to exclude evidence of the January 5, 1999 and April 19, 2004 DDMAC letters and all related materials and

communications. and the Court having considered the submissions of the parties and for good cause shown,

IT IS on this 16th day of December, 2011,

ORDERED that the motion to exclude evidence of, and/or argument about, the January 5, 1999 and April 19, 2004 DDMAC letters and all related materials and communications is hereby GRANTED *

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs'~~ posted on live counsel within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memoranda of decision.

FP01/6664398.1

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of DDMAC letters and related materials.

Defendants' motion *in limine* to exclude evidence of the January 5, 1999 Untitled Letter from DDMAC.

DDMAC defines Untitled Letters as letters that "cite violations that do not meet the threshold of regulatory significance for a Warning Letter." FDA Regulatory Procedures Manual, Ch. 4 Advisory Action (March 2010), http://www.fda.gov/ICECI/ComplianceManuals/RegulatoryProceduresManual/ucm176871.htm (last visited December 14, 2011). This type of letter can be issued by "any appropriate agency compliance official" and "does not include a warning statement that failure to take prompt correction may result in enforcement action." Ibid.

The 1999 Untitled Letter sent to Janssen by DDMAC addressed promotional activities directed at the geriatric patient population. As neither Plaintiff falls within the geriatric population, the 1999 Untitled Letter provides no relevant evidence in these bellwether cases. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to exclude evidence of DDMAC letters and related materials.

Defendants' motion *in limine* to exclude evidence of the November 10, 2003 "Dear Healthcare Provider" letter from Janssen and the April 19, 2004 Warning Letter from DDMAC.

Under N.J.R.E. 401, relevant evidence must have the tendency "to prove or disprove any fact of consequence to the determination of the action." Plaintiff Skala was first diagnosed with diabetes mellitus in July of 2002. See Defendants' brief to exclude evidence of DDMAC letters and related materials at 3. Plaintiff Laissen was first diagnosed with diabetes mellitus in May of 2000. Ibid. Plaintiffs do not dispute the diagnosis dates in their opposition to Defendants' *in limine* motion. See Plaintiffs' opposition brief in response to defendants' brief to exclude evidence of DDMAC letters and related materials. Thus, Plaintiffs were diagnosed with diabetes prior to the November 10, 2003 "Dear Healthcare Provider" letter from Janssen and the subsequent April 19, 2004 Warning Letter from DDMAC. It is not relevant to the facts of the bellwether cases that a misleading letter may have been sent to healthcare providers in 2003. As of November 2003, Plaintiffs' prescribing physicians made the decision to treat Plaintiffs with Risperdal® and Plaintiffs already suffered their alleged resulting injury. Therefore, this motion is **GRANTED**.

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Attorneys for Defendants
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(f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.,
f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	:	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	:	CIVIL ACTION
Docket No. MID-L-6820-06	:	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	:	
Docket No. MID-L-6720-06	:	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE IRRELEVANT AND PREJUDICIAL EVIDENCE OF MARKETING MATERIALS THAT WERE NOT RELIED UPON BY PLAINTIFFS OR PLAINTIFFS' PRESCRIBERS

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having heard

~~and~~ considered the moving papers, any opposition papers, and ~~the arguments of counsel,~~ and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that Defendants' Motion *In Limine* to Exclude Irrelevant and Prejudicial Evidence of Marketing Materials that were not Relied Upon by Plaintiffs or Plaintiffs' Prescribers including but not limited to:

1. internal marketing documents including sales training videos, written materials used to train detail representatives, sales message research, internal marketing emails and memoranda, and organization charts for defendants' sales and marketing divisions; and

2. any materials created or disseminated after plaintiffs claim to have suffered injuries from their use of Risperdal® – May 2000 for plaintiff Shon Laissen and July 2002 for plaintiff Gary Skala;

is hereby **GRANTED**;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs~~ posted on line counsel within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision.

FP01/ 6665637.1

Memorandum of Decision on Defendants' motions *in limine* to exclude irrelevant and prejudicial evidence, including evidence of off-label promotion, marketing materials that were not relied upon by Plaintiffs or Plaintiffs' prescribing healthcare providers, and foreign regulatory activities.

Defendants' motion *in limine* to exclude irrelevant and prejudicial evidence of marketing materials that were not relied upon by Plaintiffs or Plaintiffs' prescribers, including but not limited to:

1. internal marketing documents including sales training videos, written materials used to train detail representatives, sales message research, internal marketing emails and memoranda, and organization charts for Defendants' sales and marketing divisions; and

2. any materials created or disseminated after Plaintiffs claim to have suffered injuries from Risperdal—May 2000 for Plaintiff Laissen and July 2002 for Plaintiff Skala.

Defendants argue that distributed advertising materials are relevant only to the extent "that the absence of information or presence of misinformation in [Defendants'] advertising was in violation of FDA requirements" and in determining whether such violations, if any, were a substantial factor in bringing about the harm suffered." Perez v. Wyeth Labs. Inc., 161 N.J. 1, 26 (1999). Defendants assert that if Plaintiffs (or their prescribing doctors) did not rely upon the materials, such materials do not relate to Plaintiffs' injuries and are thus irrelevant and inadmissible. Def. Br. at 6.

The Appellate Division confronted a similar issue in McDarby v. Merck & Co. Inc., 401 N.J. Super. 10 (App. Div. 2008), certif. dismissed , 200 N.J. 267 (2009). In McDarby, the Appellate Division wrote:

> In its final evidentiary argument, Merck asserts that the trial judge erred in admitting evidence of its marketing practices with respect to Vioxx that did not target McDarby, Cona, or their physicians. Merck specifically refers to (1) the September 17, 2001 warning letter from the FDA, which we previously described, that charged Merck with minimizing the potentially serious cardiovascular findings of the VIGOR study; . . . (3) the "CV card," minimizing risk, that, in fact, McDarby's physician recalled studying; (4) the internal document identifying doctors to be "neutralized" by sales staff; and (5) a puerile video, called "Be the Power," that trained sales representatives to meet obstacles such as users of Celebrex or non-specific NSAIDs and persons fearful of a heart attack, hypertension or edema by stressing the efficacy and gastrointestinal safety of Vioxx.
>
> [McDarby, supra, 401 N.J. Super. at 79.]

The McDarby court held that all of the items listed above were "relevant to the issue of Merck's failure to adequately warn of the known dangers of its product and to its conduct in obscuring the scientific evidence of cardiovascular risk established by VIGOR and other studies." Ibid. This court believes that the post-approval marketing materials at issue in the McDarby case predated the plaintiffs' claimed injury and, therefore, were available at the time that those plaintiffs' were prescribed the drug and thus were relevant to the issues in that case. Similarly, in another antipsychotic litigation tried before this court in February 2010, this court allowed evidence of post-approval marketing materials that pre-dated the plaintiffs' claimed injuries associated with the ingestion of Seroquel® on the basis that the marketing materials were available to the plaintiffs' prescribing physicians at the time Seroquel® was prescribed to those plaintiffs. See Baker v. AstraZeneca Pharemacueticals, LP, Docket No. L-1099-07, Memorandum of Decision on Plaintiffs' Omnibus *In Limine* motions dated February 11, 1010.

Here, in contrast, there is no evidence that the marketing materials disseminated after Plaintiffs suffered their alleged injuries were relied upon by any of Plaintiffs' prescribing physicians. Therefore, this motion is **GRANTED**. The court may revisit this issue should Plaintiffs offer evidence that any of the post-approval marketing materials were available to the Plaintiffs' physicians at the time Risperdal® was prescribed to each Plaintiff.

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f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	:	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	:	CIVIL ACTION
Docket No. MID-L-6820-06	:	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	:	
Docket No. MID-L-6720-06	:	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE IRRELEVANT AND PREJUDICIAL EVIDENCE OF MARKETING MATERIALS THAT WERE NOT RELIED UPON BY PLAINTIFFS OR PLAINTIFFS' PRESCRIBERS

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers, and ~~the arguments of counsel~~, and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that Defendants' Motion *In Limine* to Exclude Irrelevant and Prejudicial Evidence of Marketing Materials that were not Relied Upon by Plaintiffs or Plaintiffs' Prescribers including but not limited to:

1. internal marketing documents including sales training videos, written materials used to train detail representatives, sales message research, internal marketing emails and memoranda, and organization charts for defendants' sales and marketing divisions; and

2. any materials created or disseminated after plaintiffs claim to have suffered injuries from their use of Risperdal® – May 2000 for plaintiff Shon Laissen and July 2002 for plaintiff Gary Skala;

is hereby **GRANTED**;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs'~~ posted on live co~~unsel~~ within seven (7) days of the date of this Order.

OPPOSED

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision

FP01/ 6665637.1

Memorandum of Decision on Defendants' motions *in limine* to exclude irrelevant and prejudicial evidence, including evidence of off-label promotion, marketing materials that were not relied upon by Plaintiffs or Plaintiffs' prescribing healthcare providers, and foreign regulatory activities.

Defendants' motion *in limine* to exclude irrelevant and prejudicial evidence of marketing materials that were not relied upon by Plaintiffs or Plaintiffs' prescribers, including but not limited to:

1. internal marketing documents including sales training videos, written materials used to train detail representatives, sales message research, internal marketing emails and memoranda, and organization charts for Defendants' sales and marketing divisions; and

2. any materials created or disseminated after Plaintiffs claim to have suffered injuries from Risperdal—May 2000 for Plaintiff Laissen and July 2002 for Plaintiff Skala.

Defendants argue that distributed advertising materials are relevant only to the extent "that the absence of information or presence of misinformation in [Defendants'] advertising was in violation of FDA requirements" and in determining whether such violations, if any, were a substantial factor in bringing about the harm suffered." Perez v. Wyeth Labs. Inc., 161 N.J. 1, 26 (1999). Defendants assert that if Plaintiffs (or their prescribing doctors) did not rely upon the materials, such materials do not relate to Plaintiffs' injuries and are thus irrelevant and inadmissible. Def. Br. at 6.

The Appellate Division confronted a similar issue in McDarby v. Merck & Co. Inc., 401 N.J. Super. 10 (App. Div. 2008), certif. dismissed , 200 N.J. 267 (2009). In McDarby, the Appellate Division wrote:

> In its final evidentiary argument, Merck asserts that the trial judge erred in admitting evidence of its marketing practices with respect to Vioxx that did not target McDarby, Cona, or their physicians. Merck specifically refers to (1) the September 17, 2001 warning letter from the FDA, which we previously described, that charged Merck with minimizing the potentially serious cardiovascular findings of the VIGOR study; . . . (3) the "CV card," minimizing risk, that, in fact, McDarby's physician recalled studying; (4) the internal document identifying doctors to be "neutralized" by sales staff; and (5) a puerile video, called "Be the Power," that trained sales representatives to meet obstacles such as users of Celebrex or non-specific NSAIDs and persons fearful of a heart attack, hypertension or edema by stressing the efficacy and gastrointestinal safety of Vioxx.
>
> [McDarby, supra, 401 N.J. Super. at 79.]

The McDarby court held that all of the items listed above were "relevant to the issue of Merck's failure to adequately warn of the known dangers of its product and to its conduct in obscuring the scientific evidence of cardiovascular risk established by VIGOR and other studies." Ibid. This court believes that the post-approval marketing materials at issue in the McDarby case predated the plaintiffs' claimed injury and, therefore, were available at the time that those plaintiffs' were prescribed the drug and thus were relevant to the issues in that case. Similarly, in another antipsychotic litigation tried before this court in February 2010, this court allowed evidence of post-approval marketing materials that pre-dated the plaintiffs' claimed injuries associated with the ingestion of Seroquel® on the basis that the marketing materials were available to the plaintiffs' prescribing physicians at the time Seroquel® was prescribed to those plaintiffs. See Baker v. AstraZeneca Pharemacueticals, LP, Docket No. L-1099-07, Memorandum of Decision on Plaintiffs' Omnibus *In Limine* motions dated February 11, 1010.

Here, in contrast, there is no evidence that the marketing materials disseminated after Plaintiffs suffered their alleged injuries were relied upon by any of Plaintiffs' prescribing physicians. Therefore, this motion is **GRANTED**. The court may revisit this issue should Plaintiffs offer evidence that any of the post-approval marketing materials were available to the Plaintiffs' physicians at the time Risperdal® was prescribed to each Plaintiff.

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(f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc.,
f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	CASE NO. 274
Gary D. Skala v. Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc., et al.	CIVIL ACTION
Docket No. MID-L-6820-06	
Shon Laissen v. Johnson & Johnson, Company, Janssen Pharmaceutica Products, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P. a/k/a Janssen Pharmaceutica, Inc.	
Docket No. MID-L-6720-06	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE IRRELEVANT AND PREJUDICIAL EVIDENCE OF FOREIGN REGULATORY ACTIVITIES INVOLVING RISPERDAL®

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having ~~heard~~

~~and~~ considered the moving papers, ~~any~~ opposition papers, ~~and the arguments of counsel~~, and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that Defendants' Motion *In Limine* to Exclude Irrelevant and Prejudicial Evidence of Foreign Regulatory Activities involving Risperdal®, including but not limited to, evidence of or relating to actions, recommendations, inquiries, correspondence, communications and/or statements of any foreign government, is hereby **GRANTED**;

IT IS FURTHER ORDERED that a copy of this Order shall be p. upl online ~~served upon plaintiffs'~~ ~~counsel~~ within seven (7) days of the date of this Order.

JESSICA R. MAYER, J.S.C.

This motion was:

✓ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision

FP01/ 6665651.1

Memorandum of Decision on Defendants' motions *in limine* to exclude irrelevant and prejudicial evidence, including evidence of off-label promotion, marketing materials that were not relied upon by Plaintiffs or Plaintiffs' prescribing healthcare providers, and foreign regulatory activities.

Defendants' motion *in limine* to exclude irrelevant and prejudicial evidence of foreign regulatory activities involving Risperdal®, including but not limited to, evidence of or relating to actions, recommendations, inquiries, correspondence, communications and/or statements of any foreign government.

Plaintiffs do not intend to introduce evidence of foreign regulatory activity involving Risperdal®. Thus, neither party shall argue or comment on this issue unless the court determines that the other party has "opened the door." Therefore, this motion is **GRANTED.**

#0232
#0241

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f/k/a Janssen Pharmaceutica Inc.)

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
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Docket No. MID-L-6720-06	

ORDER ON DEFENDANTS' MOTION *IN LIMINE* TO EXCLUDE IRRELEVANT AND PREJUDICIAL EVIDENCE OF FOREIGN REGULATORY ACTIVITIES INVOLVING RISPERDAL®

THIS MATTER having been brought before the Court by Drinker Biddle & Reath LLP, attorneys for defendants Johnson & Johnson and Janssen Pharmaceuticals, Inc. (f/k/a Ortho-McNeil-Janssen Pharmaceuticals, Inc., f/k/a Janssen Pharmaceutica Inc.); the Court having heard

~~and~~ considered the moving papers, ~~any~~ opposition papers, ~~and the arguments of counsel~~, and good cause having been shown;

IT IS on this 16th day of December, 2011, *

ORDERED that Defendants' Motion *In Limine* to Exclude Irrelevant and Prejudicial Evidence of Foreign Regulatory Activities involving Risperdal®, including but not limited to, evidence of or relating to actions, recommendations, inquiries, correspondence, communications and/or statements of any foreign government, is hereby **GRANTED**;

IT IS FURTHER ORDERED that a copy of this Order shall be ~~served upon plaintiffs~~ posted on live counsel within seven (7) days of the date of this Order.

JESSICA R. MAYER, J.S.C.

This motion was:

/ Opposed

____ Unopposed

* The parties having consented to disposition of the motion on the papers and for the reasons set forth in the attached memorandum of decision.

FP01/ 6665651.1

Memorandum of Decision on Defendants' motions *in limine* to exclude irrelevant and prejudicial evidence, including evidence of off-label promotion, marketing materials that were not relied upon by Plaintiffs or Plaintiffs' prescribing healthcare providers, and foreign regulatory activities.

Defendants' motion *in limine* to exclude irrelevant and prejudicial evidence of foreign regulatory activities involving Risperdal®, including but not limited to, evidence of or relating to actions, recommendations, inquiries, correspondence, communications and/or statements of any foreign government.

Plaintiffs do not intend to introduce evidence of foreign regulatory activity involving Risperdal®. Thus, neither party shall argue or comment on this issue unless the court determines that the other party has "opened the door." Therefore, this motion is **GRANTED.**