

THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

State of South Carolina ex. rel. Alan Wilson in his
capacity as Attorney General of the State of South
Carolina, ... Respondent,

v.

Ortho-McNeill-Janssen Pharmaceuticals, Inc., f/k/a
Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and
Johnson & Johnson, Inc., ... Defendants.

Of whom Ortho-McNeill-Janssen Pharmaceuticals, Inc.
is Appellant.

RECORD ON APPEAL - VOLUME XX

**Nelson Mullins Riley
& Scarborough LLP**
C. Mitchell Brown
William C. Wood, Jr.
A. Mattison Bogan
Miles E. Coleman
Post Office Box 11070
Columbia, SC 29201
(803) 799-2000

**Richardson Plowden
& Robinson, P.A.**
Steven J. Pugh
Steven W. Hamm
Mason A. Summers
1900 Barnwell Street
Post Office Drawer 7788
Columbia, SC 29202
(803) 771-4400

**Drinker Biddle
& Reath LLP**
Edward M. Posner
Chanda A. Miller
One Logan Square
Suite 2000
Philadelphia, PA 19103
(215) 988-2700

Attorneys for Appellant

**Office of Attorney
General**
The Honorable Alan
Wilson
C. Havird Jones, Jr.
1000 Assembly Street
Room 519
Columbia, SC 29201
(803) 734-3656

Bailey Perrin Bailey
Fletcher V. Trammell
Robert W. Cowan
Elizabeth W. Dwyer
440 Louisiana, Ste 2100
Houston, TX 77002
(713) 425-7100

**Harrison White Smith &
Coggins, P.C.**
John B. White, Jr.
Donald C. Coggins, Jr.
178 West Main Street
Post Office Box 3547
Spartanburg, SC 29304
(864) 585-5100

Simmons Law Firm, LLC
John S. Simmons
1711 Pickens Street
Columbia, SC 29202
(803) 779-4600

Attorneys for Respondent

INDEX TO RECORD ON APPEAL

PAGE

VOLUME ONE

I. ORDERS/JUDGMENTS

Order of Remand, dated July 10, 2007	1
Order Denying the State's Motion for Non-Jury Determination, dated August 27, 2011	7
Order Regarding Defendant's Motions for Summary Judgment and Parties' Motions <i>in Limine</i> , dated February 25, 2011	8
Penalty Order, dated June 3, 2011	27
Order Denying Defendant's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, dated December 20, 2011	44
Order Denying Defendant's Motion to Alter or Amend the Judgment and/or for a New Trial, dated December 20, 2011	50
Order Granting the State's Motion to Transfer Case and Certify the Case for Review by this Court, dated February 27, 2012	56

II. PLEADINGS

Complaint, filed April 23, 2007	58
Second Amended Complaint, filed March 19, 2010	102
Defendants' Answer to Plaintiff's Second Amended Civil Action Complaint, filed April 11, 2010	121

III. TRANSCRIPTS

<u>Hearing Transcript, February 2, 2011</u>	143
MOTIONS	143
<u>Transcript of Trial, March 7-22, 2011</u>	182
MOTIONS	194
PLAINTIFF'S OPENING STATEMENT	320

PUBLISHED DEPOSITION OF MAGALI HAAS 366

PUBLISHED DEPOSITION OF SALLY BERRY 399

TESTIMONY OF WILLIAM WIRSHING

Direct Examination by Mr. Trammell 414

VOLUME TWO (Begins at R. 501)

Cross Examination by Mr. Campion 593

Redirect Examination by Mr. Trammell 674

TESTIMONY OF LAURA PLUNKETT

Direct Examination by Mr. Trammell 687

Cross Examination by Mr. Murphy 885

VOLUME THREE (Begins at R. 1001)

Redirect Examination by Mr. Trammell 1038

Re-Cross Examination by Mr. Murphy 1078

Redirect Examination by Mr. Trammell 1084

PUBLISHED DEPOSITION OF EDWARD BRANN 1087

PUBLISHED DEPOSITION OF DONNA OHYE 1116

TESTIMONY OF ANGIE ALDERMAN

Direct Examination by Mr. White 1139

Cross Examination by Mr. Pugh 1175

Redirect Examination by Mr. White 1177

PUBLISHED DEPOSITION OF GAHAN PANDINA 1186

PUBLISHED DEPOSITION OF RILEY SMITH 1208

TESTIMONY OF JAMES ASSEY

Direct Examination by Mr. Coggins 1214

Cross Examination by Mr. Murphy 1230

Redirect Examination by Mr. Coggins	1236
Re-Cross Examination by Mr. Murphy	1244
Redirect Examination by Mr. Coggins	1245
Re-Cross Examination by Mr. Murphy	1248
PUBLISHED DEPOSITION OF RONALD KALMEIJER	1249
PUBLISHED DEPOSITION OF JOHN JACOPPI	1251
PUBLISHED DEPOSITION OF PHILOMENA MCARTHUR	1256
PUBLISHED DEPOSITION OF PATRICIA DESANTIS	1282
PUBLISHED DEPOSITION OF AMY GROGG	1284
PUBLISHED DEPOSITION OF OLGA MITELMAN	1295
TESTIMONY OF DAVID PATTERSON	
Direct Examination by Mr. Coggins	1299
Redirect Examination by Mr. Coggins	1316
Re-Cross Examination by Mr. Pugh	1317
PUBLISHED DEPOSITION OF IVO CAERS	1320
MOTION	1331
TESTIMONY OF RAMY MAHMOUD	
Direct Examination by Mr. Campion	1371
VOLUME FOUR (Begins at R. 1484)	
Cross Examination by Mr. Trammell	1484
Redirect Examination by Mr. Campion	1645
Re-Cross Examination by Mr. Trammell	1665
TESTIMONY OF IVO CAERS	
Direct Examination by Mr. Campion	1672
MOTION	1722

TESTIMONY OF IVO CAERS

Cross Examination by Mr. Simmons.....1726

TESTIMONY OF MICHAEL CHESTER

Direct Examination by Mr. Pugh.....1763

Cross Examination by Mr. Coggins.....1819

MOTION.....1887

TESTIMONY OF MICHAEL CHESTER

Cross Examination by Mr. Coggins.....1906

Redirect Examination by Mr. Pugh 1919

Re-Cross Examination by Mr. Coggins.....1922

TESTIMONY OF SHELDON BRADSHAW

Direct Examination by Mr. Murphy 1925

VOLUME FIVE (Begins at R. 1980)

Cross Examination by Mr. Simmons.....1980

TESTIMONY OF ROBERT BANK

Direct Examination by Mr. Murphy 1987

Cross Examination by Mr. White 2005

Redirect Examination by Mr. Murphy.....2024

Re-Cross Examination by Mr. White.....2025

TESTIMONY OF BRENDA RATLIFF

Direct Examination by Mr. Murphy 2029

Cross Examination by Mr. White 2043

Redirect Examination by Mr. Murphy.....2058

Re-Cross Examination by Mr. White.....2060

PUBLISHED DEPOSITION OF JOHN WILLIAMS.....2082

PUBLISHED DEPOSITION OF PAM DERUITER	2084
MOTIONS	2086
TESTIMONY OF DAVID FABBRI	
Direct Examination by Mr. Pugh	2103
Cross Examination by Mr. Coggins	2140
Redirect Examination by Mr. Pugh	2210
Re-Cross Examination by Mr. Coggins	2216
Redirect Examination by Mr. Pugh	2217
TESTIMONY OF JOHN NEWCOMER	
Direct Examination by Mr. Murphy	2221
Cross Examination by Mr. Trammell	2269
Redirect Examination by Mr. Murphy	2313
PUBLISHED DEPOSITION OF EDWARD BRANN	2339
MOTIONS	2340
PLAINTIFF'S CLOSING ARGUMENT	2418
DEFENDANTS' CLOSING ARGUMENT	2454
PLAINTIFF'S CLOSING ARGUMENT	2457
CHARGE BY THE COURT	2469

VOLUME SIX (Begins at R. 2480)

<u>Transcript of Penalty Hearing, April 18-19, 2011</u>	2539
PLAINTIFF'S OPENING STATEMENT	2546
TESTIMONY OF JAMES WOODLOCK	
Direct Examination by Mr. Coggins	2559
Cross Examination by Mr. Murphy	2595
Redirect Examination by Mr. Coggins	2607

Re-Cross Examination by Mr. Murphy	2612
TESTIMONY OF JAY SMITH	
Direct Examination by Mr. Coggins.....	2616
Cross Examination by Mr. Pugh.....	2629
PLAINTIFF'S PRESENTATIONS	2646
DEFENDANT'S OPENING STATEMENT	2712
TESTIMONY OF JOHN NEWCOMER	
Direct Examination by Mr. Murphy	2743
Cross Examination by Mr. Trammell	2760
Redirect Examination by Mr. Murphy.....	2767
Re-Cross Examination by Mr. Trammell.....	2769
TESTIMONY OF WILLIAM WECKER	
Direct Examination by Mr. Campion.....	2770
Cross Examination by Mr. Trammell	2812
Redirect Examination by Mr. Campion.....	2834
Re-Cross Examination by Mr. Trammell.....	2836
PLAINTIFF'S CLOSING STATEMENT	2875
DEFENDANT'S CLOSING STATEMENT	2889

IV. CHARGES

Plaintiff the State of South Carolina's Proposed Requests for Charge, filed March 17, 2011	2903
Defendants' Requested Jury Instructions, filed March 17, 2011	2913
Plaintiff the State of South Carolina's Request for Charge No. 1; Amended Request for Charge No. 6; Request for Charge No. 7; Request for Charge No. 8; and Amended Proposed Form of Verdict, filed March 18, 2011	2957

VOLUME SEVEN (Begins at R. 2966)

Plaintiff the State of South Carolina's Objections to Defendants' Requested Jury Instructions, filed March 18, 2011	2966
Defendants' Requested Verdict Sheet, filed March 18, 2011	2985
Defendants' Objections to Plaintiff's Proposed Requests for Charge and Proposed Verdict Sheet and Defendants' Request for Corrective Instruction, filed March 20, 2011	3000
Verdicts as to Johnson & Johnson, Inc. and Ortho-McNeil-Janssen Pharmaceutica, Inc., f/k/a Janssen Pharmaceutica Inc., and/or Janssen L.P., filed March 22, 2011	3030

V. EXHIBITS

Plaintiff's Trial Exhibits:

P0077 Risperdal Business Plan 2004.....	3034
P0164 Letter from R. Katz to V. Wagner-Weber, dated May 1, 2000	3087
P0165 E-mail from S. Dodd to R. Mahmoud and others, dated July 20, 2000	3089
P0166 E-mail from A. Grogg to J. Vandenbossche and others, dated August 1, 2000	3094
P0167 E-mail from A. Grogg to J. Vandenbossche and others, dated August 1, 2000	3095
P0200 Letter from L. Stockbridge to T. McIntyre, dated January 5, 1999	3102
P0232 Letter from T. Abrams to A. Shetty, dated April 19, 2004.....	3107
P0254 E-mail from R. Mahmoud to N. Dac and others, dated October 10, 2000	3112
P0280 August 2008 Risperdal Package Insert.....	3115
P0357 Diabetes Package Insert Revision, Field Training, dated November 2003	3127
P0387 Field Training, dated October 31, 2003	3157

P0435 Risperdal Hyperglycemia/Diabetes Labeling power point, IDC, dated January 13, 2004	3197
P0438 Letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated July 21, 2004	3229
P0442 Trial 113 Topline Results, dated September 9, 1999.....	3231
P0462 E-mail from S. Reines to G. Pruden, dated October 23, 2003.....	3246
P0477 E-mail from S. Reines to J. Grebb, dated November 30, 2003	3247
P0520 Letter from R. Katz to C. McGowan, dated September 12, 2003	3249
P0571 Letter from R. Temple to R. Wasserman, dated December 29, 1993	3253
P0631 1996 Risperdal Package Insert (published in 1997 Physicians' Desk Reference).....	3257
P0640 2006 Risperdal Package Insert.....	3263
P0641 March 2006 Risperdal Package Insert (published in 2007 Physicians' Desk Reference)	3270
P0643 1994 Risperdal Package Insert.....	3278
P0648 July 1998 Risperdal Package Insert.....	3283
P0649 May 1999 Risperdal Package Insert	3287
P0653 December 2000 Risperdal Package Insert	3291
P0656 Revised July 2002 Risperdal Package Insert.....	3295
P0657 March 2003 Risperdal Package Insert	3299
P0661 December 2003 Risperdal Package Insert	3303
P0662 February 2005 Risperdal Package Insert	3311
P0665 October 2006 Risperdal Package Insert.....	3351
P1027 Letter from S. Danese to R. Wasserman, dated February 9, 1994	3397

VOLUME EIGHT (Begins at R. 3406)

P1078 Risperdal 2003 Business Plan Summary	3406
--	------

P1105 E-mail from C. Shaw to B. Goff, dated September 17, 2003	3493
P1224 October 2001 Risperdal Package Insert.....	3496
P1264 Risperdal 2000 Business Plan.....	3501
P1552 Risperdal Growth Acceleration, dated February 26, 2001	3552
P1564 Differential Effects of Antipsychotics on Type II Diabetes, presented May 3-5, 2001.....	3676
P1662 Janssen First Cycle 1999	3680
P1670 Risperdal Q&A, dated July 26, 1996.....	3747
P1728 Letter from E. Brann to R. Katz, dated August 10, 2000	3753
P1731 Letter from D. Ohye to T. Abrams, dated April 28, 2004	3758
P1736 Letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated November 10, 2003.....	3762
P1741 Janssen submission to FDA, dated August 8, 2000.....	3764
P2049 September 1996 Risperdal Package Insert	3777
P2061 April 1995 Risperdal Package Insert	3781
P2352 Draft letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated November 2003.....	3788
P2353 Draft letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated November 2003.....	3790
P2354 Draft letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated November 2003.....	3791
P2364 E-mail from S. Reines to J. Waldstreicher, dated April 28, 2004	3792
P2610 Letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated April 16, 2003	3795
P2613 E-mail from S. Reines to F. Grossman, dated March 10, 2004.....	3801
P2614 E-mail from S. Reines to F. Grossman, dated June 10, 2004.....	3805
P2618 Risperdal Training Meeting.....	3806

VOLUME NINE (Begins at R. 3906)

P2651 E-mail from G. Pruden to R. Mahmoud, dated October 5, 2003	3973
P2653 Abbreviated Clinical Study Report, Trial 113, dated December 18, 1997 – February 26, 1999	3976

VOLUME TEN (Begins at R. 4406)

P2653 Abbreviated Clinical Study Report, Trial 113, dated December 18, 1997 – February 26, 1999, Cont.	4406
--	------

VOLUME ELEVEN (Begins at R. 4906)

P2653 Abbreviated Clinical Study Report, Trial 113, dated December 18, 1997 – February 26, 1999, Cont.	4906
--	------

VOLUME TWELVE (Begins at R. 5406)

P2653 Abbreviated Clinical Study Report, Trial 113, dated December 18, 1997 – February 26, 1999, Cont.	5406
P2662 Draft letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated November 2003	5430
P2682 Memo Regarding Medication Problem, Trial 113, dated September 22, 1999	5431

Plaintiff's Penalty Hearing Exhibits:

P1 Letter from S. Pugh to D. Coggins, dated April 13, 2011	5436
P6 Sample Call Note Data	5439
P7 Call Note Report Generated by James Woodlock	5441
P8 Call Note Report Generated by James Woodlock	5443
P9 Call Note Example.....	5446
P17 Court Filings (Offered; not admitted into evidence)	5447
P18 Johnson & Johnson 2010 Annual Report	5590
P19 Johnson & Johnson 2004 Annual Report	5668
P20 Johnson & Johnson 2003 Annual Report	5746
P21 Plaintiff's Calculations Regarding Potential Violations.....	5820

P22 Johnson & Johnson 10-K for Fiscal Year Ended January 2, 2011 (Offered; not admitted into evidence).....	5825
P2720 Plaintiff's Calculations Regarding Sample Quantity Data	5835
P2722 Plaintiff's Calculations Regarding Number of Sales Calls When Samples Were Left	5836

Defendants' Trial Exhibits:

D0351 Letter from Janssen Pharmaceutica Inc. to Healthcare Providers with Risperdal Package Insert, dated November 10, 2003	5837
D0442 Letter from Janssen Pharmaceutica Inc. to Healthcare Providers, dated July 21, 2004	5843
D0498 August 2007 Risperdal Package Insert	5851

VOLUME THIRTEEN (Begins at R. 5899)

D0807 Volume 1 of the 2000 Submission to FDA.....	5899
D0821 Volume 15 of the 2000 Submission to FDA.....	6165

VOLUME FOURTEEN (Begins at R. 6384)

D0841 Letter from R. Katz to E. Brann, dated March 3, 2002.....	6384
D0843 Letter from R. Katz to M. Zoschg, dated December 4, 2003.....	6418
D0919 Letter from S. Merchant to R. Katz, dated March 29, 2004	6457

VOLUME FIFTEEN (Begins at R. 6884)

D3097 Letter from R. Katz to V. Wagner-Weber, dated May 1, 2000	7051
D3140 Letter from E. Brann to R. Katz, dated September 24, 2003	7053
D3175 Letter from R. Katz to C. McGowan, dated September 11, 2003.....	7063
D3179 Letter from S. Merchant to R. Katz, dated November 26, 2003	7066
D3180 Letter from R. Katz to S. Merchant, dated November 21, 2003	7077
D4337 Chapter 4 of the 2004 Version of the FDA's Regulatory Procedures Manual.....	7080
D6211 Letter from S. Merchant to R. Katz, dated April 18, 2002	7119

D6253 Letter from M. Brony to D. Ohye, dated October 14, 2004.....	7315
D7008 Expert Report of William E. Wecker, Ph.D., dated December 3, 2010 (Referred to in Trial Transcript as “Def. Exh. A.”)	7318
D7174 Chart of South Carolina Department of Health and Human Services Drug Utilization Review Program – Patient Drug History Profile	7367
D7185 “Consensus Development Conference on Antipsychotic Drugs and Obesity and Diabetes,” The Journal of Clinical and Applied Research and Education Diabetes Care, 27:2 (2004); 596-601	7375

VOLUME SIXTEEN (Begins at R. 7382)

D7186 SC-DMH Laboratory Monitoring Guidelines for Antipsychotic Medications	7382
D7294 IND 31,931 Risperidone Tablets Annual Report July 1, 1998 – June 30, 1999.....	7388
D7336 Letter from W. Murray Yarbrough to T. Engles, dated September 19, 2003.....	7489
D7337 South Carolina Medicaid & SHP Claims Data, June 2003-October 2004 (Referred to in Trial Transcript as “Def. Exh. B”).....	7494
D7338 South Carolina Medicaid & SHP Claims Data, November 2004-December 2005 (Referred to in Trial Transcript as “Def. Exh. C”).....	7495

Defendants’ Penalty Hearing Exhibits:

D2 2007 Zyprexa Package Insert (Offer of proof; not admitted into evidence).....	7496
D5 South Carolina Fee for Service, State Health Plan, and HMO Claims Data – Antipsychotic Prescriptions by Month	7532
D6 Calculation of Net Cost of Risperdal to the State (Columns 1-7 admitted).....	7533

Court’s Exhibits:

C-2 Federal Regulations	7540
-------------------------------	------

C-3 Court's Rulings on Objections to Openings	7584
C-4 Defendants' Offer of Proof	7586
C-5 Charge by Court.....	7654
C-6 Question from the Jury.....	7670
C-7 Question from the Jury.....	7671

Physical Exhibit:

P5 Hard Drive containing sales call data produced by Defendants	7672
---	------

VI. MISCELLANEOUS AND OTHER MOTIONS

Tolling Agreement, dated February 20, 2007	7673
Notice of Removal, filed May 22, 2007	7678
Plaintiff the State of South Carolina's Motion to Exclude the Testimony of Certain Risperdal Prescribers at Trial, filed July 2, 2010.....	7737
Defendants' Motion <i>in Limine</i> and Memorandum of Law in Support Thereof to Preclude the Introduction into Evidence of the April 19, 2004 DDMAC Letter and Any Evidence of or Reference to the Letter at Trial, filed January 7, 2011.....	7747
Plaintiff the State of South Carolina's Notice of Motion and Motion to Exclude the Expert Testimony of Sheldon Bradshaw, filed January 13, 2011	7817

VOLUME SEVENTEEN (Begins at R. 7837)

Plaintiff the State of South Carolina's Motion to Exclude the Expert Testimony of Dr. William E. Wecker, filed January 13, 2011	7837
Plaintiff the State of South Carolina's Response in Opposition to Defendants' Motion <i>in Limine</i> to Preclude the Introduction of Evidence of the April 19, 2004 DDMAC Letter and Any Evidence of or Reference to the Letter at Trial, filed January 18, 2011	8093
Defendants' Memorandum of Law in Opposition to Plaintiff's Motion to Exclude the Testimony of Certain Risperdal Prescribers at Trial, filed January 20, 2011	8102

Plaintiff the State of South Carolina's Response in Opposition to Defendants' Motion for Summary Judgment as to Plaintiff's Unfair Trade Practices Claim Based on November 10, 2003 Mailing, filed January 21, 2011	8171
--	------

VOLUME EIGHTEEN (Begins at R. 8325)

Plaintiff the State of South Carolina's Response in Opposition to Defendants' Motion for Summary Judgment as to Plaintiff's Unfair Trade Practices Act Claim Based on the FDA Approved Package Insert, filed January 21, 2011	8325
Defendants' Memorandum of Law in Opposition to Plaintiff's Motion to Exclude the Expert Testimony of Dr. William E. Wecker, filed January 21, 2011	8344
Plaintiff the State of South Carolina's Reply to Defendants' Response in Opposition to the State's Motion to Exclude the Expert Witness Testimony of Defendants' Expert Witness, Dr. William E. Wecker, filed January 31, 2011	8483
Defendants' Objections to Plaintiff's Opening Statement, filed March 8, 2011	8525
Plaintiff the State of South Carolina's Response in Opposition to Defendants' Objections to Plaintiff's Opening Statement, filed March 14, 2011	8530
Defendants' Motion for a Directed Verdict and Memorandum of Law in Support Thereof, filed March 14, 2011	8600
Plaintiff the State of South Carolina's Response in Opposition to Defendants' Motion for a Directed Verdict, filed March 15, 2011	8632
Defendants' Reply in Support of Motion for a Directed Verdict, filed March 15, 2011	8664
Plaintiff the State of South Carolina's Motion for a Directed Verdict as to Defendants' Eighth Affirmative Defense on Statute of Limitations, filed March 21, 2011	8667
Defendants' Offer of Proof for the Expert Testimony of Dr. William E. Wecker, filed March 21, 2011	8696

VOLUME NINETEEN (Begins at R. 8803)

Defendants' Offer of Proof for the Post-2007 FDA-Approved Package Insert for Zyprexa and the 2010 FDA-Approved Package Insert for Latuda, filed March 21, 2011	8803
Defendants' Renewed Motion for a Directed Verdict and Memorandum of Law in Support Thereof, filed March 21, 2011	8870
Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc.'s Motion and Memorandum in Support Thereof for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, filed April 1, 2011	9030
Plaintiff's Pre-trial Brief to the Court (Civil Penalty Phase), filed April 15, 2011	9107
Janssen's Penalty Hearing Brief, filed April 15, 2011	9115
Plaintiff the State of South Carolina's Memorandum of Law in Support of its Response in Opposition to Defendant's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, filed April 15, 2011	9225

VOLUME TWENTY (Begins at R. 9303)

Defendant's Offer of Proof for the Testimony of Prescriber Physicians; and Robert L. Bank, M.D., and Brenda Ratliff, M.D., filed April 18, 2011	9343
Plaintiff the State of South Carolina's Post Civil Penalties Hearing Submission, filed May 3, 2011	9401
Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc.'s Post-Penalty Hearing Brief, filed May 3, 2011	9426
Reply Memorandum of Law in Support of Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc.'s Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, filed May 3, 2011	9440
Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc.'s Motion and Memorandum of Law in Support Thereof to Alter or Amend the Judgment and/or for a New Trial, June 13, 2011	9455
Plaintiff the State of South Carolina's Response in Opposition to Defendant's Motion to Alter or Amend the Judgment and/or For a New Trial, filed July 7, 2011	9492

Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc.'s Reply in Support of its Motion to Alter or Amend the Judgment and/or for a New Trial, filed July 15, 2011	9525
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VII. CERTIFICATE OF COUNSEL

letters that statements at issue were false and misleading); *Schering-Plough Healthcare Prods. v. Schwarz Pharma, Inc.*, 586 F.3d 500, 508 (7th Cir. 2009) (concluding that letters from “subordinate officials of the FDA” were not “final agency action *binding on the district court*”) (emphasis added); *Genendo Pharm. N.V. v. Thompson*, 308 F. Supp. 2d 881, 885 (N.D. Ill. 2003) (holding that claims for declaratory and injunctive relief regarding conduct alleged to be permissible under the FDCA were not ripe due to absence of final agency action where oral statements of subordinate FDA officials were found not to constitute final agency action).

In the only other case Defendant cites, the court simply held that the plaintiff could not prove falsity under the Lanham Act solely through statements in FDA letters describing the alleged conduct as inadequately substantiated because the Lanham Act requires a showing of actual falsity. *Bracco Diagnostics, Inc. v. Amersham Health, Inc.*, 627 F. Supp. 2d 384, 469-71 (D.N.J. 2009). At most, those cases stand for the proposition that regulatory evidence such as the DDMAC letters cannot be used as sole evidence of liability, not that such evidence can never be used. *See id.* at 471 (not excluding FDA letters where plaintiff introduced other evidence of falsity).

Further, Defendant’s assertion that the DDMAC letters are merely “informal and advisory” is expressly contradicted by the *conclusions* the FDA reached in the letters themselves—e.g., “[f]ailure to correct the violations . . . may result in FDA regulatory action, including seizure of injunction, without further notice” (2004 Warning Letter (Pl.’s Ex. 232 at 5)); “DDMAC has concluded that the [2003 Dear Doctor Letter] is false or misleading in violation of Sections 502(a) and 201(n) of the [FDCA] (21 U.S.C. 352(a) and 321 (n))” (2004 Warning Letter (Pl.’s Ex. 232 at 1)); “DDMAC has concluded that these materials are false, misleading, and/or lacking in fair balance, and in violation of the [FDCA]” (1999 Notice of

Violation (Pl.'s Ex. 200 at 1)); "The materials and promotional messages Janssen has disseminated contain false and/or misleading information about the safety and effectiveness of Risperdal. . . . Accordingly, Janssen should immediately discontinue the use of all materials that state, suggest, or imply false, misleading, or unbalanced claims of the type discussed in this letter." (1999 Notice of Violation (Pl.'s Ex. 200 at 4)); "[DDMAC] offer[s] the following comments: . . . (15) 'excellent safety profile.' 'An outstanding safety profile that offers excellent potential for compliance.' These claims are misleading. The adverse event rates of risperidone are not consistent with claims for an outstanding or excellent safety profile." (1994 Pre-Marketing Letter (Pl.'s Ex. 1027 at 1, 5)).⁴¹

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P. 4:45
M. H. P. LARLEY

b. The DDMAC Letters Were Not Hearsay, or, Alternatively, They Were Subject to the "Public Records and Reports" Exception to the Hearsay Rule.

The DDMAC letters were not hearsay because they were not offered to prove the truth of the matter asserted—i.e., that Defendant's 2003 Dear Doctor Letter and the promotional conduct referenced in the 1994 Pre-Marketing Letter and the 1999 Notice of Violation were "false and misleading" as a matter of law. *See* S.C.R. Evid. 801(c). The State did not take the position at trial that because the FDA deemed the 2003 Dear Doctor Letter false and misleading in the 2004 Warning Letter, the 2003 Dear Doctor Letter was therefore "deceptive" or "unfair" as a matter of law under SCUTPA. That ultimate question was for the jury to determine based upon all the evidence presented. Whether its conclusions are right or wrong, the 2004 Warning Letter was offered only to show that the FDA had undertaken a review of the November 10, 2003 Dear Doctor Letter, why the FDA engaged in such a review, and the official conclusions that the FDA

⁴¹ Additionally, the *Regulatory Procedures Manual* Defendant cites further clarifies that the "Warning Letter was developed to correct violations of the statutes or regulations" and "[its use is] based on the expectation that most individuals and firms will voluntarily comply with the law" as set forth in the Warning Letter. (D4337 at 4-1 to 4-2 (emphases added).)

reached. *See, e.g., State v. Thompson*, 575 S.E.2d 77, 81 (S.C. Ct. App. 2003) (“An out of court statement is not hearsay if it is offered for the limited purpose of explaining why a government investigation was undertaken.”) (quoting *State v. Brown*, 451 S.E.2d 888, 893-94 (S.C. 1994)). Of course, Defendant was free to offer admissible evidence countering those facts and conclusions, and it did so, as discussed more fully below.

Nor did the State did not take the position at trial that because the FDA deemed Defendant's promotional conduct referenced in the 1994 Pre-Marketing letter and the 1999 Notice of Violation false and misleading, it was therefore “deceptive” or “unfair” as a matter of law under SCUTPA. Indeed, the State did not contend that such conduct violated SCUTPA. Whether its conclusions are right or wrong, the 1994 Pre-Marketing letter and the January 1999 Notice of Violation were offered only to show that the FDA had undertaken a review of Defendant's promotional materials, why the FDA engaged in such a review, and the official conclusions that the FDA reached. *See, e.g., Thompson*, 575 S.E.2d at 81. Again, Defendant was free to offer admissible evidence countering those facts and conclusions. As the DDMAC letters were not introduced to prove the truth of the matter asserted, they were not hearsay.

Assuming *arguendo* that the DDMAC letters were hearsay, they fell within the “Public Records and Reports” exception to the hearsay rule. *See* S.C.R. Evid. 803(8). That exception specifically exempts the “[r]ecords, reports, statements, or data compilations, in any form, of public offices or agencies, setting forth (A) the activities of the office or agency, or (B) matters observed pursuant to duty imposed by law as to which matters there was a duty to report” *See, e.g., State v. Cutro*, 618 S.E.2d 890, 896 (S.C. 2005) (ruling that Rule 803(8) excepts, for example, autopsy reports generated pursuant to law). Plainly, the DDMAC letters constitute records, reports, or statements by a public office or agency (the FDA) and set forth the activities

the FDA undertook relative to Defendant's promotional conduct, as well as discuss matters observed pursuant to the FDA's legally authorized mission to police prescription drug labeling, including communications to doctors about prescription drugs. *See* 21 U.S.C. § 352 (governing authority under which FDA regulates prescription drug labeling).

Defendant hopes to avoid the above result by mischaracterizing the DDMAC letters as merely the "authors' 'opinions, judgments, and conclusions,'" which it argues are not covered by the Rule 803(8) exception. However, as discussed more fully above, the DDMAC letters were not just the conclusions of a lone-wolf FDA employee. And, in any event, Rule 803(8)'s limitation as to "opinions, judgments, and conclusions" expressly applies only to "investigative notes," not to an agency conclusion, as here. S.C.R. Evid. 803(8) (emphasis added). Thus, even if the DDMAC letters were hearsay, they fell within the exception of Rule 803(8) and were properly admitted.

c. The Probative Value of the DDMAC Letters Was Not Substantially Outweighed by the Danger of Unfair Prejudice.

The significant probative value of the DDMAC letters was not substantially outweighed by the danger of unfair prejudice because the jury was reasonably able to understand the information in the DDMAC letters and to distinguish between liability under SCUTPA and violation of the FDCA or FDA regulations. Those letters were highly probative of whether Defendant's alleged conduct was deceptive or unfair, whether Defendant knew or should have known that its alleged conduct was deceptive or unfair, and whether Defendant's conduct adversely affected the public interest. Those letters were also relevant to and placed into issue by Defendant's "safe harbor," federal preemption, and "primary jurisdiction" arguments. For the same reasons, the State's related statements to the jury about Defendant breaking the rules and the law were proper and not unfairly prejudicial, as Defendant asserts.

Moreover, both the State and Defendant presented their positions about the FDA investigations and conclusions described in the DDMAC letters, as well as the meaning of “false,” “misleading,” and other terms used therein.⁴² Both sides also presented expert testimony about those matters, including the accuracy of the conclusions set forth in the DDMAC letters.⁴³ With that assistance, the jury could easily understand the information contained in the DDMAC letter and was not misled or confused about standards of liability, and the use of the DDMAC letters at trial did not convey the appearance of presumptive wrongdoing. To the extent Defendant failed to present argument or expert testimony and cross-examine the State’s expert witnesses regarding the matters with which it takes issue, Defendant cannot now complain about unfair prejudice.

Any danger of unfair prejudice here must be weighed against the need to provide the jury with the entire picture so that it could properly decide to what extent Defendant’s misconduct had occurred; the mere fact that the information contained in the DDMAC letters is unfavorable to Defendant does not alone sustain its claims of prejudice. The term “prejudice” does not mean that it is detrimental to a party’s case because all evidence offered against a party is “prejudicial”; rather, it means that the evidence will have an *undue tendency* to suggest a decision on an improper basis. *State v. Wiles*, 679 S.E.2d 172, 176 (S.C. 2009). That was not the case with the DDMAC letters.

Finally, even if Defendant had suffered some prejudice—which it did not for the reasons

⁴² See, e.g., Trial Tr. at 200:19-207:16 (opening argument by the State regarding the 2004 Warning Letter and related events); *id.* at 265:10-266:3 (opening argument by Defendant regarding same); *id.* at 2646:18-21, 2663:3-23 (closing argument by the State regarding 1999 Notice of Violation and 2004 Warning Letter); *id.* at 2701:12-15, 2712:16-2713:2 (closing argument by Defendant regarding all three DDMAC letters).

⁴³ See, e.g., Trial Tr. at 465:21-489:4 (testimony of William Wirshing, M.D. regarding 2004 Warning Letter); *id.* at 700:20-703:16 (testimony of Laura Plunkett, Ph.D., D.A.B.T. regarding 1994 Pre-Marketing Letter); *id.* at 1096:25-1107:23 (testimony of Dr. Plunkett regarding 1999 Notice of Violation); *id.* at 759:23-762:6 (testimony of Dr. Plunkett regarding 2004 Warning Letter); *id.* at 1868:8-1912:13, 2029:10-2032:20 (testimony of Michael Chester, J.D. regarding 2004 Warning Letter and related events); *id.* at 1923:6-1930:12, 1931:14-1941:18, 2015:23-2024:20 (cross-examination of Mr. Chester regarding same).

described above—the Court’s limiting instruction during and at the close of trial that the State’s case was not an action brought under or to enforce any federal laws or regulations, and the Court’s further limiting instruction that “while the action of the Defendant are sometimes governed by federal laws or regulations, the violation of a federal law or regulation in and of itself does not constitute a violation of SCUTPA” when the Court recharged the jury. (Trial Tr. at 2812:19-23.)

d. The 1994 Pre-Marketing Letter and 1999 Notice of Violation Were Admissible to Show Defendant’s Conduct Was Capable of Repetition

The 1994 Pre-Marketing Letter and 1999 Notice of Violation were relevant to show that Defendant’s conduct related to the 2003 Dear Doctor Letter had the potential for repetition and thus adversely affected the public interest.⁴⁴ “Since 1986, South Carolina courts have required that a Plaintiff bringing a private cause of action under UTPA allege and prove the defendant’s actions adversely affected the public interest.” *Wright*, 640 S.E.2d at 501 (quoting *Daisy Outdoor Adver. Co. v. Abbott*, 473 S.E.2d 47, 49 (S.C. 1996)). “An impact on the public interest may be shown if the acts or practices have the potential for repetition.” *Id.* “The potential for repetition may be demonstrated in either of two ways: (1) by showing the same kind of actions occurred in the past, thus making it likely they will continue to occur absent deterrence; or (2) by showing the company’s procedures create a potential for repetition of the unfair and deceptive acts.” *Id.* at 502. Of course, “[t]hese two ways are not the only means for showing the potential for repetition or public impact, and each case must be evaluated on its own merits[.]” *Id.*; accord *Crary v. Djebelli*, 496 S.E.2d 21, 23 (S.C. 1998). A “plaintiff need not allege or prove anything further in relation to the public interest[.]” *Crary*, 496 S.E.2d at 23.

⁴⁴ Defendant does not argue that the 1994 Pre-Marketing Letter and 1999 Notice of Violation were not relevant to show that Defendant’s conduct related to Risperdal’s package insert had the potential for repetition, and Defendants thus concede that point.

Indeed, the purpose of the "public impact" requirement is simply to exempt actions for private wrong where the public interest is unaffected. See *Noack Enters., Inc. v. Country Corner Interiors of Hilton Head Island, Inc.*, 351 S.E.2d 347, 349-50 (S.C. Ct. App .1986); see also *Wright*, 640 S.E.2d at 501). Therefore, the South Carolina Supreme Court has "expressly reject[ed] any rigid, bright line test that delineates in minute detail exactly what a plaintiff must show to satisfy the potential for repetition/public impact." *Daisy*, 473 S.E.2d at 511 (emphasis added). The State submits that the 1994 Pre-Marketing Letter and 1999 Notice of Violation were relevant to show that its case was not an action for a private wrong.

The 1994 Pre-Marketing Letter and 1999 Notice of Violation were also relevant to the potential for repetition issue because they are probative of whether Defendant's "procedures create a potential for repetition of the unfair and deceptive acts." *Wright*, 640 S.E.2d at 502. Defendant does not argue otherwise and, thus, concedes that point. Instead, Defendant focuses on the other way of showing potential for repetition identified in *Wright*, which involves similar past conduct. Yet, the 1994 Pre-Marketing Letter and 1999 Notice of Violation were also admissible to show that type of potential for repetition.

In *Burbach v. Investors Management Corp. International*, the court "offer[ed] the following set of factors for consideration" to "assist trial judges in determining the admissibility of prior similar conduct under UTPA claims or for punitive damage purposes":

- (a) the length of time between each of the past incidents, and the incident under consideration;
- (b) the degree of similarity between the facts of the previous incidents and the incident under consideration;
- (c) the degree of similarity between the conduct of the defendant in each of the incidents;
- (d) the degree of similarity between the advantage foreseeably

obtained under the facts of each prior incident by the unfair conduct in each case;

- (e) the degree of similarity of harm to others in each incident; and
- (f) the number of prior incidents as compared with the relative number of prior opportunities to conduct the unfair conduct.

484 S.E.2d 119, 122 n.3 (S.C. Ct. App. 1997). However, in *Burbach*, the court did not state that trial courts were required to consider any or all of those factors.

Even if application of those factors were mandatory in each case in which prior similar conduct is offered to show the potential for repetition, the 1994 Pre-Marketing Letter and the 1999 Notice of Violation are admissible under those factors. Those letters involved conduct and representations that were very similar to Defendant's conduct related to the 2003 Dear Doctor Letter and its representations therein. As here, the conduct at issue in those letters related to Risperdal's labeling. There is also a strong similarity between the advantage foreseeably obtained as a result of its unfair conduct relative to the 1994 Pre-Marketing Letter, the 1999 Notice of Violation, Risperdal's package insert, and the 2003 Dear Doctor Letter because the advantage was the same with respect to each—i.e., increased profits. Further, the harm to others that resulted from Defendant's conduct at issue in the 1999 Notice of Violation was very similar to the harm that resulted to others from the 2003 Dear Doctor Letter. Also, the 1994 Pre-Marketing Letter and 1999 Notice of Violation show that Defendant had many opportunities to conduct the unfair conduct at issue here. Lastly, the length of time between the DDMAC letters and the 2003 Dear Doctor Letter supports a finding that Defendant's conduct related to the latter had a potential for repetition; at any rate, the length of time between the DDMAC letters and the 2003 Dear Doctor Letter does not foreclose that finding. Tellingly, Defendant cites no case law in support of its argument that the 1994 Pre-Marketing Letter and the 1999 Notice of Violation

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are inadmissible under the *Burbach* factors.

3. *The Court Properly Allowed the Introduction of Evidence Relevant to the Issue of Whether Defendant Acted Willfully Because It Knew or Should Have Known That Its Conduct Was Deceptive or Unfair.*

To establish that Defendant acted “willfully” under S.C. Code Ann. § 39-5-110, the State was required to show that Defendant knew or should have known that its conduct was deceptive or unfair within the meaning of SCUTPA. S.C. Code Ann. § 39-5-110(c). The Court properly admitted the categories of evidence about which Defendant complains, including the 1994 Pre-Marketing Letter and the 1999 Notice of Violation; evidence relating to the number of Risperdal prescriptions in South Carolina from 1994-2007; Defendant’s sales, revenues, profits, and business plans; emails sent by Dr. Scott Reines; off-label marketing and promotion and other improper marketing and promotion of Risperdal; and non-disclosures to the FDA. Those categories of evidence were relevant to the question of whether Defendant knew or should have known that its conduct was deceptive or unfair under SCUTPA during the period at issue, and the probative value of that evidence was not substantially outweighed by the danger of unfair prejudice.⁴⁵

As an initial matter, the State does not concede that the evidence Defendant cites in its Memorandum was admitted solely for the purpose of showing that Defendant acted willfully, as Defendant maintains.⁴⁶ For example, the State introduced the Reines e-mails for the purpose of showing that Defendant’s conduct was deceptive and unfair, and not solely to show willfulness. (See Trial Tr. at 115:12-24, 136:20-21.) The only ruling Defendant cites in support of its mistaken assertion that “the Court allowed virtually unlimited evidence and testimony that

⁴⁵ Those categories of evidence were also relevant to other elements of the State’s SCUTPA claims, as discussed more fully above.

⁴⁶ Nor does the State concede that the “willfulness” evidence cited by Defendant falls within the categories set forth in its Memorandum.

purportedly went to the issue and *only* to the issue – of ‘willfulness’” is a ruling as to promotional materials only. (Def.’s Mem. at 55.)

Further, the standing objections to which Defendant refers did not absolve Defendant from stating that it was relying on its standing objections when each piece of evidence was offered into evidence at trial. Some of the evidence Defendant cites was admitted subject to Defendant’s standing objections, but the vast majority of that evidence was admitted after Defendant stated that it had “no objection” and, consequently, waived its standing objections.⁴⁷ See, e.g., *State v. King*, 514 S.E.2d 578, 581 (S.C. 1999) (concluding that party waived issue by “failing to object prior to the jury’s verdict”); *State v. Hicks*, 499 S.E.2d 209, 214 (S.C. 1998) (explaining that an objection must be made contemporaneously to preserve an issue); see also *State v. Kelly*, 502 S.E.2d 99, 104 (S.C. 1998) (holding that a new trial motion may not be used to raise an evidentiary issue for the first time); *McGee v. Bruce Hosp. Syst.*, 468 S.E.2d 633, 637 (S.C. 1996) (holding that a new trial motion may not be used to raise an evidentiary issue for the first time), *rev’d on other grounds*, 545 S.E.2d 286 (S.C. 2001). Defendant even cites an exhibit that was not admitted at trial. (See Def.’s Mem. at 56 n.6 (citing “P2677”).)

⁴⁷ By way of example, Defendant made the following objections and non-objections to the Reines e-mails it claims were admitted solely for the purpose of showing willfulness:

Plaintiff’s Exhibit No. & Memorandum Cite	Defendant’s Contemporaneous Objection
Pl.’s Ex. 462 (Def.’s Mem. at 56 n.6)	No objection (Trial Tr. at 743.)
Pl.’s Ex. 477 (Def.’s Mem. at 56 n.6)	No objection (Trial Tr. at 756.)
Pl.’s Ex. 1061 (Def.’s Mem. at 56 n.6)	No objection (Trial Tr. at 1641.)
Pl.’s Ex. 2363 (Def.’s Mem. at 56 n.6)	No objection (Trial Tr. at 782.)
Pl.’s Ex. 2364 (Def.’s Mem. at 56 n.6)	Subject to standing objection
Pl.’s Ex. 2613 (Def.’s Mem. at 56 n.6)	Subject to standing objection
Pl.’s Ex. 2614 (Def.’s Mem. at 56 n.6)	Subject to standing objection
Pl.’s Ex. 2615 (Def.’s Mem. at 56 n.6)	Subject to Standing objection
“P2677”	Not admitted at trial

The States attaches hereto as Exhibit E and incorporates herein by reference, for all purposes, as if repeated in full herein a table identifying the type of objection (or non-objection) Defendant made when the rest of the evidence it claims to have been admitted solely to show willfulness was introduced into evidence.

What is more, Defendant argues for the first time in its Memorandum that there is a “temporal limitation” governing the admissibility of “willfulness” evidence that somehow prohibited the introduction of all of the evidence Defendant claims was admitted solely for the purpose of showing willfulness. First, Defendant waived that objection by not raising it at trial. *See, e.g., Kelly*, 502 S.E.2d at 104; *McGee v. Bruce Hosp. Syst.*, 468 S.E.2d at 637.

Second, Defendant’s argument misapprehends South Carolina law. Defendant cites a secondary source for the proposition that “South Carolina law provides that when evaluating . . . whether a defendant has engaged in willful conduct sufficient to constitute a SCUTPA violation – ‘courts consider only the actions at the time of the transaction in question.’” (Def.’s Mem. at 55.) Not only is the question of whether a defendant violated SCUTPA separate and distinct from the question of whether the defendant acted willfully, but Defendant fails to explain how that proposition could possibly lead to Defendant’s conclusion that all of the evidence it claims was admitted solely to show willfulness should be excluded, especially given that Defendant’s SCUTPA violations related to Risperdal’s package insert occurred on a daily basis from 1994 through 2004 with respect to the State’s weight gain and diabetes-related claims, and from 1994 through 2007 with respect to the State’s hyperprolactinemia-related claim. Furthermore, *Ward*, the only case cited by the secondary source Defendant references, does not support the conclusion that the Court should have excluded any, let alone all, of the State’s evidence Defendant claims was admitted solely to show willfulness.

Ward involved automobile purchasers’ suit against an automobile dealership that allegedly sold the purchasers a car without disclosing that it had previously been in an accident. 403 S.E.2d at 311. The plaintiffs alleged causes of action for fraud and violation of SCUTPA. *Id.* The defendant moved to strike the plaintiff’s SCUTPA cause of action on the ground that the

defendant's conduct was already governed by a South Carolina regulatory agency. *Id.* The plaintiffs moved to strike the defendant's defense that it had offered to replace the plaintiffs' car with another one of equal value or to repurchase the car. *Id.* The trial court granted both motions, and both parties appealed. *Id.* After holding that a plaintiff may bring an action against an automobile dealership under SCUTPA, the Supreme Court turned to the defendant's argument that the trial court erred by striking its offers of settlement that it sought to have admitted to show lack of bad faith on its part, and which it argued would be important when considering punitive damages. 403 S.E.2d at 313. The plaintiffs argued that "a determination of willfulness *when considering punitive damages* should involve only the actions at the time of the sale, *not subsequent to the wrongdoing*; and therefore, the alleged offer could not serve as a defense." *Id.* (emphases added). The Supreme Court agreed with the plaintiffs and held that "[s]ubsequent actions on the part of [the defendant] do not affect the alleged wrongdoing at the time of the sale and therefore such action *may not constitute a defense*." *Id.* (emphases added). Thus, the only temporal limitation set forth in *Ward* is one that prevents a defendant from introducing evidence of subsequent actions or events that are not probative of whether the defendant acted willfully in a case involving punitive damages. As the State is the plaintiff in this case and punitive damages are at issue, *Ward's* temporal limitation does not apply to evidence introduced by the State in this case.

Even if *Ward's* temporal limitation were applicable to this case and the State, it would not prohibit any of the purported "willfulness" evidence related to actions or events occurring in or before 2004 that was relevant to the State's Risperdal package insert claim based on weight gain and diabetes warnings, and it would not prohibit any of the purported "willfulness" evidence related to actions or events occurring in or before 2007 that was relevant to the State's

Risperdal package insert claim based on hyperprolactinemia warnings. Given that those SCUTPA violations occurred on a daily basis throughout those periods, such evidence necessarily related to conduct that occurred before the “alleged wrongdoing.”

Similarly, with respect to the State’s SCUTPA claim regarding the 2003 Dear Doctor Letter, even if *Ward*’s temporal limitation were applicable to this case and the State, it would not act to bar the State from introducing evidence related to actions or events that occurred before Defendant disseminated the letter. Nothing in *Ward* indicates that evidence of actions or events probative of whether a defendant knew or should have known that its conduct was deceptive or unfair at the time of the transaction in question is inadmissible simply because the action or events did not occur at the exact same time as the transaction in question. If that were the case, *Ward* would lead to the exclusion of nearly all “willfulness” evidence introduced by defendants—and if *Ward* were incorrectly applied to plaintiffs, it would lead to the exclusion of nearly all “willfulness” evidence and make it virtually impossible for plaintiffs to establish that defendants acted willfully in SCUTPA treble damages or penalties cases. Finally, even if *Ward*’s temporal limitation were applicable to this case and the State, it would not prohibit the State from introducing evidence related to actions or events after Defendant’s SCUTPA violations so long as the evidence was probative of whether Defendant knew or should have known that its conduct was deceptive or unfair *at the time of the transaction in question*.

Defendant’s argument that three categories of evidence should have been excluded for additional reasons is also unavailing.

The Number of Risperdal Prescriptions. The number of Risperdal prescriptions filled in the State of South Carolina from 1994-2007 was relevant to the issue of whether Defendant’s alleged SCUTPA violations related to each version of Risperdal’s package insert between 1994

and 2007 were capable of repetition and, therefore, satisfied SCUTPA's public impact requirement. The number of Risperdal prescriptions filled in South Carolina from 1994-2007 was also relevant to whether Defendant acted willfully under SCUTPA because it knew or should have known that its conduct was deceptive or unfair. Defendant fails to articulate how such evidence was likely to confuse the jury or was otherwise prejudicial to Defendant.

Evidence of Defendant's Profits, Sales, and Revenues. Evidence of Defendant's profits, sales, and revenues was relevant to whether Defendant acted willfully under SCUTPA because it knew or should have known that its conduct was deceptive or unfair. Defendant's reliance on *Branham v. Ford Motor Co.* is misplaced because it addressed the issue of whether evidence of a defendant's net worth, income, revenues, and cash flow could be introduced when determining punitive damages. 701 S.E.2d 5, 24-25 (S.C. 2010). The Supreme Court concluded that only the defendant's net worth and extrapolations from its net worth should have been *in assessing punitive damages*. *Id.* at 25. The Supreme Court did not hold, or even suggest, that the net worth of a defendant is only relevant to an award of punitive damages or that net worth can only be admitted into evidence in cases involving punitive damages. Nor did the Court address whether evidence of a defendant's profits, sales, and revenue can be admissible for other than determining punitive damages.

Reines E-mails. Contrary to Defendant's assertion, the State did not introduce the Reines e-mails "solely due to their inflammatory language." (Def.'s Mem. at 57.) Rather, as discussed more fully above, the State introduced the Reines e-mails introduced for the purpose of showing that Defendant's conduct was deceptive and unfair in addition to introducing them for the purpose of showing that Defendant knew or should have known that its conduct was deceptive or unfair. Defendant's reliance on *In re Boston Scientific Corp. Securities Litigation* is

misplaced because, at most, it stands for the proposition that an e-mail expressing “Monday morning remorse” and the regret that more had not been done earlier does not, **standing alone**, establish scienter. 708 F. Supp. 2d 110, 126 & n.15 (D. Mass. 2010) (concluding that the e-mail did not establish scienter only after concluding that, based on all of the evidence presented, a reasonable jury could not find that the defendants acted with the requisite scienter in a securities fraud action). *In re Boston Scientific* does not stand for the proposition that such evidence is inadmissible when introduced along with and for the purpose of putting into context other evidence of willfulness or scienter.

The Reines e-mails were highly probative because they shed tremendous light on Defendant’s deceptive and unfair handling of the 2003 Dear Doctor Letter and the deceptive and unfair nature of the representations made therein. Those emails were also highly probative of whether Defendant knew or should have known that its conduct related to the 2003 Dear Doctor Letter was deceptive or unfair. Thus, although the Reines e-mails were accompanied by a slight danger of unfair prejudice, their probative value was not substantially outweighed by that danger. Furthermore, Defendant did not preserve its Rule 403 objection to four out of the eight Reines e-mails admitted into evidence because it responded that it had “no objection” when they were introduced into evidence.⁴⁸

4. The Court Properly Excluded the Categories of Inadmissible Evidence About Which Defendant Complains.

a. Post-2004 Evidence Regarding Risperdal’s Diabetes-Related Risks and Side Effects as Compared to Other Atypical Antipsychotics Was Irrelevant to the State’s Claims.

After the State narrowed the scope of its weight gain and diabetes-related SCUTPA

⁴⁸ Defendant stated that it had no objection to Plaintiff Exhibit 462, Plaintiff Exhibit 477, Plaintiff Exhibit 1061, and Plaintiff Exhibit 2363. Also, the Reines email Defendant identifies as “P2677” was never admitted into evidence at trial.

claims, the Court correctly excluded post-2004 evidence relating to weight gain, diabetes, and other metabolic risks associated with Risperdal because such evidence was irrelevant.⁴⁹ That evidence is not relevant to whether Defendant's conduct was deceptive or unfair, nor is it relevant to whether Defendant knew or should have known that its conduct was deceptive or unfair at the time it engaged in that conduct.

Defendant argues that the evidence the Court excluded would have shown that its statements in the 2003 Dear Doctor Letter were true. As an initial matter, the evidence Defendant cites does not demonstrate that those statements were "true"; rather, that evidence only tends to corroborate some of those statements. More importantly, even if that evidence does show that Defendant's statements in the 2003 Dear Doctor Letter were ultimately determined to be accurate or "true," the evidence would still have been irrelevant because it is not probative of whether those statements were true and not otherwise deceptive or unfair at the time they were made. *See deBondt v. Carlton Motorcars, Inc.*, 536 S.E.2d 399, 407 (S.C. 2000) ("Even a truthful statement may be deceptive if it has the capacity or tendency to deceive.") (citation omitted). Nor is post-2004 evidence relevant to the issue of what Defendant knew or should have known at the time it made those statements. In other words, what the FDA and the scientific community learned after 2004 has no bearing on whether Defendant violated SCUTPA or on whether Defendant willfully violated SCUTPA. Accordingly, assuming *arguendo* that *Ward's* temporal limitation applies in cases involving SCUTPA causes of action but not claims for punitive damages, it would render Defendant's post-2004 evidence inadmissible as proof regarding willfulness because that evidence relates to actions and events that occurred after Defendant disseminated the 2003 Dear Doctor Letter, and it is not probative of whether

⁴⁹ Defendant does not assert that it was improper for the State to limit its weight gain and diabetes-related SCUTPA claims.

Defendant knew or should have known that its conduct was deceptive or unfair at the time it disseminated the letter. *See* 403 S.E.2d at 313.

Finally, the State did not place post-2004 evidence regarding diabetes-related side effects “directly at issue.” (Def.’s Mem. at 59.) The State introduced testimony and evidence showing that, based on what Defendant and the scientific community knew or should have known between 1994 and 2004, Risperdal was not associated with a lower risk of diabetes and weight gain than Zyprexa and other atypical antipsychotics. By doing so, the State did not open the door to post-2004 evidence. Furthermore, the State did not introduce evidence “on multiple occasions . . . to support its implication that the FDA has always – including to this day – viewed all atypical antipsychotics as presenting equal diabetes-related risks.” (Def.’s Mem. at 59.) The only “evidence” Defendant cites in support of that mistaken assertion is: (1) testimony by Dr. Wirshing in which he stated that he did not believe that the 2003 Dear Doctor Letter was true when it was issued or now; (2) testimony by Dr. Plunkett that the FDA has not changed its position about the 2003 Dear Doctor Letter; and (3) a question by the State’s counsel as to whether there is a diabetes warning in Risperdal’s package insert at present, to which Defendant’s witness Dr. Ramy Mahmoud responded, “If you’re referring to this day, I think they have come around to understanding that the drugs are not all the same,” and the State’s counsel replied, “No, no, no. That’s not what I’m asking.” (Trial Tr. at 488:22-489:4 (testimony of Dr. Wirshing); *id.* at 761:22-25 (testimony of Dr. Plunkett); *id.* at 1634:24-1635:5 (questioning and testimony of Dr. Mahmoud on cross-examination). As such, the State did not open the door to post-2004 evidence regarding diabetes-related side effects.

b. The Court Did Not Err In Excluding the Testimony of Dr. Eugene Barrett.

Defendant did not notify the State of its intent to present the testimony of Dr. Barrett, a

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previously undisclosed witness, until the middle of Defendant's presentation of its case. Accordingly, the Court correctly excluded that testimony based on Defendant's late notice. (Trial Tr. at 2227:4-2229:20.) The Court was also correct to exclude that testimony on the ground that Dr. Barrett could not speak for the entire Consensus Panel, let alone call into question the Consensus Panel's conclusions based solely on his opinion more than seven years after the fact. (*Id.*) Further, the Court correctly determined that Dr. Barrett's proffered testimony was not rebuttal evidence.

c. The Court Properly Excluded the Testimony of Dr. William Wecker, His "Survey," Deposition Testimony from Twenty Doctors, and the Testimony of Dr. Gerard Jebaily.

Dr. Wecker's opinions (and the underlying "data" gleaned from a purported "survey" conducted by Defense attorneys for this litigation) were irrelevant to the question of whether Defendant's dissemination of Risperdal's labeling, including the 2003 Dear Doctor Letter, was deceptive under SCUTPA because the standard is an objective one. As the Supreme Court explained in *deBondt*, "[a] deceptive practice is one which has a tendency to deceive."⁵⁰ 536 S.E.2d at 407. Defendant misinterprets language in *deBondt* in an attempt to convert the objective standard into a subjective one that requires proof of actual deception; however, the State was not required to show that Defendant actually misled doctors in order to prevail on its SCUTPA claims.

What is more, even if Dr. Wecker's opinions were somehow germane, the "survey" conducted through depositions of 20 South Carolina doctors was so flawed—because of bias created by direct Defense attorney involvement, leading questions, a skewed target population, and other failings—that it could not be deemed reliable and admissible under South Carolina

⁵⁰ Defendant does not argue that Dr. Wecker's testimony, his "survey," the depositions of the twenty doctors that formed the basis for the "survey," or Dr. Jebaily's testimony was relevant to the State's contention at trial that Defendant violated SCUTPA through "unfair" conduct.

Rule of Evidence 702. For those same reasons, Dr. Wecker's testimony about the "survey" was inadmissible hearsay. The "survey" was also not based on the type of data reasonably relied upon by experts in the fields of medicine or statistics, and therefore its admission would have violated Rule 703.⁵¹ As the Court found, "[t]he group of doctors sampled was taken from the top 101 prescribers of antipsychotics, which resulted in approximately 90% of the physicians in the State being excluded from consideration in the same." (Order of February 25, 2011 at 10.) Admission of Dr. Wecker's testimony about the "survey" would also have unfairly prejudiced the State's case under Rule 403.

Furthermore, because Defendant willfully failed to comply with the Court's deadlines relative to expert discovery in disclosing the opinions of Dr. Wecker near the close of what was more-than-three-year-long discovery period, the State was unable to meaningfully participate in expert discovery or to adequately prepare its case for trial. The State would have thus suffered significant prejudice if Dr. Wecker's opinions had been admitted at trial.

The Court also did not err in excluding the deposition testimony of the 20 South Carolina doctors that served as the basis for the Dr. Wecker's "survey." Like the "survey," that testimony was irrelevant to the State's claims and burden of proof that Defendant's labeling and communications regarding Risperdal were (objectively) deceptive. The deposition testimony was also inadmissible under Rule 403 because it had no probative value coupled with a significant danger of unfair prejudice given the unrepresentative and unreliable nature of the 20 doctor sample. Additionally, the anecdotal deposition testimony was also cumulative because the Court had already allowed doctors

⁵¹ Defendant relegates to a footnote its conclusory and completely inaccurate argument that there was no basis in the record for a determination that Dr. Wecker's methodology was flawed and no reason to exclude the "survey" and Dr. Wecker's testimony about the "survey." The record, including Dr. Wecker's deposition testimony and expert report, the "survey," the State's motion to exclude Dr. Wecker, the State's reply in support of its motion to exclude, and the hearing on the motion to exclude, provides more than adequate support for the Court's rulings. The State incorporates by reference, for all purposes, as if repeated in full herein its Motion to Exclude the Expert Testimony of Dr. William E. Wecker ("Motion to Exclude"), its Reply to in support of its Motion to Exclude, and the transcript from the hearing on the Motion to Exclude. The State also attaches hereto as Exhibit F and incorporates by reference, for all purposes, as if repeated in full herein the Affidavit of William E. Wecker.

to testify that they did not feel that Defendant had disseminated false or misleading information or that they had been misled. (See Trial Tr. at 2215:3-2217:4.)

Lastly, the Court properly excluded Dr. Gerard Jebaily's testimony from trial. Dr. Jebaily lacked the requisite knowledge, skill, experience, training, and education to advance the opinions set forth in his expert report regarding "clinical decision making with regard to the risk/benefit ratio attendant to the prescribing of any medication," including Risperdal and other antipsychotics. (Trial Tr. 2457 at 1.) By way of footnote, Defendant's suggests that Dr. Jebaily was qualified to testify about that subject because "he has taught residents and other physicians for years." (Def.'s Mem. at 61 n.10.) Not only is Defendant's offer of proof at trial the only evidence Defendant cites in support of its factual assertion, but even if Defendant had brought that information to the Court's attention in a timely manner, it would not have qualified him to present the opinions advanced in his expert report.

The opinions set forth in Dr. Jebaily's expert report were also unreliable and irrelevant, anecdotal accountings of his treatment experiences and prescribing practice with respect to "any medication," including Risperdal and all other antipsychotics, and had no bearing on the State's SCUTPA claims or any viable defense thereto. In addition to being unreliable and irrelevant, Dr. Jebaily's testimony was unfairly prejudicial and its admission would have caused confusion of the issues and unquestionably have misled the trier of fact. Moreover, as part of its SCUTPA cause of action, the State was not required to prove causation or reliance, and accordingly Defendant could not defend against the State's SCUTPA claims by way of the learned intermediary doctrine. The doctrine simply does not apply to, let alone serve to bar the State's SCUTPA claims for the recovery of civil penalties for Defendant's willfully deceptive and unfair labeling of Risperdal. Therefore, the testimony of any individual Risperdal prescriber, including Dr. Jebaily, regarding his reliance (or, lack of reliance) on Defendant's labeling, his treatment

experiences relative to Risperdal and other antipsychotics, and resultant prescribing practices, was irrelevant to any defense of the State's SCUTPA claim. Further, such testimony would have served only to prejudice the State at least by confusing the issues before the trier of fact. Such testimony was also cumulative.

d. The Court Did Not Err in Excluding Testimony Regarding the SCORxE Program.

Defendant was not entitled to introduce rebuttal evidence in response to the limited testimony of James Assey, former the South Carolina Department of Health and Human Services ("DHHS"), regarding the SCORxE program because Defendant opened the door to that evidence in its opening statement by presenting its very favorable characterization of the program. Trial Tr. at 270:10-14 ("Ladies and gentlemen, the SCORxE program recommends Risperdal. In fact, the SCORxE program materials contain that same chart showing the differences between these medicines."); *see also id.* at 269:16-270:16.) As such, Mr. Assay's testimony was rebuttal evidence, and the Court correctly excluded the evidence Defendant offered to rebut his limited rebuttal testimony regarding the SCORxE program, which did not even contain any statements that would have warranted rebuttal testimony if the State had been the party to open the door to evidence regarding the SCORxE program. Evidence as to the SCORxE program, on the whole, was irrelevant, as the Court ruled.

e. Dr. William Wecker's "Additional" Testimony Was Inadmissible.

The Court properly excluded Dr. Wecker's testimony about the incidence rates of side effects of Risperdal versus other antipsychotic medications. Dr. Wecker provided no analysis of how he analyzed or manipulated the State's claims data to obtain his results. In particular, Dr. Wecker did not describe any limitations as to the data itself that would affect the results outcome, nor does he describe any measures he took to deal with such limitations. Dr. Wecker

merely stated that he culled the database evidence for diagnoses of diabetes, metabolic adverse events (such as diabetes mellitus, secondary diabetes mellitus, abnormal glucose, abnormal weight gain, obesity, and other hyperalimentation), and increased prolactin secretion. (Expert Report of William E. Wecker, Ph.D. ¶ 30 & n.11 (Exhibit G).) But, the South Carolina claims databases produced by the State have inherent limitations that—at a minimum—must have resulted in the underinclusiveness of the data Dr. Wecker considered. Dr. Wecker failed to account for the underinclusiveness of diagnosis data that is inherent in the State's Medicaid databases.⁵² Therefore, that testimony is also unreliable and should not be admitted.

Defendant also sought to have Dr. Wecker—though not a medical doctor—give his opinion as to whether certain peer-reviewed medical literature and drug studies supported Defendant's 2003 Dear Doctor Letter. Dr. Wecker was simply not qualified to offer such opinions. He has no medical training. He has demonstrated no expertise in reviewing and analyzing peer-reviewed medical literature or pharmaceutical clinical trials. He is not a pharmacologist or toxicologist. He is simply a statistician that Defendant hoped to use as a conduit through which to present the cited studies and literature to the jury. Given the absence of a demonstration of Dr. Wecker's qualifications in that regard, the Court properly excluded his testimony on the matter. *See Jones*, 681 S.E.2d at 587 n.6 (quoting *Council*, 515 S.E.2d at 517-18 and citing *State v. Jones*, 259 S.E.2d 120 (1979)).

f. The Court Properly Struck Sheldon Bradshaw's Testimony and Instructed the Jury to Disregard His Testimony That Violated This Court's Prior Order.

By no means did the Court abuse its discretion in granting the State's request to strike

⁵² There is no merit to Defendant's assertion in a footnote that "the State has presented no competent or persuasive evidence that [Dr. Wecker's] methodology was in any way flawed." (Def.'s Mem. at 63 n.11.) As discussed more fully above, the State presented ample competent and persuasive evidence of the flaws in Dr. Wecker's methodology in its Motion to Exclude his testimony, its Reply in support of its Motion to Exclude, and at the hearing on the motion to exclude.

answer of Sheldon Bradshaw, J.D. and instructing the jury to disregard his answers because they violated the Court's prior ruling and misrepresented that the CBE provision required evidence of a causal relationship between a prescription drug and an adverse event before a drug manufacturer was obligated to strengthen its warnings unilaterally during the period at issue. (Trial Tr. at 2050:17-2051:14; 2059:21-2060:1.) Mr. Bradshaw's testimony would not have rebutted the State's contention that Defendant had a duty to update Risperdal's package insert under the CBE provision because it had knowledge of "certain risks" associated with Risperdal use. (Def.'s Mem. at 64.) Mr. Bradshaw has no scientific background or training, and his expert testimony consisted of improper (and inaccurate) legal conclusions that did more to invade the province of the Court and the jury than assist the fact finder in its determination. Lastly, Defendant's assertion that the State misrepresented the standard set forth in the CBE provision during the period at issue is baseless.

L. The State's Opening and Closing Arguments Were Proper.

Defendant next argued that the State "calculated to arouse the passion or prejudice" of the jury in its opening and closing arguments by depicting Defendant as a large and profitable out-of-state corporation with "questionable 'ethics.'" (Def.'s Mem. at 64-64.) There was nothing improper about the State's arguments. Defendant's lone case in support is inapposite. In *Branham*, 701 S.E.2d at 8, the plaintiff's attorney made impermissible jury argument by introducing inadmissible evidence. In closing arguments, plaintiff's counsel introduced inadmissible evidence of other similar incidents and requested the jury to punish the defendants for not only the injuries to the plaintiff, but also for injuries to others not parties to the lawsuit. *Id.* at 21-22 ("[Plaintiff] is here today with a brain injury and six hundred other people, or however many it is, lost their lives, and numerous others have brain injuries or are paralyzed, quadriplegic, have extremely serious injuries. We believe that you should tell Ford Motor

Company what you think about this kind of thing.”). The court held that the introduction of such evidence in closing arguments invited the jury to base its decision on passion rather than reason and was therefore improper. *Id.* at 22. Unlike *Branham*, the State’s counsel did not introduce inadmissible evidence in opening or closing arguments, which were well within the bounds of permissible jury argument.

M. The Court’s Jury Instructions and Verdict Form Were Proper.

Defendant submitted a 30-instruction request for charge to the Court together with a 16-page verdict form to cover the State’s lone claim of statutory penalties under SCUTPA. The Court reasonably rejected much of Defendant’s proposed charge, as detailed below, and opted for straightforward, easily understood jury interrogatories on the verdict form that tracked the statutory language. With respect to Defendant’s specific complaints about the charge and verdict form in its Motion at 66-70, the State responds as follows:

- Defendant claims the charge “did not enumerate the precise claims of the State.” (Def.’s Mem. at 66.) But, the Court instructed the jury that there were separate questions it was required to answer on the verdict form, one for the November 2003 Letter, and one for the package insert. (Trial Tr. at 2793-94 (Ex. A).) The Court specifically reviewed the precise inquiries as to each question with the jurors, for each Defendant. (*Id.*)
- Defendant complains that the Court did not separately charge the elements of “unfair” and “deceptive” acts and practices. (Def.’s Mem. at 66.) But the Court did separately address what constituted an “unfair” practice versus a “deceptive” practice under South Carolina law. (Trial Tr. at 2767-68 (Ex. A).) And, as noted above, the express language of the applicable statute, S.C. Code Ann. § 39-5-110(c), requires only that Defendant “knew or should have known that [their] conduct was a violation of § 39-5-20.” Defendant, however, argues that the State must additionally show that the conduct was prohibited. South Carolina courts as well as Defendant’s cited case law make clear that in order to demonstrate willfulness the State need only show that “in the exercise of due diligence, a person of ordinary prudence engaged in trade or commerce could have ascertained that his conduct violates the Act,” without more. *Haley v. Nursery Co. v. Forrest*, 381 S.E.2d 906, 909 (S.C. 1989) (quoting *State v. Nest Egg Society Today, Inc.*, 348 S.E.2d 381 (S.C. Ct. App. 1986)). The Court’s instruction that the State did not have to prove the elements of common law fraud is well-supported by South Carolina case law. See *Inman v. Hyatt Chrysler*

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Plymouth, Inc., 363 S.E.2d 691, 692 (S.C. 1988); *State ex rel. McLeod v. C & L Corp.*, 313 S.E.2d 334, 338 (S.C. Ct. App. 1984). Further, the Court correctly ruled that it would charge based upon South Carolina courts' interpretations of SCUTPA rather than FTC cases where there was controlling South Carolina precedent. Additionally, Defendant complains that the Court failed to instruct that opinions are not actionable under SCUTPA. But, consistent with South Carolina precedent, the Court did instruct that the practices or representations the jury found to be in violation of SCUTPA could not be merely "dealer talk," "trade talk," or "puffing." (Trial Tr. at 2767 (Ex. A).) See Ralph King Anderson, Jr., *South Carolina Requests to Charge – Civil*, 2009, § 34 (citing cases). Also, Defendant's request that the State may not recover if the recipient of the statements had an equal and ample opportunity to discover the truth, but failed to do so, is inconsistent with controlling South Carolina precedent and was properly refused. "[T]here is no need to show that a claim or representation was intended to deceive [or actually deceived], but only that it had the capacity or effect or tendency to deceive." *McLeod*, 313 S.E.2d at 338. The Court further instructed that the jury may decide an expert's opinion is based on "reasons [that] are not sound," addressing Defendant's request that expert opinions should be based on facts. (Def.'s Mem. at 67.) Defendant's request that the jury be instructed that attorneys' question are not evidence was properly refused as contrary to South Carolina law and procedure. Finally, the Court properly refused Defendant's requested instructions as to the "regulated activity exception," "CBE regulations," and Sheldon Bradshaw for the reasons stated elsewhere in this Memorandum.

- Defendant complains about the Court's admission of evidence, including FDA evidence, as to willfulness, and the failure to adequately instruct the jury regarding the same. But, South Carolina law permits the jury to consider evidence of regulatory violations to support a finding of willful conduct, including in the context of an award of punitive damages. See, e.g., *Ravan v. Greenville County*, 434 S.E.2d 296, 303 (S.C. Ct. App. 1993) (citing *Rhodes v. Lawrence*, 302 S.E.2d 343, 344 (S.C. 1983) and *Tant v. Dan River, Inc.*, 345 S.E.2d 495, 496 (1986)); *Cooper by Cooper v. County of Florence*, 412 S.E.2d 417, 419 (S.C. 1991). Also, the evidence that the proposed instruction purports to address is admissible and may be considered by the jury under S.C.R. Evid. 404(b) as evidence of motive, absence of mistake or accident, and intent. And, the evidence that the proposed instruction purports to address is admissible and may be considered by the jury under S.C.R. Evid. 406 as evidence of Defendant's habit or routine practice. Defendant also claims that the Court should have instructed the jury on how the FDA evidence should have been used and, at a minimum, the Court should have instructed the jury specifically that a violation of federal law or FDA regulations could not be the basis of a violation of SCUTPA. (Def.'s Mem. at 68.) But, the Court did instruct the jury that "the violation of a federal law or regulation in and of itself does not constitute a violation of SCUTPA. There must be a showing that SCUTPA has been violated by the actions of the Defendant in order for there to be a finding for the Plaintiff." (Trial Tr. at 2812-13 (Ex. A).)

- The Court properly refused Defendant's requested First Amendment instructions for the reasons stated above in § II.F.
- The Defendant avers generally that its version of the jury instructions should have been given. The State incorporates by reference, for all purposes, as if repeated in full herein its contemporaneously filed Objections to Defendant's Requested Jury Instructions, which are attached as Exhibit H and incorporated by reference.
- Finally, for the reasons stated above in this section and elsewhere herein, the verdict form was proper. Defendant cites no on-point authority for suggesting that separate interrogatories must have been included for each element of "deception" and each element of "unfairness," for example, given the Court's thorough and coherent oral and written charge to the jury. The verdict form proposed by Defendant was inconsistent with South Carolina law as described above at least to the extent that the verdict form tracked Defendant's proposed charge. (See Ex. H.)

In any event, with respect to the verdict form, the trial judge has the discretion to determine whether to submit special interrogatories. Rule 49(b) SCRPC; *Constant v. Spartanburg Steel Products, Inc.*, 316 S.C. 86, 90, 447 S.E.2d 194, 196 (1994); see MOORE'S FEDERAL PRACTICE 3D § 49.11[2][a], at 49-16 (1997) ("Rule 49 is a rule of discretionary implementation, solely in the control of the trial judge. *No party has a right to the use of a special verdict.*") (emphasis added). See also *Steele v. Dillard*, 327 S.C. 340, 343 (S.C. Ct. App. 1997).

III. CONCLUSION

For all the foregoing reasons, the State respectfully requests that the Court deny Defendant's Motion in its entirety.

Respectfully submitted,

**STATE OF SOUTH CAROLINA
OFFICE OF THE ATTORNEY GENERAL**

Alan Wilson
C. Havrid Jones, Jr.
Office of Attorney General
1000 Assembly Street, Room 519
Columbia, South Carolina 29201

HARRISON, WHITE, SMITH & COGGINS, P.C.

John B. White, Jr.
SC State Bar No. 5996
Donald C. Coggins, Jr.
SC State Bar No. 1307
178 West Main Street (29306)
PO Box 3547
Spartanburg, SC 29304
(864) 585-5100 Telephone
(864) 591-0491 Fax

SIMMONS LAW FIRM, L.L.C.

John S. Simmons
SC State Bar No. 10260
1711 Pickens Street
Columbia, South Carolina 29202
(803) 779-4600 Telephone
(803) 254-8874 Fax

BAILEY PERRIN BAILEY

Fletcher V. Trammell
Admitted *pro hac vice*
Texas State Bar No. 24042053
Robert W. Cowan
Admitted *pro hac vice*
Texas State Bar No. 24031976
Elizabeth W. Dwyer
Admitted *pro hac vice*
Texas State Bar No. 24062445
440 Louisiana, Suite 2100
Houston, Texas 77002
(713) 425-7100 Telephone
(713) 425-7249 Fax
Attorneys for the State of South Carolina

April 15, 2011
Spartanburg, South Carolina

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M. HOPE BLACKLEY

EXHIBIT C

IN THE SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
CIVIL TRIAL DIVISION

IN RE RISEPRDAL/SEROQUEL/ : CASE NO. 274
ZYPREXA LITIGATION : CIVIL ACTION

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SIXTH DIVISION

STATE OF ARKANSAS ex rel.
Dustin McDaniel, Attorney General: Plaintiff
Case No. 07-15345
JANSSEN PHARMACEUTICA, INC.,
JANSSEN, LP and JOHNSON & JOHNSON: Defendants

IN THE TWENTY-SEVENTH JUDICIAL DISTRICT COURT
IN AND FOR THE PARISH OF ST. LANDRY
STATE OF LOUISIANA

CHARLES FOTI, ATTORNEY GENERAL : NO. 04-3967-D
EX REL. STATE OF LOUISIANA :
versus
JANSSEN PHARMACEUTICA, INC., et al. :
-CONSOLIDATED WITH-
CHARLES FOTI, ATTORNEY GENERAL : NO. 04-3977-D
EX REL. STATE OF LOUISIANA :
versus :
JANSSEN PHARMACEUTICA, INC., et al. :

DEPOSITION OF RILEY SMITH - VOLUME 1
THURSDAY, JANUARY 15, 2009

Page 246

1 Q. I do see where I saw "pharmacists."
 2 If we look at the title up at the top, under
 3 "overview" on this page it says, "RISPERDAL
 4 'Consultant Pharmacist Advisory Forum.'" Is that
 5 correct?
 6 A. Yes, it does say that.
 7 Q. Does that refresh your recollection?
 8 A. It doesn't refresh my recollection.
 9 That may have been the overall title. There could
 10 have been physicians and nurses, as well, that were
 11 also invited to it.
 12 Q. All right, thank you for explaining
 13 that.
 14 On the next page, 670, down at the
 15 bottom it says "other comments of note." The first
 16 one is, "Encourage SNF to do a chart review of
 17 Risperdal patients to see if there are any problems."
 18 I won't read the whole thing, but what
 19 is NSF?
 20 MR. POWERS: Where are you reading
 21 from? I'm sorry.
 22 MR. SMITH: Page 670, E, "Other
 23 comments of note."
 24 MR. POWERS: Got it, thanks.

Page 247

1 THE WITNESS: In the context of
 2 this, I would say the SNF stands for
 3 skilled nursing facilities, which is
 4 another word for a long-term care
 5 facility.
 6 BY MR. SMITH:
 7 Q. Do you know if Janssen ever did a
 8 chart review of Risperdal patients at a skilled
 9 nursing facility?
 10 A. That I don't know.
 11 Q. Okay, let's go to another exhibit.
 12 MR. SMITH: This would be Exhibit
 13 22, I believe.
 14 (Exhibit 22 was marked for
 15 identification)
 16 BY MR. SMITH:
 17 Q. Mr. Smith, you don't have to read the
 18 whole thing, but you're welcome to if you wish.
 19 A. If you want to direct me to a specific
 20 question, I'll see how we can work it out. If I need
 21 to go back, I'll do that.
 22 Q. Let's just start with the cover page
 23 and ask you if you can identify this document.
 24 A. Okay.

Page 248

1 Q. The whole document.
 2 A. It says, "Risperdal Business Plan
 3 2004." Whether this is a final draft, I can't
 4 testify to that.
 5 Q. According to the information provided
 6 to us along with this document, it listed you as an
 7 author. Do you recall contributing to this?
 8 MR. POWERS: Objection to the
 9 form.
 10 THE WITNESS: Again, a large team
 11 that would have been involved in
 12 developing this type of program.
 13 Given the time period, 2004, I
 14 would have expected I would be on that
 15 team, but to specific slides that I
 16 developed, I will have to speak to
 17 individual ones.
 18 MR. SMITH: Okay.
 19 BY MR. SMITH:
 20 Q. Would it be possible for you to tell
 21 us what types of slide you typically contributed to
 22 in these business plans?
 23 A. Well, what I would say is, I wouldn't
 24 have put together information on market dynamics,

Page 249

1 kind of data-driven ones.
 2 If there are slides in here that
 3 talked about what we were going to be doing from a
 4 marketing perspective with our sales force in the
 5 upcoming year, that would have been something that I
 6 would have had input into, especially if it was
 7 related to primary care or eldercare.
 8 Q. All right, let's look at some
 9 individual pages and see what we find. Let's look at
 10 page 2430, if you would, please.
 11 A. Okay.
 12 Q. At the top -- the title of the slide
 13 is "Move to Mood and Anxiety Symptoms of
 14 Schizophrenia Campaign." Do you recall that
 15 campaign?
 16 A. Yes.
 17 Q. To the left, down at the bottom it
 18 says "Heritage in Schizophrenia" and then over to the
 19 right it says "Higher Functioning Patients." What
 20 does that mean to you?
 21 A. In the circle above where it says
 22 "Heritage in Schizophrenia" it says, "The 'typical'
 23 atypical 'Big Gun' Strength Positive Symptoms."
 24 So, when people looked at Risperdal, I

Page 250

1 think -- and this is my recollection -- the market
 2 data would tell us that physicians viewed us as being
 3 a very powerful antipsychotic, more aligned to how
 4 older versions of the product worked as compared to
 5 some of the newer products that were on the market
 6 that didn't have that same level of efficacy. So,
 7 they tended to use the product for the sickest
 8 schizophrenic patients.

9 So, we then were looking at Risperdal
 10 Tomorrow, and I believe that this -- again, I'm not
 11 sure of the timing of this, but this would be
 12 reflecting the. . .

13 Q. It's a 2004 business plan, right?
 14 A. Right. And if my memory serves me
 15 correctly, we would have had the bipolar indication
 16 at that particular time, or would be getting it in
 17 2004.

18 Q. I think December 2003.
 19 A. Yes, so it would be moving into that
 20 new indication as well.

21 So, you know, above "Higher
 22 Functioning Patients" it's "The 'Approachable' broad
 23 utility atypical Behavioral, psychotic, mood &
 24 anxiety symptoms."

Page 251

1 So, what I'm looking at here is trying
 2 to expand the view of Risperdal, that it's not just
 3 very powerful against the positive symptoms, but it's
 4 also very efficacious against treating the negative
 5 symptoms.

6 Q. When it says "broad utility atypical,"
 7 does that mean it can be used to treat everything?
 8 A. Well, as it reflected on this slide,
 9 we're talking about schizophrenia. Again,
 10 schizophrenia is a cluster of symptoms: Positive
 11 symptoms, which are psychosis, hallucinations;
 12 negative symptoms, which tend to be anxiety, mood,
 13 those type of symptoms, behavioral symptoms.

14 So, we were seeing data that was
 15 showing that we were being used mostly to treat the
 16 positive symptoms, so we were looking at how do we
 17 increase the awareness of physicians that we have
 18 broader use beyond positive symptoms, but actually
 19 patients who exhibit more of the negative symptoms
 20 also would be somebody that Risperdal could be highly
 21 effective at treating.

22 Q. I see in that circle on the right for
 23 the Risperdal of Tomorrow "behavioral, psychotic" and
 24 that makes me think of BPSD: Behavioral and psychotic

Page 252

1 symptoms of dementia?
 2 Do you recall, seeing that, that
 3 Janssen sought to obtain an indication approval of an
 4 indication to treat BPSD?

5 MR. POWERS: Object to the form.
 6 THE WITNESS: Prior to my time I
 7 know that we were pursuing an indication.
 8 I don't recall exactly what the wording
 9 was on it. But this, as you can see in
 10 the label, is really focused on
 11 schizophrenia.

12 BY MR. SMITH:
 13 Q. Would you look at page 2439, please?
 14 Under "CAE lessons learned," the first item is --
 15 what is the first item?

16 A. It says, "Develop SWOT team early and
 17 enroll key partners to address significant issues."
 18 Q. What is "SWOT team"?
 19 A. I think it's a euphemism for just, you
 20 know, a team that's going to tackle an issue like
 21 this. I don't think it's an acronym standing for
 22 anything, that I recall.

23 Q. What does it signify that somebody at
 24 Janssen felt that the CAE issue taught them that they

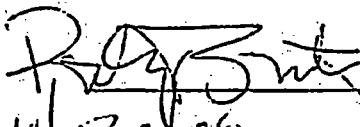
Page 253

1 should develop a SWOT team early?
 2 MR. POWERS: I'm sorry, I just --
 3 MR. SMITH: I'll rephrase the
 4 question.

5 BY MR. SMITH:
 6 Q. I take it that Janssen didn't have a
 7 SWOT team for the CAE issue, correct?
 8 A. Well, I think the lesson that was
 9 being put forth is that there was a SWOT team put in
 10 place. There was a small group of people that, as
 11 soon as the issue had been risen, this group of
 12 people proactively looked at it, tried to understand
 13 it for the company, and looked at how do we then get
 14 that information out.

15 Q. Okay. And then the next item says,
 16 "Never underestimate the impact of a DDL," or Dear
 17 Dr. letter. What does that mean?
 18 A. In vague, high-level terms, I know
 19 that there were people in the organization who, as
 20 the labeling change was taking place, looked at it
 21 and said, "Doctors are going to be able to understand
 22 this information. It's not going to have an impact on
 23 them."
 24 And I think we looked at it and wanted

Page 254 1 to heighten that any Dear Dr. letter that's going out 2 from the organization is important. It contains 3 information physicians need to know about, and it can 4 have an important impact on physician's prescribing 5 behaviors in the future. 6 Q. Would you look at page 2431 for me? 7 That's the last one I want to look at. 8 A. We're going backwards. 9 Q. Yes. It's entitled "Move to mood. 10 Lessons learned." At the bottom, the last item, can 11 you read that for me? 12 A. "We are a fast follower versus 13 innovator." 14 Q. What does mean? 15 A. I'm not sure what the context of that 16 was. I didn't come up with that. 17 Q. An innovator would be someone who 18 comes up with new ideas, right? 19 MR. POWERS: Object to form. 20 THE WITNESS: Innovation is 21 something new. 22 MR. SMITH: Let's go to the next 23 exhibit. I have time to get another one 24 in. This will be Exhibit 23.	Page 256 1 monograph? 2 A. What it looks like to me is, this is 3 the approved label for a working version of the 4 approved label in Canada for Risperdal. 5 Q. And this is some sort of a revision to 6 that monograph, right? 7 MR. POWERS: Object to the form. 8 THE WITNESS: Again, I'm not 9 familiar with the documents. You can see 10 that there are cross-outs on this. I 11 have no idea who was doing any of the 12 markups here. 13 MR. SMITH: I understand. 14 BY MR. SMITH: 15 Q. The last part of the first paragraph 16 under "use in geriatric patients" appears to be being 17 edited out, and it says, "Cerebrovascular events have 18 been observed with Risperdal in elder patients with 19 dementia. Risperdal should be used with caution in 20 patients with known cardiovascular disease, such as 21 heart failure, myocardial infarction, conduction 22 abnormalities, dehydration, hypovolemia or 23 cerebrovascular disease, and the dosage should be 24 gradually titrated as recommended."
Page 255 1 (Exhibit 23 was marked for 2 identification) 3 BY MR. SMITH: 4 Q. Have you looked that over quickly? 5 A. I've looked over the first page to get 6 an understanding of what it is. It's a very dense 7 document. 8 Q. Other than being a very dense 9 document, what is it? 10 A. It is the Canadian product monograph 11 for Risperdal. It was prepared April 14th, 1993. 12 There is a date of revision, at least on mine. It 13 looks like September 19th, 2003 is crossed out. 14 So again, it's Canadian document, so 15 I'm not sure what those are really referring to. 16 Q. I see that, thank you. Would you turn 17 to page 454, please? Are you at that page? 18 A. Yes, I am. 19 Q. Look at "Use in geriatric patients," 20 please. 21 A. Okay. 22 Q. Have you read that? 23 A. Yes. 24 Q. First let me ask, what is a product	Page 257 1 Is that language that you're familiar 2 with, what I just read? 3 A. This is the Canadian label? 4 Q. According to -- I know you indicated 5 earlier that that's what you believe it to be, and 6 I'll accept that for now. 7 A. I'm only going by what's listed on the 8 front cover, that it's the Canadian label. 9 In general, do I understand this 10 subject? We've talked quite a bit about the labeling 11 change that took place in Canada and then the 12 subsequent one that took place in the US to 13 communicate that. 14 But "use in geriatric patients" and 15 all of this other information would really be 16 something that our clinical teams would have been 17 involved in from a labeling perspective. 18 Q. Understood. I was just curious. It 19 looks like, instead of putting additional safety 20 information in, they're taking out some safety 21 information. 22 I was wondering if you had any 23 recollection of anything like that with the US label. 24 MR. POWERS: Object to the form.

1 (EXHIBITS - CONT'D)				1 ERRATA SHEET			
2	NO.	DESC.	PAGE	2	-----		
3	13	Email chain, Bates JJRE 00162505 and 506	189	3			
4	14	Two-page memo, Bates JJRE 00290382 and 383	208	4	PAGE	LINE	CORRECTION
5	15	Email chain, Bates JJRE 02411123 and 124	213	5			
6	16	Email chain, Bates JJRE 06261571 and 572	217	6			
7	17	FDA proposed text (Sept. 2002), Bates JJRE 06819859 and 860	222	7			
8	18	Email chain, Bates JJRE 06819857 and 858	223	8			
9	19	CNS MSL Weekly Report, May 16, 2003, Bates JJRE 12743220 through 223, inclusive	228	9			
10	20	Email chain, Bates JJRE 10355268 and 269	231	10			
11	21	2003 Janssen ElderCare and LTC Group RISPERDAL Consultant Pharmacist Advisory Forum, Bates JJRE 00808668 through 668, inclusive	241	11			
12	22	RISPERDAL Business Plan 2004, Bates JJRE 00242408 through 460, inclusive	247	12			
13	23	Product Monograph for Risperdal, Bates JJRS 00673442 through 487, inclusive	255	13			
14				14			
15				15			
16				16			
17				17			
18				18			
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21				21			
22				22			
23				23			
24				24			
Page 262				Page 264			
1 SIGNATURE PAGE				1 CERTIFICATION			
2	-----			2	-----		
3				3			
4				4			
5	I hereby acknowledge that I have read the			5	I hereby certify that the testimony and		
6	aforegoing transcript, and the same is a true and			6	the proceedings in the foregoing matter are		
7	correct transcription of the answers given by me to			7	contained fully and accurately in the stenographic		
8	the questions propounded, except for the changes, if			8	notes taken by me and that the copy is a true and		
9	any, noted on the Errata Sheet.			9	correct transcript of the same.		
10				10			
11				11			
12	-----			12	Lance A. Brusilow		
13				13	Registered Professional Reporter		
14				14	Certified Realtime Reporter		
15				15			
16				16			
17	SIGNATURE: 			17	The foregoing certification does not		
18	DATE: 4/30/09			18	apply to any reproduction of the same by any means		
19				19	unless under the direct control and/or supervision of		
20				20	the certifying shorthand reporter.		
21				21	-----		
22				22			
23				23			
24				24			
Page 263				Page 265			

IN THE SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
CIVIL TRIAL DIVISION

IN RE RISEPRDAL/SEROQUEL/ : CASE NO. 274
ZYPREXA LITIGATION : CIVIL ACTION

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SIXTH DIVISION

STATE OF ARKANSAS ex rel.
Dustin McDaniel, Attorney General: Plaintiff
Case No. 07-15345
JANSSEN PHARMACEUTICA, INC.,
JANSSEN, LP and JOHNSON & JOHNSON: Defendants

IN THE TWENTY-SEVENTH JUDICIAL DISTRICT COURT
IN AND FOR THE PARISH OF ST. LANDRY
STATE OF LOUISIANA

CHARLES FOTI, ATTORNEY GENERAL : NO. 04-3967-D
EX REL. STATE OF LOUISIANA :
versus
JANSSEN PHARMACEUTICA, INC., et al. :
-CONSOLIDATED WITH-
CHARLES FOTI, ATTORNEY GENERAL : NO. 04-3977-D
EX REL. STATE OF LOUISIANA :
versus :
JANSSEN PHARMACEUTICA, INC., et al. :

DEPOSITION OF RILEY SMITH - VOLUME 2
FRIDAY, JANUARY 16, 2009

Page 399

1 for me prescribing it or --

2 MR. SMITH: Janssen. I mean it in

3 a general sense, Janssen.

4 MR. POWERS: Can I get the

5 question and answer?

6 (The record was read by the court

7 reporter as requested)

8 MR. SMITH: Rather than you

9 personally.

10 MR. POWERS: I'll object to the

11 form.

12 THE WITNESS: What I'm unclear on

13 is, are you talking about our sales

14 representatives?

15 BY MR. SMITH:

16 Q. Well, there are many ways in which you

17 communicate with the doctors, right? You have sales

18 reps. You have key opinion leaders and speakers.

19 MR. POWERS: Objection to the

20 form.

21 BY MR. SMITH:

22 Q. You have presentations at medical

23 association meetings, correct?

24 A. Well, what I would say is that from a

Page 400

1 marketing --

2 Q. Could you answer? Is that correct or

3 not first?

4 MR. POWERS: Well, wait.

5 MR. SMITH: No, I want an answer

6 to my question first.

7 MR. POWERS: Well, don't interrupt

8 him and he'll answer the question.

9 MR. SMITH: I just want to stop

10 and ask him to answer my question, then

11 he can explain.

12 MR. POWERS: The last question so

13 the witness can answer, Lance, please.

14 And you're way beyond the time frame that

15 we estimated, so please wrap it up.

16 MR. SMITH: Well, that's due to a

17 number of things, some of which you're

18 responsible for, but we're about through.

19 MR. POWERS: The record should

20 reflect a series of breaks that we've

21 taken while you shuffled through

22 documents, but --

23 MR. SMITH: And a series of breaks

24 we took while you played with your

Page 401

1 computer and a lot of time spent on

2 objections which were more than just to

3 the form.

4 BY MR. SMITH:

5 So, the last question, to save some

6 time, is whether you agree that Janssen presented

7 information to doctors at medical meetings.

8 A. If there was a clinical study that had

9 been accepted at, let's say, the APA -- we've used

10 that as an example, the APA -- for presentation, one

11 of our clinicians may have been the person -- I can't

12 speak for sure -- may have been one of the people

13 that actually did the presentation.

14 Q. And Janssen publishes medical

15 articles, right? It's another way of communicating

16 with doctors?

17 A. Again, when we have a clinical trial

18 that's been completed, we feel it's important to

19 publish that information so all the prescribers have

20 access to all of the most current information.

21 Q. And Janssen places ads in magazines

22 that doctors -- medical magazines, correct?

23 MR. POWERS: Objection to the

24 form.

Page 402

1 THE WITNESS: We do have

2 promotional-approved journal

3 advertisements, yes.

4 BY MR. SMITH:

5 Q. So, with all those forms of

6 communication, my question is: Why are you using all

7 those forms of communication to communicate with the

8 doctors if you don't have more information than they

9 do?

10 MR. POWERS: Object to form.

11 THE WITNESS: Well, again, I don't

12 know what information a specific

13 physician has. What we communicate is

14 around our approved label.

15 So, our representatives come in

16 and -- just take indication of

17 schizophrenia. They're going to come in

18 and talk to the physician about

19 schizophrenia and what our package label

20 says about it and what's approved in our

21 sales aid, with the hopes that that

22 physician will take that information,

23 along with all of the other information

24 they have, and see if Risperdal is a

Page 403	Page 405
1 product they would want to prescribe for 2 one of their patients. 3 BY MR. SMITH: 4 Q. If you're not presenting any more 5 information than what's already contained in the 6 package insert, why don't you just hand the doctor a 7 package insert and give him a free pen and say thank 8 you for your time? 9 MR. POWERS: Objection to the 10 form. 11 THE WITNESS: First, we don't give 12 out free pens any more; second, the 13 package label is, as I'm sure you're 14 aware, an extensive document. We 15 certainly leave the package insert on all 16 sales calls with physicians, so that 17 information is there for them to read. 18 However, we are able to 19 communicate -- and again, all approved 20 through our group that knows all the 21 regulations -- are able to summarize the 22 efficacy benefits of the product as well 23 as the safety and tolerability issues. 24 So, it was an opportunity for us.	1 aware of those, and that's all contained 2 within the fair-balance part of it. 3 You would also like them to know 4 how to dose the drug properly, because if 5 they dose it incorrectly, that could be a 6 problem, so you would have information on 7 dosing. 8 BY MR. SMITH: 9 Q. All these forms of communication 10 contain information in addition to what is in the 11 package insert, correct? 12 MR. POWERS: Object to the form. 13 THE WITNESS: Actually, we would 14 not be able to have anything in our 15 promotional material that was not aligned 16 to the package label. 17 That's where our 18 clinical/regulatory teams really gave us 19 guidance on what was appropriate in the 20 sales aid and what wasn't; then, once we 21 had all agreed organizationally, all that 22 material was sent to the FDA for their 23 review. 24 BY MR. SMITH:
Page 404	Page 406
1 to provide that information on a basis 2 with physicians. 3 BY MR. SMITH: 4 Q. Let me ask it another way: The sales 5 reps aren't just explaining the package insert to the 6 doctors, are they? 7 MR. POWERS: Objection to form. 8 THE WITNESS: No, they -- I would 9 say that they leave the package labeling 10 behind. Again, Janssen representatives 11 would have an approved sales aid; they 12 would go through that. 13 That information that was in that 14 sales aid was contained within the 15 package labeling, but it certainly wasn't 16 all-inclusive of all the information. 17 So, if you look at what's 18 important, not that everything is not 19 important within the label, but you want 20 physicians to understand the efficacy of 21 your product, that it works. 22 You would also like them to know 23 that there are certain patients where 24 there are risk factors and you should be	1 Q. And do you remember Janssen receiving 2 a letter from the Division of Drug Advertising & 3 Marketing at FDA in 2004 regarding misrepresentations 4 in sales aids? 5 MR. POWERS: Objection to the 6 form. 7 THE WITNESS: Actually, I don't 8 recall that. It may have happened. It 9 would have been sent to our regulatory 10 group. I don't know what the form or 11 fashion of that letter would have been, 12 so it doesn't come off the top of my 13 head. 14 BY MR. SMITH: 15 Q. But let's focus just on sales aids for 16 a second, then. My question to you is, is the sales 17 aid more than the package insert? 18 A. It's different in the sense that the 19 package insert has every piece of information and 20 it's very small print, difficult to read. And unless 21 you go online to find the information, it's contained 22 in that file card as such. 23 So, the sales aid has information that 24 would be aligned to our indication, and that's --

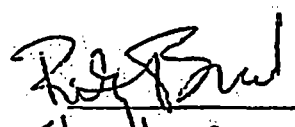
1	MR. POWERS: The deposition is	1	SIGNATURE PAGE		
2	concluded.	2			
3	THE VIDEOGRAPHER: Going off the	3	-----		
4	record. This is the end of tape four.	4			
5	The time is 1:07 p.m.	5	I hereby acknowledge that I have read the		
6	(The deposition was concluded at	6	aforegoing transcript, and the same is a true and		
7	1:07 p.m.)	7	correct transcription of the answers given by me to		
8		8	the questions propounded, except for the changes, if		
9		9	any, noted on the Errata Sheet.		
10		10			
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19		19			
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21		21			
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23		23			
24		24			
Page 419		Page 421			
1	INDEX	1	ERRATA SHEET		
2	WITNESS: RILEY SMITH (VOLUME 2)	2	-----		
3	By Mr. Smith: Page 270	3			
4		4	PAGE	LINE	CORRECTION
5	EXHIBITS	5			
6	NO. DESC. PAGE	6			
7	24 Contact Report #MP091603 en Medicus	7			
8	International letterhead, Bates	8			
9	JJRE 00280904 through 906, inclusive 275	9			
10		10			
11	25 Dementia SST Update, MSL Training	11			
12	9-25-03, Bates JJRE 05626603 through	12			
13	750, inclusive 283	13			
14	26 Email chain, Bates JJRE 00042586 289	14			
15		15			
16	27 Document entitled "Play to Win 2005,"	16			
17	Bates JJRE 00042587 through 592, inclusive 299	17			
18	28 Email chain, Bates JJRE 00278213 through	18			
19	216, inclusive 309	19			
20		20			
21	29 Multipage document, cover page an email	21			
22	dated March 16, 2004 from S. Neuman to	22			
23	A. Bing-Zaremba and others, Bates JJRE	23			
24	00510618 through 625, inclusive 330	24			
	30 Multipage document entitled "CNS Geriatric				
	Advisory Boards, Program Details and				
	Business Justification," Bates JJRIS				
	00196676 through 717, inclusive 336				
	31 Email chain, Bates JJRE 06542920 and 921 351				
	32 Multipage document, with cover email				
	with handwritten date of "Jan 04," from				
	S. Piasecki to R. Mahmud, with copies				
	to others, Bates JJRIS 01824686 through				
	699, inclusive 360				
	33 Franchise Leadership Team Meeting Minutes,				
	dated February 1, 2005, Bates JJRE				
	00169684 through 688, inclusive 370				
Page 420		Page 422			

EXHIBIT D

IN THE SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY
CIVIL TRIAL DIVISION

IN RE RISPERDAL/SEROQUEL/ : CASE NO. 274
ZYPREXA LITIGATION : CIVIL ACTION

IN THE CIRCUIT COURT OF PULASKI COUNTY, ARKANSAS
SIXTH DIVISION

STATE OF ARKANSAS ex rel.
Dustin McDaniel, Attorney General: Plaintiff
Case No. 07-15345
JANSSEN PHARMACEUTICA, INC.,
JANSSEN, LP and JOHNSON & JOHNSON: Defendants

IN THE TWENTY-SEVENTH JUDICIAL DISTRICT COURT
IN AND FOR THE PARISH OF ST. LANDRY
STATE OF LOUISIANA

CHARLES FOTI, ATTORNEY GENERAL : NO. 04-3967-D
EX REL. STATE OF LOUISIANA :
versus
JANSSEN PHARMACEUTICA, INC., et al. :
-CONSOLIDATED WITH-
CHARLES FOTI, ATTORNEY GENERAL : NO. 04-3977-D
EX REL. STATE OF LOUISIANA :
versus :
JANSSEN PHARMACEUTICA, INC., et al. :

DEPOSITION OF RONALD KALMEIJER
THURSDAY, JUNE 25, 2009 - VOLUME 1

1 Q. Thank you, that's essentially what I'm
2 asking you. One method is through a drug store.
3 A. Right.
4 Q. One is through an institutional
5 setting, such as a hospital.
6 A. Right.
7 Q. Did nursing homes dispense -- or did
8 they dispense Risperdal during the time you were in
9 sales?
10 MR. JACKSON: Objection, vague.
11 A. Yes.
12 Q. And how did they do that, through a
13 consulting pharmacist?
14 A. I don't know how exactly that went.
15 What I can say is that whatever ways medication that
16 is prescription only can be dispensed, those means
17 were open for Risperdal.
18 What exactly -- I'm not a technical
19 expert as far as, you know, which ways there are
20 available, but...
21 Q. Thank you. In addition to filling a
22 prescription, a patient could also receive a sample
23 from a doctor, correct?
24 A. That is correct.

Page 50

1 Q. Were samples distributed by the sales
2 force during the time you were in sales?
3 MR. JACKSON: Objection, vague.
4 A. In the time that I was in the sales
5 force as RBD, there were samples -- I actually don't
6 recall because samples generally are given around the
7 launch period and introduction of new put-ups, so
8 I -- I actually don't recall.
9 Q. In any event, the way that Janssen
10 generates revenue off of Risperdal is by selling it,
11 correct?
12 A. That is correct.
13 Q. And the only way it can get sold is
14 through a prescription, correct?
15 A. That's correct.
16 MR. JACKSON: Objection, vague.
17 Q. And the objective of sales
18 representatives during the time you were in sales was
19 to get the doctors they called upon to write
20 prescriptions, correct?
21 A. To get the doctors to write
22 prescriptions for the labeled indication that
23 Risperdal has, that is correct.
24 MR. PERRIN: Objection;

Page 51

1 nonresponsive.
2 BY MR. PERRIN:
3 Q. The objective of the sales force was
4 to get a prescription written, correct?
5 A. I don't think that that is a correct
6 statement.
7 Q. The sales representatives were given
8 the names of doctors likely to prescribe atypical
9 antipsychotics, correct?
10 A. I don't think that that is a correct
11 statement.
12 Q. Are you familiar with a process called
13 call planning?
14 A. Yes, I am.
15 Q. Are you familiar with a process called
16 deciling?
17 A. Yes, I am.
18 Q. And the people in some department of
19 Janssen would look at a list of every doctor in the
20 United States and come up with doctors most likely to
21 prescribe Risperdal, correct?
22 MR. JACKSON: Objection, calls for
23 speculation.
24 A. I don't think that that is correct. I

Page 52

1 think that they come up with a list of doctors that
2 are prescribing drugs. The likelihood to prescribe in
3 the future is a different thing, but it's a system
4 that looks in the past.
5 Q. Thank you. In fact, Janssen buys
6 information from commercial sources that tell Janssen
7 which doctors have in the past prescribed certain
8 drugs, correct?
9 MR. JACKSON: Objection, vague as
10 to time and otherwise.
11 A. That is correct.
12 Q. And that was true throughout the time
13 you were in sales at Janssen, correct?
14 A. Your question is whether we bought
15 information from a third-party vendor at the time
16 when I was -- is that the question?
17 Q. It's a little broader than that.
18 Let's start over. Janssen was able to identify
19 doctors who had in the past prescribed
20 antipsychotics, correct?
21 A. That is correct.
22 Q. In some instances Janssen knew for a
23 fact certain doctors had prescribed antipsychotics in
24 the past --

Page 53

STATE OF SOUTH CAROLINA
COUNTY OF SPARTANBURG

IN THE COURT OF COMMON PLEAS
FOR THE SEVENTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA ex rel.
Alan Wilson, in his capacity as
Attorney General of the State of South
Carolina,

Civil Action No. 2007-CP-42-1438

Plaintiff,

v.

JANSSEN PHARMACEUTICA, INC.,
JANSSEN, L.P. and JOHNSON &
JOHNSON, INC.,

Defendants.

**DEFENDANT'S OFFER OF PROOF FOR
THE TESTIMONY OF PRESCRIBER
PHYSICIANS; AND ROBERT L. BANK,
M.D., AND BRENDA RATLIFF, M.D.**

Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen") by and through its undersigned counsel, hereby submits this Offer of Proof pursuant to South Carolina Rule of Evidence 103.

Pursuant to this Court's Order entered July 1, 2009, Janssen deposited twenty South Carolina psychiatrists, regarding their prescribing habits, including Risperdal, their impression of Risperdal's safety profile and efficacy, their knowledge of side effects and their interaction with Janssen sales representatives. By Order dated February 25, 2011, this Court precluded the testimony of these physicians. Listed below are specific, relevant excerpts from each deposition.

LORI W. BARWICK, M.D.
(May 7, 2010)

Page/Line	Testimony
pg 7, ln 21 – pg 8, ln 14	Q: Doctor, I want to begin by asking you some questions about your professional background. What is your office address?
	A: I have two office addresses. One is here at Spartanburg Area Mental Health.
	Q: Which is 250 Dewey Avenue, Spartanburg?

Page/Line	Testimony
	A: Correct.
	Q: And you have a private practice as well?
	A: And I contract in private practice to Sherbondy's Psychiatric Services. That's S-h-e-r-b-o-n-d-y-s, Sherbondy's Psychiatric Services, and that's in Greenville.
	Q: How often are you here at the Mental Health Center?
	A: Currently I'm here two days a week [sic], Mondays and Fridays. The hours vary. And I'm there mostly Tuesday, Wednesday, and Thursday.
	Q: In Greenville?
	A: In Greenville.
pg 15, ln 3-5, 10	Q: Doctor, in your experience, is Risperdal typically better tolerated than first-generation antipsychotics?
	A: Yes.
pg 17, ln 6-10	Q: Sure. In your experience, does the use of Risperdal typically conserve health care resources as compared to the first-generation antipsychotics?
	A: Yes.
pg 19, ln 1 – pg 20, ln 18	Q: Yes, ma'am. Overall in your experience, is Risperdal a safer and more effective medication for treating schizophrenia and other psychotic disorders than the first-generation medications?
	A: Yes.
	Q: Now, Doctor, I want to talk to you about off-label use of medications. And by off-label, I mean the use or the prescribing of a drug to treat a condition for which that drug has not been specifically approved by the Food and Drug Administration, okay?
	A: Yes.
	Q: In your experience, are there any circumstances when the label use of medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Yes.
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not a common practice?
	A: Yes.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those circumstances, did you expect your patients to benefit from the off-label use of that medication?
	A: Yes.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes.

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SPARTANBURG COUNTY
2011 APR 08 PM 3:26
MICHELLE L. ACHLEY

Page/Line	Testimony
	Q: Did you expect your patients to benefit from the off-label use of Risperdal?
	A: Yes.
pg 21, ln 10 - 17	Q: Dr. Barwick, has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: They have never promoted it to me. We have had discussions about it, most commonly initiated by me. However, I would say they have always been very specific to note that they are not allowed to promote for off-label uses.
pg 22, ln 3 - 10	Q: And when those discussions have been initiated by you, while there may be some discussion, those reps have been clear to tell you, "I cannot promote to you off-label"?
	A: Correct.
	Q: Is it fair to say that no Janssen sales representative has ever promoted to you any off-label use of Risperdal?
pg 22, ln 14	A: Not to my knowledge.
pg 22, ln 16-18, ln 22	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: Not to my knowledge.
pg 24, ln 21 - pg 25, ln 3	Q: Dr. Barwick, would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes.
	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
	A: Yes.
pg 25, ln 14 - pg 26, ln 17	Q: Dr. Barwick, would you agree that the 2004 package insert for Risperdal incorporated a class warning of hyperglycemia and diabetes?
	A: Yes.
	Q: Were you aware of an association between second generation antipsychotics and weight gain or risk of diabetes prior to the 2004 revision to the package insert for Risperdal?
	A: Yes.
	Q: Did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No, did not change the circumstances.
	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and an increased mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?

Page/Line	Testimony
	A: No.
pg 28, ln 16 - 24	Q: Prior to the publication of the consensus statement by the American Diabetes Association, were you as a practicing psychiatrist aware of an association between antipsychotics and weight gain?
	A: Yes.
	Q: Were you previously aware also of an association between antipsychotics and diabetes?
	A: Yes.
pg 32, ln 2 - 6	Q: Are you, Dr. Barwick - - strike that. Dr. Barwick, has it been your experience that Risperdal is a safe and effective medication for the treatment of schizophrenia and antipsychotic disorder?
pg 32, ln 10-15	A: Yes.
	Q: Dr. Barwick, have you yourself ever experienced anything you consider to be improper marketing of Risperdal?
	A: No.
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 37, ln 17 - pg 38, ln 2	Q: Has a Janssen drug rep ever warned you about prolactinemia with Risperdal?
	A: Yes.
	Q: What did they say?
	A: That Risperdal can elevate prolactin.
	Q: Have you seen that in your patients?
	A: Yes.
	Q: Has a Janssen drug rep ever warned you about adverse cardiovascular events, cerebrovascular events - - or cerebrovascular events?
	A: In the elderly, yes.
RE-EXAMINATION BY DEFENDANTS' COUNSEL:	
pg 42, ln 2-14	Q: Doctor, let me ask you a couple of real quick follow up questions. When you have utilized samples for patients, has that been the result of some financial consideration? The patient was unable to afford the medication?
	A: Yes.
	Q: Would you as a board certified psychiatrist ever give samples of a drug to a patient that you thought would be harmful to the patient?
	A: No.
	Q: So it's purely a financial consideration in looking at prescribing or giving a sample to a patient?
pg 42, ln 18 - pg 43, ln 1	A: Yes.
	Q: But you would still expect that drug to be helpful to the patient, or otherwise you wouldn't give it to them. Is that a fair statement?
	A: Yes. I would only give them a sample medication that I thought was medically sound in treating the illness that they have.

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 SPARTANBURG COUNTY
 2011 APR 18 PM 3:26
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WILLIAM H. BRAGDON, JR., M.D.
(March 15, 2010)

Page/Line	Testimony
pg 9, ln 23 – pg 10, ln 5	Q: Okay. How long have you been an employee or a contract employee of the South Carolina Department of Mental Health?
	A: In one capacity or another, since July of 1997, with the exception of a single pay period in October of 1999.
	Q: All right, sir.
	A: So continuously since October 17 th , 19 -- 1999.
pg 21, ln 15 – pg 23, ln 3	Q: In your experience, are there circumstances when the off-label use of medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: I would say it's not uncommon.
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Sure. I could think of circumstances.
	Q: All right, sir. In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: I would say it's not uncommon.
	Q: Okay. Have you ever prescribed a medication for off-label use?
	A: Absolutely.
	Q: In those circumstances, Dr. Bragdon, did you expect your patients to benefit from that off-label use of the medication?
	A: Generally speaking, when I -- when I prescribe off-label, I do so because I think the potential benefits outweigh the potential risks.
	Q: Right. I mean that's --
	A: And so --
	Q: -- that's the reason to do it, right?
	A: Right.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes, I have.
	Q: Have you ever prescribed Risperdal for off-label use?
	A: I probably have.
	Q: Okay. With the assumption that you probably have, did you expect your patients to benefit from the off-label use of Risperdal, if you had prescribed it off-label?
	A: Yes.
pg 24, ln 17-23	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: Not that I recall.
pg 25, ln 11 – pg 27, ln 1	Q: Are you aware of an association between antipsychotic medications and weight gain?

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2011 APR 18
HOPKINS
2:26
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Page/Line	Testimony
	A: Yes, I am.
	Q: Are you aware of an association between antipsychotic medications and a risk of diabetes?
	A: Yes, I am.
	Q: When you prescribe antipsychotic medications, including Risperdal, do you monitor your patients for weight gain?
	A: It has become my standard practice to weigh my patients whenever they walk into the office to see me.
	Q: For that reason.
	A: For -- for that reason.
	Q: All right, sir. How long has that been your practice?
	A: It's become a more standard practice over the past three to five years.
	Q: Okay. And when you say standard practice, is that Dr. Bragdon's standard practice? Or is that some policy and procedure you're following? Or do you know?
	A: I don't think we have any written policies at the mental health center, but I know that it's a -- I know that it's a -- that it's a practice that -- that I follow, and -- and it's a practice that I understand all of my colleagues at the mental health center follow.
	Q: Okay. Is this something from time to time that you and your peers in -- in meetings or discussions would --
	A: Sure.
	Q: -- would talk about monitoring patients on antipsychotic medications for weight gain or diabetes? That's --
	A: Yes.
	Q: -- something y'all talk about.
	A: Yes, we do.
	Q: Okay. And y'all have been talking about that for a few years is that a fair statement?
	A: Yes.
pg 31, ln 5 - 17	Q: Were you aware of an association between second generation antipsychotics and weight gain or risk of diabetes prior to the 2004 revision to the package insert from Risperdal?
	A: From my own clinical experiences, I was.
	Q: Did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: The circumstances, no.
	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
pg 31, ln 19 - pg 32, ln 4	A: Not that I'm aware of. Not that I recall.
	Q: Okay. Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: Not that I recall.
	Q: Has any Janssen sales representative ever misrepresented to

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 2011 APR 18 PM 3:28
 DR. HOPKINS
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Page/Line	Testimony
	you information about the potential side effects associated with Risperdal use?
	A: Not that I recall.
pg 32, ln 5 – pg 36, ln 4	E EXHIBIT: Defendant's Exhibit #3 Marked for Identification
	Q: Finally, Doctor, let me show you what I'm marking as Exhibit 3 to your deposition. This is a December 10, 2003 "Dear health care provider" letter sent out by Janssen. Take a look at that, if you don't mind, Dr. Bragdon.
	A: Sure.
	A: Okay
	Q: Dr. Bragdon, have you ever seen this letter before?
	A: I probably received a copy in the mail. I don't specifically remember whether I - - whether I looked at it or not.
	Q: Okay. With that qualifier, probably don't know - - certainly don't have a - - a recollection as you sit here today of having read - -
	A: Right.
	Q: - - and reviewed that letter; is that a fair statement?
	A: Correct.
	Q: Okay. If you received this letter and if you read it, did this letter - - did Defendant's Exhibit 3 caused you to change the circumstances in which you prescribe antipsychotics to your patients?
	A: No.
	Q: Did this letter, again with that same introduction, if you received it and if you read it - -
	A: Uh-huh.
	Q: - - did it cause you to change your choice of which antipsychotic to prescribe?
	A: No.
	Q: Did this letter cause you to change your methods for monitoring for side effects in your patients on antipsychotic medications?
	A: At that point in time, no.
	Q: Okay. Help me with that. You say not at that point in time. What do you mean?
	A: Might be taking a bit of a side here. I - - one demarcating point for me is - - of course I'm in the Navy Reserve and I was called up to active duty overseas in - - in 2005.
	Q: Okay.
	A: And when I returned from active duty in early 2006, I noticed that we were - - we had begun doing things a little differently in our monitoring after I got back than before I left.
	Q: Okay.
	A: We were - - we were becoming more attentive to the practice of weighing people on a regular basis and checking labs, such as blood sugar and cholesterol.
	Q: Okay. And when you say we, you're referring to the South Carolina Department of Mental Health?

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SPARTANBURG COUNTY
2011 APR 18 PM 3:26
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Page/Line	Testimony
	A: When I say we, I know that my colleagues and I at the mental health center - -
	Q: Okay.
	A: - - were - - were taking a more - - were taking a more consistent approach to - - had begun to take a more consistent approach to - -
	Q: Sure.
	A: - - monitoring weight and metabolic parameters.
	Q: Okay. And you returned from active duty to the mental health center when in 2006?
	A: January 2006.
	Q: Okay. And how long had you been gone?
	A: For one year.
	Q: So January '05 to January '06.
	A: Correct.
	Q: All right, sir. Did you ever talk with your colleagues about, "Hey guys, we're - - now we're doing this. Where did this come from? Why are we doing this?" Anything like that, when you got back?
	A: I don't recall there being a specific discussion. I do remember that there was more attention given to that, for example, during - - during lunch programs where speakers would come and talk to us and we would have discussions. To give an example, one of my colleagues and med school classmates who at the time was employed with the VA Hospital shared with my colleagues and me how he was monitoring his patients at the VA.
	Q: Okay.
	A: And I took to heart some of the practices that he used. And also, there was more - - there were more educational materials coming out that had mentioned the - - that were listing the recommended guidelines of the American Diabetes Association for monitoring, and we were starting to - - to implement these guidelines on a regular basis.
	Q: Are you talking about guidelines that came out of the consensus statement?
	A: I think so.
	Q: Okay. All right. So when you returned from active duty in the Navy in January 2006 - -
	A: Correct.
	Q: - - this was kind of a hot topic.
	A: Exactly.
	Q: People were talking about it and people were doing things that they hadn't been doing previously.
	A: Exactly.

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SALLIE AMANDA CARTER, M.D.
(May 20, 2010)

Page/Line	Testimony
pg 14, ln 6 - 12	Q: In your experience, does Risperdal typically have a more moderate side effect profile than first generation antipsychotics?
	A: Yes.
	Q: In your experience, is Risperdal typically better tolerated than first generation antipsychotics?
	A: Yes.
pg 17, ln 21 - pg 18, ln 5	Q: Overall in your experience, is Risperdal a reasonably safe and effective medication for treating schizophrenia and other psychotic disorders?
	A: Yes.
	Q: Overall in your experience, is Risperdal a safer and more effective medication for treating schizophrenia and other psychotic disorders than the first generation medications?
	A: Yes.
pg 18, ln 15 - pg 20, ln 17	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Yes.
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: Yes.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those circumstances, did you expect your patients to benefit from the off-label use of the medication?
	A: Yes.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes.
	Q: For what conditions did you prescribe antipsychotics that your -- I'm sorry. Strike that. Have you ever prescribed Risperdal for off-label use?
	A: Yes.
	Q: Did you expect your patients to benefit from the off-label use of Risperdal?
	A: Yes.
	Q: For what conditions have you prescribed Risperdal for off-label use?
	A: Kids who are -- have severe violent tendencies or are threatening to commit violent acts or who have committed violent acts, but who don't have typical symptoms of psychosis, don't have the positive and negative symptoms that you described, but are severely emotionally disturbed and

Page/Line	Testimony
	violent.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: No.
pg 22, ln 7 - 14	Q: Okay. Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes.
	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
	A: Yes.
pg 22, ln 25 - pg 23, ln 3	Q: Would you agree that the 2004 package insert for Risperdal incorporated a class warning of hyperglycemia and diabetes?
	A: Yes.
pg 23, ln 20, pg 24, ln 9	Q: Has any Janssen sales representative ever represented anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: No.

BALBIR COSHAL, M.D.

(March 10, 2010)

Page/Line	Testimony
pg 17, ln 15 - 21	Q: In your experience, does Risperdal typically have a more moderate side effect profile than first generation antipsychotics?
	A: Yes.
	Q: In your experience, is Risperdal typically better tolerated than first generation antipsychotics?
	A: Yes.
pg 23, ln 11 - 25	Q: Has any Janssen -- the maker of Risperdal -- has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you

Page/Line	Testimony
	any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: No.
pg 27, ln 14 – pg 28, ln 16	Q: Okay. Would you agree, doctor, that the 2004 package insert for Risperdal incorporated a class warning of hyperglycemia and diabetes?
	A: Yes.
	Q: Okay. Doctor, were you aware of an association between second generation antipsychotics and weight gain or a risk of diabetes prior to the 2004 revision of the package insert for Risperdal?
	A: Prior to 2004, yes.
	Q: Okay. Did the change in this package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No.
	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
pg 28, ln 20	A: Okay. No.
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 43, ln 25 – pg 44, ln 12	Q: Did you ever perform any independent evaluation of the -- of the materials left by drug reps? Did you ever, you know, try to validate the information that was left -- was provided in those pamphlets or brochures?
	A: Well, I'm usually skeptical. Okay. I know that the representatives come and their, I mean, their interests and my interests are different. I'm very much aware of that. And I don't buy everything that they say because, I mean, I'm aware that their interest is in promoting the sale of the medication. And my interest is in helping the patient.
RE-EXAMINATION BY DEFENDANTS' COUNSEL:	
pg 46, ln 22 – pg 47, ln 20	Q: If I heard you correctly, whether the drug rep works for AstraZeneca, Eli Lilly, Janssen, whoever it may be, you understand who they work for, correct?
	A: Yes. I understand who they work for.

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SPARTANBURG COUNTY
2011 APR 18 PM 3:25
HOPKINS

Page/Line	Testimony
	Q: And I think you were clear in what you said which is their interests are different than my interests; is that correct?
	A: Yes. Yes.
	Q: And your interests as a board-certified psychiatrist are patient care first and foremost, correct?
	A: Yes.
	Q: So you as the doctor are going to exercise your clinical judgment, your experience, your background in making decisions on what you're going to prescribe for your patient; is that a fair statement?
	A: Yes.
	Q: Doctor, would you ever under any circumstance start some patient on a medication you thought was dangerous, wasn't effective simply because you had some samples of it?
	A: No.
pg 49, ln 20 – pg 50, ln 13	Q: You talk about staff meetings. Y'all talk about different classes of drugs and - -
	A: Yes.
	Q: - - prescribing?
	A: Yes. We discuss all these, you know, adverse events. Especially the metabolic events have discussed so frequently. And we discussed what we're going to do and how we're going to treat our patients and protect them from harm.
	Q: Okay. And that's within the Department of Mental Health setting?
	A: Yes. Yes.
	Q: Okay. How long have you been with the Department of Mental Health?
	A: Twenty years.
	Q: Within the Department of Mental Health, have you had the ability to prescribe Risperdal since it came on the market?
	A: Yeah.

JAMES LIDDELL ELMORE, M.D.
(November 19, 2010)

Page/Line	Testimony
pg 13, ln 5 - 9	Q: All right, sir. What year - - the 14 years you were with the Department of Mental Health of the State of South Carolina, but what years were those?
	A: 1993 to 2007.
pg 25, ln 18 – pg 26, ln 10	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No. In fact, they are at pains to point out what the guidelines are, and to indicate that they are not asking me to do anything like that.
	Q: And by guidelines, you mean they point out to you those uses for which the Risperdal has been approved by the FDA?
	A: That's correct.

Page/Line	Testimony
	Q: And those are the prescribing guidelines you had touched on earlier?
	A: Yes.
	Q: Right. Have you ever received or seen any communication from Janssen, promoting the off-label use of Risperdal?
	A: Not that I recall.
pg 30, ln 21 – pg 31, ln 24	Q: So when -- were you aware of an association between second generation antipsychotics and weight gain or risk of diabetes prior to the 2004 revision to the package insert for Risperdal?
	A: Yes.
	Q: Dr. Elmore, did the change to the package insert for Risperdal, in 2004, cause you to change the circumstances in which you prescribe Risperdal for patients?
	A: No. it reinforced what had previously been information available to use from the company, --
	Q: I got you.
	A: -- in my experience.
	Q: Yes, sir. Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided in the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: No.
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 44, ln 25 – pg 45, ln 23	Q: And has a Janssen representative ever suggested to you that Risperdal may be used by -- may be used in children?
	A: Not that I recall.
	Q: Teens?
	A: That that I recall.
	Q: The elderly?
	A: Not that I recall. I would say in the elderly, in particular, you know, they would bring up these warnings which had come out more recently about dementia and so --
	Q: Has a Janssen drug rep ever warned you about using Risperdal for a long term management for schizophrenia?
	A: Well, they, like other representatives, would cover the risks and side effects with reference to longer term use, and so on. Yeah.
	Q: They warned you about dangerous side effects of Risperdal, including weight gain?
	A: Including weight gain? Yes.
	Q: Hyperglycemia?

Page/Line	Testimony
	A: Yes.
	Q: Diabetes?
	A: Yes.

RICARDO JOSE FERMO, M.D.

(August 13, 2010)

Page/Line	Testimony
pg 13, ln 19 – pg 15, ln 11	Q: In your experience, are patients who take first generation antipsychotics, such as Haldol and Thorazine more likely to experience tardive dyskinesia than patients who take second generation antipsychotics?
	A: Yes.
	Q: In your experience, does Risperdal typically have a more moderate side effect profile than first generation antipsychotics?
	A: Yes.
	Q: In your experience, is Risperdal typically better tolerated than the first generation antipsychotics?
	A: Yes.
	Q: In your experience with antipsychotic medications, are both efficacy and tolerability important considerations in the choice of which antipsychotic to prescribe?
	A: Yes.
	Q: In your experience, do both efficacy and tolerability increase the likelihood that a patient will take an antipsychotic medication consistently?
	A: Yes.
	Q: In your experience are patients who consistently take their antipsychotic medications less likely to require costly follow-up treatment, such as inpatient psychiatric care, than patients who do not consistently take their medications?
	A: Yes.
	Q: In your experience, are patients who consistently take their antipsychotic medications less likely to require costly follow-up treatment, such as emergency room care, than patients who do not consistently take their medications?
	A: Yes.
	Q: In your experience, does increased patient compliance with antipsychotic prescriptions result in over-all conservation, as opposed to consumption of health care resources?
	A: Yes.
pg 17, ln 12 – pg 19, ln 17	Q: In your experience, does the use of Risperdal typically conserve health care resources, as compared to first generation antipsychotics?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Yes.

Page/Line	Testimony
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: Yes.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those circumstances when you did prescribe a medication for off-label use, did you expect your patients to benefit from the off-label use of the medication?
	A: Yes.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes.
	Q: For what conditions did you prescribe antipsychotics that you are unsure - - strike that. Have you ever prescribed Risperdal for off-label use?
	A: Yes.
	Q: When you prescribed Risperdal for off-label use, did you expect your patients to benefit from the off-label use of Risperdal?
	A: Yes.
	Q: For what conditions have you prescribed Risperdal for off-label use?
	A: Risperdal's been out a long time. I've used it off-label before it got on-label for bipolar disorder, in both adults and children. I believe I've used it off-label for Tourette's disorder. I've used it off-label before it got on-label with children with schizophrenia. Those are the ones I would think - - could think of off-hand.
	Q: Okay. Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: Never.
pg 23, ln 6 - 9, 11 - 13, 15	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes.
	Q: Would you agree that the 1993 package insert for Risperdal advised of association between Risperdal and diabetes?
	A: Yes.

Page/Line	Testimony
pg 24, ln 4 -7, 13 - 16	Q: Would you agree that the 2004 package insert for Risperdal incorporated a class warning of hyperglycemia and diabetes?
	A: Yes.
	Q: Did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No.
pg 25, ln 4 - 8	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: No.
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 47, ln 8 - 18	Q: What's your understanding of the FDA approval of Risperdal in the use of adolescents, that time line?
	A: That time line was only in the last two or three years that it got FDA approved for children. It was almost at the -- at the end of its patent life.
	Q: Before that was approved by the FDA, did any Janssen/J&J representative ever specifically informed you that Risperdal was not approved for use in that population?
	A: Yes.

ANDREW W. HEDGEPATH, M.D.
(March 5, 2010)

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2011 APR 18 PM 3:26
M. HOPE BACKLEY

Page/Line	Testimony
pg 20, ln 2 - 15	Q: Would you agree with me, doctor, that your clinical experience or your practice experience --
	A: Yeah.
	Q: -- I mean certainly one drug doesn't fit all?
	A: Correct.
	Q: And that is part of your clinical judgment as a board certified psychiatrist determine who am I prescribing this for and what are the risk/benefit analysis?
	A: That's accurate. Correct.
	Q: All right, sir. In your experience, is Risperdal typically better tolerated than first generation antipsychotics?
	A: Yes. I'd say it is.
pg 27, ln 6 - pg 30, ln 8	Q: In your experience, are there circumstances when off-label use of medications is appropriate?
	A: Yes.
	Q: In your experience, is it far to say that off-label use of medications is not an uncommon practice?
	A: It's not uncommon. There are certain psychiatric conditions which there's no official indication formally for that diagnosis so --
	Q: Okay.
	A: -- adhering to that rule would make treatment not viable for various illnesses.

Page/Line	Testimony
	Q: Yes, sir. In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: I'd say that. Yes.
	Q: Have you ever prescribed a medication for off-label use?
	A: Sure. Certainly.
	Q: In those circumstances, did you expect your patients to benefit from that off-label use of the medication?
	A: I did.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: I have.
	Q: For what conditions did you prescribe antipsychotics - - actually let me strike that, doctor. Have you ever prescribed Risperdal for off-label use?
	A: I have.
	Q: Okay. Did you expect your patients to benefit from the off-label use of Risperdal?
	A: I did.
	Q: For what conditions have you prescribed Risperdal for off-label use?
	A: I've had issues doing psychiatry consult liaison where persons are - - have delirium rather from sepsis infection or an unknown etiology. And that for some reason that maybe there was concerns over use of Haldol or past under experiences, so Risperdal was selected in that incident. I can recall for the short term treatment of delirium and worked fine.
	Q: Okay.
	A: Certainly, I guess, if within the child setting, although I guess now, it's the - - I guess during my training there was no official indication for the use of Risperdal for autism, head-banging or associated behaviors, although that's, I guess, now as of looking at it last night, now it has a certain official indication for that.
	Q: Okay.
	A: And then, of course, persons that have a diagnosis of schizoaffective disorder, there's not a formal indication of any of those meds for that so I expect benefit from the psychotic symptoms associated with that - - with Risperdal.
	Q: Okay. Let me ask you now about marketing.
	A: Uh-huh.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.

Page/Line	Testimony
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication from Janssen promoting off-label use of Risperdal?
	A: I have not.
pg 33, ln 8 - 16	Q: Doctor, would you agree that the 1993 package insert that we've marked as Defendant's Exhibit 1 for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes.
	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
	A: Yes.
pg 34, ln 14 - pg 35, ln 3	Q: Doctor, this is the revised Risperdal package insert dated April 13 th , 2004. And if you look it over, particularly at the highlighted section on Page 2. Would you agree that the 2004 package insert for Risperdal incorporated a class warning of hyperglycemia and diabetes?
	A: I would.
	Q: And that's what you had referred to earlier - -
	A: Correct.
	Q: - - being familiar with? All right. Were you aware of an association between second generation antipsychotics and weight gain or a risk of diabetes prior to the 2004 revision to the package insert for Risperdal?
	A: I was.
pg 37, ln 19 - pg 38, ln 8	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: No.

GLENN HOOKER, M.D.
(April 20, 2010)

Page/Line	Testimony
pg 7, ln 23 - pg 8, ln 18	Q: Doctor, I want to briefly ask you some questions about your professional background. We're here today at Orangeburg Mental Health Center. Is this typically your office?
	A: It's one of the ones I go to.
	Q: Okay. What is the address here?
	A: 2319 St. Matthews Road.

Page/Line	Testimony
	Q: In Orangeburg, South Carolina?
	A: Yes.
	Q: What other offices do you practice?
	A: There's a satellite at St. Matthews.
	Q: Okay.
	A: I practice also at the Holly Hill Mental Health Center.
	Q: Okay.
	A: And sometimes I go to the Denmark Mental Health Center.
	Q: Are those all mental health centers operated under the South Carolina Department of Mental Health?
	A: Yes.
pg 25, ln 13 – pg 26, ln 19	Q: In your experience, Dr. Hooker, are there circumstances when the off-label use of medications is appropriate?
	A: Yes.
	Q: Is it your experience, is it fair to say, that off-label use of medications is not an uncommon practice?
	A: Yes.
	Q: In your experience are there circumstances when the off-label use of anti-psychotic medications is appropriate?
	A: Yes.
	Q: In your experience is it fair to say that off-label use of anti-psychotic medications is not an uncommon practice?
	A: Yes.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those circumstances, Dr. Hooker, did you expect your patients to benefit from that off-label use of the medication?
	A: Yes.
	Q: Have you ever prescribed an anti-psychotic medication for off-label use?
	A: Yes.
	Q: Have you ever prescribed Risperdal for off-label use?
	A: Yes.
	Q: Did you expect your patients to benefit from the off-label use of Risperdal?
	A: Yes.
pg 27, ln 19 – pg 28, ln 9	Q: All right, sir. Dr. Hooker, has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication from Janssen promoting off-label use of Risperdal?

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 J. L. HARRIS

Page/Line	Testimony
pg 31, ln 5 – pg 33, ln 10	A: No.
	Q: Dr. Hooker, would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes.
	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
	A: Yes.
	Q: Doctor, you can set that one aside. Let me show you what I've marked as Defendants' Exhibit 2. And I'll represent to you this is the revised Risperdal package insert dated April 13, 2004. Again please feel free to look at this, but again I would direct your attention to the paragraphs and areas on Page 2 that I've highlighted. Dr. Hooker, would you agree that the 2004 package insert for Risperdal incorporated a class warning of hyperglycemia and diabetes?
	A: Yes, but I think they all -- that group had started carrying these types of warnings.
	Q: Yes, sir. Were you aware, Dr. Hooker, of an association between second generation anti-psychotics and weight gain or a risk of diabetes prior to the 2004 version -- or revision to the package insert for Risperdal?
	A: 2004?
	Q: Yes, sir.
	A: Once again probably through the literature and through talk with the various reps and others mainly around the area of Zyprexa there was some talk of that.
	Q: So prior to the class warning that's reflected in Exhibit 2 there -- you recall that there was some talk primarily around Zyprexa with regard to potential for weight gain and diabetes?
	A: Right.
	Q: All right, sir. Dr. Hooker, did the change in the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No.
	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided in the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: No.
RE-EXAMINATION BY DEFENDANTS' COUNSEL:	
pg 50, ln 2 – 12	Q: And have you prescribed Risperdal, I think, since 1994?

Page/Line	Testimony
	A: Yes.
	Q: Has anyone told you in connection with your practice here at the Orangeburg Mental Health Center or any other mental health centers you work at in South Carolina that you were to stop prescribing Risperdal?
	A: Asked me to stop prescribing?
	Q: Yes, sir.
	A: No.
pg 50, ln 17 – pg 51, ln 10	Q: Has anyone told you this drug is not safe to prescribe to patients and you should stop immediately?
	A: No.
	Q: Doctor, I'm -- you described for Mr. Simmons what you meant by the term potent. I want to make sure that I followed you. I tried to write it down. You said that your experience with Risperdal was that you could get an anti-psychotic effect with a lower dosage; is that correct?
	A: Right.
	Q: In comparison to some other drugs?
	A: Yes.
	Q: Okay. And also you said that your experience has been that with some patients Risperdal works more quickly to address those psychoses in comparison with some other drugs. Is that a fair statement?
	A: Yes. For some patients.

ANIL JUNEJA, M.D.
(April 20, 2010)

Page/Line	Testimony
pg 35, ln 9 - 25	Q: You told me earlier that you have prescribed Risperdal for patients?
	A: Quit a bit.
	Q: Have you -- do you continue to prescribe Risperdal for patients?
	A: I do.
	Q: Okay. And when you do that do you expect those patients to derive a benefit from Risperdal?
	A: Yes, I do.
	Q: And is it fair to say, Doctor, that you would not as a board certified general psychiatrist prescribe a drug that you thought was unsafe to a patient?
	A: I agree with you 100 percent.
	Q: And would not prescribe a drug that you believed to be ineffective for a patient?
	A: I agree with you.
pg 36, ln 19 – pg 38, ln 10	Q: You prescribe Risperdal currently?
	A: Yeah.
	Q: For certain patients?
	A: Yes.

Page/Line	Testimony
	Q: And you expect the patient for whom you prescribe Risperdal to derive some benefit from it?
	A: I do.
	Q: And you wouldn't prescribe Risperdal to that patient if you thought it was unsafe for that patient?
	A: I agree with you.
	Q: And you wouldn't prescribe Risperdal for that particular patient if you thought that Risperdal was going to be ineffective for that patient?
	A: I agree with you.
	Q: And now my question is in your experience is Risperdal a safer and more effective medication for treating schizophrenia and other psychotic disorders than first generation anti-psychotics?
	A: I think it appears that it is better tolerated than, say, Haldol, first generation anti-psychotic medication. It appears that it has less of the neurological side effects than the Haldol. It appears that more patients are compliant and may even be doing better, but again the word is may.
	Q: Sure.
	A: And it appears to me that - - that Risperdal - - again that is my own observation and that might sort of explain that I probably have prescribed Risperdal maybe as a No. 1 second generation anti-psychotic medications because I have seen, and again that's my own experience without any data collection, that it has less of a burden, though the FDA has an across-the-board labeling about metabolic syndrome warning that the - - you know, but my experience has been - - in fact that's why I have been using it a little bit more than - - that, say, Zyprexa or Seroquel, which seem to have caused to me much more weight gain than the Risperdal has.
pg 47, ln 12 - pg 48, ln 19	Q: Are you aware of an association between anti-psychotic medications and weight gain?
	A: Yes.
	Q: And we talked briefly about that earlier with Zyprexa, Seroquel, and then you anecdotally touched on Risperdal as well?
	A: I think I - - as I said to you, that the FDA has an across-the-board warning about the weight gain and hyperglycemia and metabolic syndrome.
	Q: Yes, sir.
	A: But to me it has appeared that - - that the weight gain has been less in comparison to Zyprexa and the Seroquel and Clozapine also. And with that I'm assuming would be less burden of the diabetes.
	Q: And - - and when you say less, you're referring to your experience with Risperdal in your patient population is that Risperdal has less of a prevalence of those metabolic symptoms than, say, Zyprexa, Seroquel, or others, correct?

Page/Line	Testimony
	A: I think it is true that I have seen very few cases, I would say less than five, where Risperdal caused a rather significant weight gain and then followed by a hyperglycemia or some other diabetes related manifestation. Q: Okay. A: Whereas with Zyprexa, Clozaril, and some of the Seroquel, I would say top is Zyprexa followed by Clozapine followed by Seroquel, that I've seen more cases of weight gain and resulting diabetes, or if they happen to be diabetic, amazingly it appears that these medicines throw them off. The insulin is not as effective as it was before the Seroquel was started or the Zyprexa was started.
pg 51, ln 18 – pg 52, ln 1	Q: Dr. Juneja, would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain? A: It did. Q: Okay. Would you agree that the -- this 1993 package insert for Risperdal advised of an association between Risperdal and diabetes as a metabolic disorder? A: Yes.
pg 52, ln 14 – pg 54, ln 1	Q: Doctor, would you agree that the 19 -- or excuse me. Would you agree that the 2004 package insert for Risperdal incorporated a class warning of hyperglycemia and diabetes? A: That is true. Q: And this is what you were referring to earlier -- A: Right. Q: -- in your deposition? Is it fair to say that, Dr. Juneja, your experience with Risperdal, and I'm talking about new York your experience, is that it has less of a prevalence of weight gain or diabetes as opposed to other drugs in the same class, that being second generation anti-psychotics? A: I would say it this way. From the highest, the first is the most weight gain Zyprexa. Q: Right. A: Seroquel, Risperdal, Abilify, and Geodon. That is sort of my -- Q: Okay. A: -- way of putting it. Q: Okay. And so your experience has been that there is some descending order of what you have seen in your patients of weight gain and diabetes and that these drugs are not -- the experience of your patient population is not the same for each drug? A: And -- and you -- without any data which compared has to have had those five or six -- Q: Yes. A: -- drugs, it does appear to be that Zyprexa predictably has resulted in tremendous weight gain. Q: Okay. A: Versus Risperdal weight gain, if it comes along, it is slow and

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Page/Line	Testimony
	not as much as I normally see with Zyprexa, Seroquel, and Clozapine, which can be quite a bit in the one - - first month or so.
pg 54, ln 22 – pg 55, ln 19	Q: Okay. And so in that - - let's say that ten-year time frame, to - - 1994 to 2004 when the package insert was revised to include a class warning, in your practice in your experience did you recognize an association between second generation anti-psychotics and weight gain in your patients before this class warning came out?
	A: Yes, I did. And I think the Zyprexa when it came out, that's the time because I think Zyprexa was the second to follow after Risperdal. And - - and there was definitely a - - a sort of awareness. The - - the talk of this warning issue was coming up, I think, a couple of years before the FDA finalized it. And so there was a talk about that there seems to be - - and at that time it was Zyprexa again where we were talking about it, hearing, and reading about it as a weight gain. I was not aware of Risperdal. In fact, that's why I said I tended to prescribe more because it apparently has - - it has more predictable side effects. And, say, the Zyprexa I prescribe now because I know more patients will gain weight much more.
pg 58, ln 12 - 18	Q: I understand. Okay. Dr. Juneja, has any Janssen sales representative ever misrepresented to you - -
	A: No.
	Q: - - information about the potential side effects associated with Risperdal use?
	A: No.
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 68, ln 2 – pg 70, ln 2	Q: Okay. And I think you said that in connection with your direct testimony that as regards the weight gain across-the-board with the second generation atypicals you found there to be an explosion of new cases in terms of weight gain, correct?
	A: I think the Zyprexa and Seroquel and Clozapine disproportionately it appears to me, whether it's - - it's true or not, because I am not aware of anybody finding that had to have trialed.
	Q: And - - and again I don't want to belabor the point, but just so I understand, in comparing Exhibit No. 1 and Exhibit No. 2, you don't have any personal knowledge of any clinical studies during any of that time frame as regards whether the weight gain and hyperglycemia should have been classified as a warning or an adverse event, you're just relating your anecdotal personal experience; is that correct?
	A: Right. I think the 2000 - - this warning was well-known to us coming, but whether I had access to those studies, no.
	Q: Right.
	A: But I think it was very obvious that it was coming. In fact,

Page/Line	Testimony
	people started to talk and see the association before that.
	Q: At what point in time do you think that occurred?
	A: It would be a guess because I think '99, I recall, or '98, '99 Zyprexa came along. I may be wrong there.
	Q: Yes, sir.
	A: But I would say around 2000 to 2001 there were more talk about in the journals and the -- and the -- the awareness because --
	Q: Yes, sir.
	A: -- I think with the Risperdal the weight gain was not as sort of -- sort of obvious that we saw with Zyprexa like you send a person with one months's supply and they come back a different person right away, 40 pounds of weight gain. So I think that -- and then more and more information because some people, you know, were using, I think, Zyprexa and Seroquel at a lower dose for non-schizophrenia indicated indications at that time because that caused some more, I think, population for weight gain than Risperdal. Risperdal -- Risperdal was really never used for insomnia, whereas Zyprexa people did for a time, which is not an indication at all. And that, I think, cause the more weight gain issue too.

KENNETH G. KASSEBAUM, M.D.
(JULY 8, 2010)

Page/Line	Testimony
pg 12, ln 1 - 7	Q: Okay. And you are an employee of the South Carolina Department now?
	A: Correct.
	Q: And have been continuously since you --
	A: Correct.
	Q: -- moved here? Okay.
	A: I had no private practice.
pg 17, ln 9 -- pg 19, ln 2	Q: In your experience, are patients who take first-generation antipsychotics such as Haldol and Thorazine more likely to experience extrapyramidal or anticholinergic side effects than patients who take a second-generation antipsychotic?
	A: Yes.
	Q: In your experience, are patients who take first-generation antipsychotics, again such as Haldol and Thorazine, more likely to experience tardive dyskinesia than patients who take a second-generation?
	A: Yes.
	Q: In your experience, does Risperdal typically have a more moderate side effect profile than first-generation antipsychotic?
	A: Yes.
	Q: In your experience, is Risperdal typically better tolerated than first-generation antipsychotics?

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Page/Line	Testimony
	A: Yes.
	Q: Dr. Kassebaum, in your experience with antipsychotic medications, are both efficacy and tolerability important considerations in the choice of which antipsychotic to prescribe?
	A: Yes.
	Q: In your experience, do both efficacy and tolerability increase the likelihood that a patient will take an antipsychotic medication consistently?
	A: Yes.
	Q: In your experience, are patients who consistently take their antipsychotic medications less likely to require costly follow-up treatments such as inpatient psychiatric care than patients who do not consistently take their medication?
pg 19, ln 8 - 16	A: Yes.
	Q: I sure will. In your experience, does increased patient compliance with antipsychotic prescriptions result in overall conservation as opposed to consumption of healthcare resources?
	A: Yes.
	Q: In your experience, does the use of Risperdal typically conserve healthcare resources as compared to first-generation antipsychotics?
pg 19, ln 25 - pg 20, ln 23	A: Yes.
	Q: Okay. Sure. In your experience, does increased patient compliance with antipsychotic prescriptions typically decrease the human consequences of psychiatric --
	A: Yes.
	Q: -- illness? In your experience, does compliance taking antipsychotic medications typically make patients less likely to experience a recurrence of psychosis?
	A: Yes.
	Q: Does it make those patients less likely to be violent?
	A: Yes.
	Q: Less likely to be an extreme burden on family members?
	A: Yes.
	Q: And finally, less likely to experience a worsening of their condition?
	A: Yes.
	Q: Overall in your experience, is Risperdal a reasonably safe and effective medication for treating schizophrenia and other psychotic disorders?
pg 21, ln 20 - pg 22, ln 22	A: Reasonably safe. Yes.
	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: It is not uncommon.
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.

Page/Line	Testimony
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: It's not uncommon.
	Q: Have you ever prescribe a medication for off-label use?
	A: Yes.
	Q: In those circumstances, did you expect your patients to benefit from the off-label use of the medication?
	A: Yes.
	Q: Have you ever prescribe an antipsychotic medication for off-label use?
	A: Yes.
	Q: Have you ever prescribed Risperdal for off-label use?
	A: Yes.
	Q: Did you expect your patients to benefit from the off-label use of Risperdal?
	A: Yes.

ROSEN J. LAWSIN, M.D.

(March 25, 2010)

Page/Line	Testimony
pg 16, ln 12 - 15	Q: Sure. In your experience, Dr. Lawsin, is Risperdal typically better tolerated than first generation antipsychotics?
	A: Yes.
pg 19, ln 17 - 21	Q: Overall in your experience, Dr. Lawsin, is Risperdal a reasonably safe and effective medication for treating schizophrenia and other psychotic disorders?
	A: Yes.
pg 22, ln 13 - 22	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: Yes.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those experiences when you did, did you expect your patients to benefit from the off-label use of that medication?
	A: Yes.
pg 22, ln 24 - pg 23, ln 8	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes.
	Q: Have you ever prescribed Risperdal for off-label use?
	A: Yes.
	Q: Did you expect your patients to benefit from that off-label use of Risperdal?
	A: Yes.
pg 24, ln 17 - pg 25, ln 7	Q: Sure. Okay. Doctor, now I want to ask you some questions relating to marketing. Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?

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JULIE E. KLEVEN

Page/Line	Testimony
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No, sir.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No, sir.
	Q: Have you ever received or seen any communication, documents, writings from Janssen promoting the off-label use of Risperdal?
	A: No, sir.
pg 28, ln 13-16, ln 18-25	Q: Would you agree, Doctor, that this 1993 package insert for Risperdal advised of an association between Risperdal and diabetes, which is referenced in the right-hand column?
	A: I never had any patient who developed significant weight gain, to become diabetic on Risperdal.
	Q: Okay. My question -- and -- and I appreciate the clarification. My question is simply, do you see that Exhibit 1 contains an advising of an association between Risperdal and --
	A: Yes.
	Q: -- diabetes?
pg 29, ln 2 - 7	A: As I said earlier, every medication, atypical neuroleptic including Abilify, which has the least weight gain, has still the
	Q: Sure. Okay. But your experience has been --
	A: I've never had anyone develop diabetes because of Risperdal and weight gain, no, sir.
pg 30, ln 8 - pg 31, ln 6	Q: Sure. Were you aware of an association between second generation antipsychotics and weight gain or a risk of diabetes --
	A: Yes.
	Q: -- prior to this 2004 revision to the package insert for Risperdal?
	A: For Risperdal, yes.
	Q: Okay. You were aware of that.
	A: Yes.
	Q: Okay. Did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No, sir.
	Q: Dr. Lawsin, has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: None. No, sir.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: No, sir.
pg 31, ln 14 - 18	Q: Sure. Has any Janssen sales representative ever misrepresented to you information about the potential side

Page/Line	Testimony
	effects associated with Risperdal use?
	A: No, sir.
RE-EXAMINATION BY DEFENDANTS' COUNSEL:	
pg 44, ln 16 – pg 45, ln 4	Q: I have a couple real quick. Dr. Lawsin, if -- if I heard you correctly earlier, you -- I think you characterized that you understand drug reps, whoever they work for, a drug reps job is to try and sell a product; you understand that.
	A: Give you the information --
	Q: Right.
	A: -- they are supposed to give you.
	Q: Right.
	A: Yes, sir.
	Q: And your job as a psychiatrist is to attempt to provide the best care for your patients.
	A: Yes, sir.
	Q: And those two are kind of separate, aren't they?
	Q: You have your job; they have their job.
pg 45, ln 6 - 23	A: Yes.
	Q: Right. And I think you said, "I don't always believe what drug reps tell me because my study is what I see in my patients."
	A: Oh, yeah. I mean, you know, they say "Oh, here's this study." And I said, "No."
	Q: You want to see how it's affecting your own --
	A: Exactly.
	Q: -- patients. Right. Okay. And -- and that's what you do. You bring to bear your experience and your clinical judgment when you decide what to prescribe for a patient.
	A: Yes, sir.
	Q: And you do the same thing when you decide whether to keep them on that drug or switch them to another one.
	A: Exactly.

PAUL PHILLIP LOWE, M.D.

(September 1, 2010)

Page/Line	Testimony
pg 14, ln 15 – pg 16, ln 7	Q: In your experience, Dr. Lowe, are patients who take first generation antipsychotics such as Haldol and Thorazine more likely to experience extrapyramidal and anticholinergic side effects than patients who take a second generation antipsychotic?
	A: Yes, sir.
	Q: In your experience, are patients who take first generation antipsychotics, again such as Haldol and Thorazine, more likely to experience tardive dyskinesia than patients who take a second generation antipsychotic?
	A: Much more likely.
	Q: In your experience, Dr. Lowe, does Risperdal typically have a more moderate side effect profile than first generation

Page/Line	Testimony
	antipsychotics?
	A: Yes, sir.
	Q: In your experience, is Risperdal typically better tolerated than first generation antipsychotics?
	A: Yes, sir.
	Q: In your experience with antipsychotic medications, are both efficacy and tolerability important considerations in the choice of which antipsychotic to prescribe?
	A: Yes, sir.
	Q: In your experience, do both efficacy and tolerability increase the likelihood that patient will take an antipsychotic medication consistently?
	A: Yes, sir.
	Q: In your experience are patients who consistently take their antipsychotic medications less likely to require costly follow-up treatment, for example, emergency room care, than patients who do not consistently take their medication?
	A: Yes, sir.
	Q: In your experience, does increased patient compliance with antipsychotic prescriptions result in an overall conservation, as oppose to consumption of health care resources?
	A: Yes, sir.
	Q: In your experience, does the use of Risperdal typically conserve health care resources, as compared to first generation antipsychotics?
	A: Yes, sir.
pg 17, ln 8 - 12	Q: Overall in your experience, is Risperdal a safer and more effective medication for treating schizophrenia and other psychotic disorders, than the first generation medications?
	A: By far.
pg 17, ln 22 – pg 19, ln 20	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Oh, yes, sir.
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes, sir.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: Yes, sir.
	Q: Have you ever prescribed a medication for off-label use?
	A: Absolutely.
	Q: In those circumstances, Dr. Lowe, did you expect your patients to benefit from that off-label use of the medicine?
	A: Wouldn't have prescribed it otherwise.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes, sir.
	Q: Have you ever prescribed Risperdal for off-label use?

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Page/Line	Testimony
	A: I have, sir.
	Q: Did you expect your patients to benefit from the off-label use of Risperdal?
	A: I did, sir.
	Q: For what conditions have you prescribed Risperdal for off-label use?
	A: Psychotic form disorders of some various types.
	Q: Any particular patient population that you've prescribed Risperdal off-label for?
	A: All of them.
	Q: Dr. Lowe, has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No, sir.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: Not to the best of my recollection.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: No, sir.
pg 21, ln 19 - 22	Q: Dr. Lowe, would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes.
pg 21, ln 24 - pg 22, ln 2	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
	A: Yes.
pg 22, ln 19 - pg 23, ln 19	Q: Were you aware of an association between second generation antipsychotics and weight gain or a risk of diabetes prior to the 2004 revision to the package insert for Risperdal?
	A: Yes, sir.
	Q: Did that package insert for Risperdal -- did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No. My changes were preceding that, the release.
	Q: Yes, sir. Okay. Dr. Lowe, has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No, sir.
	Q: Has any Janssen sales representative ever represented to you that there was no association between Risperdal and increased mortality in the elderly?
	A: Don't believe I've ever had a conversation about that.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?

Page/Line	Testimony
pg 25, ln 5-7, ln 9-18, ln 20-25	A: No, sir.
	Q: (Regarding Exhibit 3) If you received this letter, did it cause you to change your choice of which antipsychotic to prescribe?
	A: Again, I'm basing my decision about what medication to practice on CME material, not on the basis of what a company says.
	Q: Okay.
	A: And if you talk to the drug reps that call on me, I said that to them consistently over time.
	Q: I understand. Final question about that, Doctor, if you received this letter, did it cause you to change your methods for monitoring for side effect sin your patients on antipsychotic medications?
	A: Well, again, I don't recall exactly what shifted in my practice. I mean, talking to colleagues, attending CMEs. It was not any one source.
	Q: And not literature mailings or discussions with drug reps.
	A: That would probably be the lowest on my list.
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 29, ln 19 – pg 30, ln 17	Q: Are you aware -- or were you aware prior to today that there were changes in that package insert --
	A: Yes, sir.
	Q: -- over the years? Do you know what warnings are included now on the package Inserts for Risperdal?
	A: Well, gosh, everything but the kitchen sink. The warnings on medications are written for attorneys and -- but I -- you name it, it's probably there.
	Q: But can you explain to us what you mean by that, that the warnings are written for attorneys?
	A: Well, in a 5,000 member population group looking at the effects of a particular medication, if someone has a heart attack, then the medication is associated with a heart attack. Didn't say it caused the heart attack. And that's the way the wording would be presented in this type of information. But it doesn't give you anything in terms of probability. It just says it was there. So they didn't control for three cheeseburgers a day for the last 30 years, didn't prescreen the population for that. So you don't know if it's something that's going to drop out later as being a major side effect or if it's something that was just kind of a quirk, but they record it all.
pg 35, ln 16 – pg 36, ln 3	Q: Okay. Thank you. Out of -- out of that class, have you found that any one more than the other one has association with weight gain?
	A: Oh, yes, sir.
	Q: And what is that?
	A: Olanzapine and Questiapine.
	Q: How would Risperdal rank in the second generation in terms of --

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 2011 APR 18 PM 3:27
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Page/Line	Testimony
	A: It's sort of in the middle - -
	Q: - - association with weight gain?
	A: It's - - I - - I will put it better than the two that I just named, the Quetiapine and Olanzapine much better than those.
RE-EXAMINATION BY DEFENDANTS' COUNSEL:	
pg 46, ln 18 - pg 47, ln 15	Q: There was some discussion, Dr. Lowe, about samples being left by a drug company and the utilization of those things. Let me ask you, Dr. Lowe, would you ever prescribe a drug to a patient simply because you had a free sample of it, if you thought that drug wasn't going to help the patient?
	A: I used to tell drug reps to stop by. If I liked your drug, I'll talk to you. I'm making my decisions on other data. If I don't like your drug, you're wasting your time.
	Q: Fair enough.
	A: I remember one lady that was in tears because I said that to her.
	Q: You also talked a little bit about you tried to talk to Janssen's reps about prescribing Risperdal in the pediatric population.
	A: Yes, sir.
	Q: And that was a discussion you had initiated with them.
	A: Yes.
	Q: And they told you, essentially, I can't talk to you about that but I can get some information sent to you, correct?
	A: Well, actually, I had to press harder than that. They didn't want to talk about it.
pg 47, ln 17 - pg 48, ln 13	Q: Okay. Ultimately, you were able to receive some information that you had requested?
	A: I requested they send me some references.
	Q: Okay.
	A: It was, you know, before the databases are refined as they are now. They had them and I didn't - - now I can do it myself.
	Q: I think I know the answer to this question, based on what you told me, but I'll - - I'll ask anyway. Dr. Lowe, is it fair to say that when you are deciding which medication to prescribe for a particular patient, that you are using your background training experience in making that decision?
	A: Yes, sir.
	Q: And you're relying on a number of sources of information to help you - - you make that decision, I think the least of which is what some drug rep might tell you; is that a fair statement?
	A: Yes, sir. Doing my best not to cause any harm.

JAMES FRANK RIDDLE
(May 4, 2010)

Page/Line	Testimony
pg 16, ln 9 - pg 17, ln 14	Q: Dr. Riddle, in your experience, does Risperdal typically have a more moderate side effect profile than first generation antipsychotics?

Page/Line	Testimony
	A: It does overall.
	Q: In your experience, is Risperdal typically better tolerated than first generation antipsychotics?
	A: I think overall it is, right.
	Q: In your experience with antipsychotic medications, Doctor, would both efficacy and tolerability be important considerations in the choice of which antipsychotic to prescribe?
	A: Exactly.
	Q: In your experience, do both efficacy and tolerability increase the likelihood that a patient will take an antipsychotic medication consistently?
	A: That is a big factor in it.
	Q: Okay. Sure. Dr. Riddle, in your experience, are patients who consistently take their antipsychotic medications less likely to require costly follow-up treatment, such as in-patient psychiatric care, than patients who do not consistently take their medications?
	A: That's true.
	Q: In your experience, are patients who consistently take their antipsychotic medications less likely to require costly follow-up treatment, such as emergency room care, than patients who do not consistently take their medications?
	A: That would be what I experience, right.
	Q: That would be your experience.
	A: It would be, right.
pg 20, ln 25 – pg 21, ln 9	Q: Dr. Riddle, overall in your experience, is Risperdal reasonably safe and effective medication for treating schizophrenia and other psychotic disorders?
	A: It is.
	Q: Overall in your experience, is Risperdal a safer and more effective medication for treating schizophrenia and other psychotic disorders than the first generation medication?
	A: I would say overall, yes.
pg 21, ln 19 – pg 22, ln 24	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Right. I -- I would say it's more the -- more the rule than the exception.
	Q: Not -- not uncommon.
	A: It's not uncommon, right.
	Q: Dr. Riddle, in your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Right.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: I would agree with that.
	Q: Doctor, have you ever prescribed a medication for off-label use?
	A: I have.

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 2011 APR 18 PM 3:27
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Page/Line	Testimony
	Q: In those circumstances, did you expect that you patient or patients to benefit from the off-label use of the medication?
	A: I did.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: I have. For - -
	Q: Well, let me ask you this: Have you ever prescribed Risperdal for off-label use?
	A: Yeah. I would think that I would have. Yeah.
	Q: When you did so, did you expect your patients to benefit from that off-label use of Risperdal?
	A: I did, right.
pg 23, ln 20 – pg 24, ln 5	Q: Dr. Riddle, has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No. I don't treat children, so have no reason to.
	Q: Has any Janssen sale representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: To the best of my knowledge, no.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: Not - - not to my knowledge, they have not.
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 48, ln 6 – 20	Q: And - - and - - and Risperdal, I think we talked about, came the market in 1993.
	A: '93.
	Q: Have you prescribed Risperdal pretty much the entire time it's been on the market?
	A: I have, right.
	Q: Right. And your current practice, are you in private practice?
	A: I work for the Mental Health Center, a full-time state employee.
	Q: All right. And so you are affiliated with the Department of Mental Health?
	A: I am.
	Q: And have you been throughout your career?
	A: I have, right.
pg 58, ln 9 – pg 59, ln 3	Q: Okay. Well, I'm just - - I'm just curious as - - as to why you would have reported a pulmonary fibrosis for somebody who's on Risperdal.
	A: Right.
	Q: And the reason I'm curious is, I'm assuming that if somebody's on - - on Risperdal and - - and they develop lung cancer, you wouldn't necessarily consider those two related. So - -
	A: Right.
	Q: - - what was the basis - -
	A: Yeah.
	Q: - - for - -

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 2011 APR 19 PM 3:27
 J. HOPE LACHNEY

Page/Line	Testimony
	A: Yeah. I -- I think it -- I probably was talking to a rep about it and they -- they suggested that I report it, so --
	Q: Okay.
	A: -- which I thought was pretty decent of the rep to -- to do that. Or you know to --
	Q: All right, Doctor.
	A: -- to encourage that, so --

EUGENE F. SMITH, M.D.
(December 17, 2009)

Page/Line	Testimony
pg 22, ln 2 – page 23, ln 4	Q: All right, sir. In your experience, is Risperdal typically better tolerated than first generation antipsychotics?
	A: Yes, it is. And better patient acceptance. They will stick with their medicine and take it better than with the older medicines.
	Q: All right, sir. In your experience with antipsychotic medications, are both efficacy and tolerability important considerations in the choice of which antipsychotics to use with your patients?
	A: Yes, they are.
	Q: In your experience, do both efficacy and tolerability increase the likelihood that a patient will continue to take an antipsychotic medication consistently?
	A: Yes.
	Q: In your experience with patients who consistently take their antipsychotic medications less likely to require costly follow-up treatment, such as inpatient psychiatric care, than patients who do not consistently take their medications?
	A: That's correct.
	Q: In your experience, are patients who consistently take their antipsychotic medications less likely to require costly follow-up treatment, such as emergency room care, than patients who do not consistently take their medications?
pg 25, ln 14 - 18	A: That's correct.
	Q: Overall in your experience, Dr. Smith, is Risperdal a reasonably safe and effective medication for treating schizophrenia and other psychotic disorders?
pg 26, ln 24 – pg 27, ln 3	A: Yes, it is.
	A: Uh-huh. Yes.
	Q: Taking into consideration that patient's particular symptom – symptomology and your clinical judgment in what may or may not work best for that patient.
pg 27, ln 24 – pg 29, ln 3	A: That's correct.
	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Yes, I would say it's a common practice. I think some studies have indicated that 30 or 40 percent of prescribing is off-label prescribing.

Page/Line	Testimony
	Q: In your experience, Dr. Smith - - excuse me - - are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: That's correct.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes, I have.
	Q: In those circumstances, did you expect that your patients would benefit from that off-label use of the medication?
	A: Yes, I did.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes, I have.
	Q: Have you ever prescribed Risperdal for off-label use?
	A: Yes, I have.
	Q: Did you expect your patients to benefit from that off-label use of Risperdal?
	A: Yes, I did.
pg 29, ln 21 – pg 30, ln 13	Q: All right, sir. Dr. Smith, has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No, they have not.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No. In my experience, when I would have a question about off-label use, they would say they can't talk about that because it's off-label and they're not authorized to do that.
	Q: All right, sir. Dr. Smith, have you ever seen or received any communication from Janssen, promoting the off-label use of Risperdal?
	A: Not that I can recall.
pg 37, ln 21 – pg 38, ln 15	Q: Yes, sir. Okay. And Dr. Smith, were you aware of an association between second generation antipsychotics and weight gain or a risk of diabetes, prior to the 2004 revision to the package insert for Risperdal?
	A: Weight gain more so than diabetes.
	Q: Okay. So let me break down my question and maybe that will make it a little better. Were you aware of an association between second generation antipsychotics and weight gain prior to the 2004 revision to the package insert for Risperdal?
	A: Yes.
	Q: Were you aware of an association between second generation antipsychotics and a risk of diabetes prior to the 2004 revision

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 2011 APR 18 PM 3:27
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Page/Line	Testimony
	to the package insert for Risperdal?
	A: Well, there is an association between weight gain and diabetes. So there would be that link there. But that would be the only link that I would have been aware of.
	Q: Sure, be glad to. Did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribe Risperdal for your patients?
	A: What circumstances do you mean? Do you mean sometimes when I would have prescribed it, I -- I wouldn't prescribe it anymore because I'm --
	Q: Yes, sir.
	A: -- concerned about the diabetes? Probably a small change. I guess a problem was, that it was a class warning. So there seemed to be no advantage, as far as the warning went, of changing from one second generation medication to another, since it was a class warning, across the whole class, which was counter to my experience. My experience was that there is a risk of diabetes, but it's probably greater for some drugs than for other drugs within the class, and every drug within the same class didn't carry the same risk.
	Q: Okay.
	A: The Food and Drug Administration did not take that attitude; they just issued a class warning. Even though it didn't make sense to me. It wouldn't be a class because the medications are different; they're structurally different; they bond to different receptors. Maybe they all carry a risk, but the idea that they all carry the same risk, I don't think there was evidence for that. I think it was just assumed that they did, unless you have evidence that they didn't carry the same risk, maybe. So they were all guilty, until you proved they were innocent, sort of.
	Q: Let me -- let me make sure I understand your answer. It was your experience that amongst the class of second generation antipsychotic medications, you as a prescriber of those medications did not believe they all had the same prevalence of diabetes causation; is that a fair statement?
	A: That's correct. And that's why I read the medical literature too, that some had a greater risk and some had a lesser risk.
	Q: Okay. And so what you're saying is, the class warning lumped all the second generation antipsychotics together in the same group, whereas your experience has been, some are better -- or some have a less frequency of diabetes as a potential side effect than others.
	A: That's correct.
	Q: Okay.
	A: And weight gain.
	Q: Yes, sir. Dr. Smith, has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package

pg 38, ln 22 – pg 41, ln 11, ln 14

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2011 MAR 18 PM 3:10
M. H. HARRIS, JR.

Page/Line	Testimony
	insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there was no association between Risperdal and increased mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: No.
pg 42, ln 22 – pg 44, ln 10	Q: Did Janssen's letter or the FDA action with regard to that letter you were referring to cause you to change any of your prescribing habits?
	A: No.
	Q: Dr. Smith --
	A: I -- I think as far Risperdal goes, there might have been actually -- more prescriptions are made for Risperdal because we had a lot of people on Zyprexa, which in my experience is worse as far as causing weight gain and diabetes. And probably some people who were on Zyprexa would have been changed to Risperdal.
	Q: Okay.
	A: Or Seroquel or Geodon or some other medicine.
	Q: All right, sir. Is it fair to say -- I'm not focusing on any one drug right now -- but is it fair to say, Dr. Smith, that in your practice, you rely on your clinical judgment as a board-certified psychiatrist in treating your patients, following those patients and you, in connection with talking to the patient, making a decision as to what works best for that patient; is that a fair statement?
	A: I'll also rely on my review of literature --
	Q: Okay. Sure. And I --
	A: -- forming my opinion.
	Q: -- and I didn't mean to isolate it to --
	A: Yeah.
	Q: -- just you and the patient, but --
	A: Right.
	Q: -- but -- and that's why I included your clinical judgment. You bring to bear your education, your training, your experience --
	A: Yes. Review of literature --
	Q: -- review of literature --
	A: -- talking with peers, yeah.
	Q: -- following that patient. You bring all that to the table when you are making prescribing decisions; is that a fair statement?
	A: That's correct.
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 54, ln 3-10	Q: Has any Janssen representative ever warned you about Prolactin -- or Prolactinemia, I guess is the condition, resulting from use of Risperdal in children or adolescents?

Page/Line	Testimony
	A: Not specifically children and adolescence, but as a side effect of the medication, yes.
	Q: Okay. They have warned you about that?
	A: Hyperprolactinemia, yes.
RE-EXAMINATION BY DEFENDANTS' COUNSEL:	
	Q: When you would bring up a potential off-label usage of Risperdal with a Janssen representative, they wouldn't answer you about that; is that your testimony?
	A: They would say they couldn't talk about that. Then that's not a listed indication.
	Q: Sure. Doctor, you are currently employed by the South Carolina Department of Mental Health.
	A: I'm a contract physician - -
	Q: Okay.
	A: -- yes.
	Q: At a South Carolina Department of Mental Health facility.
	A: That's correct.
	Q: Are you still prescribing Risperdal today?
	A: Yes, I am.
	Q: Has anyone told you to cease immediately prescribing Risperdal?
	A: No.
	Q: Has anyone attempted to encourage you to stop using Risperdal?
	A: No.
	Q: You were asked a few moments ago about free samples, samples being left - -
	A: Yes.
	Q: -- at your practice. And I think you described them as helpful for your patients.
	A: Very helpful.
	Q: Very helpful for your patients. Doctor, as a board-certified psychiatrist licensed by the State of South Carolina, would you give a patient free samples of a medication you thought was unsafe?
	A: No.
	Q: Would you give that patient a free sample of a medication you thought was ineffective?
	A: No.

pg 59, ln 9 – pg 60, ln 19

MILLARD CLINTON TROTT, M.D.
(November 24, 2009)

Page/Line	Testimony
	Q: In your experience, are there circumstances when the off-label use of a medication is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of

pg 19, ln 18 – pg 20, ln 19

Page/Line	Testimony
	medications is not an uncommon practice?
	A: Yes.
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Off-label use of antipsychotics?
	Q: Yes, sir.
	A: Sometimes, yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: Yes.
	Q: Doctor, have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those circumstances, did you expect your patients to benefit from that off-label use of the medication?
	A: Right.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes.
pg 21, ln 7-20	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: No.
pg 23, ln 24 – pg 24, ln 2	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
	A: Yes.
pg 25, ln 1 -25	Q: All right, sir. Doctor, were you aware of an association between second-generation antipsychotics and weight gain and a risk of diabetes prior to the 2004 revision to the package insert for Risperdal?
	A: Yes.
	Q: Did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No.
	Q: Doctor, has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to

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MICHAEL E. BUCKLE

Page/Line	Testimony
	you that there is no association between Risperdal and increase mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: No.

DELFIN VALITE, M.D.
(December 7, 2009)

Page/Line	Testimony
pg 14, ln 1 – pg 15, ln 8	Q: In your experience, does Risperdal typically have a more moderate side effect profile than first generation antipsychotic?
	A: Yes.
	Q: In your experience, is Risperdal typically better tolerated than first generation antipsychotics?
	A: Yes.
	Q: In your experience with antipsychotic medications, are both efficacy and tolerability important considerations in the choice of which antipsychotic to prescribe?
	A: Yes.
	Q: In your experience, do both efficacy and tolerability increase the likelihood that a patient will take an antipsychotic medication consistently?
	A: Yes.
	Q: In your experience, Dr. Valite, are patients who consistently take their antipsychotic medications less likely to require costly follow-up treatment, such as in-patient psychiatric care, than patients who do not consistently take their medications?
	A: Yes.
pg 16, ln 12 - 21	Q: In your experience, are patients who consistently take their antipsychotic medication less likely to require costly follow-up treatment, such as emergency room care, than patients who do not consistently take their medications?
	A: Yes.
	Q: In your experience, does increased patient compliance with antipsychotic prescriptions result in over-all conservation, as opposed to consumption of health care resources?
	A: Yes.
	Q: Overall in your experience, is Risperdal a reasonably safe and effective medication for treating schizophrenia and other psychotic disorders?
	A: Yes.
	Q: Overall in your experience, is Risperdal a safe or a more effective medication for treating schizophrenia and other psychotic disorders, than the first generation antipsychotics?
	A: Yes.

Page/Line	Testimony
pg 17, ln 6 – pg 18, ln 9	Q: In your experience, are there circumstances when the off-label use of medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Yes.
	Q: In your experience, are the circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: Yes.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those circumstances, did you expect your patients to benefit from the off-label use of that medication?
	A: Yes.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes.
	Q: Have you ever prescribed Risperdal for off-label use?
	A: Yes.
pg 18, ln 17 – pg 19, ln 4	Q: Have any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication of Janssen promoting the off-label use of Risperdal?
pg 21, ln 12 - 19	A: No.
	Q: Dr. Valite, would you agree that the 1993 package insert for Risperdal advised of association between Risperdal and weight gain?
	A: Yes.
pg 22, ln 25 – pg 23, ln 18	Q: Would you agree that the 1993 package insert for Risperdal advised of association between Risperdal and diabetes?
	A: Yes.
	Q: Did the change in the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No.

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 2011 APR 18 PM 3:27
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Page/Line	Testimony
	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there was no association between Risperdal and increased mortality in the elderly?
	A: Ask the question again.
	Q: Sure. Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: No.

EVAN LARS VOGEL, M.D.
(August 16, 2010)

Page/Line	Testimony
pg 19, ln 9 - 22	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
pg 22, ln 8 - 15	A: No.
	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes.
	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 38, ln 3 - 10	Q: Has a Janssen drug representative ever warned you against using Risperdal with children?
	A: I'm not sure if it counts as a warning, but basically the statement that, "We do not endorse using it with children" has been told to me.
	Q: Has a Janssen drug rep ever suggested that another doctor may be using Risperdal to treat children?
	A: That's never been a conversation I've had.
pg 39, ln 15-19	Q: Has a Janssen drug rep ever warned you about the need to monitor patients and patients' blood levels if using Risperdal for long-term management?
	A: Yes.

Page/Line	Testimony
pg 40, ln 6-7, ln 11-12, ln 14-16, ln 20	Q: Has a Janssen drug rep ever warned you about dangerous side effects, like weight gain?
	A: They have warned me about the potential for weight gain.
	Q: Has a Janssen drug rep ever warned you about hyperglycemia?
	A: They have - -
	A: -- warned me about monitoring blood glucose.

KATHY MARIE WAGGETT, M.D.

(May 20, 2010)

Page/Line	Testimony
pg 15, ln 21 - 23	Q: In your experience, does the use of Risperdal typically conserve health care resources as compared to first generation antipsychotics?
pg 16, ln 2	A: Yes.
pg 18, ln 7 – pg 19, ln 13	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Yes.
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: Yes.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those circumstances, did you expect your patient to benefit from the off-label use of the medication you prescribed?
	A: Yes.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes.
	Q: Have you ever prescribed Risperdal for off-label use?
	A: I'm not sure when exactly that Risperdal got approved by the FDA for treatment of pediatric patients, I don't know the dates on that, but I probably have.
	Q: If you had prescribed Risperdal for off-label use, would you have expected your patient to benefit from the off-label use of Risperdal?
	A: Yes.
pg 19, ln 9 – pg 20, ln 7	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: Not that I recall.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: Not that I recall.
	Q: Has any Janssen sales representative ever promoted to you

Page/Line	Testimony
	any off-label use of Risperdal at all?
	A: Not that I can recall.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: Not that I can recall.
pg 23, ln 11 – pg 24, ln 11	Q: Were you aware of an association between second generation antipsychotics and weight gain or a risk of diabetes prior to the 2004 revision to the package insert for Risperdal?
	A: Are you saying for antipsychotics in general?
	Q: Yes, ma'am.
	A: Yes.
	Q: Did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribe Risperdal for patients?
	A: No.
	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: Not that I can recall.
	Q: Did the change to the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribe Risperdal for patients?
	A: Not that I can recall.

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LAUREL A. WESTON, M.D.

(May 7, 2010)

Page/Line	Testimony
pg 9, ln 17-22	Q: How long had you worked as an employee or doctor on contract with the South Carolina Department of Mental Health?
	A: Well, I was employed 1982 to 2007 when I retired. Now I'm a contract employee at the Mental Health Center.
pg 16, ln 8 – 17	Q: Now, Dr. Weston, I want to talk to you or ask you some questions about efficacy and patient outcomes. In your experience, is Risperdal generally effective for treating the positive symptoms of schizophrenia?
	A: In my clinical experience with Risperdal, I have been impressed that it is a robust antipsychotic medicine.
	Q: When you use the term robust.
	A: Very effective.
pg 17, ln 11-22	Q: In your experience, do patients who take Risperdal have better overall outcomes more frequently than patients who take a first-generation antipsychotic?
	A: In my clinical experience, I think that the second-generation

Page/Line	Testimony
	antipsychotic medicines in general have a better efficacy, combination, reduction of negative symptoms than the typical antipsychotics.
	Q: And Risperdal would be included within the class of second generation?
	A: Yes.
pg 19, ln 7-14	Q: In your experience, does Risperdal typically have a more moderate side-effect profile than first-generation antipsychotics?
	A: Risperdal has tended to have a more moderate side-effect profile, less potential for tardive dyskinesia. Of course, all of the second-generation antipsychotic medications have the potential for metabolic syndrome.
pg 23, ln 11 - 16	Q: Overall, in your experience, is Risperdal reasonably safe and effective - - a reasonably safe and effective medication for treating schizophrenia and other psychotic disorders?
	A: In my clinical experience with Risperdal, I think it has impressive efficacy and tolerability.
pg 24, ln 10 - pg 25, ln 16	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: I think it is a very common medical practice.
	Q: In your experience, are there circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: It is not an uncommon practice in my opinion.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes.
	Q: In those circumstances, did you expect your patients to benefit from that off-label use?
	A: Yes.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes. Although I want to say that whenever we use a medicine for an off-label use, we try to discuss that with the patient or with the patient's family regarding that it is an off-label use and looking at the benefit-risk ratio for the patient.
	Q: Dr. Weston, have you ever prescribed Risperdal for off-label use?
	A: Yes.
	Q: Did you expect your patient to benefit from that off-label use of Risperdal?
	A: Yes.
pg 26, ln 5 - pg 27, ln 11	Q: Dr. Weston, has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No. I have no recollection of Janssen representatives presenting any kind of off-label recommendations for Risperdal.

Page/Line	Testimony
	Q: Whether it's children, elderly, just, no, you don't recall any Janssen sales representative ever promoting to you off-label use of Risperdal?
	A: That's correct. I do remember at time I would request that our Janssen representative do a literature search and request whatever journal articles might be available on a topic. They were very good about getting with the medical department and asking their pharmacology specialist to do a literature search and send us journal articles.
	Q: And just so I'm clear, from time to time you would make a request of a Janssen sales rep --
	A: Yes.
	Q: -- with regard to some particular instance or condition, and you would ask that literature be provided to you from Janssen or some source?
	A: Right. And their medical department would look at what the ongoing research was, how far were they in the clinical trial, what was published. Then published data they would send us at my request.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: No.
pg 29, ln 17 - 24	Q: Dr. Weston, would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes.
	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
pg 30, ln 12 -- pg 34, ln 1	A: Yes.
	Q: Dr. Weston, would you agree that the 2004 package insert for Risperdal incorporated a class warning of hyperglycemia and diabetes?
	A: Yes.
	Q: Were you aware of an association between second-generation antipsychotics and weight gain or a risk of diabetes prior to the 2004 revision to the package insert for Risperdal?
	A: Yes. We actually at the Mental Health Center became aware of potential problems at a point where, to my knowledge, the only thing in the literature was two letters to the editor in the American Journal of Psychiatry that discussed cases of a metabolic syndrome. At the Mental Health Center, we started noticing that patients treating with second-generation antipsychotic medications were gaining a lot of weight. We started doing lipid panels and blood sugar tests before there was any kind of recommendation. And we became aware clinically that it looked like it was going to be a serious potential problem that would require careful monitoring.
	Q: And that observation by you and your colleagues within the Mental Health Center occurred before this package insert was

Page/Line	Testimony
	revised?
	A: Yes.
	Q: If this was - - and I'll make the representation to you this revision is April 13, 2004. How far before this do you believe you, in particular, and your colleagues were noticing those potential metabolic conditions?
	A: We didn't do anything in the way of a formal study. Just based on our clinical observations, we - - you know, we had a red warning flag go up. Again, at that point, I believe there were only two letter sot the editor in one of the journals, and that was the extent of the information that was known. So we just investigated it as we could, and we began to realize that we needed to make prudent use of this new therapy.
	Q: Can you give me some approximate time frame. If this is 2004, when do you think you all were beginning to notice those metabolic changes?
	A: I can't say with certainty. It would have been shortly after the release of Olanzapine.
	Q: What is the trade name of - -
	A: Zyprexa.
	Q: So shortly after the release and you and your colleagues beginning to use Zyprexa, you began to notice some metabolic conditions associated with second-generation antipsychotics?
	A: Again, we knew that we were seeing something that was different from what we had seen over the years with the typical antipsychotics.
	Q: Was the - - were the metabolic conditions that you began noticing after you began prescribing Zyprexa different from what you had previously observed with the other second-generation antipsychotics?
	A: It seemed to - - it seemed to be clearly associated with second-generation as compared with the typical antipsychotics. We started trying to do fasting blood sugars and lipid profiles on any new start of a medication. But we didn't really - - we weren't involved in a study where we were looking at particular agents. We were more concerned about the individual patient and being sure that that individual patient was not developing blood sugar problems or problems with their lipid studies.
	Q: And that monitoring that you just described, that was put into practice following the introduction of Zyprexa, to your prescribing?
	A: It was with the introduction of the second-generation antipsychotics, and we started noticing that - - we would see a patient. The nurse would see them in two weeks. We would see them back in four weeks, and they would have gained a tremendous amount of weight.
	Q: Let me ask you this way. Risperdal came on the market in

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Page/Line	Testimony
	1993 or 1994. This revised package insert is April of 2004. In that - - let's just say ten-year window, we know that you were noticing - - you and your colleagues were noticing and talking about metabolic changes on patients that for whom you had prescribed second-generation antipsychotics?
	A: Yes.
	Q: Including Risperdal?
	A: Yes.
pg 34, ln 5 - 13	Q: Sure. Now, in that ten-year window, we know that that observation that you made occurs before this April of 2004 class warning that we've looked at, Exhibit 2. We know Risperdal came on the market approximately ten years prior. What I'm trying to figure out is in that period, could you help me identify when this notice that you took of patients experiencing metabolic conditions and this monitoring of conditions began?
pg 35, ln 1 - 9	A: Right. I would have to look and see which agent came on the market first. Clinically what we noticed was very different from the typical antipsychotic medications. Suddenly we noticed that patients gained a tremendous amount of weight and we started doing our own informal evaluation of what was going on with their blood sugar and lipids before there was a class warning.
pg 35, ln 11 - 13, ln 17	Q: Do you know if that observation and the informal monitoring that you just described, did that occur in 2000?
	A: It would have been before 2000.
	Q: Do you know how long before 2000?
	A: No. But it was such a marked difference when we had the second-generation medicines available to us that we felt like we had to explore it further.
pg 35, ln 19 - pg 36, ln 12	Q: Dr. Weston, did the change in the package insert for Risperdal in 2004 cause you to change the circumstances in which you prescribed Risperdal for patients?
	A: No, because we were already being as prudent as we could be with monitoring a patient's weight, asking the patient to get a fasting blood sugar and lipid profile at baseline. It didn't change my prescribing practices.
	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
pg 36, ln 16 - 20	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and an increased mortality in the elderly?
	A: No.
pg 36, ln 24 - pg 37, ln 2, ln 6	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: No.

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Page/Line	Testimony
EXAMINATION BY PLAINTIFF'S COUNSEL:	
pg 50, ln 14 - 24	Q: You testified earlier with Mr. Pugh that Risperdal has, in your experience, tended to have a more moderate side effect profile. And I wanted to ask you, have you ever conducted any study? Or was that answer just solely based on your off-the-cuff recollection this morning?
	A: Based on clinical experience. And with 1982 to present, I have been practicing. So the impression that I have is that it's effective, well-tolerated. And so it's a medicine that I have prescribed frequently.
RE-EXAMINATION BY DEFENDANTS' COUNSEL:	
pg 55, ln 6 – pg 57, ln 15	Q: Dr. Weston, I just have a couple of question in follow-up. You have been practicing general psychiatry for approximately 28 years?
	A: Since '78, '82, yes.
	Q: And you have been prescribing Risperdal for patients essentially since it came on the market; is that correct?
	A: Yes.
	Q: Do you still use Risperdal?
	A: Yes, I do.
	Q: Prior to 2000, you personally began noticing what you've termed metabolic changes in patients for whom you've prescribed second-generation antipsychotics?
	A: Yes.
	Q: Including Risperdal?
	A: Yes.
	Q: And we looked previously that the package warning for Risperdal in 1994, you agreed with me contained a reference to weight changes for patients?
	A: Is that this one?
	Q: Yes, ma'am. Is that correct?
	A: Yes.
	Q: And also an association between Risperdal and diabetes, correct?
	A: Yes.
	Q: And that matched up with your experience prior to 2000 of what in your clinical experience you say in your patients; is that right?
	A: Yes.
	Q: Doctor, when you and your colleagues began talking about those incidents of metabolic changes in patients on second-generation antipsychotics and you began a monitoring program, correct?
	A: Yes.
	Q: Was that written down somewhere? Is there a protocol within the Mental Health Center of if a patient is on a second-generation antipsychotic, here's what we are going to do?
	A: Initially there wasn't a protocol, and at the Mental Health Center here we just did that with our patients. I think after

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Page/Line	Testimony
	that, other centers in the state started noticing the same thing and coming up with their own guidelines. Then I think eventually there was a discussion at the state level with the different directors getting together to at least share experience. And I guess directors came up with their own guidelines.
	Q: And to be clear, when you use the term director, you're talking about a medical director for a particular mental health center?
	A: Mental health center director, yes.
	Q: And your understanding is that from time to time those medical directors will get together and meet to discuss many things including issues at their particular centers?
	A: Yes.

MICHAEL JOSEPH WOOD, M.D.
(August 16, 2010)

Page/Line	Testimony
pg 17, ln 12 – pg 18, ln 18	Q: In your experience, are there circumstances when the off-label use of medications is appropriate?
	A: Yes, sir.
	Q: In your experience, is it fair to say that off-label use of medications is not an uncommon practice?
	A: Yes, sir.
	Q: In your experience, are the circumstances when the off-label use of antipsychotic medications is appropriate?
	A: Yes, sir.
	Q: In your experience, is it fair to say that off-label use of antipsychotic medications is not an uncommon practice?
	A: Yes, sir.
	Q: Have you ever prescribed a medication for off-label use?
	A: Yes, sir.
	Q: In those circumstances, did you expect your patients to benefit from the off-label use of the medication?
	A: Yes, sir.
	Q: Have you ever prescribed an antipsychotic medication for off-label use?
	A: Yes, sir.
	Q: Have you ever prescribed Risperdal for off-label use?
	A: Yes, sir.
	Q: Did you expect your patients to benefit from the off-label use of Risperdal?
	A: Yes, sir.
pg 19, ln 16 – pg 20, ln 4	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in children?
	A: No.
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal in geriatric patients?
	A: No.

Page/Line	Testimony
	Q: Has any Janssen sales representative ever promoted to you any off-label use of Risperdal at all?
	A: No.
	Q: Have you ever received or seen any communication from Janssen promoting the off-label use of Risperdal?
	A: No.
pg. 22, ln 2 - 9	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and weight gain?
	A: Yes, sir.
	Q: Would you agree that the 1993 package insert for Risperdal advised of an association between Risperdal and diabetes?
	A: Yes, sir.
pg 23, ln 20 – pg 24, ln 9	Q: Has any Janssen sales representative ever represented to you anything inconsistent with the warnings about Risperdal that are provided on the package insert?
	A: No.
	Q: Has any Janssen sales representative ever represented to you that there is no association between Risperdal and increased mortality in the elderly?
	A: No.
	Q: Has any Janssen sales representative ever misrepresented to you information about the potential side effects associated with Risperdal use?
	A: I am sure that no one has.

ROBERT L. BANK, M.D.
(March 15, 2010)

Page/Line	Testimony
pg 11, ln 15 - 23	Q: Are you aware there is an association between certain atypicals and metabolic condition?
	A: Yes.
	Q: And when did you first become aware of that?
	A: I would say in the late '90s, myself and other colleagues did notice patients who were gaining weight on some of the atypicals and that that could eventually be associated with various metabolic changes.
pg 21, ln 18 – pg 25, ln 9	Q: Okay. And my question to you is: Do -- as you sit here today, do you have any recollection of how many such alert letters you received on behalf of your patients? And again, this is specific to atypical antipsychotics and the side effect and risk issue.
	A: In 2002? Or anytime?
	Q: 2002.
	A: In 2002. Maybe a dozen. I -- I really don't know for certain, but that would be my best estimate.
	Q: Okay. And let's broaden it to anytime.
	A: Maybe twice that many, maybe more than that.
	Q: And is it your belief that your response to those letters always

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Page/Line	Testimony
	was as you explained it earlier?
	A: When you first asked me the question?
	Q: Yes.
	A: Yes.
	Q: When you initially received alert letters of this type, relative to atypical antipsychotics, did you have an understanding of why the state was sending these letters to you?
	A: Yes.
	Q: And what did you understand that reason to be?
	A: They felt a responsibility to make sure practitioners understood what some of the significant side effects of the medicine might be.
	Q: Okay. Now if you take a look at Exhibit 1 again, as part of the alert letter package, there is a, on the first page, a profile of the medications that were given to the specific patient; do you see that?
	A: Yes.
	Q: And then above that, and it's - - it's somewhat illegible, there's some - - some language; do you see that?
	A: Primary therapeutic considerations or consideration, is that - -
	Q: Right. But it's - - but it's tough to see.
	A: Yes.
	Q: I think I may be able to help there. I'm not going to mark these; it's already been marked. I'm going to give you a Doctor, what has previously been marked as Ratliff 1, okay? And the last page - - if we go to the last page of Ratliff 1, you'll see what's marked as Ratliff 1A. And Ratliff 1A is a much more legible version of the first page of Bank 1; do you see that?
	A: Yes.
	Q: And so under that section where it says "Primary Therapeutic Consideration," it reads, "The use of Clozapine, Olanzapine, Risperidone, and Quetiapine may increase the risk of developing Type 2 diabetes mellitus or impaired glucose tolerance. Patients with a family history of diabetes or with preexisting diabetes may need to have blood sugar monitored closely or changed to an alternative medication." Did I read that accurately?
	A: Yes.
	Q: Okay. And so is this information that was provided to you when you received your letter, like Dr. Engles' letter?
	A: Yes.
	Q: Okay. And below, or following along what I read, there is reference to an article by a Dr. Wirshing; do you see that?
	A: I do.
	Q: Have you ever read that article by Wirshing?
	A: I don't know. I've read numerous articles on the association, but I don't know if that's one of them or not.
	Q: And the articles that you read, that is the articles regarding the

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Page/Line	Testimony
	association, as you term it, had you read any of them at or about the time that you received these alert letters?
	A: At that time, before that time, and after that time.
	Q: Fair enough. With regard to articles that you have read, that discuss the association between atypical antipsychotics and metabolic condition, can you identify any of them either by title or author?
	A: Well, I think the most useful, general references would be Stephen Stahl's textbook on psychopharmacology. I couldn't give you the exact title at this moment, but - - S-T-A-H-L, Stephen Stahl.
	Q: And when did you read that?
	A: Well, it sits on my shelf. I read it regularly.
	Q: When did you first read the section or portions of that textbook that deal with the association between atypical antipsychotics and metabolic condition?
	A: Probably in the late 1990s.
Pg 25, ln 17 - 21	Q: Okay. So when the State sent you the alert letter, the information in the alert letter concerning the association, as you term it, that wasn't new because you already knew that, correct?
	A: Yeah. That's right.

BRENDA RATLIFF, M.D.
(February 18, 2009)

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Page/Line	Testimony
	Q: I'm sorry. There is a letter addressed to a - - to a physician. And it goes on to discuss that the letter is being sent in connection with the Retrospective Drug Utilization Review Program. Do you see that?
	A: Uh-huh.
	Q: Okay. The question to you is did you ever receive such a letter like this or have you received such a letter like this from the South Carolina Department of Health and Human Services?
	A: I don't know.
pg 20, ln 7 - pg 21, ln 5	Q: Okay. Now, this letter goes on. If you look at the second paragraph, it states, "During a recent review of the enclosed drug history profile, it was noted that your patient, name obliterated, is receiving Seroquel. The use of Clozapine, Olanzapine, Risperidone, or Quetiapine may increase the risk of developing Type II diabetes." And it continues on.
	A: Uh-huh.
	Q: Do you recall receiving - - ever receiving such a letter from the Department of Health and Human Services regarding connection - -
	A: Yeah.

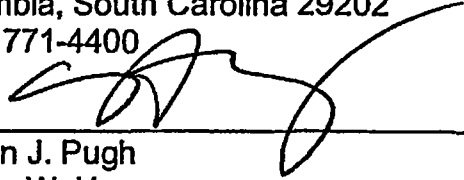
Page/Line	Testimony
pg 21, ln 8 – pg 23, ln 2	A: It looks sort of familiar, but I get a lot of things from different companies saying your patient is on such-and-such drug and there is this risk factor. And, you know, whether this exact letter came to me about a patient, I couldn't say. This is 2002 these came out, so seven years ago.
	Q: Understood.
	A: Yeah.
	Q: Now, in the course of your response you stated that you get letters from companies stating or advising that your patient or patients are on such-and-such medication?
	A: Right.
	Q: What companies or from what companies do you receive such?
	A: Lots of insurance companies. And for their drug programs when they fill the prescription they will sometimes send. I had one recently just said your patient is over a certain age and they're on this drug, and are you aware of, you know, certain things that need to be considered and what is your plan.
	Q: Do you recall receiving such communications relative to atypical antipsychotics?
	A: I have received some, but whether -- exactly where they came from I couldn't say. I have seen things.
	Q: I understand.
	A: Lots of things have been printed in all kinds of settings. I mean, there was no way to not be aware of the information.
	Q: Well, when you say there was no where not to be -- no way not to be aware of the information, what are you referring to?
	A: About the risks associated with using the drugs. I mean, once that risk was clearly identified it was -- you know, it was in journals and it was everywhere.
	Q: Okay. And so the letter that we are looking at here, you noted is a 2002 letter?
	A: Uh-huh.
	Q: And my question to you is when were you first aware of the risk as you describe it?
pg 23, ln 3 - 25	A: That patients were at a higher risk of developing diabetes in using these drugs?
	Q: Correct.
	A: That piece of information? When a patient gains weight, regardless of the source, they are at greater risk to develop Type 2 diabetes. And so even before this actual, you know, they are at risk of developing diabetes was known we knew that patients gain weight on a lot of these drugs. They gained weight on the -- you know, the older drugs, too. And that increased their risk for diabetes. And so before actually being told this, I knew they were at increased risk when they started gaining weight. And they gained weight with lots of drugs.
	Q: Is that something that you knew prior to 2002?

Page/Line	Testimony
	A: That if they gained weight they were at increased risk for diabetes? Yeah.
pg 40, ln 6 – pg 41, ln 9	Q: If I can take you toward the bottom aspect of that -- the entry relative to the A.G. lawsuit, specifically the last sentence. It states, "It is noted that the medical directors are not in agreement with the lawsuit." Do you see that?
	A: I do.
	Q: Okay. And who specifically was not in agreement with the lawsuit?
	A: Well, let me say it the other way. No one in the room said they were.
	Q: Okay.
	A: Some, of course, were being more verbal, but nobody said they thought it was a good idea.
	Q: So I take from your answer that there was some discussion about the lawsuit?
	A: Yes.
	Q: The wisdom of the lawsuit?
	A: Yes.
	Q: The basis for the lawsuit?
	A: Yes.
	Q: Okay. And of those who were vocal in stating their view, what reasons did they offer for not being in favor of the lawsuit?
	A: To the best of my memory it was all drugs have side effects. It is the physician's responsibility to monitor for any side effects. The drugs are good drugs. They help a lot of patients. They help patients that the older, first generation drugs had not helped. We need the drugs.
pg 46, ln 11 - 17	Q: All right. The next sentence, "It was communicated that we were not particularly in favor of the suit." You see that?
	A: Yes.
	Q: Okay. Is that something that you communicated to the A.G.'s office?
pg 63, ln 2 - 23	A: Yes.
	Q: And do you understand that to relate to treatment utilizing antipsychotic medicine?
	A: Yes.
	Q: Discussion of risks and expected side effects, it's your understanding that Dr. Raynor was suggesting that these discussions would be with whom?
	A: Between the patient and the physician prescribing.
	Q: Okay. Is that something that you do in your practice?
	A: It is.
	Q: Is that something that you've always done?
	A: It is.
	Q: To your knowledge, is that something that doctors and D.M.H. do as a matter of course?
	A: Yes. There are exceptions. A patient that is very paranoid, doesn't believe that they are sick, doesn't want to take

Page/Line	Testimony
	medicine, may be court-ordered, situations like that you might not discuss with them, but generally such a conversation would take place.

RICHARDSON PLOWDEN & ROBINSON, PA
 1900 Barnwell Street (29201)
 Post Office Drawer 7788
 Columbia, South Carolina 29202
 (803) 771-4400

By:


 Steven J. Pugh
 Steven W. Hamm

-and-

Thomas F. Campion (admitted pro hac vice)
 Drinker Biddle & Reath, LLP
 500 Campus Drive
 Florham Park, NJ 07932-1047
 (973) 360-1000

Edward M. Posner (admitted pro hac vice)
 Kenneth A. Murphy (admitted pro hac vice)
 Drinker Biddle & Reath, LLP
 One Logan Square
 18th and Cherry Streets
 Philadelphia, PA 19103-6996
 (215) 988-2700

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ATTORNEYS FOR DEFENDANTS

April 18, 2011

IN THE COURT OF COMMON PLEAS

FOR THE SEVENTH JUDICIAL CIRCUIT

)

) Civil Action No.: 2007-CP-42-1438

)

)

**PLAINTIFF THE STATE OF SOUTH
CAROLINA'S POST CIVIL PENALTIES
HEARING SUBMISSION**

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M

Plaintiff, the State of South Carolina, *ex rel.* Alan Wilson, in his capacity as Attorney General of the State of South Carolina (hereinafter, "the State"), by and through the undersigned counsel, hereby files its Post Civil Penalties Hearing Submission in further support of the Court's imposition of civil penalties pursuant to the South Carolina Unfair Trade Practices Act ("SCUTPA"), S.C. Code Ann. § 39-5-110(a), against Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. f/k/a Janssen Pharmaceutica, Inc., and/or Janssen, L.P., (hereinafter, "Janssen" or "Defendant") for its willful, deceptive, and unfair course of conduct in violation of SCUTPA. In particular, this Submission (1) summarizes the State's evidence supporting the jury's verdict as to the Risperdal label; (2) responds to Defendant's contentions at the penalties hearing held April 18 and 19, 2011; and (3) again urges the exclusion of testimony and evidence

offered by Defendant's expert, Dr. William Wecker. Against that backdrop, the State respectfully shows the Court as follows:

I. THE STATE OFFERED MORE THAN SUFFICIENT EVIDENCE TO SUPPORT AN AWARD OF CIVIL PENALTIES BASED ON RISPERDAL'S LABELING FROM 1994 TO 2007.

On April 23, 2007, the State initiated this action against Janssen, manufacturer of the atypical antipsychotic drug Risperdal, to recover, *inter alia*, civil penalties pursuant to S.C. Code Ann. § 39-5-110(a) for Janssen's willful, deceptive, and unfair course of conduct in its product labeling. On March 19, 2010, the State filed its Second Amended Civil Action Complaint, petitioning the Court to assess against Janssen such penalties in an amount up to five thousand dollars for each "method, act or practice declared unlawful by § 39-5-20" and the willful use thereof. S.C. Code Ann. § 39-5-110(a).

At trial, the State offered ample evidence to reach the jury in support of its civil penalties claim that Janssen's November 2003 Dear Doctor Letter and Risperdal labeling from 1994 through 2007 were unfair and deceptive, and that Janssen's dissemination of those materials willfully violated SCUTPA. The jury unanimously found that Defendant had willfully committed deceptive or unfair acts related to both the Dear Doctor Letter and Risperdal label in violation of the South Carolina Trade Practices Act ("SCUTPA"). With particular respect to the Risperdal label, the jury unanimously answered the following interrogatory in the State's favor:

As to the question of whether or not the above Defendant engaged in unfair methods of competition and unfair or deceptive acts or practices in the conduct of any trade or commerce in its label (package insert), we the jury unanimously find for: The Plaintiff

(See Verdict Sheet.) The violative acts on which the jury based its verdict included Defendant's dissemination of Risperdal labeling that contained false and misleading information, and omitted

true information regarding the association of serious hazards with Risperdal, since the time of the drug's launch in the United States and throughout the State of South Carolina.

When the Attorney General seeks to enforce State law prohibiting unfair and deceptive trade practices under SCUTPA through the imposition of civil penalties, as in this case, South Carolina law and procedure direct the circuit judge to determine and assess, in its broad discretion, appropriate penalties in an amount of up to \$5,000 per violation. S.C. Code Ann. § 39-5-110(a). In so ruling, the Court should consider the below-outlined violations of Defendant on which the State's claims and the jury's verdict were based and all related evidence presented at trial and referenced in brief herein. Importantly, South Carolina precedent recognizes that there can be "no error of law in imposing a fine within the limits authorized by [SCUTPA]." *State ex rel. McLeod v. C & L Corp.*, 313 S.E.2d 334, 340 (S.C. Ct. App. 1984) ("Within those limits [defined by SCUTPA], the amount of the fine was a matter of the judge's discretion."). Therefore, the Court may determine to award the full penalty for all violations supporting the jury's verdict, or, in the Court's abundant discretion, it may decide that the evidence supports a range of penalties based upon the egregiousness of Defendant's conduct at particular times, as further discussed below.¹ The Court should also be mindful that only a "scintilla of evidence" is necessary to support the verdict and all reasonable inferences that may be drawn therefrom. *Proctor v. Dep't. of Health & Env'tl. Control*, 696 S.E.2d 496, 504 (S.C. Ct. App. 2006); *Hessenthaler v. Tri-County Sister Help, Inc.*, 616 S.E.2d 694, 697 (S.C. 2005) (citing *Jinks v. Richland County*, 585 S.E.2d 281, 283 (S.C. 2003)).²

¹ See sections I.A, I.B, and I.C, *infra*. See also section II.D, *infra*, for further discussion of amounts and constraints on civil penalties the Court may award.

² The State maintains its claim for penalties as to the 2003 Dear Doctor Letter. However, this submission focuses in particular on the evidence supporting penalties awards as to the Risperdal label (package insert). The State relies on the record already before the Court in support of penalties attributable to the 2003 Dear Doctor Letter to the extent those issues are not addressed elsewhere in this submission.

A. Risperdal Labeling: 1994-1998

The State proved, through the testimony of its experts, Defendant's own witnesses, and documentary evidence, that Risperdal labeling contained false and misleading information, and omitted true information, since the drug's launch in the United States in 1994. Likewise, the State introduced testimony and evidence showing that, based on what Defendant knew or should have known between 1994 and 1998, and even prior to Risperdal's launch, Risperdal was not associated with a lower risk of diabetes and weight gain than Zyprexa and other atypical antipsychotics but was, in fact, associated with an increased risk of diabetes and hyperglycemia, cardiovascular and cerebrovascular complications, including stroke, cardiac arrest, and death in the elderly, hyperprolactinemia and other serious adverse events. Representations to the contrary by Defendant about Risperdal constituted unfair and deceptive conduct under SCUTPA. Additionally, the State demonstrated that Defendant was required to strengthen Risperdal's warning section in the labeling "*as soon as* there [was] reasonable *evidence of an association* of a serious hazard" with Risperdal (under the standard applicable to this case)—and not delay *until* a "*causal* association" was recognized. 21 C.F.R. § 201.57(e) (2006) (emphases added); *id.* ("a *causal* relationship need *not* have been proved") (emphasis added). (Trial Tr. at 662-679 (Dr. Plunkett describing significance of labeling regulations and requisite warnings in product labeling).) Defendant never made such a unilateral label change related to diabetes/hyperglycemia, weight gain, and hyperprolactinemia.

Moreover, Defendant failed to include a warning of the potential for any of the above-mentioned adverse events in its Risperdal labeling disseminated in the United States at the time of its product launch, through 1998, and, in some cases, for more than a decade after. More specifically, prior to and through 1998, Risperdal's label did not contain a warning for diabetes or hyperglycemia, cardiovascular or cerebrovascular adverse events, or hyperprolactinemia.

(Trial Tr. at 354-358, 362-371, 381 (Dr. Wirshing describing warnings and explaining that in 1994-1998, there was no warning for diabetes, hyperglycemia, weight gain, hyperprolactinemia, or death or cardiac arrest in the elderly); Trial Tr. at 1063-1064, 1084-1085 (Dr. Plunkett describing warnings); see Pl. Ex. 643, 2061, 2049, 631, 648.)

1. Diabetes, hyperglycemia and weight gain

The State's experts—pharmacologist, toxicologist, and regulatory expert, Dr. Laura Plunkett, and psychiatrist, Dr. William Wirshing—testified that Defendant knew or should have known of the risks associated with Risperdal based on the chemical compound of Risperdal itself, and instances of weight gain and hyperglycemia that were seen in the pre-marketing clinical studies of Risperdal. With particular respect to Risperdal's chemical compound, Dr. Plunkett explained that as soon as the drug was invented, even before Risperdal was tested in humans, Defendant knew or should have known about a potential side effect of Risperdal simply by looking at its chemical structure. (Trial Tr. at 686-689.) Dr. Plunkett further explained that “based on the chemical structure . . . [w]e know that the effects of the serotonin receptor may be related to the weight gain issue with the drug.” (Trial Tr. at 688.) Dr. Plunkett confirmed that “when you test this drug in . . . people, we saw those effects . . . just described.” (Trial Tr. at 689.) Similarly, with respect to the premarketing clinical studies of Risperdal, all “designed and performed and supported by the company,” Dr. Plunkett testified that the studies data showed significant weight gain, hyperglycemia, [and] diabetes.” (Trial Tr. at 691.)

Additionally,

- Dr. Plunkett testified that “instances of weight gain [and] hyperglycemia . . . that were seen in the pre-marketing clinical studies of Risperdal” and were predictable based on Risperdal's chemical structure were also demonstrated in clinical trials upon the inception of Risperdal marketing. (Trial Tr. at 689-690.)
- Janssen's Clinical Trial Developments Leader for the pediatric program for Risperdal, Dr. Magali Haas, confirmed that Janssen has known that Risperdal was

associated with weight gain “[s]ince 1994, when it first did its first studies with risperidone” and, likewise, that it was “well established in the diabetes literature” that “[w]eight gain . . . could be a risk factor for diabetes.” (Trial Tr. at 306-307.)

- Janssen’s Global Product Leader for Risperdal, Dr. Ivo Caers, additionally confirmed that Janssen “had weight gain reported in [its] clinical studies which were part of the submission [to the FDA for initial approval of Risperdal], so that must have been very early 90’s.” (Trial Tr. at 1319 (Caers Dep. at 163).)
- Moreover, in 1994, Defendant’s adverse event reporting system revealed this unfavorable side effect profile of Risperdal. Relatedly, at the inception of Risperdal marketing, based on preliminary adverse events data, the Division of Drug Marketing, Advertising and Communications (“DDMAC”) of the FDA warned Defendant against making “false” or “misleading” claims in its labeling and asserted, more specifically, that “[t]he adverse event rates of risperidone are not consistent with claims for an outstanding or excellent safety profile.” (Pl. Ex. 1027; see Trial Tr. at 691-692 (Dr. Plunkett outlining the significance of the adverse event reporting system mandated by the FDA “to monitor the safety of the drug” based on a collection and analysis of adverse events “that can lead to changes in the labeling”).) Given that knowledge, Defendant’s contrary representations violated SCUTPA.

2. *Hyperprolactinemia*

- Dr. Plunkett testified that “based on the chemical structure and the fact that we know it interacts with dopamine receptors, for example, and serotonin receptors, we know that antagonizing those receptors can lead to effects such as increases in prolactin in the blood . . . [or], “hyperprolactinemia.” (Trial Tr. at 688.) Dr. Plunkett confirmed that “when you test this drug in . . . people, we saw those effects . . . just described.” (Trial Tr. at 689.)
- Dr. Plunkett further testified that the pre-marketing clinical studies’ data showed significant hyperprolactinemia. (Trial Tr. at 691.) Dr. Plunkett also explained that “instances of . . . hyperprolactinemia that were seen in the pre-marketing clinical studies of Risperdal” and predictable based on Risperdal’s chemical structure, were also demonstrated in clinical trials upon the inception of Risperdal marketing. (Trial Tr. at 689-690).
- Dr. Plunkett also testified that she relied upon numerous animal and human studies investigating increases in prolactin levels produced by the administration of risperidone, published as early as 1992, well before the inception of Risperdal marketing in 1994. (Trial Tr. at 845-847; see, e.g., Pl. Ex. 1760 (animal study conducted by Janssen and published in 1992 providing data showing that risperidone can increase prolactin levels both in vitro and in vivo).)

- Dr. Caers also confirmed that Janssen had knowledge, or notice of, increased prolactin levels associated with Risperdal before December 1994. (Trial Tr. at 1319 (Caers Dep. at 163).)

3. *Cardiovascular/cerebrovascular effects*

- Dr. Plunkett explained that “based on the chemical structure . . . [w]e know that interaction with the alpha receptor can lead to cardiovascular toxicity or effects on the heart.” (Trial Tr. at 688.) Dr. Plunkett confirmed that “when you test this drug in . . . people, we saw those effects . . . just described.” (Trial Tr. at 689.)
- Similarly, Dr. Wirshing explained that the alpha toxicity and related cardiovascular/cerebrovascular, and mortality risks associated with Risperdal use in the elderly, are “inherent in the molecule.” (Trial Tr. at 527-529.) “This was studied both by Janssen and by clinical investigators.” (*Id.*) Those investigations revealed that risperidone was “associated with an increased death rate[,]” and “risperidone’s characteristics [] explain the elevated death rate,” because the “alpha blockade causes your blood pressure to drop[,] [a]nd in the elderly, . . . it changes the cerebral circulation and can cause strokes,” *inter alia*. (Trial Tr. at 527-528.) Most significantly, Dr. Wirshing explained that because these “alpha effects are known before you introduce it into any humans,” and because they “[were] tested in animal and cell cultures” before the inception of marketing in the United States, many of these dangerous cardiovascular and cerebrovascular risks were known to Janssen in the 1980s. (Trial Tr. at 528-529.) He further testified that in 1997, when the first protocols were accomplished, Janssen became fully aware of the risk of death associated with these other risks and Risperdal use in the elderly. (Trial Tr. at 624-625.)

B. *Risperdal Labeling: 1999-2003*

The State introduced testimony and evidence showing that, based on what Defendant knew or should have known between 1993 (at the time of Risperdal’s approval) and 2003, Risperdal was associated with an increased risk of diabetes and hyperglycemia, cardiovascular and cerebrovascular complications, including stroke, cardiac arrest, and death in the elderly, hyperprolactinemia and other serious adverse events. Despite its knowledge of the above-described risks associated with Risperdal use, Defendant failed to include a warning of the potential for any of the above-mentioned adverse events in its Risperdal labeling disseminated in the United States at the time of its product launch, through 2003, and, in some cases, for more than a decade after its initial approval, with one exception.

Although in 2003, Risperdal's labeling was strengthened to add a warning for certain cerebrovascular events, including stroke in the elderly and patients with dementia, prior to and through 2003, Risperdal's labeling did not contain warnings for diabetes or hyperglycemia, death or cardiac arrest in the elderly, or hyperprolactinemia. (Trial Tr. at 367-372, 381 (Dr. Wirshing describing warnings and explaining that in 1999-2003, there was no warning for diabetes, hyperglycemia, weight gain, hyperprolactinemia, or death or cardiac arrest in the elderly); Trial Tr. at 1063-1064, 1084-1085 (Dr. Plunkett describing warnings); *see* Pl. Ex. 649, 653, 1224, 656, 657.)

1. Diabetes, hyperglycemia and weight gain.

- In September 1999, Defendant completed clinical trial 113—a “gold standard,” randomized, double-blind, controlled, long-term study, with a primary endpoint of weight gain, that “support[ed] the finding of significant weight gain in the risperidone treated patients” as well as diabetes in risperidone treated patients at a rate higher than in the comparator olanzapine group. (Pl. Ex. 442; *see* Trial Tr. at 434-438 (Dr. Wirshing discussing significance of study design and findings, *inter alia*)). Despite the FDA's request for such data, Janssen did not publish the results of this study upon its completion in 1999. In fact, it was not until ten years later in 2009, after the expiration of the Risperdal patent, that Janssen (internally) released the Clinical Study Report for RIS-USA-113. (Trial Tr. at 629-631.) Defendant, of course, did not inform South Carolina doctors or patients regarding the trial 113 results.
- In 2000, Defendant reported (but, only internally) the results of a study for which it had commissioned a third-party vendor, ERI, identifying new-onset diabetes in antipsychotic users, including Risperdal. (Trial Tr. at 721-727; *see* Pl. Ex. 167.) Of the study patients who received Risperdal, there was a significant number of patients with new-onset diabetes and close to three times as many reports of new-onset diabetes in risperidone-treated patients as compared to olanzapine. (Trial Tr. at 723.) The difference in incidence rates was similar in schizophrenic study patients with three times as many reports of new-onset diabetes in schizophrenic risperidone-treated patients as compared to those in the olanzapine subpopulation for schizophrenics. (Trial Tr. at 723-724.) Of course, despite the FDA's request for such data, and Defendant's initially declared intentions to provide it, Defendant failed to release the results of ERI. (Trial Tr. at 724-736.) Likewise, Defendant neglected to inform South Carolina doctors and patients of the ERI results.

2. Hyperprolactinemia

- In addition to weight gain and diabetes, the results of trial 113 showed a mean increase in prolactin levels compared with a mean decrease in the olanzapine group. (Pl. Ex. 442.) Although the study was completed in 1999, Janssen did not publish its results. (Trial Tr. at 629-631.)
- In 2000, internal Company documents revealed that Janssen recognized Risperdal's disadvantages and knew that Risperdal "causes significant weight gain" and was "more likely to cause increased prolactin levels, gynecomastia lactation." (Pl. Ex. 1294; Trial Tr. at 848-853 (Dr. Plunkett discussing Janssen's knowledge of side effects, hyperprolactinemia in children, in particular, but discussions of related marketing opportunities in the pediatric population).)
- Dr. Haas also explained that in Janssen's clinical trials conducted during her tenure beginning in 2000, girls "developed side effects that would be consistent with alterations in prolactin," including hyperprolactinemia, gynecomastia and menstrual cycle disturbances; and, it "cause[d] breast enlargement" in boys and "cause[d] the corollary to menstrual disturbances of their testosterone, short-stature, [and] so forth." (Trial Tr. at 311-313.)
- Dr. Plunkett testified that she relied upon numerous animal and human studies investigating increases in prolactin levels and resultant hyperprolactinemia produced by the administration of risperidone, including a study published in 2003 revealing an increased number of patients developing hyperprolactinemia upon exposure to risperidone. (Trial Tr. at 845-847; *see, e.g.*, Pl. Ex. 1819.)

3. Cardiovascular/cerebrovascular effects

- Despite the FDA's warnings against Defendant's "false" and "misleading" labeling in 1994, Defendant continued to disseminate labeling violative of SCUTPA; and, resultantly, in February 1999, DDMAC issued a Notice of Violation to Defendant "[concluding] that these materials are false, misleading, and/or lacking in fair balance, and in violation of the [FDCA]," and that "[t]he materials and promotional messages Janssen has disseminated contain false and/or misleading information about the safety and effectiveness of Risperdal," including, more specifically, Janssen's false and misleading "Geriatric Campaign" to promote Risperdal to elderly patients in light of the known association between Risperdal treatment in the elderly and cardiovascular/cerebrovascular effects. (Pl. Ex. 200; Trial Tr. at 1097-1107.) DDMAC further cautioned that the "[f]ailure to correct the violations . . . may result in FDA regulatory action, including seizure of injunction, without further notice" (Pl. Ex. 200; Trial Tr. at 1107.) Despite this knowledge, Defendant continued to market Risperdal to geriatrics in South Carolina.

C. Risperdal Labeling: 2004-2007

Defendant willfully refused to strengthen Risperdal's warnings section in the labeling, as it was required to do by the FDA and also under SCUTPA, once Defendant became aware of reasonable evidence of an association between Risperdal use and a serious hazard. 21 C.F.R. § 201.57(e) (2006). Risperdal labeling contained false and misleading information, and omitted true information, for more than a decade after Risperdal's launch. More specifically, in 2004, the Risperdal label still did not include warnings for weight gain, hyperprolactinemia, or death or cardiac arrest in the elderly. (Trial Tr. at 373-375, 381 (Dr. Wirshing describing warnings and explaining that in 2004, there was no warning for weight gain, hyperprolactinemia, or death or cardiac arrest in the elderly); Trial Tr. at 1063-1064, 1084-1085 (Dr. Plunkett describing warnings); *see* Pl. Ex. 661.)

However, in December 2003, the class-wide label change applicable to all atypical antipsychotics resulted in a strengthened Risperdal label with the addition of a diabetes and hyperglycemia warning first disseminated then and in 2004. (Trial Tr. at 373, 381 (Dr. Wirshing describing class-wide label change); *see* Pl. Ex. 661.)

In 2005, however, Defendant still had failed to include a warning for weight gain—a warning it, incidentally, has never made—or for hyperprolactinemia. (Trial Tr. at 378, 381; *see* Pl. Ex. 662.) Similarly, in 2006, Defendant still had failed to include a warning for hyperprolactinemia. (Trial Tr. at 379, 381; *see* Pl. Ex. 665.) And, for most of 2007, there was no significant change in Risperdal's warning section.

I. Weight gain

- On January 20, 2004, Janssen issued a “confidential” internal report of the results of a double-blind, randomized, long-term study completed in August 2003 evaluating the glucoregulatory effects of risperidone and olanzapine in subjects with schizophrenia or schizoaffective disorder. (Trial Tr. at 507-518; Pl. Ex. 2628.) RIS-USA-275 had both primary and secondary objectives including “to look at the glucoregulatory mechanism, insulin . . . and resulting glucose . . . whereby glucose regulation is modulated in risperidone versus olanzapine, [and]

also to look at weight gain, [and] to look at impact on a person's symptoms of schizophrenia [and] general tolerability." (Trial Tr. at 510-511.) "Additional glucoregulatory parameters such as fasting glucose, fasting insulin, 20-minute glucose, 20-minute insulin, glucose distribution volume, insulin clearance, glucose disappearance and glucose effectiveness were derived and analyzed" in order to determine, *inter alia*, the potential for diabetes, hyperglycemia and weight gain in risperidone-treated patients. (Trial Tr. at 511-512; Pl. Ex. 2628.) The glucoregulatory parameters of risperidone-treated patients were no better than those of the olanzapine group, and the lipid profiles of risperidone-treated patients were actually worse. (Trial Tr. at 513-516; Pl. Ex. 2628.) Dr. Wirshing testified that "the glucose dysregulation gives rise to lipid dysregulation, and lipid dysregulation also contributes to glucose dysregulation" and agreed that "problems with lipid metabolism are intimately related to diabetes." (Trial Tr. at 516-517.) He further testified that, to his knowledge, and despite the FDA's request for the same, these results were never published. (Trial Tr. at 517.)

- Relatedly, in February 2004, the Consensus Development Statement was issued regarding the association between obesity and diabetes and antipsychotic drugs, including Risperdal. (Trial Tr. at 348-350, 440, 489-490 (Dr. Wirshing explaining the growing concern over the metabolic problems (including diabetes and weight gain), other toxicities and the potential for death associated with atypical antipsychotics, including Risperdal, that led to the development of the Consensus Development Statement); see Pl. Ex. 1750.) With respect to Risperdal, Dr. Wirshing, who participated in the development of the Consensus Development Statement, testified that the Panel concluded that there was considerable evidence that Risperdal treatment can cause a rapid increase in body weight and also observed numerous case reports documenting the onset and exacerbation of diabetes and hyperglycemia following the initiation of Risperdal treatment. (Trial Tr. at 348-350, 489-501, 518-519 (Dr. Wirshing explaining the Panel's conclusions relative to Risperdal even despite Janssen's attempts to conceal clinical trials' data demonstrating an increased risk in weight gain, diabetes and hyperglycemia associated with Risperdal use); see Pl. Ex. 1750.)

2. *Hyperprolactinemia*

- Dr. Plunkett testified regarding numerous human studies investigating the association between hyperprolactinemia and Risperdal treatment, including studies published in 2006 revealing an increased number of patients developing hyperprolactinemia and related side effects upon exposure to risperidone. (Trial Tr. at 845-847; see, e.g., Pl. Ex. 1875 (a widely published human study finding Risperdal treatment to be associated with hyperprolactinemia, galactorrhea, amenorrhea, gynecomastia, and pituitary tumors at incidence rates substantially higher than those of all other studied antipsychotics, including olanzapine).)

- It was not until the end of 2007³ that Defendant strengthened Risperdal's label to include a warning for hyperprolactinemia, despite having had reasonable evidence of an association between Risperdal use and hyperprolactinemia since Risperdal's launch and even before.

3. *Cardiovascular/cerebrovascular effects*

- In March 2004, Janssen Medical Affairs executives as well as Janssen Outcomes Research director, Dr. Ramy Mahmoud, acknowledged publications reporting that the "odds are threefold in getting a stroke on risperidone" as well as citing "death rates" and cerebrovascular event rates for certain clinical trials involving Risperdal which led to a strengthened warning for the same in Europe. (Trial Tr. at 818-821; Pl. Ex. 2613.)
- In February 2005, although the Risperdal label had not been strengthened to include warnings for weight gain or hyperprolactinemia, it was then enhanced to include a "black box warning" of the "increased rate of death when used" in the elderly and in patients with dementia based on clinical trials' data, despite that Defendant should have known of Risperdal's association with these serious risks since its product launch. (Trial Tr. at 375-378 (Dr. Wirshing describing the addition of the "black box warning" to Risperdal); Pl. Ex. 662.)

Thus, it should be readily apparent that the State has adduced sufficient evidence to support penalties awards—in amounts determined in the Court's discretion—related to Defendant's willful dissemination of the unfair and deceptive Risperdal label.

II. **THE COURT SHOULD NOT BE DETERRED FROM ITS STATUTORY OBLIGATION TO ASSESS SCUTPA PENALTIES IN THIS CASE BY DEFENDANT'S NOVEL AND UNSUPPORTED ARGUMENTS.**

In the penalties hearing held April 18 and 19, 2011, Defendant raised several issues in argument and in its evidentiary presentation in an attempt to divert the Court from its penalties assessment under SCUTPA. Those issues include: (1) whether the Court should consider the federal government's Medicaid participatory share and alleged manufacturer rebates in assessing civil penalties here; (2) whether the Court may properly consider the Topamax Corporate

³ At the April 18, 2011 penalties hearing before the Court, the State's counsel explained that the hyperprolactinemia warning was added in late 2006. (*See, e.g.*, Hr'g Tr. at 189 (attached as Exhibit A).) By this submission, and consistent with the testimony of Drs. Wirshing and Plunkett, as referenced herein, the State seeks to clarify that the Risperdal label was revised in August 2007 to include a hyperprolactinemia warning.

Integrity Agreement and related documents, as well as evidence of Defendant's ability to pay any penalties assessed; (3) what role, if any, the State's proof of Defendant's illegal off-label promotion of Risperdal should have in the Court's penalties determination; (4) constitutional and other legal considerations related to the amount of penalties to be assessed; (5) Defendant's purposeful avoidance of the most egregious language in the 2003 Dear Doctor Letter during the penalties hearing; and (6) whether the Court may properly disregard Defendant's argument that the State proved no individualized harm and no damages. The State addresses each of the foregoing in turn.

A. Medicaid's Federal Government Participatory Share and Medicaid Rebates Paid by Defendant Should Not Factor Into the Court's Penalties Assessment.

Defendant argued that the Court should take into consideration the state versus federal share of Risperdal expenditures in assessing penalties—as though the State is seeking restitution for its Risperdal-related Medicaid payments. (*See, e.g., Hr'g Tr. at 91 (Ex. A).*) But, Defendant's argument is a mere diversion.

As the Court is aware, proof of "damage[s]" is not "a prerequisite to an action under the Unfair Trade Practices Act." *State ex rel. McLeod v. Brown*, 294 S.E.2d 781, 783 (S.C. 1982). Further, the State obviously does not seek to recover any "damages" related to Risperdal expenditures or any other form of compensation. Even if it were seeking such damages, the Court would not be permitted to consider collateral payments for Risperdal by the federal government or any other source that is "wholly independent of the wrongdoer." *Atkinson v. Orkin Exterminating Co.*, 604 S.E.2d 385, 393 (S.C. 2004). Given the "liberal[] appli[cation]" of the "collateral source rule" to "preclude the reduction of damages," the same principles should apply to the Court's penalty assessment as well. Further, the amount of penalty to assess is, as mentioned, within the Court's discretion, *State ex rel. McLeod v. C & L Corp.*, 313 S.E.2d 334,

340 (S.C. Ct. App. 1984), and collateral sources of payment or the amount expended are not among the factors the Court should take into account. See 15 U.S.C. § 45(m)(C) (2011) (“In determining the amount of such a civil penalty [under the FTCA], the court shall take into account the degree of culpability, any history of prior such conduct, ability to pay, effect on ability to continue to do business, and such other matters as justice may require.”); *United States v. Reader’s Digest Ass’n, Inc.*, 662 F.2d 955, 967 (3d Cir. 1981) (“In determining the size of penalty to be assessed,” courts should consider the following “five factors”: “(1) the good or bad faith of the defendants; (2) the injury to the public; (3) the defendant’s ability to pay; (4) the desire to eliminate the benefits derived by a violation; and (5) the necessity of vindicating the authority of [the enforcement agency, here, the Attorney General’s office].”). And, certainly consideration of the full amount that Defendant was paid for Risperdal is part and parcel of any determination as to whether Defendant has the “ability to pay” the penalties assessed, as further discussed below in section II.B. 15 U.S.C. § 45(m)(C); *Reader’s Digest*, 662 F.2d at 967. Additionally, as also discussed below in section II.D, it is well established by the United States Supreme Court that state penalties provisions designed to address “public wrongs” need not be “confined or proportioned to [actual] loss or damages” *St. Louis, Iron Mt. & S. Ry. Co. v. Williams*, 251 U.S. 63, 67 (1919).

B. The Court Should Consider the Topamax Corporate Integrity Agreement, Related Documents, and Defendant’s Profits.

Defendant objected to the State’s introduction of the Topamax Corporate Integrity Agreement, the related plea in that matter, and other related documents (P-17 (marked for identification pending admission)) on the basis that the conduct “did not involve Janssen” and had “nothing to do with the issues” in this case. (Hr’g Tr. at 144-45 (Ex. A).) But, Defendant’s counsel admitted that Defendant acquired the manufacturer of Topamax, and critically *Defendant*

itself had signed and was bound by the Corporate Integrity Agreement as a result. (*Id.* (Ex. A).) Cf. *State ex rel. Daniel v. Broad River Power Co.*, 153 S.E. 537, 545 (S.C. 1930) (acknowledging that where facts show the subsidiary company was a mere agency or department of the holding company, or that it was an instrumentality to subserve some special purpose of the holding company, particularly where the public interests are involved, the Court will treat separate corporate entities as if such distinctions did not exist). Further, the same exhibits constitute evidence of “history of prior such conduct,” which the Court may justly consider in assessing penalties. 15 U.S.C. § 45(m)(C); see *Burbach v. Investors Mgmt. Corp. Int’l*, 484 S.E.2d 119, 121-22 & n.3 (admitting prior judgments against landlord in favor of other tenants over objection that other judgments involved dissimilar underlying facts; the court of appeals held that the Court must consider “specific proof of similar acts, transactions, or happenings where there is some special relation between them which would tend to prove or disprove some fact in dispute” and listed factors for the trial court to consider when determining the “admissibility of prior similar conduct under [SC]UTPA”); see also *Wright v. Craft*, 640 S.E.2d 486, 502 (S.C. Ct. App. 2006) (recognizing that “deterrence” as necessary where the evidence shows the “same kind of actions occurred in the past”).

For similar reasons, the Court should consider evidence of Defendant’s ability to pay the penalties, evidence that was offered through the Annual Reports and other financials of Defendant’s sole parent and whole-owner, Johnson & Johnson. (See, e.g., P-18, P-19, P-20; see also P-22 (marked for identification pending admission); Hr’g Tr. at 330-34 (Defendant’s financials reported through parent, Johnson & Johnson) (Ex. A).) See 15 U.S.C. § 45(m)(C) (court should consider “ability to pay”); *Reader’s Digest*, 662 F.2d at 967 (same).

C. Defendant's Complaints About Off-Label Marketing Evidence Are Themselves A Red Herring.

Defendant asserts that off-label promotion and marketing of Risperdal has nothing to do with this case, Defendant's conduct, or the Court's assessment of penalties. (*See, e.g.*, Hr'g Tr. at 176-77 ("So, off-label marketing, which was a huge focus of this trial, is really a bit of a red herring.") (Ex. A).) Defendant's position is wrong. Proof of Defendant's illegal promotion of Risperdal for "off-label" uses—such as for unapproved uses in the elderly and children, or minimizing the true diabetes risk in promotional materials while burying studies 113, ERI, and 275, as shown at trial (*see, e.g.*, discussion *supra* at section I.B.1)—goes to the heart of Defendant's "degree of culpability," 15 U.S.C. § 45(m)(C), and "bad faith," *Reader's Digest*, 662 F.2d at 967, which the Court should consider. Whether doctors may legally *prescribe* drugs for off-label uses is admitted and, therefore, is not in issue.

D. This Court's Discretion to Assess Penalties Is Bounded Only By SCUTPA Itself and United States Supreme Court Precedent Cautioning Against Penalties That Are "Wholly Disproportioned to the Offense and Obviously Unreasonable."

Similarly diversionary were Defendant's penalties hearing arguments concerning due process and so-called "excessive fines." (*See, e.g.*, Hr'g Tr. at 177 (Ex. A).) As a preliminary matter, such contentions were premature. If no specific penalty has yet been assessed against a defendant, the argument is not ripe. *United States v. Paul Revere Transp., LLC*, 608 F. Supp. 2d 175, 177 (D. Mass. 2009); *see also United States v. Am. Elec. Power Serv. Corp.*, 218 F. Supp. 2d 931, 942 (S.D. Ohio 2002) ("[W]hether a fine is excessive is a factual question that cannot be decided as a matter of law before a penalty is actually assessed."). Likewise, the issue of whether a potential penalty violates the Due Process Clause is not ripe for decision until a penalty has been assessed. *Clements v. HSBC Auto Fin., Inc.*, No. 5:09-cv-00086, 2010 U.S. Dist. LEXIS 111451, at *38 (S.D. W. Va. Oct. 19, 2010); *see also Arrez v. Kelly Servs., Inc.*, 522

F. Supp. 2d 997, 1008 (N.D. Ill. 2007) (“Defendant’s position is particularly untenable because by raising this issue . . . before any . . . penalties [have been] assessed against it – it essentially urges this Court to find [the penalties statute at issue] unconstitutional on its face.”).

Even if due process or excessiveness considerations were ripe—which they are not—South Carolina precedent recognizes that there can be “no error of law in imposing a fine within the limits authorized by [SCUTPA],” as noted previously. *C & L Corp.*, 313 S.E.2d at 340 (“Within [SCUTPA’s] limits, the amount of the fine was a matter of the judge’s discretion.”). Moreover, the United States Supreme Court established long ago that statutory penalties designed to address “public wrongs” need not be “confined or proportioned to [actual] loss or damages, for, as it is imposed as a punishment for the violation of public law, the Legislature may adjust its amount to the public wrong rather than the private injury, just as if it were going to the state.” *Williams*, 251 U.S. at 66-67. In *Williams*, the Supreme Court found that the statute at issue, a fixed penalty for railway passenger overcharges, did not violate due process. *Id.* The High Court declared that:

When [a statute] is considered with due regard for the interests of the public, the numberless opportunities for committing the offense, and the need for securing uniform adherence to [the law], we think it cannot be said to be so severe and oppressive as to be wholly disproportionate to the offense or obviously unreasonable.

Id. More recent cases have adhered to the *Williams* rule. See *Zomba Enters. v. Panorama Records, Inc.*, 491 F.3d 574, 587-88 (6th Cir. 2007); *Follman v. Village Squire, Inc.*, 542 F. Supp. 2d 816, 821-23 (N.D. Ill. 2007); *Arrez*, 522 F. Supp. 2d at 1008; *Texas v. Am. Blast Fax, Inc.*, 121 F. Supp. 2d 1085, 1090-91 (W.D. Tex. 2000); *Facebook, Inc. v. Fisher*, No. C 09-05842 JF (PSG), 2011 U.S. Dist. LEXIS 9668, at *5-7 (N.D. Cal. Jan. 26, 2011); *Gennari v. Weichert Co. Realtors*, 672 A.2d 1190, 1207 (N.J. Super. Ct. 1996).

Similarly, a fine violates the Excessive Fines Clause if it is “grossly disproportional to the gravity of a defendant’s offense.” *U.S. v. Bajakajian*, 524 U.S. 321, 334 (1998). “Because the standard is whether the fine is ‘grossly disproportional,’ the fine need only bear some relationship to the offense’s gravity; this is not a proportionality inquiry.” *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 744 (N.D. Ill. 2007). “Such an inquiry must thus recognize both that ‘judgments about the appropriate punishment for an offense belong in the first place to the legislature’ and that ‘any judicial determination regarding the gravity of a particular . . . offense will be inherently imprecise.’” *Id.* (quoting *Bajakajian*, 524 U.S. at 334-336).

Lastly, the Court should not overlook the purpose behind SCUTPA and statutory penalties such as those imposed by SCUTPA. “The purpose of the UTPA is to discourage unfair methods of competition and unfair or deceptive acts in the conduct of any trade or commerce.” *Taylor v. Medenica*, 503 S.E.2d 458, 460 (S.C. 1998). It follows that the South Carolina General Assembly would seek to “*avoid[] a situation in which the statutory penalty would be regarded by potential violators of [the Act] as nothing more than an acceptable cost of violation, rather than as a deterrence to violation.*” just as the United States Supreme Court divined to be Congress’s intent relative to the Federal Trade Commission Act. *See United States v. ITT Cont’l Baking Co.*, 420 U.S. 223, 232 (1975) (emphasis added), *cited in Reader’s Digest*, 662 F.2d at 966-67; *see also* S.C. Code Ann. § 39-5-20(b) (2010). *Accord, Reader’s Digest*, 662 F.2d at 967 n.15 (“[T]he efficacy of any regulatory program depends on the sanctions imposed in individual cases. If these sanctions are set too low, potential violators may be insufficiently motivated to minimize the social harm resulting from their behavior”) (internal quotation marks and citation omitted).

E. Defendant Purposely Avoided Damning Language of the 2003 Dear Doctor Letter.

Throughout the penalties hearing, Defendant exclusively focused its evidence and argument on debunking the notion that Risperdal caused as much or more diabetes, hyperglycemia, and weight gain as Zyprexa, so as to characterize the 2003 Dear Doctor Letter as “true” and scientifically supported. (*See, e.g.*, 180-81 (Ex. A).) In so couching its evidence and argument, Defendant carefully avoided addressing the most egregious language in the 2003 Doctor Letter—i.e., that evidence shows that Risperdal is not associated with *any* increased risk of diabetes when compared to “untreated patients”—which the State’s expert, Dr. Wirshing, characterized as “patently untrue.” (Trial Tr. at 458-49.) Defendant never once addressed that portion of the Dear Doctor Letter in its presentation during the penalties hearing. Moreover, any testimony by Dr. Wecker, Defendant’s statistician, related to “untreated patients” should be stricken as baseless and unreliable, as discussed below in section III.

F. Absence of Proof of Individualized Harm and Damages Simply Does Not Matter.

Defendant repeatedly argued at the penalties hearing that because the State failed to prove that “anyone in South Carolina was harmed” by the Dear Doctor Letter or the Risperdal label, the Court is restrained to assess either a “negligible” penalty or no penalty at all. (*See, e.g.*, Hr’g Tr. at 190.) Again, that argument is fundamentally contrary to controlling law. *State ex rel. McLeod v. Brown*, 294 S.E.2d 781, 783 (S.C. 1982) (“The trial court’s second ground for dismissal was the State’s alleged . . . inability to demonstrate . . . harm or damage to any citizen. [But, that] is [not] a prerequisite to an action under the Unfair Trade Practices Act.”); *id.* (“[I]t is in the public interest generally to prevent the use of false and misleading statements in the conduct of business . . . and actual deception need not be shown; a finding of a tendency to deceive and mislead will suffice.”). *Cf. Williams*, 251 U.S. at 66-67 (holding that state penalties

provisions addressing “public wrongs” need not be “confined or proportioned to [actual] loss or damages . . .”). (See discussion, *supra* at sections II.A and II.D.)

III. THE COURT SHOULD EXCLUDE DR. WECKER’S PENALTIES HEARING TESTIMONY AS UNRELIABLE AND DEVOID OF CREDIBILITY.

Once again, the Court should strike or at least refuse to consider Dr. Wecker’s testimony. In particular, Dr. Wecker’s testimony from the penalties hearing concerning the relatively higher rate of incidence of so-called “untreated” patients being diagnosed with diabetes, metabolic adverse events (“MAEs”), or hyperprolactinemia as compared to Risperdal-treated patients must be excluded. (See, e.g., Hr’g Tr. at 242-256 (witness’s direct testimony); *id.* at 275-76.) Dr. Defendant, through Dr. Wecker, *again* reconfirmed what the State has argued all along—that his analysis is inherently unreliable because it includes patients that may have been medically treated on an outpatient basis at a Department of Mental Health facility, therefore their medical records (including diagnosis history) would reside on the DMH claims database, but their prescription records (to the extent paid for by Medicaid) would exist on the Medicaid claims database, and there is no way to correlate those two databases (i.e., there no “crosswalk” between them). (See Pl.’s Mot. to Exclude Dr. Wecker (filed 1/13/2011) at 17-20 and Pl.’s Ltr. (3/3/2011) to Court re: exclusion of Dr. Wecker’s testimony (both of which are incorporated herein, in full, by reference).) Dr. Wecker admitted the same in the penalties hearing:

Q. Okay. Did you review the DMH claims data?

A. It was sent to us, but there was no data dictionary. So, it was totally unusable.

Q. Okay. And, so, the answer is no, you didn’t review the database, right?

A. I got the database. I looked at it. It was filled with coded numbers that I couldn’t decipher because it did not come with a dictionary explaining what the codes meant.

Q. Did you include DMH medical claims data in your analysis?

A. No.

Q. All right. Did you include patients who were treated at DMH in your analysis?

A. To the extent they were also treated in Medicaid or State Health Plan, yes.

Q. Okay. And is it your understanding that patients could be treated on an outpatient basis at DMH and have their prescription filled by Medicaid?

A. It's possible.

* * *

Q. [T]hese rates [of diabetes, MAEs, and hyperprolactinemia] are based only on a reported diagnosis in the [Medicaid] claims data, right?

A. Right.

Q. Okay. And we discussed this earlier, but that doesn't include claims data within DMH, right?

A. Correct.

* * *

Q. And not to do this over again, you're aware that patients could be treated on an out-patient basis at DMH, get their medical care there, but get drugs out-patient at a pharmacy and have Medicaid pay for that, right?

A. Right. That's exactly what I was describing.

Q. Okay. And, so, to the extent you included a Risperdal prescription in the Medicaid pharmacy data, it's possible you didn't consider medical claims data at DMH, right?

A. That's, that's exactly correct.

(Hr'g Tr. at 278-79, 300, 301 (Ex. A).) Incredibly, Dr. Wecker also initially testified that he *had accounted for* the missing DMH medical claims data discussed above by reviewing Medicaid

pharmacy claims data for instances of, for example, metformin as an indicator that a patient had been diagnosed with diabetes or other metabolic disturbance. (*Id.* at 279:7-282:6, 298:21-299:11 (Ex. A).) But, Dr. Wecker was forced to admit that he had never before presented findings regarding such instances at any point in the pre-trial or trial of this case, including at the penalties hearing:

Q. Okay. So, what you did is, if a patient had either a diagnosis or took one of the drugs for that diagnosis, you counted that as an adverse event?

A. In the rate charts [for rate of diabetes, MAEs, and hyperprolactinemia presented at the penalties hearing], those are based on the first method. Just looking at the diagnoses.

Q. Okay.

A. Because the addition of the medication made almost no change. And, so, I did elaborate the charts with that.

Q. Okay.

A. Just had one set of charts. I picked the first method [based on identifying an actual diagnosis of side effect, as opposed to medication record for that side effect].

Q. The second analysis you just said you did, where are the results of that analysis?

A. I don't have them with me. I'd have to, I'd have to get them.

Q. Have you ever reported those in this case?

A. I don't remember if we discussed them at deposition, but they're virtually identical to the, to the diagnosis results.

Q. Okay. And I guess we've just got to take your word for it because they're not in your opinion, and you've never reported them in this case, right?

A. I haven't reported them. I can tell you they're virtually identical. So, that's all I have to say.

(Hr'g Tr. at 299-300 (Ex. A).) Of course, an expert's opinion may not be supported by mere assurances of "trust me," which amount to nothing more than mere *ipse dixit*. See *Watson v. Ford Motor Co.*, 699 S.E.2d 175, 176 (S.C. 2010) ("[T]he trial court must evaluate the substance of the testimony and determine whether it is reliable."); *id.* at 181 (Pleciones, J., concurring and dissenting) (citing *Gen. Elec. Co. v. Joiner*, 522 U.S. 136, 146 (1997) for proposition that "court not required to admit opinion evidence connected to event only by the expert's *ipse dixit*"). Further, the State would be seriously prejudiced by the surprise admission of such evidence and testimony, as it was admittedly not previously disclosed (in its totality) in Dr. Wecker's expert report, his deposition, or at trial. For the above reasons, Dr. Wecker's testimony concerning the supposed rate of incidence that "untreated" and treated patients developed side effects of diabetes/hyperglycemia, MAEs, and hyperprolactinemia, must be excluded from consideration by the Court.

Lastly, the State renews all its other objections to the testimony and evidence presented at the penalties hearing by Dr. Wecker, namely:

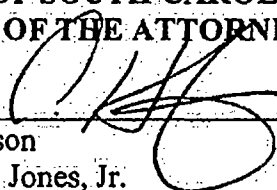
- based on relevance and Rule 403, to the extent that Dr. Wecker testified beyond the scope of or contrary to the parties' trial stipulation regarding Risperdal market share (Hr'g Tr. at 243 (Ex. A));
- based on relevance with regard to Dr. Wecker's testimony as to the rate that any person contracted diabetes or similar side effects attributable to Risperdal and other antipsychotic drugs (*id.* at 247, 248-49 (Ex. A));
- based on lack of foundation and hearsay with respect to Dr. Wecker's employment of so-called rebate information in his calculations, which were never substantiated by any evidence or testimony (*id.* at 260, 262-63, 264 Ex. A)); and
- based on lack of foundation, relevance, and Rule 403 with respect to testimony regarding the cost of Zyprexa (*id.* at 262 (Ex. A)).

IV. CONCLUSION

For all the foregoing reasons, the State respectfully requests that the Court grant it civil penalties in amounts fairly based on the evidence up to \$5000 per violation.

Respectfully submitted,

**STATE OF SOUTH CAROLINA
OFFICE OF THE ATTORNEY GENERAL**

By: 
Alan Wilson
C. Havird Jones, Jr.
Office of Attorney General
1000 Assembly Street, Room 519
Columbia, South Carolina 29201

HARRISON, WHITE, SMITH & COGGINS, P.C.

John B. White, Jr.
SC State Bar No. 5996
Donald C. Coggins, Jr.
SC State Bar No. 1307
178 West Main Street (29306)
PO Box 3547
Spartanburg, SC 29304
(864) 585-5100 Telephone
(864) 591-0491 Fax

SIMMONS LAW FIRM, L.L.C.

John S. Simmons
SC State Bar No. 10260
1711 Pickens Street
Columbia, South Carolina 29202
(803) 779-4600 Telephone
(803) 254-8874 Fax

BAILEY PERRIN BAILEY

Fletcher V. Trammell
Admitted *pro hac vice*
Texas State Bar No. 24042053
Robert W. Cowan
Admitted *pro hac vice*
Texas State Bar No. 24031976
Elizabeth W. Dwyer
Admitted *pro hac vice*
Texas State Bar No. 24062445

May 3, 2011
Spartanburg, South Carolina

440 Louisiana, Suite 2100
Houston, Texas 77002
(713) 425-7100 Telephone
(713) 425-7249 Fax
Attorneys for the State of South Carolina

STATE OF SOUTH CAROLINA)
COUNTY OF SPARTANBURG)

IN THE COURT OF COMMON PLEAS
FOR THE SEVENTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA ex rel.)
Alan Wilson, in his capacity as Attorney)
General of the State of South Carolina,)

Civil Action No. 2007-CP-42-1438

Plaintiff,)

v.)

DEFENDANT ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.'S
POST-PENALTY HEARING BRIEF

ORTHO-McNEIL-JANSSEN)
PHARMACEUTICALS, INC., f/k/a)
JANSSEN PHARMACEUTICA, INC.,)
JANSSEN, L.P. and JOHNSON &)
JOHNSON, INC.,)

Defendants.)

Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen"), by and through its undersigned counsel, hereby submits this Post-Penalty Hearing Brief to address the proof at the penalty hearing, and to further explain the factual and legal insufficiencies of the State's request for substantial money penalties.

I. INTRODUCTION

The State did not even try to prove any actual "deception," or any adverse impact on South Carolina physicians or patients or on the State itself. Yet, the State now asks for substantial penalties. Worse, it asks for substantial penalties based upon speculation as to why the jury might have found against Janssen. The State's request for substantial money penalties is factually and legally unsupported and entirely unwarranted.

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II. ARGUMENT

A. The State Did Not Satisfy Its Burden To Provide A Civil Penalty Calculation Free Of Speculation.

As the party seeking the award of penalties, it is the State's burden to provide the Court with a proper calculation of its requested relief. *Gauld v. O'Shaughnessy Realty Co.*, 380 S.C. 548, 559, 671 S.E.2d 79, 86 (Ct. App. 2009) ("[I]n order for damages to be recoverable the evidence should be such as to enable the court or jury to determine the amount thereof with reasonable certainty or accuracy. Neither the existence, causation nor amount of damages can be left to conjecture, guess, or speculation." (citations omitted)). At the penalty hearing, however, the State offered legally insufficient "penalty" theories and identified various overlapping or duplicative categories of "potential violations" keyed to what the jury *might* have decided when rendering its verdict against Janssen. See, e.g., Penalty Hr'g Tr. 399:2-340:2, Apr. 18-19, 2011 ("Hr'g Tr."); see also Ex. A to Pl.'s Pre-Hr'g Br. The State, therefore, failed to satisfy its most basic obligation and is improperly requesting the Court to engage in guesswork as to the State's requested penalties.

B. Penalties Cannot Be Based On The Number of Prescriptions, Sales Calls, And Samples – The State Is Double- And Triple-Counting.

The State proposes that this Court find a "violation" each time a Janssen representative called on a South Carolina physician and each time Janssen provided a Risperdal® sample. The State also suggests that a penalty be imposed for each prescription filled for a South Carolina patient, on the theory that prescriptions were "tainted" by the publication or distribution of the package insert and/or the letter. Indeed, the State would have this Court penalize Janssen for sending the November 2003 letter to a South Carolina physician, for showing the same letter to the same physician on the next sales call, for leaving a sample on that sales call, and for each prescription written by the physician and filled after that sales call. These "penalty" arguments are premised on the notion that

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the same physician might have been "misled" or "deceived" each time he or she might have been exposed to the "unfair" or "deceptive" package insert or letter.

The State, however, has cited no authority to support its argument that multiple violations should be found for repeated and overlapping "violative" conduct directed at the very same person. In contrast, there are state unfair or deceptive trade practices cases that have specifically rejected such a theory. See, e.g., *People v. Toomey*, 203 Cal. Rptr. 642, 656 (Cal. Ct. App. 1984) ("[W]e believe the Legislature intended that the number of violations is to be determined by the number of persons to whom the misrepresentations were made, and not the number of separately identifiable misrepresentations involved."); *People v. Bestline Prods., Inc.*, 132 Cal. Rptr. 767, 794-95 (Cal. Ct. App. 1976) ("While the intent of [the statute] was to strengthen the hand of the Attorney General in seeking redress for violations of [the statute], it is unreasonable to assume that the Legislature intended to impose a penalty of this magnitude for the solicitation of one potential customer."). The State's proposal that civil penalties be imposed multiple times for the same conduct directed at the same person when the conduct could possibly have caused some harm smacks of double- or triple-counting. For this reason alone, the State's evidence as to the number of sales calls, the number of samples, and the number of Risperdal prescriptions can and should be disregarded by the Court.¹

C. The State's Suggestion That The Court "Pick A Penalty Period" Is Improper, Given The Inability To Determine Why The Jury Found Liability - This Court May Not Speculate.

At the penalty hearing, the State invited the Court to "pick a penalty period" during which the FDA-approved Risperdal package insert purportedly contained inadequate

¹ The State's number as to Risperdal samples reflects more such "double counting." As conceded by the State's expert on cross-examination, the State's "samples" number was more than double that of Janssen, a discrepancy explained by the fact that, if two different sample doses were left on one sales call, it was counted by the State's expert as two separate sampling events. Hr'g Tr. 61:21-63:16 (Woodlock testimony).

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warnings. That was an invitation to speculate. Because the State did not request a more specific verdict form, the Court has no way of knowing why the jury found the package insert unfair or deceptive, or for what period of time. Without knowing "why," the Court cannot evaluate the severity of the violation and determine an appropriate penalty. Without knowing "for what period of time," the Court cannot determine the number of violations. The label inadequacy might have related to the diabetes warning, but it might as well have related to the placement within the label of the hyperprolactinemia discussion, or to the failure to add a "mortality in the elderly" warning. The jury may have decided that the inadequacy dated back to 1994 (when Risperdal was first sold in the United States) or 1997 (when, according to Dr. Wirshing, there was some evidence of an association with mortality in the elderly) or 1999 (when the RIS-USA-113 topline results were distributed) or 2000 (when the ERI preliminary numbers were received) or September 2003 (when the FDA asked for a "diabetes" class warning). And the jury might have decided that it ended in November 2003 (when the class warning was added to the label) or persisted until 2006 (when the language of the hyperprolactinemia precaution was revised). There is no way to know. On this record, there is no basis for imposing a "package insert" penalty based on sales calls, samples, or prescriptions filled during any of the time periods the State suggests. All that the Court knows for sure is that the jury found that at least one of the seven package inserts introduced at trial was unfair or deceptive.

D. The "Tainted Prescription" Theory Is Factually And Legally Flawed - Penalties Cannot Be Based On The Number Of Prescriptions.

The State's theory is that each and every Risperdal prescription was written in "reliance" on the Risperdal package insert - that every prescription was "tainted" by the unfair or deceptive conduct. See Hr'g Tr. 9:6-11. Thus, the State asks that a penalty be imposed for every prescription filled for a Medicaid recipient or State Health Plan participant

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during whatever "penalty period" the Court selects. Even setting aside the impossibility of determining the appropriate "penalty period," there are at least three independently sufficient reasons to reject this "tainted prescriptions" theory and the State's calculation of the number of prescriptions.

First, the Court hardly needs a reminder that the State repeatedly disclaimed any need to establish "reliance" or "causation." The State therefore presented no proof that any physician relied on the package insert or the November 2003 mailing or that any deceptive or unfair act "caused" any prescription to be written. Thus, the "taint" theory finds no support in the trial record; it is necessarily speculative. The United States Supreme Court has rejected a similar effort to attribute all sales of a particular product to allegedly "deceptive" conduct:

[Plaintiff] calculated that "potential harm" by referring to the fact that [defendant] had anticipated "gross profits of approximately \$3 million during the first five years of sales." Even if that estimate were correct, however, it would be unrealistic to assume that all of [defendant's] sales of the [product] would have been attributable to its misconduct . . . in its initial advertising materials. As the Court of Appeals pointed out, the picture of the [product] did not misrepresent the features of the original [product] and could not have deceived potential customers in any significant way. Its use was wrongful because it enabled [defendant] to expedite the promotion of its tool, but that wrongdoing surely could not be treated as the principal cause of [defendant's] entire sales volume for a 5-year period.

Cooper Indus., Inc. v. Leatherman Tool Grp., Inc., 532 U.S. 424, 441 (2001) (internal citation omitted).

Second, SCUTPA permits the imposition of penalties for the defendant's unfair or deceptive "acts" or "practices." It does not provide for penalties for acts taken by others, even if they might be thought to be "caused by" or "related to" defendant's acts. The "act" here was the distribution of at least one of the FDA-approved Risperdal package inserts.

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But, as the State's witnesses conceded, the Risperdal package insert was not distributed when a Risperdal prescription was written or filled in South Carolina. Trial Tr. vol. VI, 1221:10-1222:8, Mar. 14, 2011 (Assey testimony); *id.* at 1309:1-5 (Patterson testimony). Thus, there is no basis for the assessment of penalties based on the number of Risperdal prescriptions written or filled.

Third, the State's penalty hearing evidence as to the number of prescriptions filled was inconsistent and unreliable. As the Court will recall, the Attorney General's research analyst, Jay Smith, testified at the penalty hearing that 652,695 Risperdal prescriptions were filled for Medicaid recipients and State Health Plan participants from 1994 through 2006, while Dr. W. David Patterson, the representative of the State's Office of Research and Statistics, testified at the liability trial that 620,338 Risperdal prescriptions were filled for the same group for that time period – a discrepancy of more than 30,000 prescriptions. Compare Hr'g Tr. 83:22-84:1 (Smith testimony), with Trial Ex. P2670. Dr. Patterson's number was virtually identical to that of Janssen's expert, Dr. Wecker (620,436 prescriptions). See Hr'g Tr. 296:1-24 (Wecker testimony).

E. The State's "November 2003 Mailing" Penalty Theory And Calculations Are Similarly Flawed.

The State's arguments as to the number of violations in connection with the November 2003 mailing also suffer from speculation and a lack of factual support. First, the State argues that the Court could find violations as to every sales call from November 2003 to July 2004. But those sales calls include multiple visits to the same South Carolina physicians. As the State has acknowledged, the letter was not "published" on repeat visits to a physician. Rather, the use of the November 2003 "Dear Healthcare Provider" letter on sales calls was a "one and done" event. See Hr'g Tr. 117:4-13; Trial Tr. vol. V, 1154:13-1155:2, Mar. 11, 2011 (Alderman testimony). Additionally, the physicians upon whom the

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sales representatives called were the same physicians who received the mailing in the first instance; again, the State is seeking multiple penalties for conduct directed at the same individuals.

Second, the State notes that the November 2003 "Dear Healthcare Provider" letter was posted on Janssen's website. The State then asserts that the letter "may have been seen" by some or all of the 26,676 prescribers, pharmacists, and pharmacy technicians licensed in South Carolina who had "access" to the website. And it asks that the Court find 26,676 "violations." See Ex. A to Pl.'s Pre-Hr'g Br.; Hr'g Tr. 14:22-15:2. That clearly would be improper speculation.

F. There Is No Authority And No Basis For An Award Of The Maximum Penalty For Any Violations Of SCUTPA.

Although it acknowledges that not all "potential violations" are "necessarily" equally "egregious," the State argues for the imposition of the "maximum penalty." As previously explained by Janssen, the many decisions discussing the relevant factors for the determination of civil penalties do not support the State's "maximum penalty" approach. See Janssen's Penalty Hr'g Br. at 30-31. In particular, South Carolina civil penalty decisions concerning a truly egregious example of consumer fraud (a pyramid scheme) and potential harm from repeated environmental violations support the rejection of the State's expansive theory of civil penalties. See *State ex rel. Medlock v. Nest Egg Soc'y Today, Inc.*, 290 S.C. 124, 348 S.E.2d 381 (Ct. App. 1986) (awarding a civil penalty of \$45,000 under SCUTPA – less than \$5.00 per violation); see also *Midlands Util., Inc. v. S.C. Dept. of Health & Envtl. Control*, 313 S.C. 210, 212-214, 437 S.E.2d 120, 121-122 (Ct. App. 1998) (reducing, in part, trial court's \$101,000 civil penalty for multiple environmental violations).

Equally significant, the State has not identified a single instance where civil penalties were awarded by a Court based on an "inadequate" FDA-approved package insert for a

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prescription medicine, or even a medical communication such as the November 2003 mailing. The State also presented no evidence that Janssen continued to engage in the same challenged conduct after a determination that a particular practice had been found to be unfair or deceptive. The absence of any such precedent or factual evidence is an important consideration for purposes of any punitive award such as civil penalties. As stated by the United States Supreme Court in *BMW of North America v. Gore*, 517 U.S. 559, 577-78, 579, 584, 584-585 (1996):

As far as we are aware, at the time this action was commenced no state court had explicitly addressed whether its State's disclosure statute provides a safe harbor for nondisclosure of presumptively minor repairs or should be construed instead as supplementing common-law duties. A review of the text of the statutes, however, persuades us that in the absence of a state-court determination to the contrary, a corporate executive could reasonably interpret the disclosure requirements as establishing safe harbors.

....

In this regard, it is also significant that there is no evidence that BMW persisted in a course of conduct after it had been adjudged unlawful on even one occasion, let alone repeated occasions.

....

None of these statutes would provide an out-of-state distributor with fair notice that the first violation – or, indeed the first 14 violations – of its provisions might subject an offender to a multimillion dollar penalty. Moreover, at the time BMW's policy was first challenged, there does not appear to have been any judicial decision in Alabama or elsewhere indicating that application of that policy might give rise to such severe punishment.

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In the absence of a history of noncompliance with known statutory requirements, there is no basis for assuming that a more modest sanction would not have been sufficient to motivate full compliance with the disclosure requirement imposed by the [State] Supreme Court in this case.

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There is no support under South Carolina law, or any of the law cited by the State, for the substantial penalty request sought here.

G. The Statements About Comparative Risk Were True – Then And Now – And Should Not Be Penalized.

At the penalty hearing, the State continued with its theme that the conduct that should be penalized is Janssen's effort, in its promotion of Risperdal, to "minimize" the medicine's risks. In fact, the State argued that the jury "decided" that Janssen engaged in "overly aggressive marketing." Hr'g Tr. 110:9-12. The jury, of course, made no such finding. See Verdict Form. Indeed, the jury did not find – as the State seems to assume – that either the November 2003 mailing or the Risperdal package insert were "deceptive" because, again, the verdict form called for no such separate finding. *Id.*

Moreover, as shown by the uncontroverted evidence presented at the penalty hearing, and indeed the trial itself, the State's claim of improper "competitive" and "comparative" marketing – and its claim of likely "deception" as to risks – is factually unsupported. Although the State reiterated at the penalty hearing its assertion that there was essentially no difference between Risperdal and other antipsychotic medicines, the evidence establishes that Risperdal does indeed have a lower risk of weight gain and diabetes than Zyprexa. Dr. Newcomer testified that there "certainly are differences among antipsychotics with respect to weight gain. Hr'g Tr. 207:10-12. He testified that the latest and most comprehensive studies show that Risperdal poses less of a risk of diabetes than Zyprexa and no more of a risk than first generation antipsychotics. *Id.* at 219:8-13. And he confirmed that the statements in the November 2003 "Dear Healthcare Provider" letter were true when they were made and "still are true." *Id.* at 206:24-207:4. Dr. Wecker's testimony also went to the truthfulness of the "comparative" claims: he testified that in the South Carolina Medicaid and State Health Plan population, Risperdal actually has been

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associated with a lower incidence of diabetes than other atypical antipsychotics, typical antipsychotics, and even untreated patients. Hr'g Tr. 245:13-247:6, 249:10-253:19.

H. Substantial Penalties Should Not Be Imposed For Violations That Caused No Harm Or Loss.

An additional critical fact is that there is no evidence of any adverse impact on the State of South Carolina or any of its residents from the alleged improper conduct of Janssen. Recognizing that it could not identify any actual public or private harm, the State instead argued that penalties are warranted because "[t]he injury to the public is the misrepresentation itself." *Id.* at 345. This circular argument needs no response. What is important is (1) the indisputable benefits of Risperdal use for thousands of South Carolina residents, Hr'g Tr. 99:15-18; Trial Tr. vol. II, 236:22-24, Mar. 8, 2011; Trial Tr. vol. IX, 1993:10-17, Mar. 17, 2011; Trial Tr. vol. XI, 2728:4-6, Mar. 21, 2011 (no claim by State that any South Carolina resident suffered any personal injury); and (2) the uncontroverted evidence from Dr. Wecker that no "misrepresentation" about the relative safety of Risperdal affected Risperdal's market share in South Carolina, Hr'g Tr. 256:4-259:1, 289:6-293:4. Under any objective analysis, it would be inappropriate to impose substantial penalties on a company for a medicine that benefits South Carolina residents and for conduct that did not impact physicians' decisions and did not impact the State of South Carolina's economic interests. Regarding the State's economic interests, the testimony was that the State spent approximately \$23 million for Risperdal for Medicaid recipients and State Health Plan participants. Hr'g Tr. 269:6-19; see also Hr'g Ex. D-6. There was no evidence suggesting that even a penny of the \$23 million was wasted; for all that appears of record, it went for a medicine that worked exactly as expected, and caused no harm.

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I. The Assessment Of Substantial Penalties Would Be Unconstitutional.

The State's evidence and arguments at the penalty hearing – and the State's request for substantial civil penalties – implicate serious constitutional considerations under both the United States and South Carolina Constitutions. In particular, at the penalty hearing, the State repeatedly sought to introduce evidence as to (1) a defendant who received a favorable verdict (Johnson & Johnson), (2) alleged conduct as to different products occurring in different jurisdictions, (3) the volume of sales of Risperdal worldwide, and (4) the wealth of Janssen (through the use of the financial information of its parent company). See Hr'g Tr. 143:25-174:4. No such evidence can play any role in the penalty determination to be made by the Court.

The State does not and cannot dispute that civil penalty awards are subject to constitutional due process and excessive fine considerations. See generally *BMW*, 517 U.S. at 572-73 (economic penalties that a state imposes, "whether the penalties take the form of legislatively authorized fines or judicially imposed punitive damages, must be supported by the State's interest in protecting its own consumers and its own economy") (due process case); *In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 463 (E.D.N.Y. 2009) (excessive fine consideration where state requested civil penalties on a "prescription" basis). Further, any "award must be analyzed in the light of the same conduct, with consideration given only to the interests of [the particular state's] consumers, rather than those of the entire Nation." *BMW*, 517 U.S. at 574. The reason for these safeguards is simple: "Elementary notions of fairness enshrined in our constitutional jurisprudence dictate that a person receive fair notice not only of the conduct that will subject him to punishment, but also of the severity of the penalty that a State may impose." *Id.*

Thus, the State's request that the Court consider conduct outside South Carolina is improper. "While each State has ample power to protect its own consumers, none may use

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the punitive damages deterrent as a means of imposing its regulatory policies on the entire Nation." *Id.* at 585. "Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 421-22 (2003).

The State's request for significant civil penalties solely for Janssen's alleged non-disclosures also ignores that "the omission of a material fact may be less reprehensible than a deliberate false statement, particularly when there is a good-faith basis for believing that no duty to disclose exists." *BMW*, 517 U.S. at 580. And, since Janssen's conduct caused no loss, economic or otherwise, the State's request for substantial penalties is improper because it "is grossly disproportional to the gravity of the defendant's offense" and thus "it is unconstitutional." *United States v. Bajakajian*, 524 U.S. 321, 337, 339-40 (1998) (holding that forfeiture was excessive because the "[f]ailure to report his currency affected only one party, the Government, and in a relatively minor way. There was no fraud on the United States, and respondent caused no loss to the public" and the forfeiture "bears no articulable correlation to any injury suffered by the Government.").

In evaluating penalties, the court should consider whether "the conduct involved repeated actions or was an isolated incident." *State Farm*, 538 U.S. at 419. In conducting this analysis, however, "[a] defendant's dissimilar acts, independent from the acts upon which liability was premised, may not serve as the basis for punitive damages." *Id.* at 422; see also *Atkinson v. Orkin Exterminating Co.*, 361 S.C. 156, 168-69, 604 S.E.2d 385, 391-92 (2004) (holding that "unless [defendant's] past conduct is 'similar' to the conduct directed at the [plaintiff], it is inadmissible," and noting that admitted evidence was "extremely prejudicial because it allowed the [fact finder] to punish [defendant] for conduct unrelated to the conduct in the present case"). Further, "[t]he reprehensibility guidepost does not permit

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courts to expand the scope of the case so that a defendant may be punished for any malfeasance, which in this case extended for a 20-year period." *State Farm*, 538 U.S. at 424. Certainly, the State has not identified any authority that allows the Court to use acts of non-defendants or a defendant who obtained a favorable verdict to determine the amount of penalties for the sole remaining defendant. And the State offered no evidence of "similar misconduct" in South Carolina with respect to claims regarding the relative risks of Risperdal and Zyprexa or the "adequacy" of the package insert, and no evidence of any "misconduct" proximate in time to the conduct at issue in this case.

Finally, the State's myopic focus on the successful marketing of Risperdal and the resulting profits to Janssen calls for careful attention to the admonition of the South Carolina Supreme Court: "We caution that trial courts must be careful about considering the net worth of the defendant. Wealth cannot justify an otherwise unconstitutional punitive damages award." *Mitchell v. Fortis Ins. Co.*, 385 S.C. 570, 588 n.8, 686 S.E.2d 176, 185 n.8 (2009), *cert. denied*, 130 S. Ct. 1896 (2010). Stated another way: "[A] defendant's right to [due process] should not be diminished simply because the defendant is a deep pocket corporation." *Atkinson*, 361 S.C. at 165, 604 S.E.2d at 389-90 (citing *BMW*, 517 U.S. at 585). This warning about constitutionally mandated limitations is particularly appropriate where, as here, the State seeks to use the corporate wealth of a defendant who received a defense verdict.

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III. CONCLUSION

For all the foregoing reasons, and those set forth in Janssen's Penalty Hearing Brief, this Court should award a minimum civil penalty, if any is to be awarded at all.

Respectfully submitted,

RICHARDSON PLOWDEN & ROBINSON, PA
1900 Barnwell Street (29201)
Post Office Drawer 7788
Columbia, South Carolina 29202
(803) 771-4400

By: _____

Steven J. Pugh
Steven W. Hamm

-and-

Thomas F. Campion (admitted *pro hac vice*)
DRINKER BIDDLE & REATH LLP
500 Campus Drive
Florham Park, NJ 07932-1047
(973) 360-1000

Edward M. Posner (admitted *pro hac vice*)
Kenneth A. Murphy (admitted *pro hac vice*)
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700

ATTORNEYS FOR DEFENDANTS

May 3, 2011.

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STATE OF SOUTH CAROLINA)
)
COUNTY OF SPARTANBURG)

IN THE COURT OF COMMON PLEAS
FOR THE SEVENTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA ex rel.)
Alan Wilson, in his capacity as Attorney)
General of the State of South Carolina,)

Civil Action No. 2007-CP-42-1438

Plaintiff,

v.

ORTHO-McNEIL-JANSSEN)
PHARMACEUTICALS, INC., f/k/a)
JANSSEN PHARMACEUTICA, INC.,)
JANSSEN, L.P. and JOHNSON &)
JOHNSON, INC.,)

Defendants.)

REPLY MEMORANDUM OF LAW IN
SUPPORT OF DEFENDANT ORTHO-McNEIL-
JANSSEN PHARMACEUTICALS, INC.'S
MOTION FOR JUDGMENT
NOTWITHSTANDING THE VERDICT OR, IN
THE ALTERNATIVE, FOR A NEW TRIAL

Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen"), by and through the undersigned counsel, hereby submits this Reply Memorandum of Law to address certain arguments raised by the State in its Opposition ("Pl.'s Opp'n") to Janssen's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial ("Janssen's JNOV Motion").

I. **ARGUMENT**

A. **The State's Package Insert Claim Was Insufficient.**

The State's "evidence" as to the Risperdal® package insert was the testimony of its experts that the package insert inadequately warned as to certain risks *on the very first day it was issued*. Trial Tr. vol. V, 1084:4-24, Mar. 11, 2011 (Plunkett testimony); Trial Tr. vol. III, 624:15-625:15, Mar. 9, 2011 (Wirshing testimony). The State repeats this assertion in its opposition: "Risperdal labeling contained false and misleading information, and omitted true information, since the drug's launch in the United States." Pl.'s Opp'n at 53. The FDA, however, had determined that the package insert used on that

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very first day was neither false nor misleading, and that the medicine was both safe and effective. See Trial Ex. P571 (FDA initial approval of package insert); 21 C.F.R. § 314.125(b)(6), (14) (stating that the FDA will refuse to approve a new drug application if it determines that "[t]he proposed labeling is false or misleading in any particular"); see also *Wyeth v. Levine*, 129 S. Ct. 1187, 1196 (2009) ("*Wyeth*") ("The FDA's premarket approval of a new drug application includes the approval of the exact text in the proposed label." (citing 21 U.S.C. § 355; 21 C.F.R. § 314.105(b))); *Prohios v. Pfizer, Inc.*, 490 F. Supp. 2d 1228, 1235 (S.D. Fla. 2007) ("The information included in the labeling of a new drug reflects a determination by the FDA that the information is not 'false or misleading.'" (citing 21 C.F.R. § 314.125(b)(6))). The State's "package insert" claim, therefore, is barred for a number of independent reasons:

First, the "package insert" claim is incompatible with the FDA's determinations that the "Day One" package insert was *not* false or misleading and that Risperdal was safe and effective for use. The claim is therefore preempted by federal law. *Wyeth*, 129 S. Ct. at 1196. The narrow exception to federal conflict preemption allowed by *Wyeth*, based on the ability to "update" warnings via the FDA's "changes being effected" procedure, applies only when there is "new" scientific evidence, and the State did not argue that there was newly acquired evidence, at least in the first five years after Risperdal's launch. *Janssen's* Mot. at 22-24.

Second, this Court's previous decisions allowed the State to avoid application of the SCUTPA regulated activity exemption, S.C. Code Ann. § 39-5-40, when the "changes being effected" procedures might be used. Because those procedures cannot be used on "Day One," and because the "Day One" Risperdal package insert was expressly "permitted" by the FDA, Trial Ex. P571 (FDA initial approval of package insert), the State's "package

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insert" claim falls squarely within the statutory regulated activity exemption. Janssen's JNOV Mot. at 9-11.

Third, the State's claim is barred by considerations of primary jurisdiction, which are not "novel," Pl.'s Opp'n at 2, but well-recognized by courts where, as here, a plaintiff improperly attempts to base a claim on a package insert specifically approved by the FDA. Janssen's JNOV Mot. at 12.

Fourth, in Janssen's JNOV Motion, Janssen argued that liability cannot be imposed on the basis that the package insert might have deceived "consumers" because the package insert is written for physicians, not patients. In support of that argument, Janssen noted that a pharmaceutical manufacturer has no duty to warn patients under South Carolina law. Misconstruing the argument, the State replies that it is not bringing a common law "failure to warn" case. But that is irrelevant; the issue is whether the package insert can have a "tendency to deceive" consumers, when they are not the intended audience.

Accordingly, under numerous principles of law, the State's package insert claim failed and Janssen is entitled to judgment notwithstanding the verdict.

B. The State's November 2003 Mailing Claim Was Preempted By Federal Law.

The State argues that its SCUTPA claim as to the November 2003 mailing was based on Defendants' federal law violations" and therefore was not preempted by federal law. Pl.'s Opp'n at 20-26. But in fact, the State relied repeatedly and extensively with its expert witnesses and with virtually every fact witness – on "proof" of "federal law violations." For example, the State offered "expert" testimony that the FDA found that Janssen "broke the law" when it sent the November 2003 mailing:

Q. Now, the FDA also thought they broke the law, didn't they?

A. Yes. There was a – an action taken by the FDA.

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Q. Doctor, do you have the warning letter?

A. I don't have it here, but I have seen this before.

Q. Okay. Well, you can look on with me. Doctor, what is this document?

A. This is a warning letter that was sent by FDA to Janssen regarding their mailing of the Dear Doctor letter in November of 2003.

Q. And what does the FDA say about that letter?

A. I believe that they say that it's false and misleading and failed to disclose important information.

Q. It says, "Janssen's letter creates a serious public health issue also." Right?

A. Yes, that's correct.

Q. Now, Doctor, as an expert in the FDA regulations, do you agree with how the FDA interpreted its regulations in this case?

A. Absolutely, yes.

Trial Tr. vol. IV, 758-60, Mar. 10, 2011 (Plunkett testimony).

Indeed, the April 2004 DDMAC warning letter, with its assertion that Defendants violated federal law, became the centerpiece of the State's "November 2003 mailing" case. It was invoked again and again, with witness after witness, as evidence that the November 2003 mailing was "deceptive." Then, in its closing, the State told the jury that the determinative question would be "Did these defendants play by the rules?" Trial Tr. vol. IV, 2639:24-2640:4, Mar. 21, 2011. Although the State may be able to point to isolated statements by its experts not tied to "federal law violations," the claim presented to the jury was, in fact, a claim based on the preliminary DDMAC conclusion that the November 2003 mailing was "false" or "misleading" in violation of federal law. And that claim was preempted. See 21 U.S.C. § 337(a).

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C. The State's Other Arguments To Avoid Judgment Notwithstanding The Verdict Are Unavailing.

1. First Amendment

The State says, in its Opposition, that "[i]t is without question that the jury found both the 2003 Dear Doctor Letter and Risperdal label to be 'deceptive' based upon sufficient record evidence." Pl.'s Opp'n at 37. For that reason, it argues, "[t]hose materials are not entitled to First Amendment protections." Pl.'s Opp'n at 37 (citing *Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980)). But, in fact, the jury never "found both the 2003 Dear Doctor Letter and Risperdal label to be 'deceptive.'" The jury was never asked to make such a finding. See Verdict Form (not distinguishing between "deceptive" and "unfair"). Even if the jury focused on "deception," rather than "unfairness," at most its verdict would indicate that the November 2003 letter and the package insert had a "tendency to deceive," because that is all the Court, at the State's request, instructed the jury to find. See Trial Tr. vol. XII, 2767:1-2768:10, 2770:14-19, Mar. 22, 2011. Because the jury did not find that the November 2003 mailing or the package insert were "false" or actually "deceptive," Janssen is entitled to the benefit of First Amendment protection as to the State's requested penalty. See Janssen's Penalty Hr'g Br. at 44-46 (outlining proper application of *Central Hudson*).

Janssen certainly has not "waived" these First Amendment issues. See Pl.'s Opp'n at 38. To the contrary, Janssen requested separate instructions and separate determinations on the verdict form to address them. See Trial Tr. vol. XII, 2589:17-2592:6, 2632:19-2633:6, 2776:4-2777-10, 2789:2-25, Mar. 22, 2011. The State, however, objected to the requested jury instructions and to the proposed verdict form. See Exhibit H to Pl.'s Opp'n. The Court sustained the State's objections.

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In any event, the State confuses the issue of regulation or punishment of "commercial speech" – the "*Central Hudson*" issue – with the separate question of the burden of proof when a plaintiff seeks to recover on a state law cause of action based on the defendant's speech on a matter of public concern. Pl.'s Opp'n at 37. As to the burden of proof, the only relevant inquiry is whether the statements in the November 2003 mailing and the Risperdal package insert were about matters of public concern. Dismissing the United States Supreme Court's recent decision in *Snyder v. Phelps*, 131 S. Ct. 1207 (2011), as addressing only "protests about matters of public concern at a funeral service," Pl.'s Opp'n at 34, the State overlooks the Supreme Court's holdings that: (1) "[s]peech deals with matters of public concern when it can 'be fairly considered as relating to any matter of political, social, or other concern to the community,' or when it 'is a subject of legitimate news interest; that is, a subject of general interest and of value and concern to the public'"; and (2) the First Amendment is a defense to any state law claim. *Snyder*, 131 S. Ct. at 1215-16 (citations omitted). The importance of the "public concern" issue is that statements as to a matter of public concern cannot be punished absent a showing of falsity and proof by clear and convincing evidence that they were made with actual malice. See, e.g., *Madigan v. Telemarketing Assocs., Inc.*, 538 U.S. 600, 602 (2003) (holding that requirement that falsity and knowing misrepresentation be proved by clear and convincing evidence provides "sufficient breathing room for protected speech"); *Erickson v. Jones Street Publishers, LLC*, 368 S.C. 444, 467-68, 629 S.E.2d 653, 665-66 (2006) (requiring clear and convincing evidence of actual malice in media-defendant case involving matters of public concern).

The State's own argument as to the "purpose" of prescription drug labeling confirms that its SCUTPA claim is based on statements about matters of public concern – the State says that the purpose of prescription drug labeling "is to provide the essential 'information

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needed for the safe and effective use of the drug.” Pl.’s Opp’n at 16-17. The protections of the First Amendment, therefore, were fully available to Janssen as a defense to the State’s claim, and the State should have been required to prove the actual falsity of the statements it challenged as well as to present clear and convincing evidence that Janssen acted with actual malice.

In its Opposition, the State suggests that the actual malice requirement is limited to “media-related defamation cases.” To be sure, the requirement often is addressed in defamation cases. But the “actual malice” requirement is a general constraint on the power of the state – whether exercised directly by the state or indirectly, by using state power to enforce awards in private defamation cases – to punish speech on a matter of public concern. See *New York Times Co. v. Sullivan*, 376 U.S. 254, 265 (1964) (“The test is not the form in which state power has been applied but, whatever the form, whether such power has in fact been exercised.”); *Time, Inc. v. Hill*, 385 U.S. 374, 390 (1967) (explaining that an invasion of privacy claim arising out of a magazine article addressing a matter of public concern was subject to the actual malice standard although “[t]his is neither a libel action by a private individual nor a statutory action by a public official”). Here, where the punishment is being imposed directly by the State, the constitutional basis for application of the “actual malice” standard is even clearer than it was in *New York Times* and *Time*.

Finally, the State’s newest argument – properly relegated to a footnote – that the Risperdal package insert should be considered “government speech” not subject to First Amendment protection, Pl.’s Opp’n at 38-39 n.19, is premised on a misreading of Supreme Court and U.S. Appeals Court cases. The concept of “government speech” is a limited one that concerns speech by the government itself and, in general, precludes First Amendment challenges by those whose businesses are assessed to fund government speech with which they disagree. See, e.g., *Johanns v. Livestock Mktg. Ass’n*, 544 U.S. 550, 553, 562

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(2005); *Page v. Lexington Cnty. Sch. Dist. One*, 531 F.3d 275, 280 (4th Cir. 2008). Even a cursory review of the “government speech” cases, however, will show that the State is wrong to equate “speech that is compelled by the government” with “government speech.” Speech by a private party, or attributed to a private party, even if “compelled” by a regulator, does not lose its First Amendment protection.

2. Lack Of Support For The State's SCUTPA Claim

The State's SCUTPA-specific arguments also are meritless. First, Janssen did not rely on “extra-jurisdictional case law,” Pl.'s Opp'n at 41, to support its motion as to the deficiency of the State's unfair trade practice claim or the necessary elements of the State's deceptive trade practice claim. Rather, Janssen appropriately relied on FTC Policy Statements, federal and state court decisions interpreting those Policy Statements, and the plain text of the Federal Trade Commission Act itself, 15 U.S.C. § 45, where, as here, South Carolina courts have not spoken on all of the relevant issues. See Janssen's JNOV Mot. at 26-36. SCUTPA expressly directs that this Court be “guided by” such administrative and judicial interpretations of the Federal Trade Commission Act. S.C. Code Ann. § 39-5-20.

Second, the State asserts that it presented sufficient evidence of its SCUTPA claim – its arguments and evidence as to RIS-USA-113 and the ERI data – because “[t]his is a matter of a drug company withholding vital safety information in order to maintain its market status.” Pl.'s Opp'n at 43-44. “The failure to disclose those results demonstrating a reasonable association with the serious hazards of diabetes/hyperglycemia and weight gain,” the State argues, “permitted Janssen to steer clear of strengthening Risperdal's warnings.” *Id.* However, there is no record evidence – no testimony from the State's experts – that “those results demonstrat[ed] a reasonable association with . . . diabetes/hyperglycemia and weight gain” such that Janssen might “update” its label pursuant to the “changes being effected” procedures. And in any event, the State may not

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base a SCUTPA claim on the alleged "withholding" of information from the FDA. *Buckman Co. v. Plaintiffs' Legal Comm.*, 531 U.S. 341 (2001).

Third, the State never introduced any evidence that either the November 2003 mailing or the package insert had a "tendency to deceive" anyone in South Carolina. In its Opposition, the State simply (1) points to certain testimony by Dr. Wirshing that, in his view, certain statements were "untrue" or untrue "based on study 113 alone," and (2) asserts that it introduced "overwhelming evidence of public impact" of the alleged unfair and deceptive trade practices. Pl.'s Opp'n at 45-46. The Wirshing testimony to which the State cites relates only to the November 2003 mailing and to certain marketing or sales materials – not to the package insert. See *id.* at 45. And even as to the mailing, none of the Wirshing testimony addresses the impact of the supposedly "untrue" statements on South Carolina physicians. Thus, it does not establish a "tendency to deceive." Further, such a "tendency to deceive" cannot even be inferred given (1) Dr. Wirshing's acknowledgement elsewhere in his testimony that Risperdal does indeed pose less of a diabetes risk than Zyprexa and that he lectured physicians to that effect, Trial Tr. vol. III, 405:24-406:6, 600:3-601:6, 627:22-628:7, Mar. 9, 2011; and (2) the specific disclosure in the package insert, from Day One that Risperdal is associated with twice the weight gain as placebo, Trial Ex. P643 at 4. for the evidence of "public impact," "public impact" is an element of a SCUTPA violation separate and distinct from "tendency to deceive." See, e.g., *deBondt v. Carlton Motorcars, Inc.*, 342 S.C. 254, 269, 536 S.E.2d 399, 407 (Ct. App. 2000) (whether an act has a "tendency to deceive" or is "likely to deceive" "depends upon the surrounding facts and the impact of the transaction on the marketplace").

Fourth, the State's evidence as to the alleged "public impact" of Janssen's conduct illustrates perfectly why its SCUTPA claim is preempted by federal law: the State relies solely on the 2004 FDA warning letter as its "evidence" of public impact. Pl.'s Opp'n at

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48-49. As for alleged "repetition," the State only argues that because Janssen sent more than one letter, and because Janssen disseminated multiple copies of the package insert, the "repetition" element is satisfied. Pl.'s Opp'n at 49-52. This argument has been rejected consistently. See *Jefferies v. Phillips*, 316 S.C. 523, 529, 451 S.E.2d 21, 23-24 (Ct. App. 1994) ("In the course of human endeavor, every action has some potential for repetition. The mere proof that the actor is still alive and engaged in the same business is not sufficient to establish this element."); see also *Wilson Grp., Inc. v. Quorum Health Res., Inc.*, 880 F. Supp. 416, 428 (D.S.C. 1995) ("There is no evidence in this case of other similar acts and, therefore, no basis to conclude that Quorum's alleged acts have the potential for repetition." (footnote omitted)).

Fifth, despite the necessity to identify evidence of willful conduct, the State initially only restates the statutory definition of "willful violation." Pl.'s Opp'n at 52-54. Then, the State repeats its hackneyed argument that the Risperdal package insert was not "permitted" because it was "inadequate" and should have been updated on the first day of its use. Pl.'s Opp'n at 53. This circular argument does not address that the package insert used by Janssen was never "prohibited," and thus, under *Haley Nursery Co. v. Forrest*, 298 S.C. 520, 525, 381 S.E.2d 906, 909 (1989), use of the package insert does not constitute a "willful violation" of SCUTPA. As to the November 2003 mailing, the State does not even address Janssen's argument – that the State failed to introduce evidence that Janssen knew or should have known that the statements in the mailing were false. Courts with statutes similar to SCUTPA that also impose a "willfulness" requirement have held that, at a minimum, a plaintiff must establish that a defendant knew or should have known that the representations challenged as deceptive were false. See, e.g., *Adamson v. Worldcom Commc'ns, Inc.*, 78 P.3d 577, 583 (Or. Ct. App. 2003); *State ex rel. Corbin v. United Energy Corp. of Am.*, 725 P.2d 752, 758-59 (Ariz. Ct. App. 1986).

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3. Statute Of Limitations

Finally, the State's statute of limitations arguments, Pl.'s Opp'n at 54-69, are erroneous for the simple reason that South Carolina law does not require that "the Attorney General's Office," as opposed to the State, be on notice of a claim or that "unlawful conduct must be discovered" for the statute of limitations to begin to run. See Janssen's JNOV Mot. at 44-46. Nor does South Carolina law provide for equitable tolling in the circumstances of the present case, where there is no evidence that anyone was misled by the alleged unfair or deceptive conduct. *Id.* Thus, the Court should not have granted the State's directed verdict motion as to the statute of limitations. Moreover, as all of the alleged unfairness or deception as to both the November 2003 mailing and the package insert concerned matters on the face of the respective documents or matters well-known no later than November 2003, the Court should have granted Janssen's motion for directed verdict as to the statute of limitations. See Janssen's JNOV Mot. at 43-44.

D. The Court Made Critical And Erroneous Evidentiary Rulings.

1. Standing Objections

The State now makes the remarkable argument that Janssen "waived its standing objections" by not repeating them or referring to them "when each piece of evidence was offered into evidence at trial." Pl.'s Opp'n at 83. The entire purpose of the standing objections, of course, was to avoid repeated objections during trial. See, e.g., Trial Tr. II, 150:10-12, Mar. 8, 2011 ("[W]e'll have a continuing objection throughout the course of the trial. That way we don't have that start/stop."). The State's counsel specifically agreed to this process. *Id.* at 151:19-22 ("THE COURT: Do you have any objection to those being continuing objections throughout the trial? MR. COGGINS: No, Your Honor."). The State's "waiver" challenge to Janssen's evidentiary arguments, therefore, should be summarily rejected.

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2. DDMAC Letters

The State's attempt to justify introduction of the DDMAC letters is unpersuasive. First, while it argues on the one hand that the letters "were not offered to prove the truth of the matter asserted," it says on the other that the "letters were highly probative of whether Defendant's alleged conduct was deceptive or unfair." Pl.'s Opp'n at 75, 77. Surely, the only way the DDMAC letters could be probative of whether Janssen's letter was "deceptive" or "unfair" is if the jury accepted the author's opinion that Janssen's conduct was, in fact, "false or misleading."

Second, based on the language of Rule 803(8), SCRE, and South Carolina Supreme Court precedent, the DDMAC letters are not subject to the "public records and reports" exception. In *State v. Morris*, 376 S.C. 189, 656 S.E.2d 359 (2008), for example, the Supreme Court rejected an argument that the report of a bankruptcy examiner fell within the "public records" exception because the "report contains a great deal of investigative opinions, legal analysis, and potential conclusions." *Id.* at 207, 656 S.E.2d at 368-69 (emphasis added). The Supreme Court did not, as the State suggests this Court do here, consider a *report* – with the examiner's *conclusions* – outside the scope of the "investigative notes" exception to the exception. The DDMAC letters are no different from the bankruptcy examiner's report, especially since the State's admitted purpose in introducing them was to educate the jury as to the DDMAC's "investigation," findings, and conclusions.

Finally, any purported probative value of the DDMAC letters was substantially outweighed by the danger of unfair prejudice to Janssen. The State opened its case by telling the jury, "We don't just say that [the November 2003 letter] was false and misleading and deceptive, the FDA called them on it, they said it was, too." Trial Tr. vol. II, 212:12-14, Mar. 8, 2011. And the DDMAC letters turned out to be the primary "proof" – really the only "proof" – "of whether Defendant's alleged conduct was deceptive or unfair" and of

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"willfulness." Pl.'s Opp'n at 77. Their improper admission into evidence tainted the entire trial.

3. Reines E-mails

The State concedes that the e-mails of Scott Reines "were accompanied by a slight danger of unfair prejudice," but suggests that the "probative value" of the e-mails was not "substantially outweighed" by the danger of prejudice. Pl.'s Opp'n at 88. According to the State, "The Reines e-mails were highly probative because they shed tremendous light on Defendant's deceptive and unfair handling of the 2003 Dear Doctor Letter and the deceptive and unfair nature of the representations made therein. Those e-mails were also highly probative of whether Defendant knew or should have known that its conduct related to the 2003 Dear Doctor Letter was deceptive or unfair." *Id.*

The State's position is untenable for at least two reasons. First, Dr. Reines was not a participant in the decisions as to whether the November 2003 letter should be sent or what it should say. See Defs.' Mem. Regarding Certain E-mails of Scott Reines, M.D., Ph.D. at 3-5. Dr. Reines learned of the letter only after the fact. Second, nothing in the Reines e-mails suggests that the November 2003 mailing was "unfair" or "deceptive," and in fact, Dr. Reines testified that he believes Janssen's position as to the science is correct. *Id.* at 2.

The personal – anecdotal – views of an individual wholly unconnected with the alleged "unfair" or "deceptive" conduct that the November 2003 letter, while accurate and truthful, was not well-handled – simply as a matter of Janssen's relationship and interaction with its primary federal regulator, the FDA – are not probative at all, much less "highly probative," of the nature of the statements made in the letter or the "will" with which the statements were made. And the obvious prejudice from these e-mails is magnified by the fact that Dr. Reines was employed by a company which, like Janssen, is owned by Johnson

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& Johnson – a point exploited by the State during the trial. Accordingly, these e-mails should not have been admitted into evidence. The unfair prejudice from Dr. Reines's intemperate remarks outweighed any purported probative value.

4. Janssen's Motion To Limit Plaintiff's Claim

The State's response to Janssen's JNOV Motion – that if anyone was "surprised" it was the State, Pl.'s Opp'n at 71-72 – is curious at best. Janssen's motion to limit could not have been filed earlier because it was not until the State responded to Defendants' motions for summary judgment that the State asserted – for the first time since filing its Second Amended Complaint – that its claim was based on anything other than alleged "deception." That was the point of the "motion to limit" – that the State's change of position was last minute.

Janssen's argument is straightforward. When asked to specifically identify *all facts* upon which it based its SCUTPA claim, the State responded, "Each Risperdal package insert constitutes a separate violation of SCUTPA *because it tends to deceive* recipients about Risperdal's association with diabetes-related and hyperprolactinemia risks in addition to alpha toxicity in the elderly." See Pl.'s Answers to Janssen's Sixth Set of Interrogs., No. 1 (emphasis added) (attached to Mem. of Law in Support of Defs.' Mot. to Limit Pl.'s Unfair Trade Practices Claim to "Deceptive" Acts or Practices and to the Risperdal Package Insert and the November 10, 2003 Mailing, Ex. 11 to Aff. of S. Pugh); see *also id.*, No. 2. Notably, despite numerous opportunities, the State did not identify any "unfair" acts as the basis for its SCUTPA claim. The only time the State used the word "unfair" in an interrogatory answer, it merely was reciting back Janssen's question. See, e.g., Pl.'s Suppl. Answers to Janssen's Fifth Set of Interrogs., No. 9 (attached to Defs.' Mot. to Limit, Ex. 3 to Aff. of S. Pugh). Discovery responses should count for something; the State should have been limited to the single basis it identified in its interrogatory answers.

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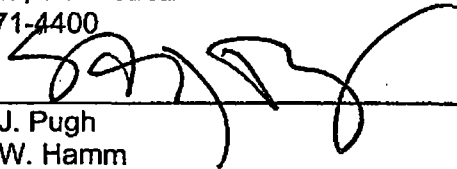
II. CONCLUSION

For the foregoing reasons, and for the reasons stated in Janssen's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial and its accompanying memorandum of law, Janssen respectfully requests that this Court enter judgment in favor of Janssen and against the State notwithstanding the jury's verdict. In the alternative, Janssen respectfully requests that this Court enter an Order granting a new trial.

Respectfully submitted,

RICHARDSON PLOWDEN & ROBINSON, PA
1900 Barnwell Street (29201)
Post Office Drawer 7788
Columbia, SC 29202
(803) 771-4400

By:



Steven J. Pugh
Steven W. Hamm

-and-

Thomas F. Campion (admitted *pro hac vice*)
DRINKER BIDDLE & REATH LLP
500 Campus Drive
Florham Park, NJ 07932-1047
(973) 360-1000

Edward M. Posner (admitted *pro hac vice*)
Kenneth A. Murphy (admitted *pro hac vice*)
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700

ATTORNEYS FOR DEFENDANT
ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.

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May 3, 2011.

STATE OF SOUTH CAROLINA)
)
COUNTY OF SPARTANBURG)

IN THE COURT OF COMMON PLEAS
FOR THE SEVENTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA ex rel.)
Alan Wilson, in his capacity as Attorney)
General of the State of South Carolina,)

Civil Action No. 2007-CP-42-1438

Plaintiff,)

v.)

**DEFENDANT ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.'S MOTION TO
ALTER OR AMEND THE JUDGMENT
AND/OR FOR A NEW TRIAL**

ORTHO-McNEIL-JANSSEN)
PHARMACEUTICALS, INC. f/k/a)
JANSSEN PHARMACEUTICA, INC.,)
and/or JANSSEN, L.P. and JOHNSON)
& JOHNSON, INC.,)

Defendants.)

TO: JOHN B. WHITE, JOHN S. SIMMONS, AND FLETCHER V. TRAMMELL
ATTORNEYS FOR PLAINTIFF

Pursuant to Rules 52(b), 59(a), and 59(e) of the South Carolina Rules of Civil Procedure, Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen"), by and through the undersigned counsel, hereby moves this Court to alter or amend the June 3, 2011 Penalty Order (and hold additional penalty hearings, if necessary).

On June 3, 2011, the Court entered an Order awarding penalties in the amount of \$327,073,700 on the State's claim that Janssen violated the South Carolina Unfair Trade Practices Act ("SCUTPA") based on: (1) a November 10, 2003 mailing from Janssen to South Carolina health care providers; and (2) the U.S. Food and Drug Administration ("FDA")-approved package inserts for Risperdal®. For a number of reasons, however, this award is inappropriate.

First, the Penalty Order does not comply with Rule 52(a) of the South Carolina Rules of Civil Procedure, because it does not set forth separate findings of fact and conclusions of law.

Second, the Court's penalty award is deficient in several critical respects. Specifically,

- (1) the penalty award based on Risperdal samples is legally and factually flawed because it is based on (i) a failure to warn patients; (ii) a conclusion that the Risperdal package insert was likely to deceive patients, which finds no support in the record; (iii) unsupported assumptions about the reasons for the jury's verdict and about the time period for which the jury found the Risperdal package insert "inadequate"; and (iv) a failure to consider the undisputed testimony of the State's and Janssen's experts that the risks at issue were risks of events that were "infrequent"; and because the award of a nine-figure penalty for the "inadequacy" of an FDA-approved package insert is unprecedented and improper; and
- (2) the penalty award based on the November 2003 mailing is legally and factually flawed because (i) it over-counts the number of "violations" on which a penalty could be assessed; (ii) it is based on an assumption – that prescribers were actually deceived – that is not supported by the record; and (iii) the amount of the penalty is not explained and is inconsistent with other South Carolina precedent awarding penalties in far less amounts for conduct far more egregious.

Third, the Court failed to defer to, or even acknowledge, the primary jurisdiction of the FDA.

Fourth, the penalty award exceeds any amount necessary to deter – the primary goal of a penalty award – any future unfair or deceptive conduct.

Fifth, the Court failed to apply properly the factors set forth in *United States v. Reader's Digest Association*, 662 F.2d 955 (3d Cir. 1981), and consider precedent imposing far less penalties in circumstances evidencing far more egregious conduct.

Sixth, the Court's penalty decision is based, in part, on evidence that should not have been admitted (including the e-mails of Scott Reines and any evidence as to Johnson & Johnson or conduct outside South Carolina), and the Court improperly excluded evidence

Janssen sought to introduce (including post-2004 scientific evidence relating to weight gain, diabetes, and other metabolic risks associated with and Risperdal and other atypical antipsychotics; the testimony of William E. Wecker; and the testimony of twenty South Carolina prescribers).

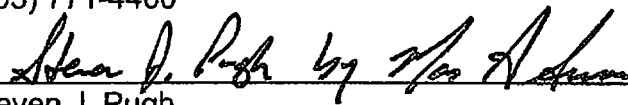
Seventh, the penalty award is unconstitutional – violative of the provisions of the United States and South Carolina Constitutions providing for Due Process, violative of the Excessive Fines Clauses of the United States and South Carolina Constitutions, and violative of the Free Speech protections of the First Amendment to the United States Constitution.

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WHEREFORE, for the reasons stated herein and in the accompanying memorandum of law, which is incorporated as though set forth fully herein, and for the reasons stated in Janssen's Penalty Hearing Brief and Post-Penalty Hearing Brief, both of which are incorporated as though set forth fully herein, the Court should grant Janssen's Motion in its entirety and alter or amend the June 3, 2011 Penalty Order. In the alternative, the Court should order a new trial as to the penalties.*

RICHARDSON PLOWDEN & ROBINSON, PA
1900 Barnwell Street (29201)
Post Office Drawer 7788
Columbia, South Carolina 29202
(803) 771-4400

By:


Steven J. Pugh
Steven W. Hamm

-and-

Thomas F. Campion (admitted *pro hac vice*)
DRINKER BIDDLE & REATH LLP
500 Campus Drive
Florham Park, NJ 07932-1047
(973) 360-1000

Edward M. Posner (admitted *pro hac vice*)
Kenneth A. Murphy (admitted *pro hac vice*)
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700

ATTORNEYS FOR DEFENDANT
ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.

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June 13, 2011.

* Nothing herein should be understood as an abandonment of the arguments set forth in Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.'s Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, which remains pending before the Court.

STATE OF SOUTH CAROLINA)
)
COUNTY OF SPARTANBURG)

IN THE COURT OF COMMON PLEAS
FOR THE SEVENTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA ex rel.)
Alan Wilson, in his capacity as Attorney)
General of the State of South Carolina,)

Civil Action No. 2007-CP-42-1438

Plaintiff,)

v.)

ORTHO-McNEIL-JANSSEN)
PHARMACEUTICALS, INC., f/k/a)
JANSSEN PHARMACEUTICA, INC.,)
and/or JANSSEN, L.P. and JOHNSON)
& JOHNSON, INC.,)

**MEMORANDUM OF LAW IN SUPPORT OF
DEFENDANT ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.'S MOTION TO
ALTER OR AMEND THE JUDGMENT
AND/OR FOR A NEW TRIAL**

Defendants.)

Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc. ("Janssen"), by and through the undersigned counsel, hereby submits this Memorandum of Law in support of its Motion to Alter or Amend the Judgment and/or for a New Trial.

I. INTRODUCTION

By Order dated June 3, 2011, the Court imposed a penalty award of \$327,073,700 against Janssen based on: (1) the use of Risperdal® package inserts approved by the U.S. Food and Drug Administration ("FDA"), and (2) a November 2003 mailing by Janssen to South Carolina health care providers. The Court assessed these enormous penalties even though there was no economic loss to the State or personal injury to any South Carolina resident, and despite the testimony of South Carolina Department of Mental Health officials that the information the Court believed was "not disclosed" actually was well-known throughout the South Carolina medical community. Without any need to deter continued wrongful conduct or any future conduct, the Court chose to punish Janssen for past conduct based solely on the successful sale of Risperdal throughout the world, sales the State never

alleged – and certainly never proved – were the result of the alleged unfair or deceptive conduct. The Court should amend or alter its findings and/or hold additional penalty hearings because:

- the Court's Penalty Order fails to set forth the required separate findings of fact and conclusions of law as mandated by South Carolina law;
- the Court's award and calculation of civil penalties is factually and legally flawed;
- the Court's Penalty Order failed to defer properly to the FDA and the penalties imposed far exceed any amount necessary to deter future misconduct;
- the Court failed to apply properly the factors set forth in *United States v. Reader's Digest Ass'n*, 662 F.2d 955 (3d Cir. 1981), which both parties agreed provided the proper framework for any consideration of penalties, and ignored precedent imposing far less penalties in far more egregious circumstances;
- the Court's Penalty Order is based, in part, on evidence that should not have been admitted, and the Court improperly excluded evidence Janssen sought to introduce; and
- the imposition of hundreds of millions of dollars of penalties, under the circumstances, is unconstitutional.

Accordingly, Janssen respectfully requests that the Court grant its motion as to the Penalty Order as well as Janssen's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial ("Janssen's JNOV Mot.").¹

II. APPLICABLE STANDARD

Pursuant to Rule 52(b) of the South Carolina Rules of Civil Procedure, [u]pon motion of a party made not later than 10 days after receipt of written notice of entry of judgment the court may amend its findings or make additional findings and may amend the

¹ Janssen incorporates by reference its Penalty Hearing Brief and Post-Penalty Hearing Brief.

judgment accordingly, and the motion may be made with a timely motion for a new trial." Rule 52(b), SCRPC. Under Rule 59(a) of the South Carolina Rules of Civil Procedure, a new trial may be granted "in an action tried without a jury, for any of the reasons for which rehearings have heretofore been granted in the courts of the State." Rule 59(a), SCRPC. "On a motion for a new trial in an action tried without a jury, the court may open the judgment if one has been entered, take additional testimony, amend findings of fact and conclusions of law or make new findings and conclusions, and direct the entry of a new judgment." *Id.* The motion for a new trial "shall be made not later than 10 days after the receipt of written notice of the entry of judgment or of the filing of an order disposing of the action, if no judgment has been entered." Rule 59(b), SCRPC. Finally, a "motion to alter or amend the judgment shall be served not later than 10 days after receipt of written notice of the entry of the order." Rule 59(e), SCRPC.

III. ARGUMENT

A. The Court's Penalty Order Is Deficient Because It Fails To Set Forth Separate Findings Of Fact And Conclusions Of Law In Violation Of Rule 52(a), SCRPC.

Rule 52(a) of the South Carolina Rules of Civil Procedure specifically provides that "[i]n all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereon." Rule 52(a), SCRPC.² That is, "Rule 52(a) of the South Carolina Rules of Civil Procedure requires a trial court to make specific findings of fact so that the parties and the appellate court may determine the basis for the ruling." *Walterboro Cmty. Hosp. v. Meacher*, __ S.E.2d __.

² "If an opinion or memorandum of decision is filed, it will be sufficient if the findings of fact and conclusions of law appear therein." *Id.*

2010 WL 5904130, at *3 (Ct. App. Dec. 15, 2010). As stated by the South Carolina Supreme Court, the purpose of this requirement is:

to allow a reviewing court to determine from the record whether the judgment – and the legal conclusions which underlie it – represent a correct application of the law. The requirement for appropriately detailed findings is thus not a mere formality or a rule of empty ritual; it is designed instead to dispose of the issues raised by the pleadings and to allow the appellate courts to perform their proper function in the judicial system.

In re Treatment & Care of Luckabaugh, 351 S.C. 122, 133, 568 S.E.2d 338, 343 (2002) (citation omitted).

The Court has decided that Janssen should pay more than \$327 million in civil penalties based on its conclusions as to Janssen's intent, the impact and significance of Janssen's "deception," and Janssen's "ability to pay." The Penalty Order, however, does not contain a single citation to the record from either the trial or the penalty hearing – a critical omission, because the key factual conclusions on which the penalty decision rests are not, in fact, supported by the evidence. For example, the Court makes the following statements that are not based on the trial record: (1) "[I]n this Case, the manipulation was to get prescribers and patients to make treatment decisions based upon misleading or incomplete data or concealing data [which] would have impacted those decisions," Penalty Order at 6; (2) "The law allowed the Defendant to unilaterally strengthen Risperdal's warning section of the label as soon as there was reasonable evidence of an association of a serious hazard with the drug. . . . Both Dr. Plunkett and Wirshing testified that the early evidence concerning the adverse events involving this drug, as well as its chemical makeup, should have given Janssen reason to strengthen the warnings in its label concerning diabetes, hyperglycemia and weight gain," *id.*; (3) "[w]hile this is not a 'fraud on the FDA' case, this concealment shows that the Company employed procedures and methods which almost guarantee repetition and further endangerment of the public," *id.* at

10; and (4) "the public interest affected by the actions of these Defendants is enormous," *id.* at 13.

But at trial and at the penalty hearing, the Court excluded testimony about the prescribing decisions of South Carolina prescribers and instructed the jury that the State need not show reliance. See Feb. 25, 2011 Order excluding testimony of Dr. William Wecker and Dr. Gerard C. Jebaily; Trial Tr. vol. XII, 2770:8-13, 2817:25-2818:4, Mar. 22, 2011 (jury instructions); Trial Tr. vol. XI, 2523:15-2525:6, Mar. 21, 2011 (oral offer of proof of Mr. Pugh, Janssen's counsel, as to twenty South Carolina prescribers, based on Court's decision to preclude testimony);³ Penalty Hr'g Tr. 302:9-315:21, 325:17-19, Apr. 18-19, 2011 (same). Further, neither Dr. Plunkett nor Dr. Wirshing testified that Janssen could have invoked the "changes being effected" procedure and "unilaterally" added a "warning" about diabetes, hyperglycemia, or weight gain based on the "early evidence" to which the Court refers or, for that matter, based on the "evidence" later developed from RIS-USA-113 and/or the ERI "study." Also, the jury made no finding – because the State presented no argument or testimony – that any "procedures" or "methods" of Janssen were "capable of repetition." See Verdict Form. Indeed, as for alleged "repetition," the State argued only that because Janssen sent more than one letter, and because Janssen disseminated multiple copies of the package insert, the "repetition" element was satisfied. See Pl.'s Opp'n to Janssen's JNOV Mot. at 49-52. Finally, there was no proof at trial or at the penalty hearing of any actual impact on the public or any adverse effect on "the public interest." See Janssen's JNOV Mot. at 38-40; Janssen's Post-Penalty Hr'g Br. at 10.

³ Consistent with Janssen's JNOV Motion, Penalty Hearing Brief, and Post-Penalty Hearing Brief, "Trial Tr." refers to the unofficial daily transcript the parties received during the trial, a true and correct copy of which was attached to Janssen's JNOV Motion as Exhibit A. Janssen will, at the Court's request, supply references to the official transcript.

As these examples reflect, the Court's failure to make the specific and separate findings mandated by Rule 52(a) renders the Court's entire Penalty Order deficient:

We do not require a lower court to set out findings on all the myriad factual questions arising in a particular case. But the findings must be sufficient to allow this Court, sitting in its appellate capacity, to ensure the law is faithfully executed below. The absence of factual findings makes our task of reviewing the court order impossible because "the reasons underlying the decision [are] left to speculation." To leave the chore of sorting through the record to review contradictory testimony taxes the judicial system and is unfair to the litigants as well as the lower court to whose factual determinations we give deference. The order now before us fails to substantially comply with Rule 52(a), SCRCP, thus failing to accomplish these purposes. Our review of the record cannot save the order from its deficiencies due to the contradictory testimony presented below.

In re Treatment & Care of Luckabaugh, 351 S.C. at 132, 568 S.E.2d at 343 (citations omitted). For this reason alone, the Court should grant Janssen's motion and amend its Penalty Order to comply with the dictates of Rule 52(a).

B. The Court's Penalty Calculation Is Deficient In Several Critical Respects.

1. The Penalty Award Based On Risperdal Samples Is Legally And Factually Flawed.

The Court imposed a penalty of \$152,849,700 for the alleged unfairness or deception as to the Risperdal package insert. Penalty Order at 17. This penalty award was based solely on Risperdal product samples provided to South Carolina prescribers by Janssen. *Id.* The Court's penalty award based on the distribution of Risperdal product samples is erroneous.

First, the penalty award as to Risperdal product samples is based on a failure to warn patients. Penalty Order at 17 ("Each distributed sample clearly contains a copy of the label and would be the most likely source of information for patients who are considering entering into an ongoing therapy with the drug."). Alleged deception as to South Carolina

patients, however, was a theory expressly disavowed by the State as the basis for its SCUTPA claim as late as its opposition to Janssen's post-trial motion. See Pl.'s Opp'n to Janssen's JNOV Mot. at 16 ("But the State is not bringing common law negligence, failure to warn, or other fraud claims; thus any existence or absence of common law 'duty' to consumers is irrelevant."); *id.* at 19 ("Defendant's contention regarding any targeted audience of prescription drug labeling is simply immaterial to the State's SCUTPA claim.").

In any event, it is improper to penalize Janssen for an alleged failure to warn patients adequately when such a legal duty is not recognized under South Carolina law. See, e.g., *Brooks v. Medtronic, Inc.*, 750 F.2d 1227, 1231 (4th Cir. 1984) ("Although the South Carolina Supreme Court has not addressed the issue, we conclude it would adopt the rule, generally accepted and supported by sound policy, restricting the manufacturer's duty to warn to the prescribing physician."); see also, e.g., *Odom v. G.D. Searle & Co.*, 979 F.2d 1001, 1003 (4th Cir. 1992) ("[T]he manufacturer's duty to warn extends only to the prescribing physician, who then assumes responsibility for advising the individual patient of risks associated with the drug or device."). It is specifically recognized that a package insert is written solely for physicians, not consumers. See 73 Fed. Reg. 49603, 49604 (Aug. 22, 2008) ("FDA's comprehensive scientific evaluation is embodied in the labeling for the product which reflects thorough FDA review of the pertinent scientific evidence and communicates to *health care practitioners* the agency's formal, authoritative conclusions regarding the conditions under which the product can be used safely and effectively." (emphasis added)).

Second, there is no basis in the record for the conclusion that the Risperdal package insert was likely to deceive patients. There is, for example, no evidence that a patient would think it important that the hyperprolactinemia discussion was in the "precautions" section of the package insert, rather than in the "warnings" section. And there was no

evidence supporting the Court's statement that the package inserts "distributed" with samples – assuming that a package insert was distributed by the physician each time a sample was given to a patient – "would be the most likely source of information for patients who are considering entering into an ongoing therapy with the drug." Penalty Order at 17.

Third, in determining the number of samples-related violations, the Court chose to use the time period from Risperdal's introduction to the United States market in 1994 up until the day the State filed its complaint (April 23, 2007). Penalty Order at 17. Because the verdict form was non-specific, however, there is no way of knowing whether the jury based its verdict on the conclusion that the package insert was "inadequate" for that entire period, or whether the jury believed that there was some "inadequacy" for only a part of the period. Similarly, there is no way of knowing what "inadequacy" prompted the verdict – e.g., whether it related to the absence of a "diabetes" warning from, say, 1999 to 2003, or to the placement within the label of the "hyperprolactinemia" discussion from 1994 to 2007, or whether it simply related to the short time period before which Janssen added the class wide warning after the FDA's request in September 2003. At most, all that the jury's verdict shows is the jury found that one Risperdal package insert was "inadequate." Thus, there is no basis for the imposition of a penalty for samples given to physicians for the entire thirteen-year period, and no basis for the Court's decision to "average the penalty awarded for the labeling issue" or to set the "average" penalty at \$300. Penalty Order at 8, 17. The use of a non-specific verdict form – at the insistence of the State – and the consequent lack of any factual support for the time period chosen renders the penalty award as to the Risperdal package insert hopelessly speculative.

Fourth, in awarding a penalty for every single Risperdal product sample ever distributed to physicians in South Carolina based on an alleged failure to disclose adequately certain risks as to the use of Risperdal, the Court failed to consider the

undisputed testimony of the State's and Janssen's experts that the risks at issue were risks of events that were "infrequent." In particular, the State's expert, Dr. Wirshing, agreed that any alleged "risk of death" to the elderly was only supposition and that diabetes-related adverse events were infrequent. Trial Tr. vol. III, 529:1-7, 457:4-458:4, Mar. 9, 2011 (Dr. Wirshing testimony). An "infrequent" event is one that occurs less than 1% of the time. See, e.g., *id.* at 480:23-24 (Dr. Wirshing testimony that "One in a hundred to one in a thousand is infrequent"); see also Pl.'s Trial Exs. 643, 656, 657, 661, 662, 665, 2049, 2061 (Risperdal package inserts stating that "infrequent adverse events are those occurring in 1/100 to 1/1000 patients"). Similarly, the State never contested the testimony of Janssen's expert, Dr. Newcomer, that problems relating to elevated prolactin are reversible by discontinuing the medicine. Trial Tr. vol. X, 2433:4-7, Mar. 18, 2011 ("[T]he prolactin elevation is a completely reversible thing, if you stop the medicine, or treat it, it can go down, and prolactin elevation and its symptoms go away."). There is no justification for the imposition of a 100% penalty – a penalty for every product sample – for adverse events that occur less than 1% of the time.

Finally, to the best of Janssen's knowledge, no other court has ever imposed a penalty, much less a nine-figure penalty, for the "inadequacy" of an FDA-approved package insert. Assessment of such a penalty in this case was not only unprecedented, but also improper. See generally *State v. Am. Recycling Techs., Inc.*, No. CV040832985, 2009 WL 1532330, at *6 (Conn. Super. Ct. May 5, 2009) (imposing civil penalty of \$50,000 for violation of unfair trade practices act and solicitation of charitable funds act after the court concluded "that this is the first case in Connecticut construing the SCFA, and that defendant conceivably could have been uncertain of the applicability of some of its provisions to it").

In sum, the Court's penalty award for the Risperdal package insert is flawed both legally and factually in numerous respects. The decision imposing penalties for the

Risperdal package insert thus should be vacated or, at the least, amended to conform to the evidence.

2. **The Penalty Award Based On The November 2003 Mailing Is Flawed.**

The Court imposed a penalty of \$174,224,000 for the alleged unfairness or deception as to the November 2003 mailing. Penalty Order at 17-18. This award also is flawed.

As an initial matter, the Court imposed multiple penalties for what it believed was an effort to "mislead" the same physician with the same letter. Specifically, the Court imposed a penalty for every single mailing to a South Carolina health care "provider"⁴ and then imposed the same penalty amount again for every single "sales call" during which the Court asserted that the "letter [was] published." *Id.* at 18. The physicians upon whom the sales representatives called, however, were the very physicians who received the mailing in the first place. Awarding a penalty for every subsequent visit to a recipient of the mailing improperly double- or triple-counts the number of violations. See, e.g., *People v. Toomey*, 203 Cal. Rptr. 642, 656 (Cal. Ct. App. 1984) ("[W]e believe the Legislature intended that the number of violations is to be determined by the number of persons to whom the misrepresentations were made, and not the number of separately identifiable misrepresentations involved."); *People v. Bestline Prods., Inc.*, 132 Cal. Rptr. 767, 794-95 (Cal. Ct. App. 1976) ("While the intent of [the statute] was to strengthen the hand of the Attorney General in seeking redress for violations of [the statute], it is unreasonable to assume that the Legislature intended to impose a penalty of this magnitude for the

⁴ The November 10, 2003 mailing was sent not only to physicians but to pharmacists and others who could not prescribe medicines.

solicitation of one potential customer.”). At the very least, imposing the same \$4,000 penalty for the second or third or fourth “publication” of the same letter is an abuse of the Court’s discretion.

Equally important, when imposing a penalty for every sales call, the Court assumed that the November 2003 mailing was shown at every sales call from November 2003 until July 2004. This assumption, however, is belied by the undisputed evidence of record. Trial Tr. vol. V, 1154:13-1155:2, Mar. 11, 2011 (Alderman testimony that use of the November 2003 “Dear Healthcare Provider” letter on sales calls was a “one and done” event). As the State provided no evidence whatsoever as to the actual number of “one and done” sales calls where the November 2003 mailing actually was published, the award based on sales calls in connection with the November 2003 mailing is speculative and must be amended and vacated.

The amount of the penalty per violation (\$4,000) also is based on a factually unsupported assumption. In particular, the Court stated that the November 2003 mailing “was done in such a fashion so as to directly influence the prescribing decisions of doctors.” Penalty Order at 10-11 (“Who knows how many of those mothers, fathers and patients referenced in their Credo, to be owed their best, were influenced into making incorrect decisions concerning their drug therapy?”). Again, however, the Court (erroneously) precluded any testimony as to South Carolina physicians and instructed the jury that the State need not show that anyone actually was deceived. See Feb. 25, 2011 Order excluding testimony of Dr. William Wecker and Dr. Gerard C. Jebaily; Trial Tr. vol. XII, 2769:14-19, 2818:5-9, Mar. 22, 2011 (jury instructions); Trial Tr. vol. XI, 2433:4-7, Mar. 21, 2011 (oral offer of proof of Mr. Pugh, Janssen’s counsel, as to twenty South Carolina prescribers, based on Court’s decision to preclude testimony); Penalty Hr’g Tr. 302:9-315:21, 325:17-19, Apr. 18-19, 2011 (same). Indeed, the only evidence of record is

that prescribing decisions did *not* change either when the November 10, 2003 mailing was sent or when it was "corrected" in July 2004. See Defs.' Trial Ex. 7337.⁵ Imposing a per-violation penalty that is 80% of the statutory maximum for what is at best a speculative effect on prescribing decisions is improper.

Finally, the rationale for the \$4,000 per violation penalty amount is not explained and, in any case, is not consistent with South Carolina precedent. The Court, for example, does not acknowledge or attempt to distinguish the decision of *State ex rel. Medlock v. Nest Egg Society Today, Inc.*, 290 S.C. 124, 348 S.E.2d 381 (Ct. App. 1986), where, for the far more egregious conduct of a pyramid scheme expressly prohibited by statute, the defendant was penalized only approximately \$5 per violation. *Id.* at 126, 348 S.E.2d at 382. Under the circumstances of the present case, a \$4,000 per violation civil penalty award is unwarranted.

Thus, the Court's penalty award as to the November 2003 mailing, like its award as to the package insert, is flawed. As such, the Court should also vacate and/or amend this aspect of its Penalty Order.

C. The Court Failed To Defer To Or Even Acknowledge The Primary Jurisdiction Of The United States Food And Drug Administration:

The Court's Penalty Order ignores the regulatory context within which the composition and distribution of the Risperdal package insert and the mailing of the November 2003 letter took place. The State has never contested that the FDA specifically approved every single aspect of the Risperdal package insert and that the FDA has never said that Janssen should have updated its package insert to add any warnings earlier. See, e.g., Trial Tr. vol. IV, 928:12-19, Mar. 10, 2011 (Dr. Plunkett testimony). The FDA's

⁵ The State did not challenge the reliability of this part of Dr. Wecker's testimony.

approval of the Risperdal package insert was, and remains, significant (and should have been dispositive) because, as part of that approval, the FDA specifically determined that the package insert was not false or misleading. See, e.g., *Prohios v. Pfizer*, 490 F. Supp. 2d 1228, 1235 n.6 (S.D. Fla. 2007) ("The information included in the labeling of a new drug reflects a determination by the FDA that the information is not 'false or misleading.'" (citing 21 C.F.R. § 314.125(b)(6))).

The Court erroneously allowed the jury to decide whether the Risperdal package insert was unfair or deceptive – despite the FDA's primary jurisdiction over labeling and despite the effective codification of the primary and exclusive jurisdiction of federal regulatory authorities such as the FDA in the SCUTPA regulated activity exemption. See, e.g., *Mut. Pharm. Co. v. Watson Pharm. Co.*, Civ. A. No. CV 09-5700, 2009 WL 3401117, at *5 (C.D. Cal. Oct. 19, 2009) ("Plaintiffs' contentions concerning the product labels and inserts are even weaker, both because the evidence of confusion is weaker and because disputes concerning the content of those labels and inserts falls even more squarely within the primary jurisdiction of the FDA."); see also, e.g., S.C. Code Ann. § 39-5-40(a) (SCUTPA inapplicable to "[a]ctions or transactions permitted under laws administered by any regulatory body or officer acting under statutory authority of . . . the United States"). The Court compounded this liability-phase error by imposing a penalty of more than \$100,000,000 just for the allegedly unfair or deceptive Risperdal package insert. The Court should have deferred to, not ignored, the FDA's determination that the periodic and prospective changes made by Janssen to the Risperdal package insert – changes made multiple times over more than a decade – were sufficient.

Similarly, the Court should have deferred to the FDA's determination of the appropriate remedy for the "November 2003 mailing" violation. At the liability trial, the Court allowed the State to argue that the jury should defer to the FDA's conclusions in the

DDMAC Warning Letter – to argue that the DDMAC characterization of the letter as “false or misleading” was persuasive, if not dispositive. See, e.g., Trial Tr. vol. III, 467:21-468:12, Mar. 9, 2011 (testimony of Dr. Wirshing, reviewing 2004 DDMAC letter and “[a]bsolutely” agreeing with the FDA’s assessment that November 2003 mailing was “false and misleading”); Trial Tr. vol. XI, 2662:18-2663:2, Mar. 21, 2011 (counsel for the State during closing statements: “Question for you that you will have to answer as to each one of these two Defendants: Was that November 10th, 2003 Dear Doctor letter . . . unfair and deceptive? Were these Defendants willful in that conduct? . . . We know that the FDA thought so. Remember the warning letter?”). But when it came to penalties, the Court did not defer at all to the FDA’s conclusion that the problems with the November 2003 mailing could be cured completely by the sending of a corrective letter – which Janssen did. Pl.’s Trial Ex. 438 (July 2004 letter); Defs.’ Trial Ex. 6253 (DDMAC considered the “matter closed” and took no further enforcement action). Again, the actions of the FDA should have been given at least some consideration, if not deference, by the Court in its penalty determination.

D. The Court’s Penalty Award Far Exceeds Any Amount Necessary For Deterrence Of Alleged Unfair Or Deceptive Conduct.

The Penalty Order makes clear that the Court’s determination was to impose an award sufficient, in the Court’s view, to “punish” Janssen. Penalty Order at 15 (“In this Case, however, the issue is the level of penalties that is appropriate to punish the wrong.”). Under South Carolina law, however, the principal purpose of any penalty award must be deterrence. *Midlands Util., Inc. v. S.C. Dep’t of Health & Env’tl. Control*, 313 S.C. 210, 212, 437 S.E.2d 120, 121 (Ct. App. 1993) (“[E]ach fine must be analyzed individually to determine if it is appropriate under the circumstances. The assessment of a civil penalty for violation of an environmental statute is committed to the informed discretion of the circuit

court; in exercising this discretion, the court should give effect to the major purpose of a civil penalty – deterrence.”).

The magnitude of the Court's penalty award does not square with any need for deterrence of future misconduct. Indeed, completely overlooked by the Court is that, despite extensive regulation and oversight, in more than sixteen years of the sale and marketing of Risperdal, there were only two isolated instances where the FDA ever raised any concern as to Janssen's activities in relation to Risperdal – and only one where the concern prompted a Warning Letter. See Pl.'s Trial Exs. 200, 232. There was no apparent need for “deterrence.” Certainly, there was no need for a penalty award remotely approaching the amount imposed by the Court to “deter” repeat misconduct.

Equally clear is that the Court's penalty award was prompted by a belief that Janssen intended to mislead or “manipulate,” and that the “intent” should be punished, without regard to scientific truth or actual impact on South Carolina prescribers. Penalty Order at 5-6. Thus, the Court explained that, “[i]n this Case, the manipulation was to get prescribers and patients to make treatment decisions based upon misleading or incomplete data or concealing data [which] would have impacted those decisions.” Penalty Order at 6. And the Court stated that “those issues concerning fairness or deceptiveness must be weighed using the information that was available and existed when the statements were made. The actions must be weighed in light of the intentions that existed when they were made.” *Id.* at 5. Consistent with its understanding, the Court excluded evidence about scientific developments post-dating the “deception.” See, e.g., Trial Tr. vol. I, 61:21-62:4, Mar. 7, 2011 (excluding post-2004 evidence relating to weight gain, diabetes, and other metabolic risks associated with Risperdal and other atypical antipsychotics).

The refusal to consider the actual “impact” on the intended audience is error under South Carolina law. See *deBondt v. Carlton Motorcars, Inc.*, 342 S.C. 254, 269, 536 S.E.2d

399, 407 (Ct. App. 2000) (explaining that whether an act has a "tendency to deceive" or is likely to deceive "depends upon the surrounding facts and the impact of the transaction on the marketplace").⁶ So, too, is the refusal to consider the objective truth of the statements at issue, not only at the liability trial but also, and especially, in the context of the penalty determination. Because the Court's inquiry was impermissibly narrow, the Court gave little or no weight to the following record facts:

- the State, from the beginning of the trial, did not contest the substantial benefits of Risperdal for South Carolina residents, Trial Tr. vol. II, 236:19-21, Mar. 8, 2011; Trial Tr. vol. XI, 2728:1-7, Mar. 21, 2011;
- there is no evidence that the State or its mental health professionals were actually deceived or misled by the November 2003 mailing or the Risperdal package insert, Trial Tr. vol. XI, 2581:18-2583:3, 2583:17-2584:3, 2584:22-2585:2, Mar. 21, 2011;
- the State has no evidence that any South Carolina physician or resident relied, to his or her detriment, on the November 2003 mailing or the Risperdal package insert, Trial Tr. vol. II, 204:14-19, Mar. 8, 2011 (no need to show any reliance);
- the State has no evidence that any South Carolina physician or resident actually was deceived by either the November 2003 mailing or the Risperdal package insert, Trial Tr. vol. II, 234:12-15, 236:25-237:1, Mar. 8, 2011; Trial Tr. vol. IX, 1993:10-17, Mar. 17, 2011; Trial Tr. vol. XI, 2728:6-7, Mar. 21, 2011;
- there was no evidence that either the Risperdal package insert or the November 2003 mailing was *likely* to deceive any South Carolina physician or resident, see, e.g., Trial Tr. vol. IX, 2112:12-23, 2118:11-18, 2119:4-6, 2125:2-23, 2161:21-2163:13, Mar. 17, 2011 (testimony of Dr. Robert Bank and Dr. Brenda Ratliff, current and former Directors of the South Carolina Department of Mental Health, that South Carolina physicians knew, before the November 2003 mailing was sent, about the associations between various antipsychotics and weight gain and diabetes);

⁶ In support of its penalty award, the Court stated that it found "excerpts" from a periodical (which the State did not rely upon or identify) "to be very helpful in my analysis of this case." See Penalty Order at 5 (citing http://philosophynow.org/issue27/The_Truth_About_Lying).

- the State did not even attempt to prove, and never contended, that any statement in the package insert was untrue;
- the State's own expert confirmed that the statement challenged by the State as deceptive – that Risperdal is different from Zyprexa – has been confirmed to be accurate by her own "weight of the evidence" assessment, Trial Tr. vol. V, 1036:24-1037:22, Mar. 11, 2011 (Dr. Plunkett testimony);
- the State's own expert also testified that the statements from the November 2003 mailing were supported by the studies identified by Janssen, Trial Tr. vol. III, 613:15-614:11, Mar. 9, 2011 (Dr. Wirshing testimony); and
- the truth of the statements in the mailing was confirmed by the penalty hearing testimony of Dr. Wecker (erroneously dismissed by the Court as unreliable and entitled to no weight, without explanation, Penalty Order at 3).

Under South Carolina law, all of these facts are relevant to the determination of penalties. There is no need for hundreds of millions of dollars of penalties to "deter" the making of statements in 2003 that were (and are still) in fact true, that deceived no one, and that harmed no one.

E. The Court Failed To Apply Properly The Reader's Digest Factors And Ignored Precedent Imposing Far Less Penalties In Far More Egregious Circumstances.

In determining the appropriate amount of civil penalties to be imposed pursuant to state consumer protection laws, courts generally engage in a careful, deliberate, and case-specific analysis of the factors set forth by the *Reader's Digest* court. These factors include: (1) the good faith or bad faith of the defendant; (2) the injury to the public; (3) the desire to eliminate the benefits derived from a violation; (4) the need to vindicate the authority of the agency involved; and (5) the defendant's ability to pay. *Reader's Digest*, 662 F.2d at 967. As discussed below, the Court failed to apply properly the *Reader's Digest* factors, which do not support the substantial penalty award in this case.

1. Whether Janssen Acted In Good Faith.

The evidence in the record does not support a finding by this Court that Janssen acted in bad faith.

a. Package Insert.

The Court determined that Janssen's conduct in connection with the package insert demonstrated "considerable" bad faith. Penalty Order at 9. In making this determination, the Court assumed that the jury had found that the package insert was "deceptive" because Janssen "hid" the topline results of RIS-USA-113 and other "studies" relating to weight gain and diabetes risk. But there is no basis for that assumption. The jury verdict may have had nothing to do with weight gain or diabetes risk. It may, for example, have been based on the placement of the "hyperprolactinemia" discussion in the "precautions" section of the label rather than in the "warnings" section. If so, RIS-USA-113 and the other purported "hidden studies" – the basis for the "bad faith" determination – would be irrelevant. Similarly, the jury verdict may have been based on the "inadequacy" of the label prior to 1999, when the topline results of RIS-USA-113 were first distributed, before the ERI "study," or any of the other conduct the Court considered. The "bad faith" finding, then, is speculative; it is not tied to the jury's general verdict.

Moreover, the Court has ignored the ample evidence in the record of Janssen's good faith. For example, Janssen repeatedly proposed and implemented label changes to reflect new information about risks. See Trial Tr. vol. IV, 899:12- 901:2, Mar. 10, 2011 (Dr. Plunkett testimony that Janssen changed label as to cerebrovascular events); Trial Tr. vol. VII, 1519:10-1520:2, Mar. 15, 2011 (Dr. Mahmoud testimony that after 2000, Janssen went to the FDA and said label needed to be changed); Trial Tr. vol. VIII, 1780:16-1781:8, Mar. 16, 2011 (Dr. Caers testimony that in 2002, Janssen went to the FDA to request a label change as to the issue of hyperglycemia). Further, there is nothing in the record that reflects that Janssen had reason to believe that the FDA-approved package insert ever was "inadequate" given the fact that, despite multiple revisions over a number of years, the FDA never suggested that the package insert was previously inadequate or had been used

inappropriately. The lack of any such concern is confirmed by the fact that the FDA has never taken any "enforcement" action, formal or informal, with respect to the package insert. Trial Tr. vol. IV, 928:12-19, Mar. 10, 2011.

b. November 2003 Mailing.

The Court also determined that Janssen's conduct in connection with the November 2003 mailing "exhibited extreme bad faith." Penalty Order at 10. As in its discussion of the package insert, the Court assumed that the jury had found that the letter was "deceptive" rather than "unfair" and that it was deceptive because it suggested that Risperdal had less of a risk of weight gain and diabetes than Zyprexa. Again, there is no basis for that assumption. The verdict could have reflected nothing more than the jury's conclusion that the letter was "unfair" because Janssen purportedly "broke the rules" when it sent the letter – even if what the letter said was true.

In any event, the "evidence" of "extreme bad faith" on which the Court relied is not consistent with the trial record. "Examples of the clever deception included in this letter," the Court wrote in its Penalty Order, "include the effort to contrast [Risperdal] with Zyprexa." Penalty Order at 9-10. The Court expressed concern that this "was done in such a fashion so as to directly influence prescribing decisions of doctors" and that patients might have been "influenced into making incorrect decisions." *Id.* at 11. But all of the experts who testified at trial – the State's experts and Janssen's experts – agreed that Risperdal is different from Zyprexa. Even after taking into account the "studies" alleged to have been "hidden," for example, Dr. Plunkett concluded that "Zyprexa has a greater risk of producing weight gain and diabetes in individuals." Trial Tr. vol. V, 1036:24-1037:22, Mar. 11, 2011.⁷

⁷ The FDA itself has concluded that Zyprexa poses a greater risk of metabolic side effects. But the Court excluded evidence of the FDA's change of position. See, e.g., Trial Tr. vol. I,

(continued...)

Dr. Wirshing agreed; he testified that the statements in the November 2003 mailing were supported by the studies Janssen identified in the mailing. Trial Tr. vol. III, 613:15-614:11, Mar. 9, 2011. Neither Dr. Plunkett nor Dr. Wirshing testified that a physician might have made an "incorrect" prescribing decision as a result of any statement in the letter about the relative risks of Risperdal and Zyprexa. There was, moreover, no evidence that any physician actually made an incorrect decision.

As with the package insert, the Court did not address the uncontested testimony that negates any conclusion that Janssen acted in bad faith. In particular, the Court did not take into account the rigorous internal review process undertaken prior to the mailing, which was sent only after it had undergone a comprehensive review by Janssen's Promotional Review Committee ("PRC"). The PRC included members from a number of disciplines (e.g., medicine, marketing, regulatory, and legal). Further, the mailing was authorized only after *unanimous* agreement by the PRC members. Trial Tr. vol. VIII, 1859:4-1864:14, 1882:11-1883:13, 1886:17-1894:3, Mar. 16, 2011 (Chester testimony as to PRC and review and approval of November 2003 mailing); Defs.' Trial Ex. 6366 (sign-off sheet for November 2003 mailing). There was not even a contention by the State that any member of the PRC acted in bad faith.

The Court also did not consider that Janssen's good faith basis for its position was reflected in the fact that Janssen relied upon the exact same articles in the November 2003 mailing that it used in its September 2003 letter to the FDA requesting certain changes to the label. Compare Defs.' Trial Ex. 351, with Defs.' Trial Ex. 3140; see also Trial Tr. vol.

(...continued)

61:21-62:4, Mar. 7, 2011; Trial Tr. vol. VII, 1376:20-1378:2, Mar. 15, 2011. That change of position was relevant to both liability and penalty determinations.

VIII, 1877:5-1882:7, 1936:23-1937:11, Mar. 16, 2011 (Chester testimony identifying articles sent to the FDA and in the November 2003 mailing). Significantly, the FDA then agreed to the deletion of the sentence on the Janssen label that indicated that there were no differences in diabetes-related risks between Risperdal and other atypicals. Trial Tr. vol. VIII, 1938:4-1941:12, Mar. 16, 2011 (Chester testimony). Given the FDA's acceptance of Janssen's position, it was hardly bad faith for Janssen to use that same information as the basis of its mailing to South Carolina providers.

In addition, the Court overlooked that the DDMAC 2004 warning letter (which the State relied on as the primary basis for its claim as to the mailing) itself negates any finding of bad faith because, pursuant to the FDA Regulatory Procedure Manual in effect at the time, DDMAC issued a warning letter, rather than taking enforcement action, precisely because it did *not* conclude that Janssen acted "willfully" or "intentionally" in disseminating "false or misleading" materials. Defs.' Trial Ex. 4337; Trial Tr. vol. IX, 2083:11-2086:6, Mar. 17, 2011 (Bradshaw testimony as to when warning letters are, and are not, appropriate). Janssen's good faith is also indicated by its cooperation with DDMAC, when DDMAC asked that Janssen send a "corrective" letter advising health care providers that DDMAC took issue with some of the statements in the first letter. DDMAC subsequently closed the matter without any further action.

Instead of considering any of this properly admitted and persuasive evidence, the Court relied on the e-mails of Scott Reines – e-mails that should not even have been admitted into evidence. See Defs.' Mem. Regarding Certain E-mails of Scott Reines, M.D., Ph.D.; Trial Tr. vol. II, 150:4-151:7, Mar. 8, 2011. Dr. Reines, contrary to the Court's Penalty Order, was not an employee of Janssen; he was an employee of one of Janssen's sister companies. Notably, Dr. Reines did not participate in any aspect of the November 2003 mailing. More important, he never questioned the scientific accuracy or the

truthfulness of the statements in the November 2003 mailing. Instead, he merely expressed his personal view that the November 2003 mailing was not well-handled, as a matter of Janssen's relationship with and interaction with its primary federal regulator, the FDA. See, e.g., Defs.' Mem. Regarding Certain E-mails of Scott Reines, M.D., Ph.D.; Jansen's JNOV Mot. at 46, 57-58.

These facts simply do not support a finding of bad faith, let alone evidence "considerable" or "extreme" bad faith.

2. Whether There Is Any Evidence Of Injury To The Public.

In evaluating this factor, the Court noted that SCUTPA does not require a showing that the unfair or deceptive act caused "any specific injury to the public." Penalty Order at 11. For that reason, the Court did not focus on whether there was "injury," but rather on public policy: whether the public has an "interest in requiring that drug manufacturers fully disclose all information available to them concerning the effects of their drugs in a fair and non-deceptive manner." *Id.* at 13. A finding of "injury to the public" supporting an award of substantial penalties, however, requires more than a finding that there was a violation of a public policy favoring "full disclosure." A finding of "injury to the public" must be based on evidence that the violation of that "full disclosure" policy actually had a significant impact that it actually caused some "injury." A violation of public policy alone is not even a basis upon which liability may be imposed under SCUTPA. See 15 U.S.C. § 45(n); FTC Policy Statement on Unfairness (Dec. 17, 1980), available at <http://www.ftc.gov/bcp/policystmt/ad-unfair.htm>.

There is no evidence that the November 2003 Risperdal letter or the Risperdal package insert actually caused any injury to the public. There is, however, no doubt that the availability of Risperdal significantly benefited – and continues to this day to benefit – South Carolina residents. Trial Tr., vol. III, 529:16-530:25, 531:13-533:15 at 532:14-17,

561:7-563:3, 563:17-565:3, 568:3-569:6, Mar. 9, 2011 (Dr. Wirshing testimony); *see also* Penalty Order at 4 (“[I]t is acknowledged by all concerned that Risperdal is an excellent drug for the treatment of mental illnesses. It has been a quality of life saver for millions of patients. It allows those who are treated with it to escape many of the effects of their mental illnesses and live a more open and productive life.”). Given the absence of any evidence of bodily injury to any South Carolina resident and the admitted substantial benefits of the use of Risperdal by South Carolina residents for serious mental health issues, this factor does not support the assessment of a substantial penalty.

3. Whether Janssen Benefited From The Alleged Violations.

The Court determined that it would be “virtually impossible” to determine the benefit Janssen derived from its conduct. Penalty Order at 13. The Court nevertheless concluded that there was some benefit because, it said, Risperdal’s market “share did not suffer as a result of the ever expanding warnings.” *Id.* In reaching that conclusion, the Court assumed that but for some “deception” the market share would have dropped. The Court then justified the imposition of enormous penalties by reference to Janssen’s supposedly “enormous” profits from the sale of Risperdal. The Court, however, ignored the undisputed evidence that Risperdal’s market share did not drop in response to the “corrective” letter. The fact that physicians’ prescribing patterns did not change even when they were told, in the “corrective” letter, that the FDA considered the November 10, 2003 letter to be “false or misleading,” establishes conclusively that the November 10, 2003 letter had no impact at all on Janssen’s market share. See Defs.’ Tr. Ex. 7337; Trial Tr. vol. XI, 2547:15- 2548:24, Mar. 21, 2011. There were, then, no “enormous” profits and no benefit “derived from a violation” of SCUTPA. In the absence of any evidence that Janssen benefited from the alleged violations – as opposed to benefiting from the sale of a good, effective medicine that

helped thousands of South Carolina residents – a substantial penalty award was not justified.

4. **Whether Civil Penalties Will Vindicate The Authority Of The Administrative Agency Involved.**

In evaluating this factor, the Court simply relied on the authority of the Attorney General to bring an action under SCUTPA. Penalty Order at 14. This is not the relevant inquiry. Rather, this factor focuses on the need to punish a defendant's failure to comply with an authority's directives – typically, a defendant's violation of an agency's cease-and-desist order or an injunction entered, at the agency's request, in a previous enforcement action. The "vindication of agency authority" factor does not apply at all where there is no directive or injunction; it certainly does not apply in every SCUTPA action merely because "it is the responsibility" of the Attorney General's office "to vindicate the public's interest" through enforcement of SCUTPA. See Penalty Order at 14.

Here, Janssen complied with every regulatory directive of the FDA. And here, there was no order or directive of the Attorney General that Janssen ignored. Indeed, the Attorney General never expressed any concern about the Risperdal package insert or about the November 2003 mailing before he filed this lawsuit. There is no contention that any conduct violative of SCUTPA post-dated that filing. Thus, appropriate application of this factor does not support a penalty award as there is no authority in need of vindication by this Court.

5. **Janssen's Ability To Pay.**

The "ability to pay factor" seems to have been the primary basis for the Court's penalty award. See Penalty Order at 15 ("Where the number of wrongs is extremely large and the profits derived enormous, the penalties must have a direct relationship to those numbers."). Nothing in the case law, however, indicates that this factor is to be used to

Although Janssen does not argue "inability to pay" and the "ability to pay" factor thus never even comes into play, it should be noted that the "worldwide" sales of Risperdal to which the Court refers at pages 15-16 of the Penalty Order include sales of Risperdal by companies other than Janssen. The "worldwide sales" of Johnson & Johnson and the "operating profits" of the "Pharmaceutical Division" to which the Court refers at page 16 of the Penalty Order include sales of Risperdal by companies other than Janssen and sales of products other than Risperdal. Finally, as explained by Dr. Ivo Caers at trial, but not referenced in the Penalty Order, Janssen's "profit margin" is not "97%." See Trial Tr. vol. VIII, 1753:25-1755:13, Mar. 16, 2011.

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collection notices to consumers that improperly threatened legal action on their accounts and contained false threats to sue); *Commonwealth v. AmCan Enters., Inc.*, 47 Mass. App. Ct. 330, 331-32, 340, 712 N.E.2d 1205, 1207-08, 1212 (1999) (affirming award of only \$100 per violation where defendants violated the Massachusetts Consumer Protection Act by sending misleading and deceptive advertisements to consumers by using the phrase "New England Yellow Pages" and the "walking fingers" logo to solicit advertising space in a telephone directory that was not connected to any telephone company). The Court's penalty award reflects a failure to apply properly the *Reader's Digest* factors.

F. The Court's Penalty Award Is Constitutionally Infirm In Multiple Respects.

The Court's Penalty Order failed to recognize or discuss any of the significant constitutional issues raised by Janssen before and during both the trial and the penalty hearing. That, in itself, was error. Moreover, given all the facts and circumstances, and in light of all the evidence, the assessment of more than \$327 million in penalties was constitutionally impermissible. In particular, the Court's focus on the "extremely large" number of "violations" and the "enormous" profits of Janssen and its affiliates, and its failure to give appropriate weight to the lack of evidence of "deception" and the absence of injury and loss, violated the Excessive Fines and Due Process clauses of the State and Federal Constitutions. And the imposition of a \$327 million penalty, without a determination that nothing less would suffice, violated the First Amendment.

1. The Court's Penalty Award Is Subject To Constitutional Limitations.

Civil penalty awards are subject to constitutional due process and excessive fine considerations. See generally *BMW of N. Am. v. Gore*, 517 U.S. 559, 572-73 (1996) (economic penalties that a state imposes, "whether the penalties take the form of legislatively authorized fines or judicially imposed punitive damages, must be supported by

the State's interest in protecting its own consumers and its own economy") (due process case); *In re Zyprexa Prods. Liab. Litig.*, 671 F. Supp. 2d 397, 463 (E.D.N.Y. 2009) (excessive fine consideration where state requested civil penalties on a "per prescription" basis); see also *St. Louis, I. M. & So. Ry. Co. v. Williams*, 251 U.S. 63, 66-67 (1919) (civil penalty violates due process rights "where the penalty prescribed is so severe and oppressive as to be wholly disproportioned to the offense and obviously unreasonable"). Even the State, in its post-hearing brief, acknowledged that the Court's "discretion to assess penalties" would be "bounded" by these constitutional safeguards. See Pl.'s Post Civil Penalties Hr'g Submission at 16 ("This Court's Discretion to Assess Penalties Is Bounded Only By SCUTPA Itself and United States Supreme Court Precedent Cautioning Against Penalties That Are 'Wholly Disproportioned to the Offense and Obviously Unreasonable.'" (emphasis added)). The Court, therefore, committed a threshold error of law when it failed to consider the applicable constitutional standards. It went on to assess penalties in violation of the substantive prohibitions, in the State and Federal Constitutions, of excessive, unreasonable, and unnecessary fines.

a. Excessive Fines.

Janssen is entitled to the protection against excessive fines afforded by the United States and South Carolina Constitutions. See U.S. Const. amend. VIII; S.C. Const. art. I, § 15; see also *United States v. Bajakajian*, 524 U.S. 321, 328 (1998) ("The Excessive Fines Clause thus 'limits the government's power to extract payments, whether in cash or in kind,' as punishment for some offense." (citation omitted)); *Singletary v. Wilson*, 191 S.C. 153, 156, 158, 3 S.E.2d 802, 804 (1939) ("It is generally the case that in enacting penal statutes the Legislature fixes and designates a maximum penalty, but when it is not done, the power to impose a fine is limited by the constitutional provision that excessive fines shall not be imposed. . . . It necessarily follows that the discretion of the trial Court in its determination

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of the amount of the penalty, where the maximum amount of the fine is not fixed by the statute, must be subject to be reviewed on appeal to this Court, if clearly abused, under Article I, Section 19 [now Section 15] of the Constitution, which not only forbids the infliction of cruel and unusual punishment, but forbids the imposition of excessive fines.”). Although *Singletary* involved a statute with no maximum penalty, the South Carolina Supreme Court stated explicitly that the excessive fines clause applied not only to the exercise of discretion by the courts when the legislature had set no bounds, but also in other circumstances. *Id.* 191 S.C. at 158, 3 S.E.2d at 804.

In evaluating whether a fine is excessive, “[t]he touchstone of the constitutional inquiry under the Excessive Fines Clause is the principle of proportionality: The amount of the forfeiture must bear some relationship to the gravity of the offense that it is designed to punish.” *Bajakajian*, 524 U.S. at 334. The substantial financial penalty awarded in this case based on the supposed “inadequacy” of an FDA-approved product label and an alleged “unfair” or “deceptive” mailing to health care professionals – without any economic harm or physical injury – is an unconstitutional “excessive fine.”

In *In re Zyprexa Products Liability Litigation*, 671 F. Supp. 2d 397, 460 (E.D.N.Y. 2009), the court rejected the same type of expansive statutory penalty theory that the Court adopted in this action for every Risperdal product sample, every mailing, and every sales call on physicians. In *Zyprexa*, the State of Mississippi asked that the court impose a penalty for every prescription written. As recognized by the *Zyprexa* court, to make such an award required “individualized consideration of the circumstances of each prescription alleged to be in violation of the statute,” which would be impracticable, if not impossible:

Because the penalty is said to apply regardless of any costs or damages borne by the State, Mississippi requests a penalty to be assessed for each of almost a million estimated Zyprexa prescriptions in Mississippi. The statutory language indicates that the enforcing court is invested with discretion to determine

the appropriate amount of the penalty with respect to each violation, whether the maximum of \$10,000 or some smaller amount. The statute does not specify what factors are to inform the court's determination, but in the present case the court may wish to consider a number of issues as they bear on each Zyprexa prescription, including but not limited to: whether the prescription was for an on-label or off-label use; whether the prescription was medically necessary; whether the patient received any benefit from Zyprexa; whether and the extent to which the patient experienced any of Zyprexa's potential metabolic side effects; the information about Zyprexa available to the medical community at the time the prescription was written; and the times of the various alleged instances of misconduct by Lilly, and whether and to what extent each instance may have impacted the prescription in question.

....

Regardless of the lack of individualized evidence, imposition of civil penalties on a per-violation basis would entail separate examination of each of hundreds of thousands of claimed violations for purposes of determining the appropriate fine. Such an inquiry is impractical and beyond the resources of any court.

Id. at 458-59. Most significant, the *Zyprexa* court held that any such award for substantial civil penalties would implicate *constitutional* considerations. *Id.* at 463.

This Court found hundreds of thousands of violations and awarded hundreds of millions of dollars of penalties (1) without any analysis of any of the factors outlined by the *Zyprexa* court; (2) despite the State's admission that Risperdal use did nothing but benefit South Carolina residents; (3) although the alleged "risks" that were purportedly inadequately disclosed or concealed already were well-known in the South Carolina medical community; and (4) in the absence of any evidence of actual deception of anyone. The Court's penalty award thus is an unconstitutional "excessive fine." *Bajakajian*, 524 U.S. at 337, 339-40 (holding that forfeiture was excessive because the "[f]ailure to report his currency affected only one party, the Government, and in a relatively minor way. There was no fraud on the

United States, and respondent caused no loss to the public" and the forfeiture "bears no articulable correlation to any injury suffered by the Government.").

b. Due Process.

Any penalty award also is limited by the federal and state due process clauses. U.S. Const. amend. XIV; S.C. Const. art. I, § 3; see also, e.g., *Cooper Indus., Inc. v. Leatherman Tool Grp., Inc.*, 532 U.S. 424, 433 (2001) ("Despite the broad discretion that States possess with respect to the imposition of criminal penalties and punitive damages, the Due Process Clause of the Fourteenth Amendment to the Federal Constitution imposes substantive limits on that discretion."); *Mitchell v. Fortis Ins. Co.*, 385 S.C. 570, 584, 686 S.E.2d 176, 183 (2009) (same). Further, it cannot seriously be contested that "grossly excessive or arbitrary punishments" violate a defendant's due process rights and that an excessive penalty "furthers no legitimate purpose and constitutes an arbitrary deprivation of property." *State Farm Mut. Auto. Ins. Co. v. Campbell*, 538 U.S. 408, 416-17 (2003).

For purposes of Due Process, any penalty "award must be analyzed in the light of the same conduct, with consideration given only to the interests of [the particular state's] consumers, rather than those of the entire Nation." *BMW*, 517 U.S. at 574.; see also *Campbell*, 538 U.S. at 421-22 ("Nor, as a general rule, does a State have a legitimate concern in imposing punitive damages to punish a defendant for unlawful acts committed outside of the State's jurisdiction."). This Court, however, based its penalty award on worldwide sales of Risperdal – including sales in other states and other countries and sales by companies other than Janssen. Even more important, there was no proof of sales made or profits earned by reason of any "deception" or "unfairness" in South Carolina – no proof of any sales made or profits earned because the package insert was "inadequate" or the letter "misleading." The State did not contend – and did not prove – that even a single physician was misled or even one inappropriate prescription written.

The Court also should have considered whether "the conduct involved repeated actions or was an isolated incident." *State Farm*, 538 U.S. at 419. In addition, the Court should have recognized that "the omission of a material fact may be less reprehensible than a deliberate false statement, particularly when there is a good-faith basis for believing that no duty to disclose exists." *BMW*, 517 U.S. at 580. The State offered no evidence of "similar misconduct" in South Carolina with respect to claims regarding the "adequacy" of the package insert, and no evidence of any repeated actions of alleged misconduct similar to the conduct at issue as to the one-time November 2003 mailing.

In the end, the Court's penalty award was based on its understanding as to the wealth and success of Janssen (and even its parent, Johnson & Johnson) without any showing that Janssen's profits resulted from the conduct alleged by the State to be deceptive or unfair. Penalty Order at 13 ("It is clear from the information stated below that the profits from this drug, to the Defendants, were enormous"). The Court's award therefore also violated due process principles. See generally *Mitchell*, 385 S.C. at 588 n.8, 686 S.E.2d at 185 n.8 (2009), cert. denied, 130 S. Ct. 1896 (2010) ("We caution that trial courts must be careful about considering the net worth of the defendant. Wealth cannot justify an otherwise unconstitutional punitive damages award."); *Atkinson v. Orkin Exterminating Co.*, 361 S.C. 156, 165, 604 S.E.2d 385, 389-90 (2004) ("[A] defendant's right to [due process] should not be diminished simply because the defendant is a deep pocket corporation." (citing *BMW*, 517 U.S. at 585)).

2. First Amendment.

The First Amendment to the United States Constitution also prevents a court from imposing excessive civil penalties. Even under the lesser scrutiny provided to restrictions on commercial speech, regulation of (1) speech about a lawful commercial activity that is not misleading must (2) directly and materially advance a substantial state interest and

(3) be no more restrictive than reasonably necessary. *Cent. Hudson Gas & Electric Corp. v. Pub. Serv. Comm'n*, 447 U.S. 557, 564 (1980). Therefore, to satisfy the requirements of the First Amendment, the relief awarded by this Court must be no more restrictive than reasonably necessary to directly and materially advance a substantial state interest.

The State, no doubt, will argue that First Amendment protections are inapplicable to "misleading" statements. But the jury in this case was not required to find – and, for all that appears on the verdict sheet, did not find – that any statements were actually false or misleading. As such, the Constitution required that any government action with respect to the statements challenged, including the Court's decision to impose penalties, satisfy the other elements of the *Central Hudson* test, i.e., that the remedy the State seeks is no more restrictive than reasonably necessary to directly and materially advance a substantial state interest. See, e.g., *Peel v. Attorney Registration & Disciplinary Comm'n of Ill.*, 496 U.S. 91, 100-01, 106-07 (1990) (finding that bar of commercial speech violates First Amendment where "[t]here is no contention that any potential client or person was actually misled or deceived by petitioner's stationery. Neither the Commission nor the State Supreme Court made any factual finding of actual deception or misunderstanding . . ."); see also, e.g., *Video Gaming Consultants, Inc. v. S.C. Dep't of Revenue*, 342 S.C. 34, 42, 535 S.E.2d 642, 646 (2000) ("A governmental body seeking to sustain a restriction on commercial speech must demonstrate that the harms it recites are real and that its restrictions will in fact alleviate them to a material degree." (quoting *Greater New Orleans Broad. Ass'n v. United States*, 527 U.S. 173, 188, 119 S. Ct. 1923, 1932 (1999))).

Thus, to award any civil penalty, the Court was required to find that any such penalty would directly and materially advance a substantial state interest, and that other forms of regulation less restrictive than punishment, such as requiring disclaimers or other clarifying speech, would be insufficient to satisfy the State's interests. See *Thompson v. W. States*

Med. Ctr., 535 U.S. 357, 371 (2002) ("If the Government could achieve its interests in a manner that does not restrict speech, or that restricts less speech, the Government must do so."). As the Court made no finding that only an award of hundreds of millions of dollars in penalties would suffice, the Court's award fails to satisfy the applicable First Amendment constitutional standards.

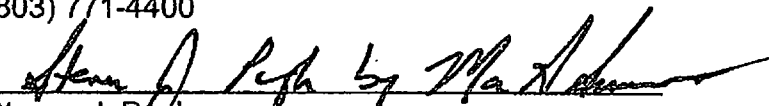
IV. CONCLUSION

For the foregoing reasons, Janssen respectfully requests that the Court grant Janssen's Motion in its entirety and alter or amend the June 3, 2011 Penalty Order. In the alternative, the Court should order a new "penalty" trial.

Respectfully submitted,

RICHARDSON PLOWDEN & ROBINSON, PA
1900 Barnwell Street (29201)
Post Office Drawer 7788
Columbia, South Carolina 29202
(803) 771-4400

By:


Steven J. Pugh
Steven W. Hamm

-and-

Thomas F. Campion (admitted *pro hac vice*)
DRINKER BIDDLE & REATH LLP
500 Campus Drive
Florham Park, NJ 07932-1047
(973) 360-1000

Edward M. Posner (admitted *pro hac vice*)
Kenneth A. Murphy (admitted *pro hac vice*)
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700

ATTORNEYS FOR DEFENDANT
ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.

June 13, 2011.

STATE OF SOUTH CAROLINA

COUNTY OF SPARTANBURG

STATE OF SOUTH CAROLINA
ex. rel. Alan Wilson, in his capacity
as Attorney General of the State of
South Carolina,

PLAINTIFF,

v.

ORTHO-MCNEIL-JANSSEN
PHARMACEUTICALS, INC., f/k/a
JANSSEN PHARMACEUTICA, INC.,
and/or JANSSEN, L.P., AND
JOHNSON & JOHNSON, INC.

DEFENDANTS.

IN THE COURT OF COMMON PLEAS

FOR THE SEVENTH JUDICIAL CIRCUIT

Civil Action No.: 2007-CP-42-1438

PLAINTIFF THE STATE OF SOUTH
CAROLINA'S RESPONSE IN
OPPOSITION TO DEFENDANT'S
MOTION TO ALTER OR AMEND
THE JUDGMENT AND/OR
FOR A NEW TRIAL

TO: STEVEN J. PUGH, KENNETH A. MURPHY, EDWARD M. POSNER, AND
THOMAS F. CAMPION, ATTORNEYS FOR DEFENDANTS

Plaintiff, the State of South Carolina, *ex rel.* Alan Wilson, in his capacity as Attorney General of the State of South Carolina (hereinafter, "the State"), by and through the undersigned counsel, hereby files its response in opposition to the Motion to Alter or Amend the Judgment and/or for New Trial (the "Motion") filed by Defendant Ortho-McNeil-Janssen Pharmaceuticals Inc. f/k/a Janssen Pharmaceutica, Inc. and/or Janssen, L.P. (collectively "Defendant" or "Janssen"), and would respectfully show the Court has follows:

I.

SUMMARY OF THE RESPONSE

The Court should maintain its Penalties Order, which issued on or about June 3, 2011 (the "Penalties Order"). Janssen's Motion fails to credibly argue a different result. Specifically,

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- the Penalties Order substantially complies with South Carolina Rule of Civil Procedure 52(a), despite Janssen's contrary view, in satisfaction of recent South Carolina Supreme Court precedent;
- the Penalties Order as to both the November 2003 Dear Doctor Letter and the Risperdal package insert is well-founded on the record evidence and the law applicable to the case;
- the so-called "primary jurisdiction" of the FDA continues to have no application to this case, where the State has sued for and the jury has found violations of South Carolina law independent of any violation of FDA regulations;
- the penalties award is sufficient to deter future deceptive and unfair acts by Janssen and others in South Carolina;
- the Court correctly applied the *Reader's Digest* guidelines; and
- the penalties award is constitutional.

The Court should deny Janssen's Motion in all respects.

II. ARGUMENT & AUTHORITIES

A. Standard

The standard for determining whether S.C.R. Civ. P. 52(a) has been complied with is discussed in the next section.

With respect to motions to alter or amend the judgment or for new trial, "a trial judge's order . . . will be upheld unless the order is 'wholly unsupported by the evidence, or the conclusion reached was controlled by an error of law.'" *Norton v. Norfolk S. Ry. Co.*, 567 S.E.2d 851, 854 (S.C. 2002) (citing *Folkens v. Hunt*, 387 S.E.2d 265, 265 (S.C. 1990)). "[R]eview [of the order denying a motion for new trial] is limited to consideration of whether evidence exists to support the trial court's order." *Norton*, 567 S.E.2d at 854 (citing *Folkens*, 387 S.E.2d at 267)).

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B. The Court's Penalty Order Satisfied Rule 52(a)'s Requirements.

In a 17-page memorandum opinion, this Court explained in substantial detail the bases for its award of \$327,073,700.00, explaining the factual and legal bases for the penalties assessed for the Dear Doctor Letter and the Risperdal label. As the most recent case law makes clear, nothing more is required of the Trial Court.

South Carolina Rule of Civil Procedure 52 provides, in pertinent part:

(a) In all actions tried upon the facts without a jury or with an advisory jury, the court shall find the facts specially and state separately its conclusions of law thereupon. . . . If an opinion or memorandum of decision is filed, it will be sufficient if the findings of fact and conclusions of law appear therein.

S.C.R. Civ. P. 52(a). As a preliminary matter, it is not entirely clear under South Carolina procedure that Rule 52(a) applies to this matter, as this case was neither tried entirely without a jury nor before an advisory jury. As the South Carolina Court of Appeals recognized in *In the Matter of the Care and Treatment of Corley*: “There are, to be sure, innumerable instances where the strictures of Rule 52(a) do not apply. Trial courts routinely make rulings in a variety of settings (preliminary to, and in the context of a, trial) without the need to issue a formal order containing specific findings of fact.” 616 S.E.2d 441, 443 (S.C. Ct. App. 2005). There is case law directly on point. Given that the penalties hearing was conducted “in the nature of a trial,” the State will assume for argument’s sake—without conceding the point—that the Court’s Penalties Order must meet Rule 52(a)’s requirements.

In any event, the Penalties Order *does satisfy the Rule*. Notwithstanding Janssen’s characterizations of the Penalties Order as “deficient” and Janssen’s misplaced reliance on *In re Treatment & Care of Luckabaugh*, 568 S.E.2d 338 (S.C. 2002) (Def.’s Mot. at 6), the Penalties Order satisfies the South Carolina Supreme Court’s most recent pronouncements as to Rule 52(a)’s strictures:

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This Court has held that this rule is “directorial in nature ‘so where a trial court substantially complies with Rule 52(a) and adequately states the basis for the result it reaches, the appellate court should not vacate the trial court’s judgment for lack of an explicit or specific factual finding.’”

Mathis v. Brown & Brown of S.C., Inc., 698 S.E.2d 773, 784 (S.C. 2010) (quoting *Luckabaugh*, 568 S.E.2d at 342 (quoting *Noisette v. Ismail*, 403 S.E.2d 122, 123 (S.C. 1991))); see also *Dixon v. Besco Eng’g, Inc.*, 463 S.E.2d 636, 639 (S.C. Ct. App. 1995) (“Rule 52(a), SCRCP, is directory; noncompliance alone does not invalidate the judgment . . .”). Thus, in *Mathis*, the South Carolina Supreme Court considered a four-page order that expressly addressed issues related to the existence of an employment contract in that case, the contract terms, its breach, mitigation, damages, and the application of law and deemed the order “sufficient to allow this Court to perform its role of appellate review.” 698 S.E.2d at 784.

Contrasting the order in *Mathis* with the order in *Luckabaugh*, the case relied upon by Janssen, the Supreme Court held in *Luckabaugh* that the one-paragraph order finding that a convicted prisoner was not a sexually violent predator “fail[ed] to substantially comply with Rule 52(a)” 568 S.E.2d at 343. There, the lower court wrote only that the State had failed to meet its burden to prove that Luckabaugh was a sexually violent predator and that, even if Luckabaugh suffered from a condition called “sexual sadism,” the State failed to show that condition made it likely that Luckabaugh would engage in future acts of sexual violence. *Id.* at 342. “The order did not find any facts to support its legal conclusion that the State failed to carry its burden of proof.” *Id.* Indeed, the order wholly ignored the testimony of three medical experts that agreed that Luckabaugh suffered from sexual sadism, which only Luckabaugh himself denied. *Id.* at 343. “The testimony leads us to speculate if the court below reached its conclusion because it believed Luckabaugh’s self-diagnosis over the diagnosis of three medical

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experts.” *Id.* But, because “the order below provide[d] no findings of fact to support its ultimate legal conclusion,” the *Luckabaugh* order was deficient.

It simply cannot be said that the Penalties Order contains no findings of fact to support the judgment. Therefore, Janssen twists the argument ever-so-slightly to complain about the Court’s *lack of citations to the record* to support its findings of fact. But, that too is a red herring. First, there is no mandate that the trial court cite to the record. Instead, it is the *reasoning supporting the ruling* that must be set forth. *See Dixon*, 463 S.E.2d at 639 (“The trial judge will not be reversed for failing to make specific findings of fact on the record for each factor [at issue] if there is sufficient evidentiary support on the record for the finding”); *see also Luckabaugh*, 568 S.E.2d at 343 (“We do not require a lower court to set out findings on all the myriad factual questions arising in a particular case. But the findings must be sufficient to allow [the appellate courts] to ensure the law is faithfully executed”; the “task of reviewing the court order [becomes] impossible [where] ‘the reasons underlying the decision [are] left to speculation’”). It is completely disingenuous to suggest that this Court’s Penalties Order omits the “reasons underlying the decision,” leaving the appellate courts to speculate about its grounds.

Second, if it is citations to the record alone that Janssen claims is necessary, that issue is easily resolved. Janssen provides examples of statements in the Penalties Order, listed below that are purportedly unsupported by the record. But, as the State shows immediately below, each one, the record amply supports every statement.

1. “In this case, the manipulation was to get prescribers and patients to make treatment decisions based upon misleading or incomplete data or concealing data [which] would have impacted those decisions[.]” (Def.’s Mot. at 4.)

➤ *Despite the statement being mere obiter dictum, the following evidence is among the litany of record evidence to support it—*

- (a) Pl.’s Ex. 200—Janssen was directed by FDA in 1999 to cease the use of marketing and promotional materials that

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stated or implied that Risperdal had been proven to be safe and effective in the geriatric population, when the drug had not been so proven.

- (b) **Pl.'s Ex. 228**—the FDA “strongly object[ed]” in 1994 to marketing and promotional materials that attempted to position Risperdal as a safer alternative to other antipsychotics like clozapine, and found generally that the “adverse event rates for risperidone are not consistent with [Janssen’s marketing] claims for an outstanding or excellent safety profile,” instructing Janssen not to make such claims, which it proceeded to do anyway. (*See, e.g., Pl.’s Exs. 316* (May 2002 sales aid: Risperdal provides “Excellent safety and tolerability”).)
- (c) **Pl.’s Ex. 254**—Sally Berry, the Associate Director of CNS Medical Affairs for Janssen, responded as follows to an email informing her the author of a to-be-published article recommended glucose screening for all patients on antipsychotics: “This is what we need to prevent from happening! That is we do not want to be lumped in to the atypical class for diabetes. I think we need to work hard on a strategy to avoid Risperdal being thought of as a diabetes inducing medication. Instead, when worried about diabetes, we want doctors to prescribe risperdal.”
- (d) **Pl.’s Ex. 316**—a 2002 Risperdal sales aid that instructed salespersons to tell doctors that “Zyprexa has been known to cause diabetes, serious hyperglycemia, diabetic ketoacidosis, and diabetic coma” and that “[w]eight gain is a frequent and disturbing Zyprexa side effect.” Risperdal, the sales aid countered, “has a low incidence of diabetes, and few reports of hyperglycemia, diabetic ketoacidosis, and diabetic coma”; the sales aid mentioned no Risperdal weight gain complications. The statements and omission in the sales aid are directly contrary to the results of Trial 113, for example, which the jury and Court considered, and which showed that long-term potential to cause diabetes and weight gain were approximately the same for Zyprexa and Risperdal. (*Pl.’s Exs. 442, 2653; compare also Pl.’s Exs. 1700* (“Gold Voicemail Message” from Janssen’s Senior Product Director for Risperdal, Riley Smith, informing sales representatives, relative to the sales aid mentioned above (*Pl.’s Ex. 316*), that is was “important that we proactively address how patients taking olanzapine had a significantly increased risk of developing diabetes vs.

Risperdal”); 1703 (“Message review” and “Sales Training Role Play[]” slides instructing that “Risperdal is a safer alternative to Zyprexa”).)

- (e) **Pl.’s Ex. 815**—Janssen executives evaluated the upside and downside financial outcomes of accepting or attempting to modify or avoid the FDA-requested hyperglycemia and diabetes mellitus warning in 2003, determining that there was a \$200 million swing from profit to loss depending on the labeling that would be ultimately adopted, and acknowledging the team was on the road to try to “‘prove’ differences” between Risperdal and other antipsychotics to the FDA. Of course, Trial 113 was never disclosed to the FDA in this process; instead, Janssen represented to the FDA that it had not conducted such a study comparing Risperdal and Zyprexa. (Pl.’s Ex. 1741.)
- (f) **Pl.’s Ex. 1736**—the November 2003 Dear Doctor Letter, which represented that Risperdal had the same diabetogenic potential as taking no drug at all. The State’s qualified psychiatrist and Risperdal clinical research expert, Dr. William Wirshing, testified that the statement was “patently untrue.” (See Trial Tr. at 458-59.) The FDA determined the letter was false and misleading. (Pl.’s Ex. 232.)

2. “The law allowed the Defendant to unilaterally strengthen Risperdal’s warning section of the label as soon as there was reasonable evidence of an association of a serious hazard with the drug Both Dr. Plunkett and Dr. Wirshing testified that the early evidence concerning the adverse events involving this drug, as well as its chemical makeup, should have given Janssen reason to strengthen the warnings in its label concerning diabetes, hyperglycemia, and weight gain.” (Def.’s Mot. at 4.)

➤ *The supportive testimony of Drs. Plunkett and Wirshing is as follows, notwithstanding Janssen’s claim that there is no such testimony in the record (Def.’s Mot. at 5)—*

- (a) **Dr. Plunkett** testified that a warning may be strengthened on a drug label whether or not it is asked to do so by the FDA—i.e., the warning may be added and then the new label is submitted to the FDA. (Trial Tr. at 673.) “[T]he manufacturer is the one who is responsible for insuring the drug remains safe. So they don’t have to wait for the FDA to tell them, Your drug is not safe. If [the manufacturer] know[s] it, [the manufacturer] needs to provide that information to the physician and the consumer.” (*Id.*) She further testified that “I believe at least as of 1999, [the

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warning label] was inadequate for diabetes, weight gain and all of the issues related to metabolic disturbances So by having [those issues listed only] in the adverse reaction section and not elevating it to warnings for that period of time, there was enough evidence to do that. There was reasonable evidence of an association at that point in time, definitely. . . . On hyperprolactinemia, . . . yes, there was reasonable evidence of an association in the – at launch time for the drug [in 1994].” (*Id.* at 935.)

(b) **Dr. Wirshing** similarly testified as follows:

Q. Doctor, do you have an understanding as to what is required in terms of the level of evidence for a drug company to add a warning to its product label?

A. I do.

Q. What’s that understanding based on?

A. When there’s a reasonable association between the adverse experience and the use of the medication, a causal relationship does not have to be proven, that is to say you don’t necessarily have to prove that this bad outcome, this serious outcome was a consequence of the drug, there just has to be reasonable association.”

Q. Do you have an opinion as to whether after trial 113 there was a reasonable association between Risperdal and diabetes?

A. Again, my personal opinion, and I talked about this at length throughout these years, is that that should have been in the way before the FDA said for all of these drugs. You know, these drugs have had a known problem with weight gain, and it was my feeling that therefore, the warning about diabetes should have been in there and it was not. . . .

Q. Your opinion is it should have been in the warning section even earlier than trial 113, right?

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A. Oh yes. I mean, you know, when we did the trials, comparing risperidone to haloperidol, risperidone unequivocally had an increased rate of weight gain compared to the major comparator, haloperidol. Therefore, it's going to have a greater impact on glucose dysregulation, on diabetic risk as a consequence of that weight gain.

(Trial Tr. at 475-76.)

3. "While this is not a 'fraud on the FDA' case, this concealment shows that the Company employed procedures and methods which almost guarantee repetition and further endangerment of the public." (Def.'s Mot. at 4.)

➤ *Janssen complains that "the jury made no finding – because the State presented no argument or testimony – that any "procedures" or "methods" of Janssen were "capable of repetition," but the record again betrays Janssen's argument—*

- (a) The jury was unmistakably and accurately instructed—*twice*—on the requirement that Janssen's conduct be "capable of repetition," and had the jury followed the Court's instructions, which they are presumed to have, such a finding is implicit in their verdict. (Trial Tr. at 2768-2769, 2806-2808; see Penalties Order at 10-12.) See *Conner v. City of Forest Acres*, 363 S.C. 460, 471 (S.C. 2005) (juries are presumed to heed the instructions of the trial court); *Arnold v. State*, 309 S.C. 157, 166 (S.C. 1992) (same). The Court had the discretion to refuse to submit special interrogatories, such as that proposed by Janssen S.C.R. Civ. P. 49(b); *Constant v. Spartanburg Steel Products, Inc.*, 447 S.E.2d 194, 196 (1994); see MOORE'S FEDERAL PRACTICE 3D § 49.11[2][a], at 49-16 (1997) ("Rule 49 is a rule of discretionary implementation, solely in the control of the trial judge. *No party has a right to the use of a special verdict.*" (emphasis added). See also *Steele v. Dillard*, 327 S.C. 340, 343 (S.C. Ct. App. 1997).

- (b) Janssen's argument here is based on a continued misunderstanding of South Carolina law in that the law does not require the State to prove "actual" impact, but, rather, that the alleged unfair or deceptive act or practice

had the mere *potential* for repetition.¹ The November 2003 Dear Doctor Letter not only had the potential for repetition, its message was in fact repeated thousands of times in both the mail and through personal presentations of the letter. (Trial Tr. at 1151-1156, 1158-1161, 1713.) Relative to the Risperdal labeling, or package insert, the State has also introduced evidence of the extent to which the Defendant's false and misleading labeling and the extent to which Defendant's actionable conduct was repetitious. Through the testimony of Dr. David Patterson, for example, the State presented evidence of the accurate number of Risperdal prescriptions filled in the State of South Carolina between 1994 and 2007, which included, *inter alia*, numerous prescriptions for particular patient populations to which Defendants most heavily promoted Risperdal through their labeling during the relevant time period, as described more fully above. (See Pl.'s Ex. 2670; Pl.'s Ex. 2671; Pl.'s Ex. 2672; Trial Tr. at 1292-1307.) With each such prescription, Defendant's false and misleading labeling was disseminated. (See Trial Tr. at 1061-1075, 1084-1085.)

- 4. "[T]he public interest affected by the actions of these Defendants is enormous." (Def.'s Mot. at 5.)

➤ *Janssen complains that "there was no proof at trial or at the penalty hearing of any actual impact on the public or any adverse effect on 'the public interest,'" but Janssen both misapprehends the applicable standard and underestimates the quantum of evidence presented—*

- (a) Janssen repeatedly ignores the controlling standard that "[a]n impact on the public interest may be shown if the acts or practices have the *potential* for repetition." *Wright v. Craft*, 640 S.E.2d 486, 501 (S.C. Ct. App. 2006); *accord Dowd v. Imperial Chrysler-Plymouth, Inc.*, 381 S.E.2d 212, 214 (S.C. Ct. App. 1989) (holding that, in order to impact the public interest, unfair or deceptive acts or practices in the conduct of trade or commerce must simply have "the *potential* for repetition") (emphasis added) (citations omitted). Indeed, the purpose of the "public impact" requirement is simply to exempt actions for *private* wrong where the public interest is unaffected. *See Daisy Outdoor*

¹ The State incorporates by reference for all purposes as if repeated in full its Memorandum in Support of its Response in Opposition to the Defendant's Motion for Judgment Notwithstanding the Verdict or, in the Alternative, for a New Trial, filed by the State on or about April 15, 2011 (hereinafter, "State's JNOV Response") and, here in particular, pages 47-52.

Adver. Co. v. Abbott, 473 S.E.2d 47, 49 (S.C. 1996); *Noack Enters., Inc. v. Country Corner Interiors of Hilton Head Island, Inc.*, 351 S.E.2d 347, 349-50 (S.C. Ct. App. 1986); see also *Wright*, 640 S.E.2d at 501. Therefore, the South Carolina Supreme Court has “*expressly reject[ed] any rigid, bright line test* that delineates in minute detail exactly what a plaintiff must show to satisfy the potential for repetition/public impact.” *Daisy*, 473 S.E.2d at 51 (emphasis added). As shown by the evidence cited above regarding the thousands of repetitions of disclosures of the November 2003 Dear Doctor Letter and Risperdal’s labeling in South Carolina, the Court rightfully described the potential (and actual) impact as “enormous.”² (See Penalties Order at 10-12.)

Therefore, though it is unnecessary to amend the Penalties Order to include citations to relevant, supporting record evidence, those citations are nevertheless provided for the Court above.

C. The Court’s Penalty Calculation Is Factually and Legally Correct.

1. The Award Based on Prescription Drug Samples Containing Package Inserts Is Both Factually and Legally Sound.

In characteristic fashion, Janssen attempts to morph the Court’s Penalties Order and the State’s claims and verdict into something they are not in order to fit the arguments Janssen wants to make. Plowing ahead with arguments that were previously rejected at summary judgment (Order of Feb. 25, 2011 (“this cause of action does not require that any person in particular has been the victim of this activity or has suffered any particular harm”)), Janssen continues to pretend that the State’s SCUTPA claim and verdict is the legal equivalent of a garden variety “failure to warn” claim. (See Def.’s Mot. at 7 (“[I]t is improper to penalize Janssen for an alleged failure to warn patients adequately when such a legal duty is not recognized under South Carolina law.”).) The State has at least three times explained for the Court in response to Janssen’s filings why the issue of common law “legal duty to consumers” simply does not arise

² See State’s JNOV Response at 47-52, incorporated herein by reference as if repeated in full.

in the context of a SCUTPA claim.³ The State did not bring and the jury and Court did not consider common law negligence, failure to warn, or other fraud claims; thus any existence or absence of common law “duty” to consumers is irrelevant. That is because SCUTPA “creates *new substantive rights* by making unlawful conduct that was *not actionable under the common law*.” *State v. C & L Corp.*, 313 S.E.2d 334, 338 (S.C. Ct. App. 1984) (emphasis added). No “duty” prerequisite may be found in SCUTPA’s express language, and none has been determined to exist by any court. As the South Carolina cases make abundantly clear, unlike a common law fraud or negligence claim, there exists no requirement that the State prove that any prescriber or consumer was actually deceived, or that anyone relied upon deceptive information disseminated by Defendant about Risperdal. *See id* (“[T]here is no need to show that a claim or representation was intended to deceive, but only that it had the capacity or effect or tendency to deceive.”); *see also Dowd*, 381 S.E.2d at 213-14 (“To recover for fraud, the familiar [sic] nine elements must be proved ‘by clear, cogent, and convincing evidence.’ No such proof is required to recover under [SCUTPA].”).

Furthermore, the Court’s statement in the Penalties Order that “[e]ach distributed sample clearly contains a copy of the label and would be the most likely source of information for patients who are considering entering into ongoing therapy with the drug” (at 16) does not state or signify that the patient’s prescriber is excluded from conveying the information contained in the label to the patient. Thus, Janssen’s contention that there was “no evidence that a patient would think it important that the hyperprolactinemia discussion was in the ‘precautions’ section of the package insert rather than in the ‘warnings’ section” is a nonstarter. (Def.’s Mot. at 7 (emphasis added).) There can be no disagreement that the *purpose* of prescription drug labeling,

³ Pl.’s Resp. to Defs.’ Mot. Summ. J. Based on FDA-Approved Package Insert (filed Jan. 21, 2011) at 5-9 (incorporated herein by reference as if repeated in full); Pl.’s Resp. to Defs.’ Mot. Directed Verdict (filed Mar. 15, 2011) at 14-17 (incorporated herein by reference as if repeated in full); State’s JNOV Resp. at 15-19.

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whether directed at physicians or consumers, is to provide the essential “information needed for the safe and effective use of the drug” *ultimately by the consumer*, even where that information is to be communicated through the physician. 21 C.F.R. § 215.56(1)(1); *see id.* § 201.57(a)(10) (labeling must contain “information . . . critical to the *safe use* of the drug” by the consumer “and measures that can be taken to prevent or mitigate harm” to the consumer) (emphasis added). And, in any event, the State is not required to prove actual deception or reliance. *C & L Corp.*, 313 S.E.2d at 338; *Dowd*, 381 S.E.2d at 213-214. And, there need be no “assum[ption]” that a package insert was distributed by the physician each time a sample was given to a patient—as Janssen asserts (Def.’s Mot. at 8)—because Janssen already admitted that a package insert accompanies every sample package. (Trial Tr. at 1177 (every sample provided contains a package insert).)

Next, Janssen again complains that the general verdict form selected by the Court signifies that “there is no way of knowing whether the jury based its verdict on the conclusion that the package insert was ‘inadequate’ for [the] entire period” from 1994 to 2007. (Def.’s Mot. at 8.) Janssen’s argument simply ignores the evidence and the jury’s verdict. The State presented evidence that the label was deceptive or unfair throughout the time period from 1994 to 2007. (See State’s JNOV Resp. at 39-54; Pl.’s Post Civil Penalties Hearing Submission (incorporated herein for all purpose as if repeated in full) at 2-12.) Janssen cannot credibly show otherwise.⁴ And, the jury unanimously answered the question in the State’s favor: the “Defendant engaged in unfair or deceptive acts or practices in the conduct of any trade or

⁴ Only a “scintilla of evidence” was necessary to support the verdict and all reasonable inferences that may be drawn therefrom. *Proctor v. Dep’t of Health & Envtl. Control*, 696 S.E.2d 496, 504 (S.C. Ct. App. 2006); *Hessenthaler v. Tri-County Sister Help, Inc.*, 616 S.E.2d 694, 697 (S.C. 2005) (citing *Jinks v. Richland County*, 585 S.E.2d 281, 283 (S.C. 2003)).

commerce in its label (package insert)” Plainly, the jury considered all labels during the relevant time period to have violated SCUTPA.

Janssen also summarily argues that the Court had no basis to set the label penalty at \$300 per violation, calling the decision “hopelessly speculative.” (Def.’s Mot. at 8.) Janssen, of course, ignores South Carolina precedent recognizing that there can be “no error of law in imposing a fine within the limits authorized by [SCUTPA].” *State ex rel. McLeod v. C & L Corp.*, 313 S.E.2d 334, 340 (S.C. Ct. App. 1984) (“Within those limits [defined by SCUTPA], the amount of the fine was a matter of the judge’s discretion.”). Therefore, the Court was free to award the full penalty for all violations supporting the jury’s verdict; but, in the Court’s abundant discretion, it decided that the evidence supported a lower penalty based on particular conduct, as described in the Penalties Order.

Janssen’s fourth contention is that the Court should have accounted for the purported “infrequen[cy]” of diabetes and hyperprolactinemia-related adverse events, claiming there is “no justification for the imposition of a 100% penalty – a penalty for every product sample – for adverse events that occur less than 1% of the time.” (Def.’s Mot. at 9.) But, this argument is (again) flawed because it hinges on supposed frequency of *actual* harm (as alleged by Janssen). The controlling law is clear, though, and this Court has ruled in its Feb. 25, 2011 Order that it is the *tendency to deceive and unfairness* that is punishable, not the *harm* caused, under SCUTPA. (See, e.g., State’s JNOV Resp. at 39-54.)

Finally, Janssen tepidly suggests that it might have “conceivably . . . been uncertain of the applicability of some of [SCUTPA’s] provisions to it,” relying only on a Connecticut Superior Court case concerning a penalty assessed under that State’s solicitation of charitable funds act. But, here there is no mystery as to whether Janssen understood that SCUTPA applied

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to it. Its regulatory counsel, Michael Chester, testified at trial that Janssen had a duty to comply with South Carolina law—and specifically SCUTPA—when it marketed and sold Risperdal in South Carolina. (Trial Tr. at 1921-22, 1924.)

2. *Likewise, the Penalty Award Based on the November 2003 Dear Doctor Letter Is Well-Reasoned.*

Janssen next argues that the Court erroneously double or triple-counted the number of violations with respect to multiple, violative publications of the November 2003 Dear Doctor Letter. But, in citing inapposite California law discussing the legislative intent of the California General Assembly, Janssen ignores SCUTPA's express language permitting the Court to assess a civil penalty "not exceeding five thousand dollars *per violation*." S.C. Code Ann. § 39-5-110(a) (2010). Janssen cites no South Carolina law nor legislative history suggesting the Court's count is improper. Of course, as noted, South Carolina precedent recognizes that there can be "no error of law in imposing a fine within the limits authorized by [SCUTPA]." *C & L Corp.*, 313 S.E.2d at 340 ("Within [SCUTPA's] limits, the amount of the fine was a matter of the judge's discretion."). And, the Court should not overlook the purpose behind SCUTPA and statutory penalties such as those imposed by SCUTPA. "The purpose of the UTPA is to discourage unfair methods of competition and unfair or deceptive acts in the conduct of any trade or commerce." *Taylor v. Medenica*, 503 S.E.2d 458, 460 (S.C. 1998). It follows that the South Carolina General Assembly would seek to "avoid[] a situation in which the statutory penalty would be regarded by potential violators of [the Act] as nothing more than an acceptable cost of violation, rather than as a deterrence to violation," just as the United States Supreme Court divined to be Congress's intent relative to the Federal Trade Commission Act. *See United States v. ITT Cont'l Baking Co.*, 420 U.S. 223, 232 (1975) (emphasis added), *cited in United States v. Reader's Digest Ass'n, Inc.*, 662 F.2d 955, 966-67 (3d Cir. 1981); *see also* S.C. Code Ann. § 39-5-20(b)

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(2010). *Accord Reader's Digest*, 662 F.2d at 967 n.15 (“[T]he efficacy of any regulatory program depends on the sanctions imposed in individual cases. If these sanctions are set too low, potential violators may be insufficiently motivated to minimize the social harm resulting from their behavior”) (internal quotation marks and citation omitted).

Also, it must be noted that there is no evidence in the record (and Janssen cites none) to support Janssen’s contention in its Motion that “[t]he physicians upon whom the sales representatives called . . . were the very physicians who received the mailing in the first place.” (Def.’s Mot. at 10.) Absent that record evidence, the Court should disregard Janssen’s contention.

Janssen further contends that the Court erred in counting every sales call that occurred during the period in which the November 2003 Dear Doctor Letter was disseminated, between November 2003 and July 2004. (Def.’s Mot. at 11.) Janssen, however, again ignores the law and facts by overlooking their failure to correct the affirmative misimpression created by the November 2003 Dear Doctor Letter during that time period, as well as the governing law that the failure to disclose material information constitutes conduct that tends to deceive and is unfair or deceptive under SCUTPA. *See Inman v. Ken Hyatt Chrysler Plymouth, Inc.*, 363 S.E.2d 91, 692 (S.C. 1988); *Wright v. Craft*, 640 S.E.2d 486, 501 (S.C. Ct. App. 2006). There is no evidence in the record that Janssen even attempted to correct the deceptive and unfair misimpression created by the November 2003 Dear Doctor Letter until the July 2004 Correction Letter was distributed.

The remainder of Janssen’s attack on the penalty attaching to the November 2003 Dear Doctor Letter seizes upon *obiter dictum* in the Penalties Order, in which the Court wonders aloud concerning the possible number of mothers, fathers and patients who might have been influenced

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by Janssen's violative conduct. (Def.'s Mot. at 11-12.) As has been already well established herein and in the State's prior briefing, there is no requirement that the State prove actual harm or that anyone relied or took any action based upon Janssen's deceptive and unfair marketing messages—despite Janssen's tireless insistence to the contrary. Likewise, it was not error for the Court to have excluded Dr. William Wecker's testimony or that of the South Carolina prescribers handpicked by Janssen to testify at trial for the reasons set forth in the State's JNOV Response (at 91-94). Lastly, as noted above, the Court does not err by setting, in its exclusive discretion, a penalty amount within the range provided for in SCUTPA. The Court's penalty as to the November 2003 Dear Doctor Letter is well-founded.

D. The Primary Jurisdiction Doctrine Has No Application to the Case.

The State will spare the Court reargument of this repetitious tenet of Janssen's JNOV Motion and Memorandum other than to say, for all the reasons set forth in the State's JNOV Response at 4-15, the so-called "primary jurisdiction doctrine" is inapplicable here. The State will also add that gross mischaracterizations such as "[t]he State has never contested that the FDA specifically approved every single aspect of the Risperdal package insert and that the FDA has never said that Janssen should have updated its package insert to add any warnings earlier" should be viewed with a jaundiced eye in light the argument presented in the State's JNOV Response at 12.⁵

⁵ First, there is no dispute that the FDA oversees, reviews, and approves prescription drug labeling. But, there is "no merit" in the argument that Congress had entrusted the FDA *exclusively* "to make drug labeling decisions that strike a balance between competing objectives." [*Wyeth v. Levine*, [555 U.S. 555, ___,]129 S. Ct. [1187,] at 1199 [2009]. "The most glaring problem with this argument," the Supreme Court recognized, "is that all evidence of Congress' purpose is to the contrary." *Id.* The High Court concluded there was "powerful evidence that *Congress did not intend FDA oversight to be the exclusive means of ensuring drug safety and effectiveness.*" *Id.* (emphasis added). Further, the Court determined that "the FDA [itself] long maintained that *state law offers an additional, and important, layer of consumer*

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Lastly, as explained at length in the State's JNOV Response, the jury's verdict as to the November 2003 Dear Doctor Letter was not contingent upon the FDA's finding that it was "false and misleading." (State's JNOV Resp. at 20-26.) And, regardless of any determination by the FDA that the July 2004 Correction Letter "cured completely" the FDA's issues with the false and misleading November 2003 Dear Doctor Letter, the FDA had no power to suggest (and did not suggest) that SCUTPA violations might be similarly remedied. Fashioning *that* remedy was the "primary jurisdiction" of the South Carolina courts.

E. The Penalty Is Sufficient to Deter Future Deceptive and Unfair Acts by Janssen and Others in South Carolina.

Janssen also conflates deterrence under FDA regulations with deterrence of violations of South Carolina law. It argues that because the FDA considered a Warning Letter and the July 2004 Correction Letter to be sufficient to remedy the deceptive and unfair conduct relative to the November 2003 Dear Doctor Letter, so too should this Court. But, of course, the flaw in that argument is that the jury and this Court have no interest in correcting and deterring violations of FDA regulations and other federal law, but instead sought to remedy and deter violations of SCUTPA only. Indeed, SCUTPA's primary purpose, as mentioned above, "is to discourage unfair methods of competition and unfair or deceptive acts in the conduct of any trade or commerce" in South Carolina. *Taylor*, 503 S.E.2d at 460; *see ITT Cont'l Baking Co.*, 420 U.S. at 232; *see also* S.C. Code Ann. § 39-5-20(b); *Reader's Digest*, 662 F.2d at 967 n.15.

And, once again, proof of actual deception or "impact," as Janssen refers to it, is plainly not required under South Carolina cases interpreting SCUTPA, including *deBondt v. Carlton Motorcars, Inc.*, 536 S.E.2d 399 (S.C. Ct. App. 2000), relied exclusively upon by Janssen. As

protection that complements FDA regulation." 129 S. Ct. at 1202 [(emphasis added)].

State's JNOV Resp. at 12; *see id.* n.3.

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the Supreme Court explained in *deBondt*, “[a] deceptive practice is one which has a tendency to deceive. *Id.* at 407. Defendant misinterprets language in *deBondt* in an attempt to convert the objective standard into a subjective one that requires proof of actual “‘impact of the transaction on the marketplace.’” (Def.’s Mot. at 16 (quoting *deBondt*).) But, *deBondt* itself explains that “[a]n unfair or deceptive act or practice has an impact” on the marketplace “if the act or practice has the potential for repetition,” just as the State has explained above and its prior briefing. 536 S.E.2d at 407. Nothing in *deBondt* requires or demonstrates “actual impact” or “actual” repetition. *Id.* at 407-08. Instead, in reversing summary judgment against the plaintiff, *deBondt* recognizes that the acts alleged by the plaintiff “were *capable of repetition*,” and no proof of actual repetition was nor need have been offered. *Id.*

Lastly, Janssen lists “record facts” that the Court purportedly failed to consider in assessing the penalty amount, but they should have no impact on the Court’s judgment for these reasons:

- whether or not Risperdal benefited some patients does not excuse or permit SCUTPA violations;
- proof of actual deception is not required, as repeatedly explained above and in the State’s prior briefing;
- proof of reliance is not required, as repeatedly explained above and in the State’s earlier submissions;
- the jury determined that the Risperdal package insert was *likely* to deceive by answering the relevant jury interrogatory in the affirmative; the State submitted a mountain of evidence that the package insert and November 2003 Dear Doctor Letter had a tendency to deceive, as explained above and in the State’s prior briefing;
- the State was not required to prove that any statement in the Risperdal package insert was untrue, because even true statements may be deceptive or unfair in violation of SCUTPA, *deBondt*, 436 S.E.2d at 407, and the nondisclosure of material information is actionable under SCUTPA, as shown above;

- that “Risperdal is different from Zyprexa” is not “the statement challenged by the State” (Def.’s Mot. at 17)—that is Janssen’s ‘spin’ on the State’s contentions;
- Dr. Wirshing did not testify that all the studies cited in the November 2003 Dear Doctor Letter supported Janssen’s claims (Trial Tr. at 487-489; see 613-14 (“Q. Is it fair to say that six of those eight articles based upon your review of them support the contents of the November 10 letter? * * * A. I think it supports a portion of what’s in the second paragraph.”), and made clear that he agreed with the FDA that the November 2003 Dear Doctor Letter omitted material information relative to Risperdal’s true diabetogenic risk (Trial Tr. at 484-85);
- the Court properly excluded the testimony of Dr. Wecker at the penalties hearing for the reasons argued by the State in its Post Civil Penalties Hearing Submission at 20-24.

In sum, Janssen’s argument that the penalties award is unnecessary to deter future occurrences of extensive and years-long SCUTPA violations, as was found here, is without merit.

F. The Court Faithfully Applied the *Reader’s Digest* Factors.

1. The Court Correctly Found an Absence of Janssen’s Good Faith.

(a) Package insert

Janssen considers the Court’s “bad faith” finding to be “speculative” because it cannot be determined whether the jury considered the nondisclosure of Trial 113 and “other ‘studies’ relating to weight gain and diabetes risk” to be the basis of the jury’s finding. (Def.’s Mot. at 18.) As a preliminary matter, the jury found that Janssen’s conduct was “willful,” meaning that Janssen knew or should have known that its conduct violated SCUTPA. S.C. Code Ann. § 38-5-110(c). “Bad faith” has been defined by the South Carolina Supreme Court as “[t]he opposite of good faith, generally implying or involving actual or constructive fraud, or a design to deceive or mislead another, . . . not prompted by an honest mistake as to one’s rights or duties, but by some interested or sinister motive.” *Estate of Carr v. Circle S Enters.*, 664 S.E.2d 83, 88-89 (S.C. Ct. App. 2008) (quoting *State v. Griffin*, 84 S.E. 876, 877 (S.C. 1915)). Certainly it is not a

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tremendous leap from the jury's finding of "willful" SCUTPA violations to the Court's deeming Janssen's actions in "bad faith" under the *Reader's Digest* test.

In any event, Janssen's questioning the rationale behind the jury's verdict and, concomitantly, the Penalties Order is again resolved by simple reference to South Carolina case law. "In a law case which was tried by a jury, [the courts] must uphold the verdict if there is *any evidence which reasonably supports it.*" *Neil v. Byrum*, 343 S.E.2d 615, 616 (S.C. 1986) (emphasis added) (citing *Townes Assocs., Ltd. v. City of Greenville*, 221 S.E.2d 773 (1976)). "Additionally, in passing on motions by defendants for nonsuit, directed verdict, judgment non obstante veredicto, and a new trial, the evidence must be viewed in a light most favorable to the plaintiff." *Neil*, 343 S.E.2d at 616. "A general finding for the plaintiff is sufficient to dispose of the issues both on the petition and on the [defendant's] counterclaim." *Cole v. Raut*, 663 S.E.2d 30, 35 (S.C. 2008) (quoting *Hussman Refrigerator & Supply Co. v. Cash & Carry Grocer, Inc.*, 132 S.E. 173, 174 (S.C. 1926)). The Court rightly found that Janssen's hiding the results of Trial 113 and other studies relating to weight gain and diabetes risk reasonably supported the jury's verdict as to deceptive and unfair conduct. No further pondering the basis for the jury's verdict is required. And, Janssen's so-called evidence of "good faith" was plainly rejected by the jury.

(b) November 2003 Dear Doctor Letter

The same analysis above for the package insert applies here. The Court determined that the November 2003 Dear Doctor Letter reasonably supported the verdict. Again, Janssen attempts to characterize the central issue as being whether "Risperdal is different from Zyprexa." Indeed, throughout the penalties hearing, Defendant exclusively focused its evidence and argument on debunking the notion that Risperdal caused as much or more diabetes, hyperglycemia, and weight gain as Zyprexa, so as to characterize the 2003 Dear Doctor Letter as "true" and scientifically supported. But, Janssen carefully avoided (and continues to avoid)

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addressing the most egregious language in the 2003 Doctor Letter—i.e., that evidence shows that Risperdal is not associated with *any* increased risk of diabetes when compared to “untreated patients”—which the State’s expert, Dr. Wirshing, characterized as “patently untrue.” (Trial Tr. at 458-49.) Janssen never once addressed that portion of the Dear Doctor Letter in its presentation during the penalties hearing. Moreover, any testimony by Dr. Wecker, Defendant’s statistician, related to “untreated patients” was correctly stricken as baseless and unreliable.

Janssen’s argument that the 2004 Warning Letter “itself negates any finding of bad faith” as to the November 2003 Dear Doctor Letter also does not hold water. Whether or not Janssen’s characterizations of the 2004 Warning Letter and related dealings with DDMAC were proven at trial, it is simply not enough to overcome the evidence that reasonably supports the jury’s finding that the November 2003 Dear Doctor Letter was *willfully deceptive or unfair*. (See discussion *supra* at § II.B., II.C.2.; see State’s JNOV Resp. at 39-54.) See *Neil*, 343 S.E.2d at 616; *Cole*, 663 S.E.2d at 35. The Court’s finding that the November 2003 Dear Doctor Letter was issued in bad faith is amply supported by the jury verdict and record evidence.

Lastly, the Scott Reines emails also support a finding of bad faith. It is undisputed that Reines was the President of Johnson & Johnson Pharmaceutical Research and Development (“JJPRD”) during relevant time periods. Janssen attempts to paint JJPRD and Reines as outliers because Reines was “not an employee of Janssen,” he “did not participate in any aspect of the November 2003 mailing,” and he was allegedly expressing his “personal view that the November 2003 mailing was not well-handled.” (Def.’s Mot. at 21-22.) But, the evidence showed otherwise. In particular, it is flatly untrue that Reines had no involvement in the November 2003 Dear Doctor Letter—instead, the State presented evidence that the November 2003 Dear Doctor Letter was Reines’s idea *from the inception*. (Pl.’s Ex. 462 (email from Reines to Gary Pruden

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at Janssen stating: "Lilly's DDL is pretty clever. How much commercial liability would we incur if we sent a similar letter about Risperdal, assuming the FDA is unwilling to communicate the issue?").) And, the record evidence revealed that the business and regulatory dealings of Janssen and JJPRD relative to Risperdal were inextricably interwoven. The FDA first informed JJPRD (not Janssen) of the need for a hyperglycemia/diabetes warning on Risperdal's label in September 2003. (Pl.'s Ex. 520.) Written correspondence with the FDA concerning the November 2003 Dear Doctor Letter and diabetes/hyperglycemia label change was on JJPRD letterhead, signed by JJPRD employees, including Janssen/JJPRD's response to the 2004 Warning Letter itself. (Pl.'s Exs. 430, 436, 1731, & 1734.) Donna Ohye, who corresponded with the FDA concerning the November 2003 Dear Doctor Letter and the July 2004 Correction Letter, was a Senior Director of Advertising and Promotion for JJPRD. (Pl.'s Ex. 1731.) Also, when the Clinical Study Report for Risperdal Trial 113 finally issued in 2009, it was issued by JJPRD, not Janssen. (Pl.'s Ex. 2653.) JJPRD plainly "participate[d] in [significant] aspects of the November 2003 mailing," and Dr. Reines, as its president, was clearly more than a disinterested bystander when he commented, *inter alia*, that "no competent person" would have let the November 2003 Dear Doctor Letter go out. The Reines emails were admissible and properly considered as relevant evidence by the jury and Court.⁶ They are among the considerable record evidence of Janssen's bad faith.

2. The Court Correctly Found Evidence of Impact on the Public Interest.

As mentioned above, Janssen persists in arguing that because the State failed to prove that "anyone in South Carolina was harmed" by the Dear Doctor Letter or the Risperdal label, the Court was restrained to assess either a negligible penalty or no penalty at all. (*See, e.g., Hr'g*

⁶ As noted in the State's JNOV Response (at 83 & n.47), Janssen waived its objections to many of the Reines emails by not contemporaneously objecting to them at their proffer by the State.

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Tr. at 190.) Again, that argument is fundamentally contrary to controlling law. *State ex rel. McLeod v. Brown*, 294 S.E.2d 781, 783 (S.C. 1982) (“The trial court's second ground for dismissal was the State’s alleged . . . inability to demonstrate . . . harm or damage to any citizen. [But, that] is [not] a prerequisite to an action under the Unfair Trade Practices Act.”); *id.* (“[I]t is in the public interest generally to prevent the use of false and misleading statements in the conduct of business . . . and actual deception need not be shown; a finding of a tendency to deceive and mislead will suffice.”) (emphasis added). *Cf. St. Louis, Iron Mt. & S. Ry. Co. v. Williams*, 251 U.S. 63, 66-67 (1919) (holding that state penalties provisions addressing “public wrongs” need not be “confined or proportioned to [actual] loss or damages . . .”).

Indeed, to suggest that the *Reader's Digest* test trumps the case law cited above and herein (and in the State’s other briefing) concerning proof of actual deception and injury would allow the guidance of that secondary authority to supplant controlling South Carolina law, which is impermissible. The Court properly found sufficient evidence of impact on the public interest.

3. *Janssen Benefitted Because It Avoided the Market Share Losses It Feared as a Result of the 2003 Label Change.*

Janssen argues that because the evidence purportedly showed that “Risperdal’s market share did not drop” as a result of the 2004 Warning Letter and July 2004 Correction Letter, there was no evidence of any benefit to Janssen by and through its deception. (Def.’s Mot. at 23.) But, that reasoning ignores the Court’s finding that “[i]t is clear . . . that if the aim of [Janssen’s] actions . . . was to protect the market share of Risperdal[,] then it succeeded.” And, the record evidence demonstrated precisely that. One of the very first things Janssen did after it received word of the class warning from the FDA was measure the financial impact of various scenarios—outright compliance with the FDA labeling request, some modification of the class label, or avoidance of the class label altogether. (Pl.’s Ex. 815.) Ultimately, Janssen executives

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considered their strategy a success because the “[s]ales impact [was] minimal . . . due to Risperdal [being] viewed as positively differentiated from Zyprexa” after transmission of the November 2003 Dear Doctor Letter. (Pl.’s Ex. 435.)

In any event, the Court is correct that its purpose “is to penalize the actions of the Defendants and . . . not . . . to award damages based upon any measure of damages or ill-gotten gains.” Janssen’s attempts to tie the penalties to some measure of unjust enrichment or other profits as a way to nullify the penalties are futile.

4. *The Penalties Award Vindicates the Authority of the South Carolina Attorney General to Enforce SCUTPA.*

Whether or not Janssen complied with every regulatory directive of the FDA—which the evidence showed Janssen clearly did not—Janssen again misses the point. The question is not whether Janssen complied with the FDA, but whether Janssen complied with SCUTPA. The jury unanimously found Janssen had not. The Attorney General acted under his legislatively mandated authority to bring this action, and his authority as the chief enforcer of SCUTPA is vindicated by the Court’s penalties award.

5. *The Court Properly Considered Janssen’s Ability to Pay.*

Janssen contends in its Motion that the Court need not have considered Janssen’s ability to pay because that factor only comes into play if the defendant argues an “inability to pay” (Def.’s Mot. at 25.) Whether or not that is true, Janssen admits that *it* does not argue an “inability to pay”—and therefore concedes an ability to pay the penalties award. That issue from the State’s perspective, resolved. Both parties agree that Janssen has the ability to pay the penalties award.

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In summary, the State will simply reiterate that the Court must avoid a situation in which Janssen considers the penalty nothing more than the cost of doing business in South Carolina. The penalty must instead deter the violation of South Carolina laws by Janssen and others, and the penalties award satisfies but does not exceed that requirement.

G. The Penalties Award Is Constitutional.

Finally, none of the grounds upon which Janssen contends the penalties award is unconstitutional have any merit, as the State demonstrates below.

1. *The Penalties Award Is Neither Unconstitutionally Excessive Nor Violative of Due Process.*

Janssen begins its current argument that the penalties award is constitutionally impermissible by citing to a random collection of cases for the proposition that the Court's penalties award is subject to constitutional limitations. In particular, Janssen cites to *BMW of N. Am. v. Gore*, 517 U.S. 559 (1996), which, as the Court knows, is a punitive damages-multiplier case, not a civil penalties award, where the Supreme Court found a 500 to one ratio of punitive damages to compensatory damages to be unreasonable. Moreover, the discussion on which Janssen's Motion relies (at 26-27) from *BMW* concerned whether or not an Alabama court could impose punitive damages based on wrongdoing that occurred nationwide, as the plaintiff in the case argued it should. *BMW*, 517 U.S. at 572. The Supreme Court stated plaintiff could not hold that one state cannot impose economic sanctions (i.e., punitive damages) based on conduct that occurred in other jurisdictions, particular where that conduct may have been lawful. Here, there has been no suggestion by either party that the State is attempting to penalize conduct that occurred anywhere else but South Carolina.

Further, there is considerable doubt as to whether *BMW* and its progeny, including *State Farm Mut. Auto Ins. Co. v. Campbell*, even apply to civil penalty awards. See *Zomba Enters. v.*

Panorama Records, Inc., 491 F.3d 574, 587 (6th Cir. 2007) (“We know of no case invalidating such an award of statutory damages under *Gore*”); *Lowry's Reports, Inc. v. Legg Mason, Inc.*, 302 F. Supp. 2d 455, 459 (D. Md. 2004) (“[T]he Court will not subject this award to a *Gore* analysis.”); see also *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 744 (N.D. Ill. 2007) (“the Due Process Clause does not apply to statutory damages”); *Verizon California Inc. v. OnlineNIC, Inc.*, C 08-2832 JF, 2009 U.S. Dist. LEXIS 84235, at *20 (N.D. Cal. Aug. 25, 2009) (discussing the difficulty of applying *BMW* to statutory penalties). And, as mentioned, the policy implications of *BMW* and its progeny are simply not present here. Such cases were “designed essentially to constrain the otherwise ‘unregulated and arbitrary use of judicial power’ inherent in punitive damages awards, their holdings are ‘not implicated by [the Legislature’s] carefully crafted and reasonably constrained’ statutory damages regime.” *Verizon*, 2009 U.S. Dist. LEXIS 84235, at *22 (quoting *Lowry's Reports*, 302 F. Supp. 2d at 460). Further, “the very notion of ‘applying’ *Gore* . . . to awards of statutory damages is problematic.” *Verizon*, 2009 U.S. Dist. LEXIS 84235, at *23 Those cases “prescribe a relatively rigid framework, one that results in considerable misalignment with the notions underlying statutory damages,” and this misalignment is exacerbated when dealing with statutory penalties brought by the government, *i.e.*, civil penalties. *Id.* For example, in the context of a SCUTPA penalties case, as here, *BMW*’s factor concerning the “degree of reprehensibility” would be irrelevant. See *Verizon*, 2009 U.S. Dist. LEXIS 84235, at *24. The *BMW* factors are designed to address harm to a private plaintiff, whereas civil penalties are “imposed as a punishment for the violation of a public law.” *St. Louis, I. M. & S. R. Co. v. Williams*, 251 U.S. 63, 66 (U.S. 1919). Additionally, a “penalty statute presupposes that its violation produces damages beyond that which is compensable [through individual punitive damages awards]”—*i.e.*, the public impact of the

violative conduct. *People ex rel. State Air Res. Bd. v. Wilmshurst*, 68 Cal. App. 4th 1332, 1351 (Cal. App. 3d Dist. 1999).

The *In re Zyprexa Prods. Liab. Litig.* opinion, containing Judge Weinstein's musings concerning punitive damages and/or civil penalties that were never decided or awarded and therefore not ripe for determination. See 671 F. Supp. 2d 397, 462 (E.D.N.Y. 2009) ("The scale of the *potential recovery* sought by Mississippi *may implicate* the constitutional limitations on excessive fines and punitive damages.") (emphasis added); see also *United States v. Paul Revere Transp., LLC*, 608 F. Supp. 2d 175, 177 (D. Mass. 2009); see also *United States v. Am. Elec. Power Serv. Corp.*, 218 F. Supp. 2d 931, 942 (S.D. Ohio 2002) ("[W]hether a fine is excessive is a factual question that cannot be decided as a matter of law before a penalty is actually assessed.").

With respect to the *Williams* case, as mentioned above, the United States Supreme Court established long ago that statutory penalties designed to address "public wrongs" need not be "confined or proportioned to [actual] loss or damages, for, as it is imposed as a punishment for the violation of public law, the Legislature may adjust its amount to the public wrong rather than the private injury, just as if it were going to the state." 251 U.S. at 66-67. In *Williams*, the Supreme Court found that the statute at issue, a fixed penalty for railway passenger overcharge, did not violate due process. *Id.* The High Court declared that:

When [a statute] is considered with due regard for the interests of the public, the numberless opportunities for committing the offense, and the need for securing uniform adherence to [the law], we think it cannot be said to be so severe and oppressive as to be wholly disproportionate to the offense or obviously unreasonable.

Id. More recent cases have adhered to the *Williams* rule. See *Zomba Enters.*, 491 F.3d at 587-88; *Follman v. Village Squire, Inc.*, 542 F. Supp. 2d 816, 821-23 (N.D. Ill. 2007); *Arrez v. Kelly Servs., Inc.*, 522 F. Supp. 2d 997, 1008 (N.D. Ill. 2007); *Texas v. Am. Blast Fax, Inc.*, 121 F.

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Supp. 2d 1085, 1090-91 (W.D. Tex. 2000); *Facebook, Inc. v. Fisher*, No. C 09-05842 JF (PSG), 2011 U.S. Dist. LEXIS 9668, at *5-7 (N.D. Cal. Jan. 26, 2011); *Gennari v. Weichart Co. Realtors*, 672 A.2d 1190, 1207 (N.J. Super. Ct. 1996).

Accordingly, a fine only violates the Excessive Fines Clause if it is “grossly disproportional to the gravity of a defendant’s offense.” *U.S. v. Bajakajian*, 524 U.S. 321, 334 (1998). “Because the standard is whether the fine is ‘grossly disproportional,’ the fine need only bear some relationship to the offense’s gravity; this is not a proportionality inquiry.” *United States ex rel. Tyson v. Amerigroup Ill., Inc.*, 488 F. Supp. 2d 719, 744 (N.D. Ill. 2007). “Such an inquiry must thus recognize both that ‘judgments about the appropriate punishment for an offense belong in the first place to the legislature’ and that ‘any judicial determination regarding the gravity of a particular . . . offense will be inherently imprecise.’” *Id.* (quoting *Bajakajian*, 524 U.S. at 334-336).

Lastly, the State must reiterate the widely accepted rule that “[c]ivil penalties may be imposed without regard to actual damage that may have been sustained.” *Hinerfeld-Ward, Inc. v. Lipian*, 188 Cal. App. 4th 86, 98 (Cal. App. 2d Dist. 2010). (*Accord*, State’s JNOV Resp. at 39-54; Order (Feb. 25, 2011) at 3-5.) “Indeed, a ‘characteristic feature of a penalty is its lack of proportional relation to [actual] damages.’” *Lipian*, 188 Cal. App. 4th at 98. *See* *Woolworth Co. v. Contemporary Arts, Inc.*, 344 U.S. 228, 233 (U.S. 1952). “Even for uninjurious and unprofitable invasions of copyright the court may, if it deems it just, impose a liability within statutory limits to sanction and vindicate the statutory policy.”); *San Francisco Bay Area Rapid Transit Dist. v. Spencer*, No. C 04-04632 SI, 2007 U.S. Dist. LEXIS 40075, at *34 (N.D. Cal. May 14, 2007) (“[A]ctual damages need not be shown in order to impose the civil penalty under the CFCA.”); *United States v. Irizarry-Colon*, No. 05-1607, 2006 U.S. Dist.

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LEXIS 38850, at *35 (D.P.R. June 8, 2006) (“[T]he United States is entitled to recover civil penalties solely upon proof that false claims were made, without proof of any damages.”); *United States ex rel. Wright v. Agip Petroleum Co.*, No. 5:03-CV-264-DF, 2005 U.S. Dist. LEXIS 16264, at *28 (E.D. Tex. Jan. 14, 2005); *United States ex rel. V.I. Hous. Auth. v. Coastal Gen. Constr. Servs. Corp.*, 299 F. Supp. 2d 483, 489 (D.V.I. 2004) (upholding \$50,000 in civil penalties although United States suffered no actual damages); *United States ex rel. Trice v. Westinghouse Hanford Co.*, No. CS-96-0171-WFN, 2000 U.S. Dist. LEXIS 8838, at *68 (E.D. Wash. Mar. 1, 2000) (“Plaintiffs’ inability to show damages sustained by the Government does not preclude an FCA claim.”); *see also Accounting Outsourcing, LLC v. Verizon Wireless Pers. Communs.*, 329 F. Supp. 2d 789, 809 (M.D. La. 2004) (stating that statutory penalties do not have to be proportion to actual damages); *Native Am. Arts, Inc. v. Bundy-Howard, Inc.*, 168 F. Supp. 2d 905, 914 (N.D. Ill. 2001); *Am. Blast Fax*, 121 F. Supp. 2d at 1090 (same).

2. *The Penalties Award Does Not Violate the First Amendment.*

The State incorporates by reference as if repeated in full its briefing on Defendant’s First Amendment defense in the State’s JNOV Response at 33-39. In particular, the State reiterates that it was not required to show under *Central Hudson Gas & Elec. Corp. v. Public Serv. Comm’n* or otherwise that “any statements were actually false or misleading,” contrary to Janssen’s Motion (at 32). Instead, “[t]he States and the Federal Government are free to prevent the dissemination of commercial speech that is false, deceptive, or misleading” *Zauderer v. Office of Disciplinary Counsel of Supreme Ct.*, 471 U.S. 626, 638 (1985) (emphasis added); *see Thompson v. Western States Med. Ctr.*, 535 U.S. 357, 364-77 (2002) (under *Central Hudson*, “we ask as a threshold matter whether the commercial speech concerns unlawful activity or is misleading. If so, then the speech is not protected by the First Amendment”) (emphasis added). It is without question that the jury found both the November 2003 Dear Doctor Letter

and Risperdal label to be “deceptive” and unlawful based upon the record evidence. Those materials are not entitled to First Amendment protection

The State additionally distinguishes the cases cited by Janssen in its Motion as follows. The plurality opinion in *Peel v. Attorney Registration & Disciplinary Comm’n of Ill.*, 496 U.S. 91 (1990) is obviously inapposite to constitutionality of the Penalties Order here. The case did not involve the award of civil penalties for deceptive and unfair conduct, but instead concerned the State of Illinois’s attempt to restrict attorneys from stating in their letterhead that he was certified by the National Board of Trial Advocacy. *Id.* at 93-94, 96-99. Because the petitioner’s statement in the letterhead was not found to be misleading, the plurality determined that a “categorical ban” on the use of such language was unconstitutional. *Id.* at 100, 110-111. Of course, this Court has neither imposed nor attempted to impose such categorical ban on any of Janssen’s speech.

Similarly, *Video Gaming Consultants, Inc. v. S.C. Dep’t of Revenue*, 535 S.E.2d 642 (2000) concerns the constitutionality of a statute banning the advertising of video poker games. It does not address the issue of the constitutionality of a civil penalty award, but instead overturns a statutory, prospective restriction on certain types of advertising—that is, a categorical ban akin to that found to be unconstitutional in *Peel*.

In any event, the State unquestionably has a substantial interest in protecting the health and welfare of its citizens from unfair and deceptive marketing tactics like those the jury found Janssen to have employed here, and the imposition of the penalties award directly advances that interest by penalizing and deterring such conduct and it is not more extensive than necessary to serve that interest.

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III.
CONCLUSION

For all the foregoing reasons, the State respectfully requests that the Court uphold its Penalties Order and deny Defendant's Motion.

Respectfully submitted,

STATE OF SOUTH CAROLINA
OFFICE OF THE ATTORNEY GENERAL

Alan Wilson
C. Havrid Jones, Jr.
Office of Attorney General
1000 Assembly Street, Room 519
Columbia, South Carolina 29201

By: HARRISON, WHITE SMITH & COGGINS, P.C.

John B. White, Jr.
SC State Bar No. 5996
Donald C. Coggins, Jr.
SC State Bar No. 1307
178 West Main Street (29306)
PO Box 3547
Spartanburg, SC 29304
(864) 585-5100 Telephone
(864) 591-0491 Fax

SIMMONS LAW FIRM, L.L.C.

John S. Simmons
SC State Bar No. 10260
1711 Pickens Street
Columbia, South Carolina 29202
(803) 779-4600 Telephone
(803) 254-8874 Fax

BAILEY PERRIN BAILEY

Fletcher V. Trammell
Admitted *pro hac vice*
Texas State Bar No. 24042053
Robert W. Cowan
Admitted *pro hac vice*
Texas State Bar No. 24031976

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M. HOPE BLACKLEY

Elizabeth W. Dwyer
Admitted *pro hac vice*
Texas State Bar No. 24062445
440 Louisiana, Suite 2100
Houston, Texas 77002
(713) 425-7100 Telephone
(713) 425-7249 Fax
Attorneys for the State of South Carolina

July 7, 2011
Spartanburg, South Carolina

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STATE OF SOUTH CAROLINA)
)
COUNTY OF SPARTANBURG)

IN THE COURT OF COMMON PLEAS
FOR THE SEVENTH JUDICIAL CIRCUIT

STATE OF SOUTH CAROLINA ex rel.)
Alan Wilson, in his capacity as Attorney)
General of the State of South Carolina,)

Civil Action No. 2007-CP-42-1438

Plaintiff,)

v.)

ORTHO-McNEIL-JANSSEN)
PHARMACEUTICALS, INC. f/k/a)
JANSSEN PHARMACEUTICA, INC.)
and/or JANSSEN, L.P. and JOHNSON)
& JOHNSON, INC.,)

**DEFENDANT ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.'S REPLY
IN SUPPORT OF ITS MOTION TO ALTER
OR AMEND THE JUDGMENT AND/OR
FOR A NEW TRIAL**

Defendants.)

Defendant Ortho-McNeil-Janssen Pharmaceuticals, Inc.* ("Janssen") hereby submits the following reply in further support of its Motion to Alter or Amend the Judgment and/or for a New Trial.

First, in attempting to justify the "samples" penalty award – the award based on the improper "failure to warn patients" theory – the State relies on the unremarkable proposition that the purpose of prescription drug labeling is to provide "information needed for the safe and effective use of the drug." State's Response at 13 (quoting 21 C.F.R. § 201.56(a)) (incorrectly cited as 21 C.F.R. § 215.56(1)(1)). But when the State quotes that language from the federal regulation in its Response, it adds the words "ultimately by the consumer." *Id.* Similarly, when the State quotes from 12 C.F.R. § 201.57(a)(10), it adds the words "by the consumer." *Id.* The State thereby suggests that federal labeling regulations support the

* On June 22, 2011, Ortho-McNeil-Janssen Pharmaceuticals, Inc. changed its name to Janssen Pharmaceuticals, Inc.

argument that prescription drug labels are written for the consumer. The words "ultimately by the consumer" and "by the consumer," however, do not appear in those regulations. And there can be no dispute that the labels for "prescription" drugs are written for and used by *prescribers*. See Janssen's Motion at 7-8. It is inappropriate to penalize Janssen for an alleged failure to warn *patients* when such a legal duty is not recognized under South Carolina law. Insofar as it is tied to "samples," then, the penalty award is clearly erroneous.

Second, the State has drawn its own conclusion as to why the jury found "package insert" liability: "Plainly," the State says, "the jury considered all labels during the relevant time period to have violated SCUTPA." State's Response at 14. Thus, in the State's view, penalties were properly awarded for all samples distributed between 1994 and 2007. The verdict form, however, contains no such "plain" finding by the jury. Because the State resisted a more specific verdict form, it is now impossible to determine why, or for what period of time, the jury concluded that the package insert violated SCUTPA. Indeed, given the instructions and the verdict form, it is "plain" that the jury could have considered only one package insert to be violative of SCUTPA and still found for the State. The "package insert" penalty award thus is based on an unprovable and unproven assumption – that the jury found each and every Risperdal package insert was "inadequate."

Third, the State's argument that the Court should impose a penalty for each post-November 10, 2003 sales call because Janssen "fail[ed]" to correct the affirmative misrepresentation created by the November 2003 Dear Doctor Letter" misses the point. See *id.* at 16. The jury did not find that Janssen violated SCUTPA because it "fail[ed]" to correct" the statements in the November 2003 letter, and the Court certainly did not award penalties to the State because of any "failure to correct." See Penalty Order at 18 (penalties for "sales calls where letter published"). Moreover, the State does not address the undisputed testimony that the November 2003 letter was a "one and done" event (i.e., it

FILED
CLERK OF COURT
SPARTANBURG COUNTY
2011 JUL 15 PM 4:21
M. HOPE BLACKLEY

was shown only on the first sales call to each prescribing physician). See Trial Tr. vol. V, 1154:13-1155:2, Mar. 11, 2011 (Alderman testimony). In the absence of any evidence as to the number of November 2003 letters actually "published" during sales calls, the "sales calls" penalty award also is impermissibly speculative.

Fourth, the State fails to address at all that the clear focus of the Penalty Order was punishment for past conduct, rather than deterrence of future conduct. This distinction is critical because it is deterrence of future misconduct – not punishment – that is and should be the principal purpose of any penalty award. See *Midlands Util., Inc. v. S.C. Dep't of Health & Envtl. Control*, 313 S.C. 210, 212, 437 S.E.2d 120, 121 (Ct. App. 1993) ("[T]he court should give effect to the major purpose of a civil penalty – deterrence.").

Fifth, when addressing the *Reader's Digest* factors, the State confuses "penalty" issues and "liability" issues. It contends, for example, that a jury finding of "willfulness" is determinative of "bad faith." Similarly, the State argues that it need not prove "actual deception" to prove a SCUTPA violation, apparently in the belief that whether anyone was in fact harmed is therefore not relevant to the penalty determination. The State's treatment of other *Reader's Digest* issues is superficial. For instance, rather than confront the fact that the "ability to pay" factor was the primary basis for the determination of the penalty amounts and that the Court improperly focused the "ability to pay" factor on worldwide sales of Risperdal, the State simply observes that Janssen does not argue "inability to pay" and pronounces the matter "resolved."

Sixth, the State, for the first time, argues that it should be able to rely on the e-mails of Scott Reines because the businesses of Janssen and Johnson & Johnson Pharmaceutical Research & Development, L.L.C. ("J&JPRD"), the company for which Dr. Reines worked, were "inextricably interwoven." State's Response at 23. As the State did not present any evidence, and the jury did not determine, that Janssen and J&JPRD

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2011 JUL 15 PM 4:21
M. HOPE BLACKLEY

should be considered the "same" for purposes of determining whether the Reines e-mails were admissible, there is no basis upon which the Reines e-mails should have been admitted, let alone considered by the Court in determining the appropriate penalty to assess against Janssen, a separate legal entity.

Seventh, recognizing that it never introduced a single piece of evidence that Janssen's alleged unfair or deceptive trade practices had any impact on the South Carolina marketplace, the State deliberately misstates the holding of *deBondt v. Carlton Motorcars, Inc.*, 342 S.C. 254, 536 S.E.2d 399 (Ct. App. 2000), to argue that it was not required to show any such impact. State's Response at 19 ("But, *deBondt* itself explains that '[a]n unfair or deceptive act or practice has an impact' on the marketplace 'if the act or practice has the potential for repetition.'"). The *deBondt* decision, however, actually says something quite different. Specifically, the Court of Appeals makes clear in *deBondt* that there are two "impacts" that matter: an impact of the transaction on the marketplace and an impact on the public interest. The first determines whether an act or practice is unfair or deceptive at all. *deBondt*, 342 S.C. at 269, 536 S.E.2d at 407 ("Whether an act or practice is unfair or deceptive within the meaning of the UTPA depends upon the surrounding facts and the impact of the transaction on the marketplace."). The second determines whether an unfair or deceptive act or practice is actionable under SCUTPA. *Id.* at 270, 536 S.E.2d at 407 ("[I]f an act or practice is unfair or deceptive within the meaning of the UTPA, the unfair or deceptive act or practice must have an impact upon the public interest."). The *deBondt* court explains – only with respect to impact on the public interest – that "[a]n unfair or deceptive act or practice has an impact upon the public interest if the act or practice has the potential for repetition." *Id.*, 536 S.E.2d at 407 (emphasis added) (internal and further citations omitted). The Court's failure to consider the impact of the challenged acts and practices on the marketplace was reversible error.

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2011 JUL 15 PM 4:21
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Eighth, the State improperly relies on *State ex rel. McLeod v. C & L Corp.*, 280 S.C. 519, 528, 313 S.E.2d 334, 340 (Ct. App. 1984), for the proposition that there can never be an abuse of discretion when the penalty award is less than the statutory maximum. State's Response at 14 ("reasoning" that because there can be "no error of law" in imposing the maximum penalty, there also can be no abuse of discretion). South Carolina law is clear that any discretion exercised by the trial court, including discretion within statutory bounds, must be "informed discretion." *Midlands*, 313 S.C. at 212, 437 S.E.2d at 121 ("The assessment of a civil penalty for violation of an environmental statute is committed to the informed discretion of the circuit court[.]"). Further, contrary to the State's belief, any penalty award is subject to constitutional scrutiny under the First Amendment and the Due Process and Excessive Fines Clauses. See, e.g., *Sorrell v. IMS Health Inc.*, No. 10-779, 2011 WL 2472796, *4 (U.S. June 23, 2011) ("Speech in aid of pharmaceutical marketing, however, is a form of expression protected by the Free Speech Clause of the First Amendment."); *BMW of N. Am. V. Gore*, 517 U.S. 559, 572-73 (1996). Even the authority cited by the State recognizes that penalty awards should be subject to review under both the Excessive Fines and Due Process Clauses. See, e.g., *Zomba Enters., Inc. v. Panorama Records, Inc.*, 491 F.3d 574, 587 (6th Cir. 2007) ("Regardless of the uncertainty regarding the application of *Gore* and *Campbell* to statutory-damage awards, we must review such awards under *St. Louis, I.M. & S. Ry. Co. v. Williams*, 251 U.S. 638, 666 (1919), to ensure they comport with due process."); *Tyson v. Amerigroup Ill., Inc.*, 2007 Supp. 2d 719, 744 (N.D. Ill. 2007) (analyzing penalty award under Excessive Fines Clause).

* * *

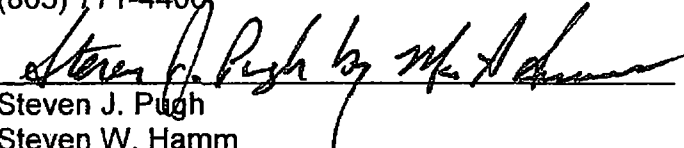
In sum, the State has failed to address adequately the significant issues outlined in detail in Janssen's Motion as to the Court's Penalty Order.

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WHEREFORE, for the reasons stated herein and in Janssen's Motion to Alter or Amend the Judgment and/or for a New Trial and accompanying memorandum of law, the Court should grant Defendant's Motion in its entirety.

RICHARDSON FLOWDEN & ROBINSON, PA
1900 Barnwell Street (29201)
Post Office Drawer 7788
Columbia, South Carolina 29202
(803) 771-4400

By:


Steven J. Pugh
Steven W. Hamm

-and-

Thomas F. Campion (admitted *pro hac vice*)
DRINKER BIDDLE & REATH LLP
500 Campus Drive
Florham Park, NJ 07932-1047
(973) 360-1000

Edward M. Posner (admitted *pro hac vice*)
Kenneth A. Murphy (admitted *pro hac vice*)
One Logan Square, Suite 2000
Philadelphia, PA 19103-6996
(215) 988-2700

ATTORNEYS FOR DEFENDANT
ORTHO-McNEIL-JANSSEN
PHARMACEUTICALS, INC.

July 15, 2011.

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THE STATE OF SOUTH CAROLINA
In The Supreme Court

APPEAL FROM SPARTANBURG COUNTY
Court of Common Pleas

Roger L. Couch, Circuit Court Judge

Case No. 2007-CP-42-1438

State of South Carolina ex. rel. Alan Wilson in his
capacity as Attorney General of the State of South
Carolina, ... Respondent,

v.

Ortho-McNeill-Janssen Pharmaceuticals, Inc., f/k/a
Janssen Pharmaceutica, Inc., and/or Janssen, L.P., and
Johnson & Johnson, Inc., ... Defendants.

Of whom Ortho-McNeill-Janssen Pharmaceuticals, Inc.
is Appellant.

CERTIFICATE OF COUNSEL

The undersigned certifies that the Record on Appeal contains all material
proposed to be included by any of the parties and not any other material.

NELSON MULLINS RILEY & SCARBOROUGH LLP

By: A. Mattison Bogan

C. Mitchell Brown
William C. Wood, Jr.
A. Mattison Bogan
Miles E. Coleman
Post Office Box 11070 (29211-1070)
Columbia, South Carolina 29201
(803) 799-2000

Richardson Plowden & Robinson, P.A.

Steven J. Pugh
Steven W. Hamm
Mason A. Summers
1900 Barwell Street
Post Office Drawer 7788
Columbia, South Carolina 29202
(803) 771-4400

Drinker Biddle & Reath LLP

Edward M. Posner
Chanda A. Miller
One Logan Square, Suite 2000
Philadelphia, Pennsylvania 19103-6996
(215) 988-2700
Attorneys for Appellant
Ortho-McNeil-Janssen Pharmaceuticals, Inc.

Columbia, South Carolina
October 19, 2012.