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MIDDLE & REATH LLP
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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.)

FILED
DEC 16 2011
JUDGE JESSICA R. MAYER

IN RE: RISPERDAL/SEROQUEL/ ZYPREXA LITIGATION	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION : MIDDLESEX COUNTY
	:	
	:	CASE NO. 274
	:	
<i>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.</i>	:	CIVIL ACTION
	:	
Docket No. MID-L-6820-06	:	
	:	
<i>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.</i>	:	
	:	
Docket No. MID-L-6720-06	:	
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ORDER ON DEFENDANTS' MOTION *IN LIMINE*
TO LIMIT THE TESTIMONY OF PLAINTIFFS' EXPERT
LAURA M. PLUNKETT, Ph.D.

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 limit

the testimony of Plaintiffs' expert Laura M. Plunkett, Ph.D. 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~~ ^{order} to limit the testimony of Plaintiffs' expert Laura M. Plunkett, Ph.D. is hereby ~~GRANTED~~ as follows:

1. Dr. Plunkett is prohibited from offering "bad company" testimony and/or commentary about corporate ethics; - *Granted*
2. Dr. Plunkett is prohibited from offering state-of-mind-testimony; - *Granted*
3. Dr. Plunkett is prohibited from offering testimony about her legal interpretation of FDA regulations; - *Denied*
4. Dr. Plunkett is prohibited from offering testimony regarding FDA labeling regulations based on lack of qualifications; and - *Denied*
5. Dr. Plunkett is prohibited from offering testimony regarding Janssen's alleged failure to warn based on lack of qualifications. - *Denied*

IT IS FURTHER ORDERED that a copy of this Order shall be ^{postdated in} served upon ~~plaintiffs' 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 limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to exclude Dr. Plunkett's bad company testimony and/or commentary about corporate ethics.

Plaintiffs do not intend to have Dr. Plunkett testify that Janssen or Johnson & Johnson is a bad company or unethical. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to preclude Dr. Plunkett from offering state of mind testimony.

Plaintiffs do not intend to have Dr. Plunkett offer state of mind testimony. Issues regarding the state of mind, intent, motives or ethics of pharmaceutical companies or their employees are not the proper subjects of an expert opinion, but instead, matters to be argued by counsel based on the evidence. In re: Seroquel Products Liability Litig., Case No. 6:06-md-1769-Orl-22DAB at 7-8 (M.D. Fl. July 20, 2009). This court adopts the reasoning of the MDL judge on this issue. Dr. Plunkett will be precluded from offering state of mind testimony at trial including explanation of possible motives for Janssen's actions. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to exclude Dr. Plunkett's legal interpretation of FDA standards and regulations.

Plaintiffs agree that Dr. Plunkett will not offer legal conclusions about FDA regulations or any other subject matter. (Pl. Opp. Br. at 5). FDA's requirements are a legal matter to be explained to the jury by the court. The court will charge the jury on the applicable law at the conclusion of the testimony. Therefore, Plaintiffs' experts should not give legal explanations to the jurors.

Plaintiffs intend to have Dr. Plunkett testify regarding the content of FDA regulations. Dr. Plunkett is a pharmacologist, toxicologist and FDA regulatory specialist. She has served as an advisor to numerous entities regulated by the FDA. See State of South Carolina ex rel. Wilson v. Ortho-McNeil – Janssen Pharmaceuticals, Inc., et al., (Order of Feb. 25, 2011, No. 2007-CP-42-1438 at 14-15) and Caldwell ex rel. the State of Louisiana v. Janssen Pharmaceutica, Inc., Trial Tr., Nos. 04-C-3967-D, 04-C-3977-D, Trial Day 2 at 196-202 (La. 27th D. Ct. Sept. 29, 2010). Dr. Plunkett has the expertise necessary to opine on FDA regulations and the regulatory process. Therefore, this motion is **DENIED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to exclude Dr. Plunkett's testimony regarding FDA labeling regulations based on her lack of qualifications.

Dr. Plunkett is a toxicologist and pharmacologist. Throughout her career she has worked with clients to develop regulatory strategies for prescription medications. She has also served as a consultant numerous times in the drafting of regulatory applications for prescription drug products. Based on this experience, Dr. Plunkett is qualified to offer testimony regarding FDA labeling regulations. See State of South Carolina ex rel. Wilson v. Ortho-McNeil – Janssen Pharmaceuticals, Inc., et al., (Order of Feb. 25, 2011, No. 2007-CP-42-1438 at 15). Defendants may cross-examine Dr. Plunkett as to her education, experience and the documents that she may or may not have considered in rendering her opinion on this issue. Therefore, this motion is **DENIED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to exclude testimony by Dr. Plunkett regarding Janssen's alleged failure to warn based on lack of qualifications.

Dr. Plunkett can offer opinions regarding the adequacy of Risperdal[®]'s label based upon her experience, training and education. The MDL judge in the federal Seroquel[®] litigation held that Dr. Plunkett is an expert in FDA regulations, pharmacology and toxicology; thus qualifying her to testify on this issue. In re: Seroquel Products Liability Litig., Case No. 6:06-md-1769-Orl-22DAB at 17 (M.D. Fl. July 20, 2009). As such, she is qualified to offer testimony on the effect Risperdal[®] has on a person's body and whether the drugs label adequately conveyed that message. Therefore, Defendants' motion is **DENIED**.

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Attorneys for Defendants Johnson & Johnson
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IN RE: RISPERDAL/SEROQUEL/
ZYPREXA LITIGATION

: SUPERIOR COURT OF NEW JERSEY
: LAW DIVISION : MIDDLESEX COUNTY

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: CASE NO. 274

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: *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

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: Docket No. MID-L-6720-06
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ORDER ON DEFENDANTS' MOTION *IN LIMINE*
TO LIMIT THE TESTIMONY OF PLAINTIFFS' EXPERT
LAURA M. PLUNKETT, Ph.D.

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 limit

the testimony of Plaintiffs' expert Laura M. Plunkett, Ph.D. 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~~^{order} to limit the testimony of Plaintiffs' expert Laura M. Plunkett, Ph.D. is hereby ~~GRANTED~~ as follows:

1. Dr. Plunkett is prohibited from offering "bad company" testimony and/or commentary about corporate ethics; - *Granted*
2. Dr. Plunkett is prohibited from offering state-of-mind-testimony; - *Granted*
3. Dr. Plunkett is prohibited from offering testimony about her legal interpretation of FDA regulations; - *Denied*
4. Dr. Plunkett is prohibited from offering testimony regarding FDA labeling regulations based on lack of qualifications; and - *Denied*
5. Dr. Plunkett is prohibited from offering testimony regarding Janssen's alleged failure to warn based on lack of qualifications. - *Denied*

IT IS FURTHER ORDERED that a copy of this Order shall be ^{served upon} ~~served upon~~ plaintiffs' 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 the position of the motion on the papers and for the reasons set forth in the attached memorandum of decision.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to exclude Dr. Plunkett's bad company testimony and/or commentary about corporate ethics.

Plaintiffs do not intend to have Dr. Plunkett testify that Janssen or Johnson & Johnson is a bad company or unethical. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to preclude Dr. Plunkett from offering state of mind testimony.

Plaintiffs do not intend to have Dr. Plunkett offer state of mind testimony. Issues regarding the state of mind, intent, motives or ethics of pharmaceutical companies or their employees are not the proper subjects of an expert opinion, but instead, matters to be argued by counsel based on the evidence. In re: Seroquel Products Liability Litig., Case No. 6:06-md-1769-Orl-22DAB at 7-8 (M.D. Fl. July 20, 2009). This court adopts the reasoning of the MDL judge on this issue. Dr. Plunkett will be precluded from offering state of mind testimony at trial including explanation of possible motives for Janssen's actions. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to exclude Dr. Plunkett's legal interpretation of FDA standards and regulations.

Plaintiffs agree that Dr. Plunkett will not offer legal conclusions about FDA regulations or any other subject matter. (Pl. Opp. Br. at 5). FDA's requirements are a legal matter to be explained to the jury by the court. The court will charge the jury on the applicable law at the conclusion of the testimony. Therefore, Plaintiffs' experts should not give legal explanations to the jurors.

Plaintiffs intend to have Dr. Plunkett testify regarding the content of FDA regulations. Dr. Plunkett is a pharmacologist, toxicologist and FDA regulatory specialist. She has served as an advisor to numerous entities regulated by the FDA. See State of South Carolina ex rel. Wilson v. Ortho-McNeil – Janssen Pharmaceuticals, Inc., et al., (Order of Feb. 25, 2011, No. 2007-CP-42-1438 at 14-15) and Caldwell ex rel. the State of Louisiana v. Janssen Pharmaceutica, Inc., Trial Tr., Nos. 04-C-3967-D, 04-C-3977-D, Trial Day 2 at 196-202 (La. 27th D. Ct. Sept. 29, 2010). Dr. Plunkett has the expertise necessary to opine on FDA regulations and the regulatory process. Therefore, this motion is **DENIED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to exclude Dr. Plunkett's testimony regarding FDA labeling regulations based on her lack of qualifications.

Dr. Plunkett is a toxicologist and pharmacologist. Throughout her career she has worked with clients to develop regulatory strategies for prescription medications. She has also served as a consultant numerous times in the drafting of regulatory applications for prescription drug products. Based on this experience, Dr. Plunkett is qualified to offer testimony regarding FDA labeling regulations. See State of South Carolina ex rel. Wilson v. Ortho-McNeil – Janssen Pharmaceuticals, Inc., et al., (Order of Feb. 25, 2011, No. 2007-CP-42-1438 at 15). Defendants may cross-examine Dr. Plunkett as to her education, experience and the documents that she may or may not have considered in rendering her opinion on this issue. Therefore, this motion is **DENIED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Plunkett.

Defendants' motion *in limine* to exclude testimony by Dr. Plunkett regarding Janssen's alleged failure to warn based on lack of qualifications.

Dr. Plunkett can offer opinions regarding the adequacy of Risperdal[®]'s label based upon her experience, training and education. The MDL judge in the federal Seroquel[®] litigation held that Dr. Plunkett is an expert in FDA regulations, pharmacology and toxicology; thus qualifying her to testify on this issue. In re: Seroquel Products Liability Litig., Case No. 6:06-md-1769-Orl-22DAB at 17 (M.D. Fl. July 20, 2009). As such, she is qualified to offer testimony on the effect Risperdal[®] has on a person's body and whether the drugs label adequately conveyed that message. Therefore, Defendants' motion is **DENIED**.

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500 Campus Drive
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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.)

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JUDGE JESSICA R. MAYER

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

ORDER ON DEFENDANTS' MOTION *IN LIMINE*
TO LIMIT THE TESTIMONY OF PLAINTIFFS' EXPERT
WILLIAM C. WIRSHING, M.D.

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 limit

the testimony of Plaintiffs' expert William C. Wirshing, M.D., 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~~^{NW} to limit the testimony of Plaintiffs' expert William C. Wirshing, M.D. is hereby ~~GRANTED~~ as follows:

1. Dr. Wirshing is prohibited from offering "state of mind" testimony; - *Granted in part*
2. Dr. Wirshing is prohibited from offering "bad company" testimony and/or any commentary about corporate ethics; - *Granted*
3. Dr. Wirshing is prohibited from offering regulatory history narrative and related legal interpretation; and - *Granted*
4. Dr. Wirshing is prohibited from offering opinions regarding the contents of Risperdal's FDA-approved labeling and related FDA regulations. - *Granted in part*

IT IS FURTHER ORDERED that a copy of this Order shall be ^{posted online} ~~served upon~~ plaintiffs' 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 this 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 limit the testimony of William C. Wirshing, M.D.

Defendants' motion *in limine* to exclude Dr. Wirshing's "state of mind" testimony.

Defendants seek to preclude "state of mind" testimony regarding Defendants' corporate knowledge, motivation and intent as such matters within the ken of the average juror and are not the proper subject of an expert's opinion. Plaintiffs respond that "Dr. Wirshing does not intend to offer expert testimony concerning Janssen's 'state of mind.'" See Plaintiffs' Brief in opposition to *in limine* motion ("Pl. Opp.") at 3. However, Plaintiffs argue that Dr. Wirshing should be permitted to testify regarding documents or other evidence from which the jury may infer corporate state of mind, intent, or knowledge. Pl. Opp. at 5. Furthermore, as a former lecturer, consultant, and clinical trial director for Janssen, Plaintiffs assert that Dr. Wirshing is a fact witness and should be permitted to present factual testimony regarding Janssen's internal decisions and affairs based upon his personal knowledge and experience. Pl. Opp. at 2.

This court finds that Dr. Wirshing may not testify regarding the intent, motives or state of mind of Defendants. Such testimony does not require specialized expertise for the jury to understand the issues. The jury may infer corporate knowledge, motive and intent based upon the evidence and the arguments of counsel. The court must await the trial testimony to determine whether Dr. Wirshing has factual information that may be relevant and admissible in these cases. Therefore, Defendants' motion is **GRANTED IN PART**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of William C. Wirshing, M.D.

Defendants' motion *in limine* to exclude Dr. Wirshing's "bad company" testimony and/or commentary about corporate ethics.

Plaintiffs do not intend to have Dr. Wirshing testify that Janssen is a "bad company" or offer his opinion regarding Janssen's corporate ethics. The court finds that Dr. Wirshing is not an expert on corporate ethics. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of William C. Wirshing, M.D.

Defendants' motion *in limine* to exclude Dr. Wirshing's regulatory history narrative and related legal interpretation.

Dr. Wirshing is psychiatrist and researcher in his field of expertise. Dr. Wirshing's work focuses on individuals suffering from schizophrenia and bipolar disorder. In addition to his active and extensive clinical practice, Dr. Wirshing has published and lectured in his field. Further, for approximately ten years, Dr. Wirshing served as a consultant, lecturer and clinical trial director for Janssen.

Based upon his knowledge, experience, training, and expertise as a practicing psychiatrist and prescriber of antipsychotic drugs, Dr. Wirshing is permitted to testify regarding the history of antipsychotic drugs, including Risperdal®, and the use of antipsychotic medications. However, legal interpretations are to be explained to the jury by the court. Therefore, Plaintiffs' expert should not give legal explanations to the jurors. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of William C. Wirshing, M.D.

Defendants' motion *in limine* to exclude Dr. Wirshing's opinions regarding the contents of Risperdal®'s FDA-approved labeling and related FDA regulations.

Dr. Wirshing is researcher and psychiatrist whose work focuses on individuals suffering from schizophrenia and bipolar disorder. He has an extensive clinical practice, has published articles regarding antipsychotic drugs, and has lectured on antipsychotic medications. Additionally, Dr. Wirshing served as a consultant, lecturer and clinical trial director for Janssen. Based on the foregoing, Dr. Wirshing may offer his opinions regarding the content of Risperdal®'s labeling based upon his knowledge and experience as a practicing clinician, psychiatrist, lecturer, author and researcher in the area of antipsychotic drugs.

However, Plaintiffs agree that Dr. Wirshing will not testify regarding FDA regulations governing labels, or opine that Defendants defrauded the FDA or failed to satisfy FDA standards. The FDA's requirements are legal matters for the court to explain to the jury. Counsel and expert witnesses may not offer legal explanations to the jury. The court will charge the jury on the applicable law at the conclusion of the testimony. Therefore, this motion is **GRANTED IN PART**.

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Attorneys for Defendants Johnson & Johnson
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FILED

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JUDGE JESSICA R. MAYER

IN RE: RISPERDAL/SEROQUEL/ : SUPERIOR COURT OF NEW JERSEY
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: *Gary D. Skala v. Johnson & Johnson*
: *Company, Janssen Pharmaceutica Products,*
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ORDER ON DEFENDANTS' MOTION *IN LIMINE*
TO LIMIT THE TESTIMONY OF PLAINTIFFS' EXPERT
WILLIAM C. WIRSHING, M.D.

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 limit

the testimony of Plaintiffs' expert William C. Wirshing, M.D., and the Court having considered the submissions of the parties and for good cause shown, ^A

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

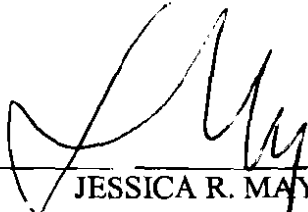
ORDERED that the ^{OW} ~~motion~~ to limit the testimony of Plaintiffs' expert William C.

Wirshing, M.D. is hereby ~~GRANTED~~ as follows:

1. Dr. Wirshing is prohibited from offering "state of mind" testimony; - *Granted in part*
2. Dr. Wirshing is prohibited from offering "bad company" testimony and/or any commentary about corporate ethics; - *Granted*
3. Dr. Wirshing is prohibited from offering regulatory history narrative and related legal interpretation; and - *Granted*
4. Dr. Wirshing is prohibited from offering opinions regarding the contents of Risperdal's FDA-approved labeling and related FDA regulations. - *Granted in part*

IT IS FURTHER ORDERED that a copy of this Order shall be ^{posted on line} ~~served upon plaintiffs' 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 limit the testimony of William C. Wirshing, M.D.

Defendants' motion *in limine* to exclude Dr. Wirshing's "state of mind" testimony.

Defendants seek to preclude "state of mind" testimony regarding Defendants' corporate knowledge, motivation and intent as such matters within the ken of the average juror and are not the proper subject of an expert's opinion. Plaintiffs respond that "Dr. Wirshing does not intend to offer expert testimony concerning Janssen's 'state of mind.'" See Plaintiffs' Brief in opposition to *in limine* motion ("Pl. Opp.") at 3. However, Plaintiffs argue that Dr. Wirshing should be permitted to testify regarding documents or other evidence from which the jury may infer corporate state of mind, intent, or knowledge. Pl. Opp. at 5. Furthermore, as a former lecturer, consultant, and clinical trial director for Janssen, Plaintiffs assert that Dr. Wirshing is a fact witness and should be permitted to present factual testimony regarding Janssen's internal decisions and affairs based upon his personal knowledge and experience. Pl. Opp. at 2.

This court finds that Dr. Wirshing may not testify regarding the intent, motives or state of mind of Defendants. Such testimony does not require specialized expertise for the jury to understand the issues. The jury may infer corporate knowledge, motive and intent based upon the evidence and the arguments of counsel. The court must await the trial testimony to determine whether Dr. Wirshing has factual information that may be relevant and admissible in these cases. Therefore, Defendants' motion is **GRANTED IN PART**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of William C. Wirshing, M.D.

Defendants' motion *in limine* to exclude Dr. Wirshing's "bad company" testimony and/or commentary about corporate ethics.

Plaintiffs do not intend to have Dr. Wirshing testify that Janssen is a "bad company" or offer his opinion regarding Janssen's corporate ethics. The court finds that Dr. Wirshing is not an expert on corporate ethics. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of William C. Wirshing, M.D.

Defendants' motion *in limine* to exclude Dr. Wirshing's regulatory history narrative and related legal interpretation.

Dr. Wirshing is psychiatrist and researcher in his field of expertise. Dr. Wirshing's work focuses on individuals suffering from schizophrenia and bipolar disorder. In addition to his active and extensive clinical practice, Dr. Wirshing has published and lectured in his field. Further, for approximately ten years, Dr. Wirshing served as a consultant, lecturer and clinical trial director for Janssen.

Based upon his knowledge, experience, training, and expertise as a practicing psychiatrist and prescriber of antipsychotic drugs, Dr. Wirshing is permitted to testify regarding the history of antipsychotic drugs, including Risperdal®, and the use of antipsychotic medications. However, legal interpretations are to be explained to the jury by the court. Therefore, Plaintiffs' expert should not give legal explanations to the jurors. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of William C. Wirshing, M.D.

Defendants' motion *in limine* to exclude Dr. Wirshing's opinions regarding the contents of Risperdal®'s FDA-approved labeling and related FDA regulations.

Dr. Wirshing is researcher and psychiatrist whose work focuses on individuals suffering from schizophrenia and bipolar disorder. He has an extensive clinical practice, has published articles regarding antipsychotic drugs, and has lectured on antipsychotic medications. Additionally, Dr. Wirshing served as a consultant, lecturer and clinical trial director for Janssen. Based on the foregoing, Dr. Wirshing may offer his opinions regarding the content of Risperdal®'s labeling based upon his knowledge and experience as a practicing clinician, psychiatrist, lecturer, author and researcher in the area of antipsychotic drugs.

However, Plaintiffs agree that Dr. Wirshing will not testify regarding FDA regulations governing labels, or opine that Defendants defrauded the FDA or failed to satisfy FDA standards. The FDA's requirements are legal matters for the court to explain to the jury. Counsel and expert witnesses may not offer legal explanations to the jury. The court will charge the jury on the applicable law at the conclusion of the testimony. Therefore, this motion is **GRANTED IN PART**.

#0048

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Docket No. MID-L-6820-06 :
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ORDER ON DEFENDANTS' MOTION *IN LIMINE*
TO LIMIT THE TESTIMONY OF PLAINTIFFS' EXPERT
JOEL ZONSZEIN, M.D.

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 limit
the testimony of Plaintiff's expert Joel Zonszein, M.D. and the Court having considered the
submissions of the parties and for good cause shown,

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

^{order}
ORDERED that the ~~motion~~ to limit the testimony of Plaintiffs' expert Joel Zonszein, M.D. is hereby ~~GRANTED~~ as follows: *

1. Dr. Zonszein is prohibited from testifying about Risperdal[®]'s history and Risperdal[®]'s regulatory history; - *Granted*
2. Dr. Zonszein is prohibited from offering his legal interpretation of FDA regulations; - *Granted*
3. Dr. Zonszein is prohibited from offering his personal opinions about Janssen's documents and Risperdal[®]'s labeling; - *Denied*
4. Dr. Zonszein is prohibited from offering state-of-mind testimony regarding the knowledge, motivations and intent of Janssen and the FDA; and - *Granted*
5. Dr. Zonszein is prohibited from offering testimony regarding the content or adequacy of Risperdal[®]'s labeling and/or the FDA's regulation of Risperdal[®]. - *Granted*

IT IS FURTHER ORDERED that a copy of this Order shall be ^{posted in line} 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.

FP01/6664392.1

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Zonszein.

Defendants' motion *in limine* to exclude Dr. Zonszein's testimony regarding the history of Risperdal[®] and its regulatory history.

Plaintiffs do not intend to have Dr. Zonszein testify about the history of Risperdal[®] or its regulatory history. If Plaintiffs pursue testimony from Dr. Zonszein on this topic, the court will determine, based on trial testimony, whether he has the requisite experience, background and training to offer an opinion. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Zonszein.

Defendants' motion *in limine* to exclude Dr. Zonszein's testimony regarding his legal interpretation of FDA regulations.

Plaintiffs agree that Dr. Zonszein will not offer opinions regarding his legal interpretation of FDA regulations. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Zonszein.

Defendants' motion *in limine* to exclude Dr. Zonszein's testimony regarding Janssen's documents and Risperdal[®]'s labeling.

Plaintiffs' experts may not use corporate documents to "provide a narrative history of [the corporation's] marketing and labeling practices." In re: Seroquel Products Liability Litig., Case No. 6:06-md-1769-Orl-22DAB, at 7 (M.D. Fl. July 20, 2009). Such testimony is within the knowledge of the average juror and does not require expert testimony.

However, Dr. Zonszein will be permitted to testify as to the Janssen documents that he relied upon in forming his opinions. The fact that Plaintiffs' counsel may have selected documents for Dr. Zonszein to review goes to the weight a jury may accord his testimony but does not render his testimony inadmissible. At trial, the court will determine if there is a sufficient foundation for Dr. Zonszein to comment on specific documents. Therefore, this motion is **DENIED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Zonszein.

Defendants' motion *in limine* to preclude Dr. Zonszein from offering state of mind testimony regarding the knowledge, motivation or intent of Janssen and the FDA.

Plaintiffs agree that Dr. Zonszein will not offer opinions regarding the knowledge, motivation or intent of Janssen and the FDA. Therefore, this motion is **GRANTED**.

Memorandum of Decision on Defendants' motion *in limine* to limit the testimony of Dr. Zonszein.

Defendants' motion *in limine* to exclude Dr. Zonszein's commentary on the content or adequacy of Risperdal[®]'s labeling and/or FDA's regulation of Risperdal[®].

Plaintiffs do not intend to have Dr. Zonszein testify about the content or adequacy of Risperdal[®]'s labeling and/or FDA's regulation of Risperdal[®]. If Plaintiffs pursue testimony from Dr. Zonszein on this topic, the court will determine based on trial testimony whether he has the necessary experience, background and training to offer an opinion. Therefore, this motion is **GRANTED**.