COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS

SUPERIOR COURT DEPT.
CIVIL NO. SUCV 2008-04392-A

ALMA AVILA, AS NEXT FRIEND OF AMBER N. AVILA,
Plaintiff

vs.

JOHNSON & JOHNSON COMPANY, ET AL.,
Defendants

PLAINTIFF'S RESPONSE IN OPPOSITION TO NON-PARTY JOSEPH BIEDERMAN, M.D'S MOTION TO QUASH AND/OR MOTION FOR PROTECTIVE ORDER

Plaintiff in the above-referenced litigation submits this Response in Opposition to Non-Party Joseph Biederman, M.D.'s Motion to Quash Subpoena Duces Tecum And Ad Testificandum And/Or Motion For Protective Order. The above action is brought pursuant to Massachusetts General Laws, Chapter 233, §45 seeking an order compelling the attendance at a deposition in Massachusetts of an individual named in an Order for Commission and Commission Authorizing the Issuance Of An Out-Of-State Subpoena Ad Testificandum And Duces Tecum ("Order for Commission") issued by the Superior Court of the New Jersey, Law Division, Middlesex County (Honorable Judge Jamie D. Happas) on August 20, 2008 authorizing the taking of the deposition Duces Tecum and Ad Testificandum of Dr. Joseph Biederman. True and correct copies of said Order for Commission are annexed hereto as Exhibit A. Following an *ex parte* hearing on Plaintiff's Motion in this Court, an Order compelling the attendance of Dr. Joseph Biederman at deposition was issued on October 3, 2008. Deponent, Dr. Joseph Biederman, was served with the Deposition Subpoena on October 6, 2008. At the request of counsel for Defendants on October 9, 2008, the original deposition subpoena

was withdrawn and Plaintiff's counsel agreed to re-subpoena the deponent. The deponent, through counsel, sent a letter dated October 15, 2008 acknowledging that the subpoena was being withdrawn.

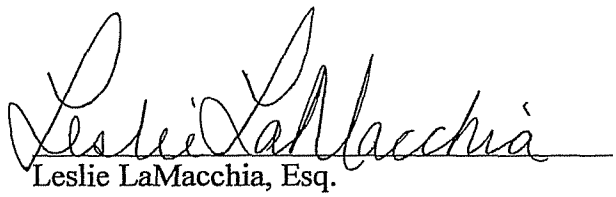
On October 23, 2008, Dr. Joseph Biederman, named in the Order for Commission, was served with the Deposition Subpoena Duces Tecum. On the same day, deponent, through counsel, sent Plaintiff's counsel a letter stating that he was not agreeing to appear for a deposition on November 19, 2008 and November 20, 2008. These two dates were previously discussed between Plaintiff's counsel and Defense counsel on a conference call with the Special Master of the Superior Court of New Jersey, Law Division, Middlesex County (Agatha N. Dzikiewicz) on October 15, 2008 and then again on October 27, 2008. Dr. Joseph Biederman, through counsel, served a motion to quash said subpoena and/or motion for protective order upon Plaintiff on November 3, 2008.

Plaintiff opposes said motion and avers that all relevant procedural requirements for the issuance of said Deposition Subpoena Duces Tecum have been met; and, that the Order for Commission of the Superior Court of New Jersey, Law Division, Middlesex County should be given full faith and credit. The Order issued by the Superior Court of New Jersey is entitled to be honored by this Court, as Massachusetts has a reciprocal obligation, per Massachusetts General Laws, Chapter 233, §45. Therefore, Plaintiff requests that this Court deny Non-Party Joseph Biederman, M.D.'s Motion to Quash Subpoena Duces Tecum And Ad Testificandum And/Or Motion For Protective Order.

By her attorneys,

John J. Russell by permission LL

John J. Russell, Esq.
15 Court Square
Suite 1150
Boston, MA 02108
(617) 720-1640



Leslie LaMacchia, Esq.
Michael W. Perrin, Esq.
Bailey Perrin Bailey
440 Louisiana Street, Suite 2100
Houston, TX 77002
(713) 425-7100

Dated: November 12, 2008

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, SS

SUPERIOR COURT DEPT.
CIVIL NO. SUCV 2008-04392-A

ALMA AVILA, AS NEXT FRIEND OF AMBER N. AVILA
Plaintiff

vs.

JOHNSON & JOHNSON COMPANY, ET AL,
Defendants

PLAINTIFF'S MEMORANDUM IN OPPOSITION TO NON-PARTY JOSEPH BIEDERMAN, M.D.'S MOTION TO QUASH SUBPOENA DUCES TECUM AND AD TESTIFICANDUM AND/OR MOTION FOR PROTECTIVE ORDER

A. Background and Underlying Action.

Plaintiff submits this Memorandum of Law in support of her *Opposition to Non-Party Joseph Biederman, M.D.'s Motion to Quash Subpoena Duces Tecum and Ad Testificandum And/Or Motion For Protective Order* ("Motion to Quash") and related to the involvement of Dr. Joseph Biederman with Johnson & Johnson and the other Defendants and his research related to the use of Risperdal and other atypical antipsychotic drugs in the treatment of minor patients.

Plaintiff opposes the Motion to Quash and seeks the Court's order compelling the deposition of this crucial witness. Accordingly, the relevance of Dr. Biederman's testimony in Plaintiff's case may be established through the use of documents provided in the Appendix to the Plaintiff's Motion to De-Designate, attached hereto as Ex. B is the July 17, 2008 Certification of Teresa A. Curtin ("Curtin Cert."). The twenty-six (26) documents attached as Appendix A are part of a massive umbrella production of approximately 2.5 million documents (19,623,569

pages) in which 98.4% or 2,460,000 of the documents produced to date have been marked "Confidential/Produced In Litigation" by Defendants Janssen, L.P., Janssen Pharmaceutica, Inc., and Johnson & Johnson (collectively "Defendants") pursuant to the Parties' August 7, 2007 Stipulated Protective Order of Confidentiality. (*See* June 5, 2008 Affidavit of Rhonda Radliff, Research Project Manager at Bailey Perrin Bailey at ¶ 4(l) attached as Ex. B to the Curtin Cert.). These documents were recently de-designated . (*See* June 25, 2008 e-mail from Jeffrey A. Peck to Paul Pennock attached as Ex. C to Curtin Cert.) In light of Defendants' de-designation, Plaintiff is not required, or even permitted, to file the attached documents under seal. Since Defendants' June 25, 2008 agreement to de-designate a limited number of documents, Plaintiff has found other documents related to Dr. Biederman's proposed deposition that are not filed with this Court as part of this Motion because they have not yet been de-designated as non-confidential. (*See* Curtin Cert. at ¶4.)[1]

The 26 attached documents demonstrate Defendants' view that clinical research is a "growth opportunity" marketing tool[2] to generate Risperdal revenues related to unapproved off-label uses of Risperdal in children as part of the establishment of a $6.4 million "overall tactical budget" for child and adolescent programs.[3] The attached documents also provide a glimpse into an improper and illegal collaborative relationship between Defendants and certain leading child

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[1] Plaintiff respectfully contends that Defendants' designation of so many documents as confidential is a clear misuse of the August 7, 2007 Stipulated Protective Order of Confidentiality which explicitly stated that "the term 'PROTECTED DOCUMENT' refers to information protected by Rule 4:10-3 of the New Jersey Rules of Court." R. 4:10-3 allows confidentiality *only* "for good cause shown" when "justice requires to protect a party or person from annoyance, embarrassment, oppression, or undue burden or expense" or to protect "trade secret or other confidential research, development, or commercial information." N.J. Ct. R. 4:10-3. While many documents designated by Defendants contain information adverse to the Defendants' interests in this litigation, such documents clearly do not satisfy the requirements for protected status under the "good cause" standard under R. 4:10-3. Courts have previously compelled the de-designation of documents impropaerly labeled confidential by Defendants. *See, e.g.,* March 23, 2007 *Order To Declassify Documents Subject To A Stipulated Protected Order of Confidentiality* in *Brown v. Johnson & Johnson, Johnson & Johnson Pharmaceuticals Research & Developmental, LLC, and Ortho-McNeil Pharmaceutical, Inc.*, Doc. No. MID-L-5446-05 MT attached as Exhibit H to Curtin Cert. ("Ortho Evra MDL De-Designation Decision") (de-designating documents improperly designated as confidential under stipulated discovery order). Thus Defendants have been cautioned against the vast over-designation of documents as confidential. Nevertheless, Defendants have continued to employ the Stipulated Protective Order as a shield to hide documents from public scrutiny.

[2] *See* Ex. B, Appendix Tab 2 (herein "App. Tab.") at Bates No. JJRE 03856494.

[3] *See* Ex. B., App. Tab. 19 at Bates No. JJIS 00166283.

psychiatrists, including Dr. Biederman, who promote the use of atypical antipsychotic drugs in children. Such promotion included what appears to be $700,000 in the year 2002 alone[4] to sponsor this Harvard child psychiatrist's[5] Johnson & Johnson Center for Pediatric Psychopathology at Massachusetts General Hospital with the stated purpose "to generate and disseminate data supporting the use of risperidone in the Child and Adolescent bipolar population."[6] The attached documents also show that Defendants sought to cultivate and use Key Opinion Leaders ("KOLs") such as Dr. Biederman in the field of child psychiatry,[7] including training KOLs to handle the media.[8] The attached documents show that twelve "[t]op level" KOLs, including Dr. Biederman, were paid $2,500 per meeting for being on a Johnson & Johnson "Advisory Board" where the KOLs appeared to be providing specific recommendations related to a retrospective analysis of data related to weight gain, growth and development issues in an effort to provide "reassuring" information to clinicians.[9] In addition, the attached documents show that Defendants were actively involved in drafting a research abstract to be submitted to the American Academy of Child and Adolescent conference for presentation under Dr. Biederman's name.[10] Lastly, the attached documents suggest that Defendants sought the help of purportedly independent researchers such as Dr. Biederman in dealing with potentially unfavorable research results,[11] and in making suggestions for changes to proposed research findings.[12]

The financial relationship between physicians and drug companies has been declared a serious public health issue and is currently under intense Congressional investigation and media

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[4] *See* Ex. B, App. Tab. 13 at Bates No. JJRE 00052307.
[5] *See* Gardiner Harris and Benedict Carey, Researchers Fail to Reveal Full Drug Pay, NEW YORK TIMES, Sunday June 8, 2008 at 1, attached as Exhibit D to Curtin Cert.
[6] *See* Ex. B, App. Tab. 4 at Bates No. JRE 02256029.
[7] *See* Ex. B, App. Tab. 9 at Bates No. JJRE 00128940; App. Tab. 12 at Bates No. JJRE 00070502; App. Tab. 16 at Bates No. 00057039; App. Tab. 19 at Bates No. JJRIS 00166272.
[8] *See* Ex. B, App. Tab. 16 at Bates No. JJRE 00057039.
[9] *See* Ex. B, App. Tab. 12 at Bates No. JJRE 00070502.
[10] *See* Ex. B, App. Tab. 6 at Bates No. JJRE 04017358.
[11] *See* Ex. B, App. Tab. 6 at Bates No. JJRE 04017358

scrutiny.[13] The focus is a potential concern that "funding by pharmaceutical companies can influence scientific studies, continuing medical education, and the prescribing patterns of physicians." (*See* Congressional Record, June 3, 2008 at S5031 attached as Ex. G to Curtin Cert.) All of these issues are crucial to this litigation and Dr. Biederman is a pivotal figure in this debate.

For the reasons set forth herein, the Court should deny Non-Party Joseph Biederman, M.D.'s Motion to Quash Subpoena Duces Tecum And Ad Testificandum And/Or Motion For Protective Order and deponent's attendance should be compelled at deposition.

ARGUMENT

Plaintiff's case, brought by Alma Avila as the next friend of her daughter Amber N. Avila, a minor, is one of the 2,242 current Risperdal/Seroquel/Zyprexa cases[14] centralized as a mass tort case in the Superior Court of New Jersey, involving claims of personal injuries caused by the use of Risperdal, Seroquel or Zyprexa. Risperdal is an atypical antipsychotic medication and one of Defendants' best selling drugs with over $3.6 billion in sales in 2005 alone. (*See* March 15, 2006 CNN Money article attached as Ex. I to the Curtin Cert.) One of Plaintiff's allegations is that Defendants marketed and promoted Risperdal as being safe and effective while minimizing information about the drug's risks, including that Defendants improperly provided financial inducements to physicians to promote Risperdal for uses beyond which the FDA approved and beyond those for which the drug was medically accepted. (*See, e.g.,* August 30,

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[12] *See* Ex. B, App. Tab. 11 at Bates No. JJRIS 02390986.

[13] *See, e.g.,* Gardiner Harris and Benedict Carey, Researchers Fail to Reveal Full Drug Pay, NEW YORK TIMES, Sunday June 8, 2008 at 1, attached as Exhibit D to Curtin Cert. (discussing how Senate investigation discovered three top Harvard researchers accepted drug company payments of at least $2.6 million over the past seven years while potentially receiving federal funds to research the same drugs; raising question of whether "such hefty inducements" affected the research outcome); Bloomberg.com website June 8, 2008 attached as Exhibit E to Curtin Cert. ("Harvard Medical School doctors who helped pioneer the use of psychiatric drugs in children violated U.S. government and school rules by failing to disclose at least $3.2 million from drugmakers"; mentions Johnston & Johnston and Risperdal); S*ee also* St. Petersburg Times Editorial Medical Research Corrupted, June 10, 2008 available at http://www.tampabay.com/opinion/editorials.article614734.ece and attached as Exhibit F to Curtin Cert. (suggesting that "the credibility of a supposed breakthrough in treating childhood bipolar disease is now in doubt").

[14] The number of cases was obtained from the New Jersey Mass Tort web site at http://www.judiciary.state.nj.us/mass-

2006 Avila Complaint and Request for Jury Trial at ¶¶ 31, 33-34, 58, and 64 as Ex. J to the Curtin Cert.) The following are examples of documents recently de-designated that show the hidden relationship between physicians and the drug industry:

Appendix Tab 1: November 1999 non-confidential e-mail chain[15] in which John Bruins of Janssen "beg[s]" his supervisors to approve of a $3000 honorarium check for Dr. Biederman related this physician's participation in a program at the University of Connecticut. The e-mail states that "Dr. Biederman is not someone to jerk around. He is a very powerful national figure in child pysch and has a very short fuse."[16] Describes Dr. Biederman's earlier "fury" when a 280k proposal had been turned down and states that since then "our business became non existant (sic) within his area of control. He now has enough projects with Lilly to keep his entire group busy for years."[17]

Bates No. JJRE 02510305-06.

Appendix Tab 2: A November 9, 2001 non-confidential internal e-mail chain that shows clinical trial programs were discussed by Defendants as part of "growth opportunity" exercises similar to "money on the table" exercises of the prior year. Specifically states that "trial proposals would need to be focused on those which could produce external impact before the end of 2003" and that such would have to "financial measures worked up with your respective marketing counterparts."[18] Gahan Pandina, the Assistant Director of CNS Clinical Development at Janssen Pharmaceuticals Products, L.P., asks whether this would be "an appropriate forum to discuss the J&J center idea with Dr. Biederman.[19]

Bates No. JJRE 03856494-95.

Appendix Tab 4: A February 5, 2002 internal e-mail chain initiated by George Gharabawi M.D. of Janssen Pharmaceutica Inc. related to the Johnson & Johnson Pediatric Research Center which claims that Dr. Biederman "approached Janssen multiple times to propose the creation of a [Center] . . . to generate and disseminate data supporting the use of risperidone in this patient population."[20] States that focus was to be on two topics" (1) teaching pediatricians and general psychiatrists "how to diagnose C & A BPD

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tort/rsz/risplist_061608.pdf. Not all of these cases involve Risperdal.

[15] The fact that this non-confidential e-mail chain was initially marked confidential is another example of the fact Defendants have improperly designated non-confidential documents as confidential in this litigation.

[16] Bates No. JJRE 02510305.

[17] *Id.*

[18] Bates No. JJRE 03856494.

[19] *Id.*

[20] Bates No. JJRE 02256029.

(BiPolar Disorder]" and (2) short and long term outcomes of management of C & A BPD with risperidone.[21] Plan was to get sister J & J companies to act together to participate in Center and share financial support.[22] Discussion of how the Risperdal Brand Team had agreed to fund the Center for the 2002 year in the amount of $500k and how Dr. Biederman's team had produced a "Risperdal Reanalyzes, Research and Publication grid . . . that included a "5-year plan of deliverables including retrospective analyses and prospective exploratory research."[23]

Bates No. JJRE 02256029-30.

Appendix Tab 5: March 2002 internal e-mail with a boilerplate confidentiality notice written by Gahan Pandina, the Assistant Director of CNS Clinical Development at Janssen Pharmaceuticals Products, L.P., regarding Dr. Biederman's presentation at an educational seminar involving over 1000 physician, $700 CME course a week after Dr. Biederman had visited Janssen. The e-mail describes Dr. Biederman's presentation as being "very well-received" and that "the validity of the diagnosis of pediatric mania was completely accepted."[24] The e-mail also describes Dr. Biederman as not being "perceived to be aligned with any company in particular."[25] Also indicates that a topic of Dr. Biederman's presentation was that olanzapine (Zyprexa) should not be prescribed to children and adolescents due to its effect on metabolic issues. Describes Dr. Biederman's presentation as "a clear example of the utility of partnering with a group such as MGH [Massachusetts General Hospital], who has the potential of reaching and having a significant impact upon the field of child and adolescent psychiatry with these kind of professional activities in non-sponsored venues."[26]

Bates No. JJRIS 00566318.

Appendix Tab 6: An June 11, 2002 e-mail chain initiated by Gahan J. Pandina, the Assistant Director of CNS Clinical Development at Janssen Pharmaceutica Products, L.P. to other Janssen employees and to Dr. Joseph Biederman which shows that Defendants were actively involved in drafting a research abstract submitted for the 2002 American Academy of Child and Adolescent Conference- related use of Risperdal in children with disruptive behavior disorders which Dr. Biederman was to be listed as the presesenting author. Dr. Biederman is asked to review what Pandina had written and to "be prepared to sign and fax a disclosure form [to the AACAP] as presenting author, unless you would rather have another

[21] *Id.*
[22] *Id.*
[23] *Id.*
[24] Bates No. JJRIS 00566318.
[25] *Id.*
[26] *Id.*

present the data then assignee a designee, as we cannot submit without a signed disclosure."[27] Pandina also sought the Dr. Biederman's help in dealing with what appeared to be unfavorable research results ("[B]ased on the improvement in the placebo group, both group may demonstrate significant improvement overall on the two domains, so, if you could, please give some thought to how to handle this if the issue occurs. I will send the results as soon as possible.").[28] The proposed abstract by Pandina did not mention this improvement in the placebo group., but instead states that the placebo group did not show improvement.[29] Only first e-mail on this chain contained a boilerplate confidentiality notice.

Bates No. JJRE 04017358-59.

Appendix Tab 7: July 2, 2002, non-confidential e-mail chain initiated by Carrie Steffe, the Risperdal Extramural Research Program Coordinator for Janssen Pharmaceutica CNS Medical Affairs to Dr. Joseph Biederman related to payment for Risperdal Study-RIS-USA-T295 listing payments due under the contract according to various "milestones" including separate conference presentations of eight week and ten month data and manuscript payments. Total payments for this study were to be $369,000.[30] States to Dr. Biederman that the purpose of asking for information was that "Janssen Pharmaceutical is . . . evaluating all ongoing research studies to ensure projects continue to align with our Business Strategy and that monetary and manpower (sic) resources are being efficiently allocated."[31]

Bates No. JJRIS 00615803-05.

Appendix Tab 11: October 11, 2002 e-mail chain with boilerplate confidentiality notices regarding a Janssen review of Dr. Biederman's poster on Risperidone for affective symptoms in children with disruptive behavior disorders stating that Janssen had been "designated as a review for Pediatrics publications."[32] Related to this poster, which was to be presented at the AACAP,[33] a Janssen reviewer Carin Binder requested that a qualifier be placed in the poster regarding a concern that some of the symptoms that Dr. Biederman's poster classified as depressive or manic could be comorbid ADHD symptoms.

Bates No. JJRIS 02390986-87.

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[27] Bates No. JJRE 04017358.
[28] *Id.*.
[29] Bates No. JJRE 04017359.
[30] Bates No. JJRIS 00615803.
[31] Bates No. JRIS 00615804.
[32] Bates No. JJRIS 02390986.
[33] Most likely referring to the American Academy of Child and Adolescent Psychiatry.

Appendix Tab 12: October 21, 2002 internal e-mail chain with a boilerplate confidentiality notices which discusses Defendants' "National Child and Adolescent Advisory Board" meeting in which twelve KOLs [key opinion leaders] were each paid $2500 to attend. States the Board included "'top-tier KOLs (Drs. Biederman, Peter Jensen and Gabrielle Carlson. etc)."[34] This e-mail chain shows how Defendants and the KOLs worked collaboratively to re-analyze data in that the KOLs appeared to have provided specific recommendations related to a re-analysis of datasets on whether there was any correlation of prolactin to weight gain, growth and development including recommending that re-analysis be completed as soon as soon as possible because "safety information could be very reassuring for clinicians."[35] Defendants' clinical team requested that the KOLs be reconvened "to help us interpret the findings from the [now finished] re-analysis."[36]

Bates No. JJRE 00070502-03.

Appendix Tab 13: November 12, 2002 e-mail with a boilerplate confidentiality notice shows that sister companies were also funding the Johnson & Johnson Pediatric Research Center at Massachusetts General Hospital. This e-mail shows that as well as receiving $500k in 2002 funding from Defendants, the Johnson & Johnson Pediatric Research Center was given $200k to be used "for this year's MGH initiative with PI Joe Biederman" by sister corporation McNeil, with a statement that McNeil also intend to fund $200k for the center next year,"[37] (which together with Janssen's monies already paid would be 700k for MGH Initiative in 2002). States McNeil also intended to pay 200k towards the incentive for 2003.

Bates No. JJRE 00052307.

Appendix Tab 14: Annual Report 2002: The Johnson & Johnson Center for Pediatric Pathology at the Massachusetts General Hospital which lists as an "essential feature" of the Center is its ability to conduct research that "will move forward the commercial goals of Johnson & Johnson."[38] While this document has many redacted sections, it is clear that a purpose was to increase the market demand for Risperdal and other Johnson & Johnson drugs.

Bates No. JJRE 00053089-109.

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[34] Bates No. JJRE00070502.
[35] *Id.*
[36] *Id.*
[37] Bates No. JJRE 00052307.
[38] Bates No. JJRE 00053091.

Appendix Tab 16: Document titled "2003 Child & Adolescent Business Plan Session 2-6/12/02 Sales and Marketing" that states "KEY: Need to train KOL's [Key Opinion Leaders] to handle the media; need a proactive media plan."[39] Discusses the J&J Center for Study of Pediatric Psychopathology as a "joint effort by Janssen, OMP, and McNeil-in Boston with Joe Biederman."[40]

Bates No. JJRE 00057039.

Appendix Tab 17: A "New Initiative! J&J Pediatric Research Center at Mass General Hospital" PowerPoint Presentation by Gahan J. Pandina of Janssen which *inter alia* admits that most pharmacological treatment of C&A [child and adolescents] is "off-label with limited data to guide treatment" and that future legislation requiring data when C&A use was expected."[41] Explains that 21% of Risperdal market is C&A and that limited data exists, especially related to BiPolar disorder which leads to a "potential for medical mis-use."[42] Discusses Dr. Joseph Biederman as a "global expert" in the diagnosis and treatment of BiPolar Disorder and ADHD, whose research group was identified by JPI as being "one of the most important international scientific research centers."[43] Discusses partnership with sister J & J companies to coordinate support of MGH collaboration with "specific scientific deliverables and timeline for delivery,"[44] including providing a model for sister companies of "partnerships with key opinion leaders."[45]

Bates No. JJRE 03857473-80.

Appendix Tab 19: 2003 Business Plan Summary regarding Child and Adolescent Market Segment. Despite allegedly having "no quantitative goals for the child and adolescent segment due to the lack of FDA indication for child and adolescent use"[46] establishes an "overall tactical budget" of $6.4 million dollars for child and adolescent programs.[47] Budget items listed included a proposed $ 0.4 million one day Children's Health and Media Summit involving presentations from "scientific opinion leaders" and advocacy on the impact of [negative media] reports on the research, diagnosis, and treatment of children with mental illnesses;"[48] a "branded" pediatric educational institute at a cost of $1.8 million and the establishment of Child and Adolescent "Advisory Boards" involving "Key Academic

[39] Bates No. JJRE 00057039.
[40] *Id.*
[41] Bates No. JJRE 03857474.
[42] Bates No. JJRE 03857475.
[43] Bates No. JJRE 03857476.
[44] Bates No. JJRE 03857477.
[45] Bates No. JJRE 03857478.
[46] Bates No. JJRIS 00166280.
[47] Bates No. JJRIS 00166283.
[48] Bates No. JJRIS 00166283.

Thought Leaders" at $2.1 million.[49] A key business strategy identified is to "clarify FDA requirements for pediatric exclusivity and support efforts to obtain child and adolescent labeling." [50]

Bates No. JJRIS 00166272-89.

Appendix Tab 20: 2003 Business Plan for Risperdal that lists as a "key tactic" use of academic collaboration (MGH[51] and CAPRI[52]) to develop an "educational platform to establish the role of APSs in the treatment of [child and adolescent] mental illness.[53] States that "[p]rolaction, EPS, TD and weight gain continue to be important issues (especially long term implications)" related to the marketing of Risperdal in children and suggests *that* "dissemination of re-analyses *Id.* of safety databases is critical."[54] The same document doubles the amount of money available for grants from 160k to 300k.[55]

Bates No. JJRE 02399406-51.

Appendix Tab 21: May 23, 2003 e-mail chain initiated by Karen Williams, Manager, Janssen CNS-Medical Science Liaison Boston Region regarding Dr. Joe Biederman not using Janssen consents for his adolescent bipolar study which apparently had been completed with data presented and a paper in progress, including discussion of Dr. Biederman's request for free Janssen drugs for redoing this study with proper protocols and expressing concern how redoing this study would effect the already reported research results. E-mails also discusses how Dr. Biederman was requesting Janssen drugs for the MRA study with Janssen employees expressing concern that the MRA study was a substudy of the adolescent bipolar study that did not specify additional free drugs. Dr. Biederman is described as pushing a Janssen employee "hard" related to his requests. Describes how Dr. Biederman had "dismantled" the Stanley grant into three separate arms for Olanzapine[56],Seroquel and Risperdal stating "[e]ach is funded also by pharmaceuticals and has pharmaceuticals supplying drugs. Draw your own conclusion." [57]

Bates No. JJRIS 00623507-08.

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[49] *Id.*
[50] Bates No. JJRIS 00166281.
[51] Most likely referring to Massachusetts General Hospital, one of the hospitals under current Congressional scrutiny. See June 3, 2008 Congressional Record (attached as Ex. G to Curtin Cert.).
[52] Possibly referring to the Combination Antipsychotic Prescribing Reduction Initiative study at the prestigious University of Manchester in England. See http://www.south.manchester.ac.uk/psychiatry/capri/.
[53] Bates No. JJRE 02399421.
[54] Bates No. JJRE 02399415.
[55] Bates No. JJRE 02399426.
[56] Olanzapine is the generic name of Zyprexa.
[57] Bates No. JJRIS 00623507.

Plaintiff attached an Appendix containing twenty-six (26) documents or e-mail chains with a summary of each attached as Ex. A to the Curtin Cert.. The attached documents reviewed to date are only a handful of the many examples evidencing Dr. Biederman's relationship with Defendants. These documents demonstrate the crucial and relevant nature of Dr. Biederman's testimony as it relates to Plaintiff's ability to meaningfully participate in the Court's discovery program and to prepare her case for trial.

New Jersey Court Rule 4:11-5 authorizes orders compelling witnesses' testimony upon due issuance of out-of-state commissions. (*See, e .g.* Pressler, Current N.J. COURT RULES, Comment R. 4:11-5 (GANN 2008) (noting that "[w]ith respect to a commission . . . [R. 4:12-1] simply incorporates the procedural provisions of R. 4:12-3, which provides for this technique in respect of depositions to be taken in foreign countries . . . [and] permits the issuance of a commission . . . without a showing of necessity or convenience")). In addition, Massachusetts law specifically allows depositions to be taken in Massachusetts for use in proceedings outside Massachusetts. (*See* Mass. Gen. L. Ch. 223A, §11 and §45. New Jersey's discovery rules are to be construed liberally in favor of broad pretrial discovery. *See Payton v. New Jersey Turnpike Authority*, 148 N.J. 524, 535 (1997) (citing *Jenkins v. Rainner,* 69 N.J. 50, 56 (1976) ("[the N.J.] court system has long been committed to the view that essential justice is better achieved when there has been full disclosure so that the parties are conversant with all available facts")). Under New Jersey law, the only way that the Order for Commission to compel Dr. Biederman's deposition can be challenged is to apply for a protective order under R. 4:10-3, which states, in relevant part, that "for good cause shown, the court may make any order which justice requires to protect . . . [a] person from annoyance, embarrassment, oppression or undue burden of expense." N.J. Ct. R. 4:10-3. Given the importance of Dr. Biederman's deposition to this litigation, this high standard cannot be met. It would be a miscarriage of justice to not allow the deposition of

this crucial physician, whose efforts to promote the use of atypical antipsychotic drugs in children reaches far beyond the borders of the State of Massachusetts.

The question of whether the information sought and the documents to be produced upon Dr. Biederman's deposition are personally injurious and unduly burdensome should be addressed to the Court and that issued the Order for Commission. This Court is the wrong forum to be raising this issue. Thus, this Court should deny Non-Party Joseph Biederman M.D.'s Motion to Quash Subpoena Duces Tecum And Ad Testificandum And/Or Motion For Protective Order.

B. Procedural Defects

(1) It is immaterial that the subpoena served upon Dr. Biederman on October 23, 2008 was significantly longer than subpoena served upon him on October 6, 2008. The subpoena served on October 6, 2008 was withdrawn and is not at issue here.

(2) It is erroneous for deponent's counsel to assert that Dr. Biederman was not provided 30 days notice in this matter. Per Case Management Order Number 4 ("CMO 4") entered into in the Risperdal/Seroquel/Zyprexa cases centralized as a mass tort case in the Superior Court of New Jersey, with reference to "General Discovery of Third Parties," Section I.D. states, "Any party seeking such discovery shall provide all other parties with at least 30 days notice." Deponent, through his counsel, had 30 days notice of Plaintiff's intention to take his deposition by acknowledging that the October 6, 2008 subpoena would be withdrawn by way of letter dated October 15, 2008 attached hereto as Exhibit C. Plaintiff, through her counsel, sent via federal express on October 16, 2008 a copy of an amended notice to take the deposition of Dr. Joseph Biederman with Subpoena Duces Tecum to counsel for Defendants, which is attached hereto as Exhibit D.

Additionally, CMO4 (I)(D) provides for notice to the parties, and not to the deponent. Dr. Biederman is not a party to this action. As outlined above, all parties to the action received appropriate notice.

(3) It is erroneous for deponent's counsel to assert that Dr. Joseph Biederman's subpoena is materially incomplete and deficient. Counsel for the deponent argues that the "Subpoena is missing materially relevant page(s), including apparently every page but one of the 'Subpoena Instructions.'" Counsel for deponent also argues that "the remainder of the Subpoena Instructions section is nowhere to be found." All four pages that contain the Subpoena's Instructions are enclosed therein the Subpoena and numerically ordered 1 to 12.

C. Conclusion

Based upon the foregoing, Plaintiff requests that this Court deny the deponent's Motion to Quash Subpoena Duces Tecum And Ad Testificandum And/Or Motion For Protective Order.

By her attorneys,

John J. Russell BY PERMISSION

John J. Russell, Esq.
15 Court Square
Suite 1150
Boston, MA 02108
(617) 720-1640

Leslie LaMacchia

Leslie LaMacchia, Esq.
Michael W. Perrin, Esq.
Bailey Perrin Bailey
440 Louisiana Street, Suite 2100
Houston, TX 77002
(713) 425-7100

Dated: November 12, 2008

Exhibit A

WEITZ & LUXENBERG, P.C.
A New York Professional Corporation
210 Lake Drive East, Suite 101
Cherry Hill, New Jersey 08002
(856) 755-1115

SUPERIOR COURT OF NEW JERSEY LAW DIVISION
MIDDLESEX COUNTY

---X

In re: Risperdal/Seroquel/Zyprexa Litigation
Case Code 274

---X

Alma Avila, as Next Friend of Amber N. Avila,
an Individual Case,

Plaintiff,

DOCKET NO.: L-6661-06

CIVIL ACTION

JOHNSON & JOHNSON COMPANY, JANSSEN PHARMACEUTICA PRODUCTS, L.P. a/k/a/ Janssen, L.P. a/k/a/ Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc., JOHN DOE Nos. 1 through 20 and JANE DOE Nos. 1 through 20.

ORDER FOR COMMISSION AND COMMISSION AUTHORIZING THE ISSUANCE OF AN OUT-OF-STATE SUBPOENA *AD TESTIFICANDUM* AND *DUCES TECUM*

Defendants.

---X

THIS MATTER having been open to the Court upon application by attorneys for Plaintiff, pursuant to Rule 4:11-5 for entry of an Order compelling to produce records and documents and to provide sworn testimony at deposition, and for good cause having been shown for the entry of issuance of a Commission authorizing the issuance of a deposition subpoena and the production of documents in this matter;

IT IS on this Wednesday, day of August ~~13~~ 20, 2008;

ORDERED that the application to issue a commission for the issuance of a subpoena compelling deposition testimony and the production of documents by Joseph Biederman, MD, Massachusetts General Hospital, Pediatric Psychopharmacology Dept., 55 Fruit St, Warren 7, Boston, MA 02114 is hereby **GRANTED**; and the following Commission is hereby issued:

COMMISSION

1. Plaintiffs Weitz & Luxenberg having demonstrated the need for certain information and documents to be produced in connection with the matter herein and requiring a subpoena from the Courts of the State of Massachusetts for their production, the Superior Court of New Jersey, through the undersigned Judge, hereby respectfully commissions and solicits the assistance of the Courts of the State of Massachusetts or such subordinate office as it may designate, to issue with due diligence to Plaintiffs subpoenas Duces Tecum and Ad Testificandum in a form acceptable to the Court Rules of the State of Massachusetts and in accordance with the customs and traditions of the Courts of Massachusetts compelling the following to produce documents and things and give testimony related to Dr. Joseph Biederman, MD, Massachusetts General Hospital, Pediatric Psychopharmacology Dept., 55 Fruit St, Warren 7, Boston, MA 02114

2. A copy of the order shall be served upon all counsel of record in this action within seven days from the date of entry.

Dated: 8/30, 2008

By: Jamie D. Happas
Honorable Judge Jamie D. Happas

TRUE COPY

FILED
AUG 20 2008
Judge Jamie D. Happas

WEITZ & LUXENBERG, P.C.
A New York Professional Corporation
210 Lake Drive East, Suite 101
Cherry Hill, New Jersey 08002
(856) 755-1115

SUPERIOR COURT OF NEW JERSEY LAW DIVISION
MIDDLESEX COUNTY

In re: Risperdal/Seroquel/Zyprexa Litigation
Case Code 274

Alma Avila, as Next Friend of Amber N. Avila,
an Individual Case,

Plaintiff,

DOCKET NO.: L-6661-06

CIVIL ACTION

JOHNSON & JOHNSON COMPANY, JANSSEN PHARMACEUTICA PRODUCTS, L.P. a/k/a/ Janssen, L.P. a/k/a/ Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc., JOHN DOE Nos. 1 through 20 and JANE DOE Nos. 1 through 20.

ORDER FOR COMMISSION AND COMMISSION AUTHORIIZING THE ISSUANCE OF AN OUT-OF-STATE SUBPOENA *AD TESTIFICANDUM* AND *DUCES TECUM*

Defendants.

THIS MATTER having been open to the Court upon application by attorneys for Plaintiff, pursuant to Rule 4:11-5 for entry of an Order compelling to produce records and documents and to provide sworn testimony at deposition, and for good cause having been shown for the entry of issuance of a Commission authorizing the issuance of a deposition subpoena and the production of documents in this matter;

IT IS on this Wednesday, day of August ~~13~~ 20, 2008;

ORDERED that the application to issue a commission for the issuance of a subpoena compelling deposition testimony and the production of documents by Joseph Biederman, MD, Massachusetts General Hospital, Pediatric Psychopharmacology Dept., 55 Fruit St, Warren 7, Boston, MA 02114 is hereby **GRANTED**; and the following Commission is hereby issued:

COMMISSION

1. Plaintiffs Weitz & Luxenberg having demonstrated the need for certain information and documents to be produced in connection with the matter herein and requiring a subpoena from the Courts of the State of Massachusetts for their production, the Superior Court of New Jersey, through the undersigned Judge, hereby respectfully commissions and solicits the assistance of the Courts of the State of Massachusetts or such subordinate office as it may designate, to issue with due diligence to Plaintiffs subpoenas Duces Tecum and Ad Testificandum in a form acceptable to the Court Rules of the State of Massachusetts and in accordance with the customs and traditions of the Courts of Massachusetts compelling the following to produce documents and things and give testimony related to Dr. Joseph Biederman, MD, Massachusetts General Hospital, Pediatric Psychopharmacology Dept., 55 Fruit St, Warren 7, Boston, MA 02114

2. A copy of the order shall be served upon all counsel of record in this action within seven days from the date of entry.

Dated: 8/20, 2008

By: Jamie D. Happas
Honorable Judge Jamie D. Happas

TRUE COPY

Exhibit B

WEITZ & LUXENBERG, P.C.
A New York Professional Corporation
210 Lake Drive East, Suite 101
Cherry Hill, New Jersey 08002
(856) 755-1115

SUPERIOR COURT OF NEW JERSEY LAW DIVISION
MIDDLESEX COUNTY

In re: Risperdal/Seroquel/Zyprexa Litigation
Case Code 274

Alma Avila, as Next Friend of Amber N. Avila,
an Individual Case,

Plaintiff,

JOHNSON & JOHNSON COMPANY, JANSSEN PHARMACEUTICA PRODUCTS, L.P. a/k/a/ Janssen, L.P. a/k/a/ Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc., JOHN DOE Nos. 1 through 20 and JANE DOE Nos. 1 through 20.

Defendants.

DOCKET NO.: L-6661-06

CIVIL ACTION

CERTIFICATION OF TERESA CURTIN IN SUPPORT OF MOTION TO DE-DESIGNATE

TERESA CURTIN, hereby certifies as follows:

1. I am an attorney licensed to practice law in the State of New Jersey and am an associate of the law firm of Weitz & Luxenberg, P.C. As part of the team that is counsel for Plaintiff in the above-captioned matter I am fully familiar with the facts recited herein and relevant to the instant motion.

2. This matter arises as a pharmaceutical products liability action brought to recover damages suffered by plaintiff as a consequence of Plaintiff's ingestion of Risperdal.

3. Attached as Exhibit A is an Appendix containing twenty-six (26) documents (separated by appendix tabs) that have been produced are part of a massive umbrella production of approximately 2.5 million documents (19,623,569 pages) in which 98.4% or 2,460,000 of the

documents produced to-date have been marked "Confidential/Produced In Litigation" by Defendants Janssen, L.P., Janssen Pharmaceutica, Inc., and Johnson & Johnson (collectively "Defendants") as discussed in a true and accurate copy of the June 20, 2008 Affidavit of Rhonda Radliff which is attached as Exhibit B.

5. Attached as Exhibit C is a true and accurate copy of a June 25, 2008 e-mail from Jeffery A. Peck to Paul Pennock de-designating certain documents that were designed as confidential under the Parties' August 7, 2007 Stipulated Protective Order of Confidentiality. Since Attorney Peck's June 25, 2008 e-mail, I have reviewed and become familiar with additional documents that are relevant to the proposed deposition of Dr. Bierderman. Such documents have not been attached to this Motion because they are still designated as confidential documents under the Parties' Stipulated Protective Order.

6. Attached as Exhibit D is a true and accurate copy of Gardiner Harris and Benedict Carey, Researchers Fail to Reveal Full Drug Pay, NEW YORK TIMES, Sunday June 8, 2008

7. Attached as Exhibit E is a true and accurate copy of Rob Waters, Harvard Doctors Failed to Disclose Fees, Senator Says (Update2), Bloomberg.com, June 8, 2008.

8. Attached as Exhibit F is a true and accurate copy of an article titled "Medicine Research Corrupted," St. Petersburg Times, June 9, 2008.

9. Attached as Exhibit G is a true and accurate copy of June 3, 2008 Congressional Record.

10. Attached as Exhibit H is a true and accurate copy of the March 23, 2007 *Order To Declassify Documents Subject To A Stipulated Protected Order of Confidentiality* in *Brown v. Johnson & Johnson, Johnson & Johnson Pharmaceuticals Research & Developmental, LLC, and Ortho-McNeil Pharmaceutical, Inc.*, Doc. No. MID-L-5446-05 MT.

11. Attached as Exhibit I is a true and accurate copy of a March 15, 2006 CNNMoney news article.

12. Attached as Exhibit J is a true and accurate copy of the Alma Avila Complaint and Demand for Jury Trial I the instant action.

Dated: July 18, 2008

TERESA CURTIN
WEITZ & LUXENBERG, P.C.
180 Maiden Lane
New York, New York 10038
Telephone: 212-558-5500
Fax: 212-363-2721
E-Mail – tcurtin@weitzlux.com

Exhibit A attached to
Exhibit B

APPENDIX OF CHALLENGED DOCUMENTS
(IN CHRONOLOGICAL ORDER)

Appendix Tab 1: November 1999 non-confidential e-mail chain in which John Bruins of Janssen "beg[s]" his supervisors to approve of a $3000 honorarium check for Dr. Biederman related this physician's participation in a program at the University of Connecticut. The e-mail states that "Dr. Biederman is not someone to jerk around. He is a very powerful national figure in child pysch and has a very short fuse."[1] Describes Dr. Biederman's earlier "fury" when a 280k proposal had been turned down and states that **since then "our business became non existant (sic) within his area of control. He now has enough projects with Lilly to keep his entire group busy for years."**[2]

Bates No. JJRE 02510305-06.

Appendix Tab 2: A November 2, 2001 non-confidential internal e-mail chain that shows clinical trial programs were discussed by Defendants as part of "growth opportunity" exercises similar to "money on the table" exercises of the prior year. Specifically states that "**trial proposals would need to be focused on those which could produce external impact before the end of 2003" and that such would have to "financial measures worked up with your respective marketing counterparts."**[3] Gahan Pandina, the Assistant Director of CNS Clinical Development at Janssen Pharmaceuticals Products, L.P., asks whether this would be "an appropriate forum to discuss the J&J center idea with Dr. Biederman.[4]

Appendix Tab 3: A list of approved 2002 Risperdal studies that the **Defendants were sponsoring** with different physicians in an amount **totaling $224,670.**

Bates No. JJRE 02713907.

Bates No. JJRE 03856494-95.

Appendix Tab 4: A February 5, 2002 internal e-mail chain initiated by George Gharabawi M.D. of Janssen Pharmaceutica Inc. related to the

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[1] Bates No. JJRE 02510305.
[2] *Id.*
[3] Bates No. JJRE 03856494.
[4] *Id.*

Johnson & Johnson Pediatric Research Center which claims that Dr. Biederman "approached Janssen multiple times to propose the creation of a [Center] . . to generate and disseminate data supporting the use of risperidone in this patient population."[5] **States that focus was to be on two topics" (1) teaching pediatricians and general psychiatrists "how to diagnose C & A BPD (BiPolar Disorder]" and (2) short and long term outcomes of management of C & A BPD with risperidone.**[6] **Plan was to get sister J & J companies to act together to participate in Center and share financial support.**[7] Discussion of how the Risperdal Brand Team had agreed to fund the Center for the 2002 year in the amount of $500k and how Dr. Biederman's team had produced a "Risperdal Reanalyzes, Research and Publication grid . . . that included a **"5-year plan of deliverables including retrospective analyses and prospective exploratory research."**[8]

Bates No. JJRE 02256029-30.

Appendix Tab 5: March 2002 internal e-mail with a boilerplate confidentiality notice written by Gahan Pandina, the Assistant Director of CNS Clinical Development at Janssen Pharmaceuticals Products, L.P., regarding Dr. Biederman's presentation at an educational seminar involving over 1000 physician, $700 CME course a week after Dr. Biederman had visited Janssen. **The e-mail describes Dr. Biederman's presentation as being "very well-received" and that "the validity of the diagnosis of pediatric mania was completely accepted."**[9] The e-mail also describes Dr. Biederman **as not being "perceived to be aligned with any company in particular."**[10] Also indicates that a topic of Dr. Biederman's presentation was that olanzapine (Zyprexa) should not be prescribed to children and adolescents due to its effect on metabolic issues. **Describes Dr. Biederman's presentation as "a clear example of the utility of partnering with a group such as MGH [Massachusetts General Hospital], who has the potential of reaching and having a significant impact upon the field of child and adolescent psychiatry with these kind of professional activities in non-sponsored venues."**[11]

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[5] Bates No. JJRE 02256029.
[6] *Id.*
[7] *Id.*
[8] *Id.*
[9] Bates No. JJRIS 00566318.
[10] *Id.*
[11] *Id.*

Bates No. JJRIS 00566318.

Appendix Tab 6: An June 11, 2002 e-mail chain initiated by Gahan J. Pandina, the Assistant Director of CNS Clinical Development at Janssen Pharmaceutica Products, L.P. to other Janssen employees and to Dr. Joseph Biederman which shows that **Defendants were actively involved in drafting a research abstract submitted for the 2002 American Academy of Child and Adolescent Conference-related use of Risperdal in children with disruptive behavior disorders which Dr. Biederman was to be listed as the presesenting author. Dr. Biederman is asked to review what Pandina had written and to "be prepared to sign and fax a disclosure form [to the AACAP] as presenting author, unless you would rather have another present the data then assignee a designee, as we cannot submit without a signed disclosure."**[12] Pandina also sought the Dr. Biederman's help in dealing with what appeared to be unfavorable research results ("[B]ased on the improvement in the placebo group, both group may demonstrate significant improvement overall on the two domains, so, if you could, please give some thought to how to handle this if the issue occurs. I will send the results as soon as possible.").[13] **The proposed abstract by Pandina did not mention this improvement in the placebo group.**, but instead states that the placebo group did not show improvement.[14] Only first e-mail on this chain contained a boilerplate confidentiality notice.

Bates No. JJRE 04017358-59.

Appendix Tab 7: July 2, 2002, non-confidential e-mail chain initiated by Carrie Steffe, the Risperdal Extramural Research Program Coordinator for Janssen Pharmaceutica CNS Medical Affairs to Dr. Joseph Biederman related to payment for Risperdal Study-RIS-USA-T295 listing payments due under the contract according to various "milestones" including separate conference presentations of eight week and ten month data and manuscript payments. Total payments for this study were to be $369,000.[15] States to Dr. Biederman that the purpose of asking for information was that "Janssen Pharmaceutical is . . . **evaluating all ongoing research studies to ensure projects continue to align with our Business**

[12] Bates No. JJRE 04017358.
[13] *Id.*
[14] Bates No. JJRE 04017359.
[15] Bates No. JJRIS 00615803.

Strategy and that monetary and manpower (sic) resources are being efficiently allocated."[16]

Bates No. JJRIS 00615803-05.

Appendix Tab 8: An e-mail dated July 10, 2002 which states that a check for $55k was just processed for Dr. Biederman and that a check req for Meltzer in the amount of $260k was to be completed.

Bates No. JJRE 02634646.

Appendix Tab 9: July 2002 Child & Adolescent Segment Priorities **memo outlining the need to meet with select KOLs**. Dr. Biederman is identified.

Bates No. JJRE 00128940-41.

Appendix Tab 10: August 28, 2002 e-mail from Gahan Pandina, Assistant Director, CNS Clinical Development of Janssen Pharmaceuticals Products, L.P., related to a collaborative initiative between Defendants and Massachusetts General Hospital which discusses Dr. Biederman referring to an earlier meeting with the McNeil team as being "highly productive and successful"[17] and proposing an evening meeting at a Boston hotel between Defendant employees and the MGH Group. Discusses the group agenda as including a **"discussion of top-line major incentives for the current year and how these fit within the current clinical environment as well as corporate goals."**[18]

Bates No. JJRE 00704705-06.

Appendix Tab 11: October 11, 2002 e-mail chain with boilerplate confidentiality notices regarding a Janssen review of Dr. Biederman poster on Risperidone for affective symptoms in children with disruptive behavior disorders stating that Janssen had been "designated as a review for Pediatrics publications."[19] Related to this poster, which was to be-presented at the AACAP,[20] **a Janssen reviewer Carin Binder requested that a qualifier be placed in the poster**

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[16] Bates No. JRIS 00615804.
[17] Bates No. JJRE 00704705.
[18] *Id.*
[19] Bates No. JJRIS 02390986.
[20] Most likely referring to the American Academy of Child and Adolescent Psychiatry.

regarding a concern that some of the symptoms that Dr. Biederman's poster classified as depressive or manic could be comorbid ADHD symptoms.

Bates No. JJRIS 02390986-87.

Appendix Tab 12: October 21, 2002 internal e-mail chain with a boilerplate confidentiality notices which discusses Defendants' "National Child and Adolescent Advisory Board" meeting in which twelve KOLs [key opinion leaders] were each paid $2500 to attend. States the Board included "'top-tier KOLs (Drs. Biederman, Peter Jensen and Gabrielle Carlson. etc)."[21] This e-mail chain shows how Defendants and the KOLs worked collaboratively to re-analyze data in that **the KOLs appeared to have provided specific recommendations related to a re-analysis of datasets on whether there was any correlation of prolactin to weight gain, growth and development** including recommending that re-analysis be completed as soon as soon as possible because "safety information could be very reassuring for clinicians."[22] Defendants' clinical team requested that the KOLs be reconvened "to help us interpret the findings from the [now finished] re-analysis."[23]

Bates No. JJRE 00070502-03.

Appendix Tab 13: November 12, 2002 e-mail with a boilerplate confidentiality notice shows that sister companies were also funding the Johnson & Johnson Pediatric Research Center at Massachusetts General Hospital. **This e-mail shows that as well as receiving $500k in 2002 funding from Defendants, the Johnson & Johnson Pediatric Research Center was given $200k to be used "for this year's MGH initiative with PI Joe Biederman" by sister corporation McNeil, with a statement that McNeil also intend to fund $200k for the center next year,"**[24] (which together with Janssen's monies already paid would be 700k for MGH Initiative in 2002). States McNeil also intended to pay 200k towards the incentive for 2003.

Bates No. JJRE 00052307.

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[21] Bates No. JJRE00070502.
[22] *Id.*
[23] *Id.*
[24] Bates No. JJRE 00052307.

Appendix Tab 14: Annual Report 2002: The Johnson & Johnson Center for Pediatric Pathology at the Massachusetts General Hospital which lists as a **"essential feature"** of the Center is its ability to conduct research that **"will move forward the commercial goals of Johnson & Johnson."**[25] While this document has many redacted sections, it is clear that a purpose was to increase the market demand for Risperdal and other Johnson & Johnson drugs.

Bates No. JJRE 00053089-109.

Appendix Tab 15: An unsigned December 12, 2002 Research Grant Agreement related a Dr. Biederman study in the amount of $181,500[26] which raises questions as to Defendants' control over the study in that (1) the Agreement stated that information developed from the study would be considered confidential and the joint property of Massachusetts General Hospital and Defendants[27]; (2) **required Dr. Biederman to give notice to Defendants' before prior to publishing scientific data developed from the Study**[28]; (3) required Dr. Biederman to update Defendants on a monthly basis and[29] (4) **allows Defendants to discontinue its support for the Study at any time.**[30]

Bates No. JJRE 02684107-09.

Appendix Tab 16: Document titled "2003 Child & Adolescent Business Plan Session 2-6/12/02 Sales and Marketing" that states **"KEY: Need to train KOL's [Key Opinion Leaders] to handle the media; need a proactive media plan."**[31] Discusses the J&J Center for Study of Pediatric Psychopathology as a "joint effort by Janssen, OMP, and McNeil-in Boston with Joe Biederman."[32]

Bates No. JJRE 00057039.

Appendix Tab 17: A "New Initiative! J&J Pediatric Research Center at Mass General Hospital" PowerPoint Presentation by Gahan J. Pandina of Janssen which *inter alia* admits that most pharmacological treatment of

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[25] Bates No. JJRE 00053091.
[26] Bates No. JJRE 02684107.
[27] *Id.*
[28] *Id.*
[29] Bates No. JJRE 02684108.
[30] *Id.*
[31] Bates No. JJRE 00057039.
[32] *Id.*

C&A [child and adolescents] is "off-label with limited data to guide treatment" and that future legislation requiring data when C&A use was expected."[33] Explains that 21% of Risperdal market is C&A and **that limited data exists, especially related to BiPolar disorder which leads to a "potential for medical misuse."**[34] Discusses Dr. Joseph Biederman as a "global expert" in the diagnosis and treatment of BiPolar Disorder and ADHD, whose research group was identified by JPI as being "one of the most important international scientific research centers."[35] **Discusses partnership with sister J & J companies to coordinate support of MGH collaboration with "specific scientific deliverables and timeline for delivery,"**[36] including providing **a model for sister companies of "partnerships with key opinion leaders."**[37]

Bates No. JJRE 03857473-80.

Appendix Tab 18: July 16, 2003 e-mail chain which discusses improvement of relationship between Defendants and Massachusetts General Hospital including mentioning a physician who had "MANY bipolar children in his practice."[38] States Defendants hoped to use improved relationship to find "potential sites for our trials."[39]

Bates No. JJRE 03165087-88.

Appendix Tab 19: 2003 Business Plan Summary regarding Child and Adolescent Market Segment. Despite allegedly having "no quantitative goals for the child and adolescent segment due to the lack of FDA indication for child and adolescent use"[40] **establishes an "overall tactical budget" of $6.4 million dollars for child and adolescent programs.**[41] Budget items listed included a proposed $ 0.4 million one day Children's Health and Media Summit involving presentations from "scientific opinion leaders" and advocacy on the impact of [negative media] reports on the research, diagnosis, and treatment of children with mental illnesses;"[42] **a "branded" pediatric educational institute at a cost of $1.8 million and the**

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[33] Bates No. JJRE 03857474.
[34] Bates No. JJRE 03857475.
[35] Bates No. JJRE 03857476.
[36] Bates No. JJRE 03857477.
[37] Bates No. JJRE 03857478.
[38] Bates No. JJRE 03165087.
[39] *Id.*
[40] Bates No. JJRIS 00166280.
[41] Bates No. JJRIS 00166283.
[42] Bates No. JJRIS 00166283.

establishment of Child and Adolescent "Advisory Boards" involving "Key Academic Thought Leaders" at $2.1 million.[43] A key business strategy identified is to "clarify FDA requirements for pediatric exclusivity and support efforts to obtain child and adolescent labeling." [44]

Bates No. JJRIS 00166272-89.

Appendix Tab 20: 2003 Business Plan for Risperdal that lists as a "key tactic" use of academic collaboration (MGH[45] and CAPRI[46]) to develop an "educational platform to establish the role of APSs in the treatment of [child and adolescent] mental illness.[47] States that "[p]rolaction, EPS, TD and weight gain continue to be important issues (especially long term implications)" related to the marketing of Risperdal in children and suggests *that* **"dissemination of re-analyses** *Id.* **of safety databases is critical."**[48] The same document doubles the amount of money available for grants from 160k to 300k.[49]

Bates No. JJRE 02399406-51.

Appendix Tab 21: May 23, 2003 e-mail chain initiated by Karen Williams, Manager, Janssen CNS-Medical Science Liaison Boston Region regarding Dr. Joe Biederman not using Janssen consents for his adolescent bipolar study which apparently had been completed with data presented and a paper in progress, **including discussion of Dr. Biederman's request for free Janssen drugs for redoing this study with proper protocols and expressing concern how redoing this study would effect the already reported research results.**[50] E-mails also discusses how Dr. Biederman was requesting Janssen drugs for the MRA study with Janssen employees expressing concern that the MRA study was a substudy of the adolescent bipolar study that did not specify additional free drugs. Dr. Biederman is described as pushing a Janssen employee

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[43] *Id.*
[44] Bates No. JJRIS 00166281.
[45] Most likely referring to Massachusetts General Hospital, one of the hospitals under current Congressional scrutiny. See June 3, 2008 Congressional Record (attached as Ex. G to Curtin Cert.).
[46] Possibly referring to the Combination Antipsychotic Prescribing Reduction Initiative study at the prestigious University of Manchester in England. See http://www.south.manchester.ac.uk/psychiatry/capri/.
[47] Bates No. JJRE 02399421.
[48] Bates No. JJRE 02399415.
[49] Bates No. JJRE 02399426.
[50] Bates No. JJRIS 00623507.

"hard" related to his requests. Describes how **Dr. Biederman had "dismantled" the Stanley grant into three separate arms for Ol[51],Seroquel and Risperdal stating "[e]ach is funded also by pharmaceuticals and has pharmaceuticals supplying drugs. Draw your own conclusion."** [52]

Bates No. JJRIS 00623507-08.

Appendix Tab 22: Internal E-mail chain regard Dr. Joseph Biederman's claim that his pharmacy charged him $100,000 for drug that was dispersed to him and request for reimbursement for the same.

Bates No. JJRIS 00623517-19.

Appendix Tab 23: Undated "**Selling, Marketing and Medical Affairs**"[53] Department Budget which lists as " Spent/Committed 2003 YTD"[54] for Massachusetts General Hospital as being 345k and" Spent 2002 Act[uals] as 631k.[55]

Bates No. JJRE 02591434+36.

Appendix Tab 24: Undated Powerpoint Presentation which lists the Johnson & Johnson Center for Pediatric Psychopathology Research Center's Allocation of Funds for 2003 as being a total of $425,000.

Bates No. JJRIS 00132362.

Appendix Tab 25: Final Draft of a "SurveyRX" Questionnaire offering to pay a honorarium to physicians for their time in filling out the questionnaire seeking "to identify the names of physicians who are KOL [key opinion leaders] on a region and national level for the pharmacological treatment of children and adolescent s with Autism using psychotropic medicines."[56] Includes a list of names for physicans to choose as KOLs.

Bates No.: JJRIS 00749515-24.

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[51] Olanzapine is the generic name of Zyprexa.
[52] Bates No. JJRIS 00623507.
[53] Bates No. JJRE 02591434.
[54] *Id.*
[55] Bates No. JJRE 02591436.
[56] Bates No. JJRE 00749516.

Appendix Tab 26: E-mail chain reflecting a total of **$500,000 paid by Janssen "for the Year 2004 MGH Center for Pediatric Psychopharmacology Research activities."**[57] Chain starts with Novemeber 23, 2004 e-mail from Dr. Joseph Biederman's business manager Deb Thiboutot stating that "Joe has asked me to contact you regarding a payment of $250,000 for **his** Johnson and Johnson Center for Study of Pediatric Psychopharmacology at Massachusetts."[58] (emphasis added).

Bates No. JJRE 00704358-61

[57] Bates No. JJRE 00704358.
[58] Bates No. JJRE 00704361.

From: Wolfe, Michael A. (JAN)
Sent: Sunday, November 21, 1999 4:05 PM
To: Sachak, Sohel [JANUS]; Bruins, John [JANUS]
Cc: Burgos, Licette [JANUS]; Mahmoud, Ramy [JANUS]
Subject: RE: Dr. Joseph Biederman payment

John and Sohel,

I am not aware of these issues with the exception of what was discussed with Sohel over the past two weeks via aspen. Let me know if I can be of assistance. I am not sure who or where the field sales force (which ever one it was -HS, CNS or Eldercare) made this commitment. But, we need to make this right with Dr. Biederman. Johns, please advise me on how we can support you with this effort.

Regards,

Mike Wolfe

-----Original Message-----
From: Sachak, Sohel [JANUS]
Sent: Thursday, November 18, 1999 9:53 AM
To: Bruins, John [JANUS]
Cc: Burgos, Licette [JANUS]; Mahmoud, Ramy [JANUS]; Wolfe, Michael A. (JAN)
Subject: RE: Dr. Joseph Biederman payment

The check has been authorized and should be sent out in three business days.
Sohel

-----Original Message-----
From: Bruins, John [JANUS]
Sent: Wednesday, November 17, 1999 11:49 AM
To: Sachak, Sohel [JANUS]
Cc: Burgos, Licette [JANUS]; Mahmoud, Ramy [JANUS]; Wolfe, Michael A. (JAN)
Subject: Dr. Joseph Biederman payment

Sohel;

As I am writing this memo, I am FAXing you all the documentation which I have on this Grand Rounds Program.

As of yesterday, 11/16/99, Dr. Biederman was promised delivery via Federal Express a check for $3K. I made this promise to him since I was assured that this matter would be resolved. It has not.

Let me start from the beginning so that it is crystal clear with everyone involved:

-Dr. Biederman is not someone to jerk around. He is a very powerful national figure in child psych and has a very short fuse.

-Three or four years ago Janssen H.O. requested that he put together a study to evaluate RIS in the child and adolescent population. He submitted a thourough and lengthy proposal which amounted to approkimately $280K. We dragged our heels on this request (which we made) for over a year. He finally recieved a standard ding letter. By the time I found out about it a week later and went to see him his secretary advised me of his fury. The sales representative who called on him and I took an hour of verbal beating. I have never seen someone so angry.

-Dr. Biederman is the Head of Adolescent Psych at MGH. Since that time our business became non existant within his area of control. He now has enough projects with Lilly to keep his entire group busy for years.

-Although I occasionally call on him and invite him to our Ad Boards, he acts with scepticism about our sincerity.

-Six months ago I recieved a call from Leighton Huey (the Chairman at UConn). He informed me that Dr. Biederman was coming to give GR in September of this year. According to him, some previous discussion had taken place between the Boston rep (covering Dr. Biederman) and the Hartford rep (covering UConn). The Boston rep was doing everthing she could think of to get Dr. Biedrerman back in our graces. Anyway they had done some behind the scenes negotiating to schedule this program. Dr. Huey informed me that Dr. Biederman recieved commitment that Janssen would pay for this program. This included a promise of $2.5K honorarium and expenses. Dr. Huey and I were both surprised by the figure but we were not part of the negotiating and stayed out of it. Dr. Huey FAXed me the e-mail correspondance. I told him that I would take care of it since the sales reps were no longer working.

-I then filled out the grant request paperwork and sent it to you for approval. This was about three months ago and well before the program on September 20, 1999.

-You then returned to paperwork to me and requested me to get the sales force to pay for it.

-I discusses the issue with Mike Wolfe (new RBD for New England) and forwarded the materials to Rick Atkinson (new DM for Hartford).

-At a sales meeting in Boston which was addressing finances I committed to taking back this Grant Request since no one was willing to champion this program and pay for it.

-On or about September 20 I resubmitted the paperwork to you with a verbal explaination.

-A month later you requested further documentation.

-Over a week ago Dr. Biederman was on his way back to tirade. He was calling me and Dr. Huey's office and was starting to ruffle Dr. Huey's feathers that we had not payed him. I asked Dr. Biederman for further documentation and committed to him that we would get his check to him by yesterday in exchange for documentation from him. In two lengthy voice mails to you I explained the situation and promised the documentation to pass in the mail with the check.

-Dr. Biederman paged me yesterday and I did not know why he had not recieved his check. I told him to call you.

-Dr. Biederman has done everything we have asked of him. Again, we have jerked him around. I am truely affraid of the repercussions.

-I beg you to approve the payment of his ckeck.

Sincerely,

JBB

From: Pandina, Gahan [JANUS]
Sent: Friday, November 09, 2001 3:56 PM
To: Gharabawi, Georges [JANUS]
Subject: FW: Growth Opportunity Exercise

Georges,

Would this be an appropriate forum to discuss the J&J center idea with Dr. Biederman? I can think of other potential opportunities in this area as well. We can discuss further.

Gahan

-----Original Message-----
From: Mahmoud, Ramy [JANUS]
Sent: Friday, November 09, 2001 8:21 AM
To: Amatniek, Joan; Berry, Sally; Danyluk, Alexander; Gharabawi, Georges; Grogg, Amy; Lasser, Robert; Lilienfeld, Sean; Markowitz, Michael; Morrison, Randy; Pandina, Gahan; Piasecki, Susan; Weaver, Lori
Cc: Caracci, Melanie [JANUS]; Donohue, Tara [JANUS]; Watson, Debi [JANUS]; Domann, David [JANUS]; Farup, Christina [JANUS]; Weaver, Lori [JANUS]
Subject: Growth Opportunity Exercise

Team:
Remember "money on the table"? Well, put aside that flavor and lets call this the "growth opportunity exercise"...please note the dates below. Lori, please put the 21st and 18th on my calendar.
Susan - please help coordinate a team response. I suggest we discuss this with everyone at an upcoming CNS core team meeting prior to ACNP (all ideas - Mike and Alex especially please note that this does not mean simply data generation!).
Rob - this may be a good opportunity to get extra funding for the titration study and/or an experience trial, but we have to put together a good case (with financials - will have to coordinate that with Melanie and Tara from finance and Debi from CONSTA marketing).
Amy - you were saying money is very tight and more could be done....now is the chance to make the case...
George, Sally, and Gahan - all ideas welcome, not just trials - - trial proposals would need to be focused on those which could produce external impact before the end of 2003, and we would have to have NPVs or other financial measures worked up with your respective marketing counterparts.
-Ramy

-----Original Message-----
From: Vergis, Janet [JANUS]
Sent: Friday, November 09, 2001 8:02 AM
To: Kalmeijer, Ronald [JANUS]; Glasspool, John [JANUS]
Cc: Donohue, Tara [JANUS]; Mahmoud, Ramy [JANUS]; Lilienfeld, Sean [JANUS]; Walsman, Mike [JANUS]; Bailey, Jeff [JANUS]; McCaffrey, Kathleen [JANUS]
Subject: FW: Meeting Dates

FYI - please note the following dates for presentations to Joe Scodari. Per our brief discussion last week, let's start thinking about ways to grow the business in 2002. While long term projects will be considered, the more revenue generated in 2002, the better. RIS and REM will continue to be top priorities, so let's have the teams approach this with much rigor. If additional monies are needed for clinical trial programs and/or more heads are needed in the field, this is our opportunity!

John/Ronald: please coordinate with each other and your teams and let's prepare to discuss early next month (before ACNP).
Kathy: please print and track.

Ronald/Ramy: Impt - the Quicksolv presentation should also include a launch update on Consta!!

Thanks!
Janet

----Original Message----
From: Gorsky, Alex [JANUS]
Sent: Friday, November 02, 2001 2:42 PM
To: Vergis, Janet [JANUS]; Pruden, Gary [JANUS]
Cc: Mehrotra, Louise [JANUS]; Graney, Tom [JANUS]; Deem, Virginia [JANUS]; Cote, Christine [JANUS]
Subject: FW: Meeting Dates

All,

As per some of my earlier discussions, please note the dates that Joe Scodari has requested. Specifcially, on January 21, we will review "Growth Opportunities" with him. These are similar to the "Money on the Table" exercises we conducted last year. For these, we should look at investment opportunities that we did not include in our 2002 plan due to budget constraints that we feel can generate top-line growth in the 2002 and 2003 timeframe. These should also include commercial and medical affairs activities.

By way of this email, I will ask Ginny Deem to schedule a preview of these plans the week of January 7th. I will also ask her to schedule a one hour meeting with the 7 of us sometime before the holidays to discuss the strategy on how we might want to approach this request.

Please note the dates on your calendars.

Alex

ALEX GORSKY
PRESIDENT
JANSSEN PHARMACEUTICA
PHONE: 609-730-2119
AGORSKY@JANUS.JNJ.COM

----Original Message----
From: Deem, Virginia [JANUS]
Sent: Friday, November 02, 2001 1:26 PM
To: Gorsky, Alex [JANUS]
Subject: Meeting Dates

Alex -

Andrea Bartels called and scheduled the following meetings. She asked that I check w/ you for additional Janssen attendees.

Stretch Plans
January 21
1 to 5
Janssen

Risperdal EmRP – 2002 Approved Studies

7. R. Salomon, MD

   Risperdal Augmentation in Depressed Partial Responders to SRI Treatment

   $73,000

8. J. Biederman, MD

   Proton Magnetic Resonance Spectroscopy in Manic Children and Adolescents

   $49,670

9. I. Galynker, MD

   A Single Blind Trial Of Risperidone vs. Paroxetine for Treatment of Panic Attacks

   $102,000

From: Cote, Christine [JANUS]
Sent: Tuesday, February 05, 2002 12:55 PM
To: Gharabawi, Georges [JANUS]; Vergis, Janet [JANUS]; Parish, Irene [JANUS]
Cc: Mahmoud, Ramy [JANUS]; Pandina, Gahan [JANUS]; Kovacs, Clare [JANUS]; Deloria, Carmen [JANUS]; Kalmeijer, Ronald [JANUS]
Subject: RE: Janssen-MGH Child and Adolescent Bipolar Center - Dr Joe Biederman

I am able to do the 14th March and will block out the day ,,I am leaving for a big trip on the 28th so unless it was early am and local I would not be able to do 28th

Dr. Christine Cote
V.P. Medical Affairs
Janssen Pharmaceutica, Inc.
Tel: 609-730-3677
Fax: 609-730-3406

-----Original Message-----
From: Gharabawi, Georges [JANUS]
Sent: Tuesday, February 05, 2002 7:42 AM
To: Vergis, Janet [JANUS]; Cote, Christine [JANUS]
Cc: Mahmoud, Ramy [JANUS]; Pandina, Gahan [JANUS]; Kovacs, Clare [JANUS]; Deloria, Carmen [JANUS]; Kalmeijer, Ronald [JANUS]
Subject: Janssen-MGH Child and Adolescent Bipolar Center - Dr Joe Biederman

Subject
Invitation to a meeting with Prof Biederman and his team at Janssen on March 14 or March 28, 2002 (date pending your approval) to agree on the main deliverables from the Janssen/MGH Center for Child and Adolescent Bipolar Disorders and prioritize the different activities - Your attendance of the 1st hour is needed.

Background
Dr Biederman is the pioneer in the area of C&A Bipolar Disorders. He approached Janssen multiple times to propose the creation of a Janssen-MGH center for C&A Bipolar disorders. The rationale of this center is to generate and disseminate data supporting the use of risperidone in this patient population. I met with Dr Biederman in August 2001 and discussed with him the feasibility of this center and agreed that, should Janssen decide to support it, the main focus will be on 2 topics: 1) Diagnostics, including the creation of a screening/diagnostic tool to train clinicians (Pediatricians and General Psychiatrists) on how to diagnose C&A BPD, use of genetics and Neuro-imaging techniques to recognize C&A BPD and the different variants of the disorders and 2) Therapeutics, including short and long-term outcomes of the management of C&A BPD with risperidone including the long-term prophylactic effect on drug abuse. Following a number of internal discussions within the Brand team and with Janet, it was decided to 1) explore the feasibility of involving other J&J companies that would be interested in participating in the center and share the financial support and 2) fund the center pending the submission of a 5-year plan of deliverables including retrospective analyses and prospective exploratory research.

Current status
* In a number of meetings with McNeil and OMP, it was agreed that there was a need for all J&J companies to act as partners and share this research, data generation and dissemination opportunity. Further, it was agreed that the 3 teams should meet and elaborate a plan that would ultimately include research initiatives on combination therapies.
* A Risperdal Reanalyses, Research and Publication grid was produced by Dr biederman's team. The grid includes proposed deliverables over the upcoming 5 years starting from 2002. It is planned to produce similar grids for the J&J sister companies over the next 3-6 months.
* The Risperdal Brand team agreed to fund the center for the year 2002. 500KUS$ were paid and assigned to the

year 2002.

Next Steps
We recently organized a meeting with Dr Biederman including the marketing group from McNeil in order to discuss the next steps. We invited Dr Biederman and his group to an HOV at Janssen Titusville. This meeting will involve, in addition to Dr Biederman's research team, the Risperdal, REDACTED teams with the objective of elaborating a full research plan for the years 2002-2007 including a reanalyses and publications plan.

Proposed agenda
- Opening address (J&J)
- Background on Child and Adolescent Bipolar Disorders- A clinical and research perspective (Dr Joe Biederman)
- Breakout session:
- Epidemiology and genetics of C&S BPD
- Diagnosis: Reanalyses, validation and publication of screening tools
- Neuro-imaging plans, publication plan
- Reanalyses of the existing Risperdal data, publication plan
- Prospective short and long-term studies

Christine and Janet, Your presence, at least at the first part of the meeting is highly desirable and would allow us to continue positioning Janssen as a major partner in the area of C & A psychopharmacology. Further, following your approval of the proposed date, we will extend the invitation to S. Spielberg but will eet with him first.

Sincerely

Georges

Georges Gharabawi M.D.
Janssen Pharmaceutica Inc.
Tel (609) 730 3277
e-mail: ggharaba@janus.jnj.com

Parish, Irene [JANUS]

From: Pandina, Gahan [JANUS]
Sent: Friday, March 22, 2002 9:38 AM
To: Cote, Christine [JANUS]; Mahmoud, Ramy [JANUS]; Deloria, Carmen [JANUS]
Subject: Feedback regarding MGH pediatric seminar

Christine, Ramy, and Carmen,

Georges and I wanted to share some information as a follow-up to the meeting with Dr. Biederman. This feedback came from an attendee of the large 3-day educational seminar (over 1000 physicians, $700 CME course) in child psychopharmacology and pediatric bipolar disorder that Dr. Biederman and his group conducted. This meeting began the day immediately after our meeting with him at Janssen last week. Dr. Biederman was very well-received by the group. The validity of the diagnosis of Pediatric Mania was completely accepted, and his diagnostic techniques deemed to be excellent. He was very balanced in his approaches to treatment, and not perceived to be aligned with any company in particular. Evidently, he made quite a point regarding the metabolic issues related to olanzapine, to the extent of stating that this drug should not be used in the treatment of children and adolescents, highlighting the issues with published data.

I think this is a clear example of the utility of partnering with a group such as MGH, who has the potential of reaching and having a significant impact upon the field of child and adolescent psychiatry with these types of professional activities in non-sponsored venues.

Regards,

Gahan

Gahan J. Pandina, Ph.D.
Assistant Director, CNS Clinical Development
Janssen Pharmaceutica Products, L.P.

1125 Trenton-Harbourton Rd • Titusville, NJ 08560
OFFICE: (609) 730 2324 • **FAX:** (609) 730 3125
EMAIL: gpandina@janus.jnj.com

From: Biederman, Joseph,M.D. [BIEDERMAN@HELIX.MGH.HARVARD.EDU]
Sent: Wednesday, June 12, 2002 1:34 PM
To: 'Pandina, Gahan [JANUS]'
Subject: RE: AACAP 2002 Draft Abstract

I will review this morning. I will be happy to sign the forms if you could kindly send them to me

> ----------
> From: Pandina, Gahan [JANUS]
> Sent: Tuesday, June 11, 2002 5:50 PM
> To: Biederman, Joseph,M.D.; Stephen V. Faraone Ph. D. (E-mail); Mick, Eric
> Cc: Gharabawi, Georges [JANUS]; Bossie, Cyndi [JANUS Non J&J]
> Subject: AACAP 2002 Draft Abstract
>
> Dear All,
>
> I am sending the most recent draft of the abstract for AACAP 2002, with some missing data (analyses were supposed to be completed this evening, but will be here in the morning instead). I was able to have our statistics department generate the summary data for each of the two symptom areas (depression and mania), but this resulted in the delay. Please take a look, and provide any comments you think appropriate. We have generated a review abstract, but I must review this longer abstract before passing this along (this is less crucial). Based upon the improvement in the placebo group, both groups may demonstrate significant improvement overall on the two domains, so, if you could, please give some thought to how to handle this issue if it occurs. I will send the results as soon as possible. Dr. Biederman, if you could be prepared to sign and fax a disclosure form as presenting author, unless you would rather have another present the data then assign a designee, as we cannot submit without a signed disclosure. I will be at an off-site meeting tomorrow, but available via cell phone at 609-954-5646, and checking my email periodically during the day as possible.
>
> Please cc: Cynthia Bossie on these communications as well, as she is helping with the coordination and technical issues. Please also forward to Stephanie for comment, as I do not appear to have her email address handy.
>
> Thank you all, and I look forward to your comments.
>
> Regards,
>
> Gahan Pandina
>
> BRIEF ABSTRACT
>
> American Academy of Child and Adolescent Psychiatry Conference - 2002
>
> Symptoms of affective instability respond to risperidone treatment in children with disruptive behavior disorders.
>
> Biederman1, J., Faraone1, S., Mick1, E, van Patten1, S., Pandina2, G., Gharabawi2, G.
>
> 1Massachusetts General Hospital, Boston, MA
>

> 2Janssen Pharmaceutica Inc., Titusville, NJ
>
> Objective: To examine the response of affective symptoms to
> risperidone treatment in children with disruptive behavior disorder (DBD).
>
> Method: Children with DBD (oppositional defiant disorder/conduct
> disorder/disruptive behavior NOS; n=118; mean, age 8.6 years, 97
> males) and subaverage IQ were randomized to placebo or risperidone in
> a 6-week, double blind study. Weekly assessments were made with the
> Nisonger Child Behavior Rating Form (NCBRF), along with other
> efficacy, safety and cognitive assessments. While the NCBRF Conduct
> Problem Subscale was the primary outcome measure, secondary analyses
> were performed on items classified as symptoms of depression or mania.
> Change in symptoms from baseline to endpoint was evaluated.
>
> Results: Analysis of covariance for symptoms of depression and mania
> showed significant improvement at endpoint in the risperidone group
> (depression: p=0.0001; mania: p=0.0001), while the placebo group did
> not (ns). Individual symptom analysis showed a greater improvement in
> children treated with risperidone than placebo. Example: the
> risperidone group improved significantly on "crying, tearful"
> (p<0.05), "irritability"
> (p<0.001) "feels worthless or inferior" (p<0.001), while the placebo group
> showed no improvement in these symptoms.
>
> Conclusions: Risperidone is effective in the treatment of manic and
> depressive symptoms frequently found in children with DBD. Implications
> for treatment are discussed.
>
>
> Gahan J. Pandina, Ph.D.
> Assistant Director, CNS Clinical Development
> Janssen Pharmaceutica Products, L.P.
> 1125 Trenton-Harbourton Rd * Titusville, NJ 08560
> OFFICE: (609) 730 2324 * FAX: (609) 730 3125
> EMAIL: gpandina@janus.jnj.com
>

>
>
>
>

Steffe, Carrie [JANUS]

To: Murphy, Heather M.
Subject: RE: Risperdal Study-RIS-USA-T295: Joseph Beiderman, MD

Hi Heather

Here are the milestones listed on the contract

20%	$73,800	Study Initiation
15%	$55,350	Enrollment of First 15 Patients
15%	$55,350	Enrollment of Second 15 Patients
10%	$36,900	Conference presentation 8 Week data
15%	$55,350	Manuscript 8 Week Data
10%	$36,900	Conference Presentation 10 Month data
15%	$55,350	Manuscript 10 Months data
100%	$369,000	

For each time a milestone is met, please send us documentation and we will process a payment.

Again, if you have any question, let me know

thanks

Carrie

1-609-730-4398

-----Original Message-----
From: Murphy, Heather M. [mailto:HMURPHY1@PARTNERS.ORG]
Sent: Tuesday, July 09, 2002 2:10 PM
To: 'Steffe, Carrie [JANUS]'
Subject: RE: Risperdal Study-RIS-USA-T295: Joseph Beiderman, MD

Thank you Carrie for letting us know about the payment. We are a huge hospital, so it does help when we can keep an eye out for things. When should I send you another update?

Heather

> ----------
> From: Steffe, Carrie [JANUS]
> Sent: Tuesday, July 9, 2002 11:53 AM
> To: Murphy, Heather M.
> Subject: RE: Risperdal Study-RIS-USA-T295: Joseph Beiderman, MD
>
> Hi Again
>
> Also, I noticed that the Second milestone was met for this study, so I
> will be processing a payment today. Let me know when you get it.
>
> Thanks
>
> Carrie
>
> -----Original Message-----
> From: Murphy, Heather M. [mailto:HMURPHY1@PARTNERS.ORG]
> Sent: Wednesday, July 03, 2002 11:35 AM
> To: 'csteffe@janus.jnj.com'
> Subject: FW: Risperdal Study-RIS-USA-T295: Joseph Beiderman, MD

> Hi Carrie-
>
> I am the coordinator of Dr. Biederman's study listed below. I was forwarded
> your email regarding enrollment numbers and wanted to let you know how we
> are doing thus far.
>
> We have enrolled 23 patients as of today, and will be adding two more next
>
> week. Of the 23 enrolled, 4 have dropped from the study.
>
> It is expected that the study will run through the end of August of 2003.
>
> Please let me know if there is anything else I can help with.
>
> Enjoy the holiday weekend!
>
> Heather Murphy
>
>
> > ----------
> > From: Johnson, Mary Ann,Mgh - Psychiatry
> > Sent: Tuesday, July 2, 2002 4:12 PM
> > To: Murphy, Heather M.
> > Subject: FW: Risperdal Study-RIS-USA-T295: Joseph Beiderman, MD
> >
> >
> >
> > ----------
> > From: Biederman, Joseph,M.D.
> > Sent: Tuesday, July 2, 2002 12:49 PM
> > To: Johnson, Mary Ann,Mgh - Psychiatry
> > Subject: FW: Risperdal Study-RIS-USA-T295: Joseph Beiderman, MD
> >
> >
> >
> > ----------
> > From: Steffe, Carrie [JANUS]
> > Sent: Tuesday, July 2, 2002 1:56 PM
> > To: Biederman, Joseph,M.D.
> > Cc: Morrison, Randy [JANUS]; Jones, Robert [JANUS]
> > Subject: Risperdal Study-RIS-USA-T295: Joseph Beiderman, MD
> >
> >
> > RE: "Risperidone in the treatment of mania in Children and Adolescents",
>
> > Joseph Beiderman, MD
> > Hello Dr. Beiderman
> > My name is Carrie Steffe, Risperdal Extramural Research Program
> > Coordinator, for Janssen Pharmaceutica CNS Medical Affairs.
> >
> > Janssen Pharmaceutica is currently evaluating all ongoing Risperdal
> > research studies to ensure projects continue to align with our Business
> > Strategy and that monetary and manopwer resources are being efficiently
> > allocated.
> >
> > With this is mind, I am requesting the following information regarding
> > your on-going study with Janssen:
> > # Patients Committed _____ Total # Patients Screened _____
> > Total # Patients Enrolled _____ Estimated Date of Completion __/__/__
>
> > Additional Comments:
> > Thank you for your attention to this matter. If you have any questions
> or

> > concerns please do not hesitate to contact me at 609-730-4398.
> >
> > Carrie Steffe
> > EMRP Coordinator
> > CNS Medical Affairs
> > Janssen Pharm
> > 1-609-730-4398
> > csteffe@janus.jnj.com
> >
> > Carrie Steffe
> > EMRP Coordinator
> > CNS Medical Affairs
> > Janssen Pharm
> > 1-609-730-4398
> > csteffe@janus.jnj.com
> >
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> >
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>

From: Morrison, Randy [JANUS]
Sent: Wednesday, July 10, 2002 4:09 PM
To: Reid, Brian [JANUS]
Subject: RE: EMRP Tracking sheets

CNS RIS EMRP June.xls (86 KB)

Brian:

fyi we have just processed a $55,000 check req for Biederman, and expect to complete a check req for Meitzer for approximately $260,000 within the next wek or so. Neither payment is reflected on the attached spreadsheet.

Randy

-----Original Message-----
From: Reid, Brian [JANUS]
Sent: Wednesday, July 03, 2002 11:26 AM
To: Harte, Clare [JANUS]; Morrison, Randy [JANUS]; Filippone, Joseph [JANUS]
Subject: EMRP Tracking sheets

Hello Everyone:

Please forward me your EMRP tracking sheets by Wednesday, July 10th. I want to do my quaterly check on where we stand for 2002 and beyond.

Brian Reid
Senior Analyst
Janssen Pharmaceutica
609-730-7629

Child & Adolescent Segment Priorities
July 28, 2002

1. Proactive Media Management Plan
   - Develop proactive media management plan to address "crises" that may arise due to media portrayal of use of antipsychotics in children.
   - Plan should include identification of spokespeople (medical), families (personalize issues), and other support organizations.
   - CABF follow-up required. Grant provided in the amount of $50K, request for additional $12K. Need to determine how these monies have been utilized.

2. Execution of 2H02 medical marketing plans
   - Review with Rob L. all medical marketing programs (completed, ongoing, and new).
   - What monies are not yet allocated/spent that may be used for other activities.

3. Assessment of pediatric market opportunity
   - Recalculate market opportunity in pediatrics (total number of patients, % diagnosed, % treated, overlaps with other conditions)
   - Update/revise work previously completed in 2001.
   - Discuss forecasting efforts with John Yi.
   - Table of diagnosis vs. symptoms (this already exists?)
   - Need to discuss DBCD with Gahan.

4. Develop advocacy relationships
   - Contact Peter Bell regarding relationships with external organizations and identify partnering opportunities.
   - CAN (Cure Autism Now), CABF (Child, Adolescent Bipolar Foundation), NMHA (National Mental Health Association), NAMI (National Alliance of Mentally Ill).

5. KOL visits/MSL partnering
   - Make plans to visit with select KOLs (Peter Jensen, Bob Findling, Mike Aman).

     Michael Aman, PhD, Ohio State University
     Joseph Biederman, MD, Harvard Medical School
     Gabrielle Carson, MD, SUNY Stonybrook
     Robert Hendren, DO, UC Davis
     Lawrence Scahill, MD, Yale School of Medicine
     Robert Findling, MD, University Hospitals of Cleveland
     Lawrence Greenhill, MD, New York Psychiatric Institute
     Peter Jensen, MD, Columbia University
     James McCracken, MD, Stanford University School of Medicine
     Christopher McDougle, MD, Indiana University School of Medicine

   - Get list of MSLs from Ann.

6. Opportunities for partnering with Concerta/McNeil
   - RIS and Concerta have similar issues – need to identify opportunities for partnering (i.e. treatment of ADHD as primary mechanism, addition of RIS to stimulants).
   - Potential "pediatric summit" where respective teams share business plans and identify opportunities for partnering.
   - Contact Diana Bacci at McNeil to discuss.

7. Goals and Objectives
   - Find form @Janssen HR site)

- Select 4 or 5 goals and objectives to include in form (use this list as reference).

8. Employee development – JPASS
   - Select on the job tools – phone number.
   - Assign Carmen to be administrator.

Kovacs, Clare [JANUS]

From: Pandina, Gahan [JANUS]
Sent: Wednesday, August 28, 2002 1:09 PM
To: Bacci, Diana [MCCUS]; Ciccone MD, Patrick [MCCUS]; Starr, H. Lynn [MCCUS]; Bell, Peter [MCCUS]; Puszkar, Mary Jane [MCCUS]; Maryak, Monica [MCCUS]; Sachak, Sohel [JANUS]; Short, Paul [OMP]; Lin, Joseph [JANUS]; DeJoria, Carmen [JANUS]; Gharabawi, Georges [JANUS]
Cc: Kovacs, Clare [JANUS]
Subject: MGH Initiative - Update!!

Importance: High

Dear Team,

Thank you for your participation in the recent teleconference to discuss the MGH J&J Center for Pediatric Psychopathology (regrets to those unavailable based upon hectic summer schedules!). As was planned previously, I spoke with the MGH group on August 19, 2002 about continuing to structure center processes, and the potential for meeting as a group prior to AACAP to discuss the Center. The group agreed that a face to face meeting would be productive. The meeting agenda would tentatively include the following:

- Formalize the group structure and communication process
- Plan a monthly meeting schedule for the remainder of the year, with a focus on discussion of key clinical issues in relevant areas
- Brief discussion of top-line major initiatives for the current year and how these fit with the current clinical environment as well as corporate goals
- Plan for next year's activities and collaboration

The MGH group suggested having a evening meeting (patterned after a recent "highly productive and successful" meeting with the McNeil team- Dr. Biederman's words!) **from 5-10 PM on Tuesday September 24, 2002.** We can hold the meeting at a local Boston hotel as a dinner meeting, and individuals can book rooms in the hotel for overnight stays on Tuesday night. I will work on the arrangements for the meeting, once we have all agreed to the time and the approximate number of attendees. This is designed to be a working meeting, so individuals who have *direct* responsibilities with the J&J Center should attend.

I am attaching a copy of a recent report on ongoing center activities generated by MGH, with summaries of presentations and ongoing research initiatives. At our upcoming meeting, we can also comment on the structure of this document, as it pertains to our ongoing business planning and clinical timelines.

Please let me know if you can attend the meeting in Boston on the date above ASAP, in order to begin the planning process.

In addition, it would be productive for us to have one more teleconference prior to the Boston meeting, to review the agenda and discuss any ongoing initiatives and/or activities that might impact our meeting with MGH.

Thank you in advance for your response.

Sincerely,

Gahan

OngoingProj.doc

Gahan J. Pandina, Ph.D.
Assistant Director, CNS Clinical Development
Janssen Pharmaceutica Products, L.P.
1125 Trenton-Harbourton Rd • Titusville, NJ 08560

SEPT 24 MTG

215-273-8421	☑	MARY JANE PUSZKAR	yes
	☑	GAHAN	yes
	☑	GEORGES	yes
215-273-8656	☑	P. CICCONE	yes
215-273-8831	☑	H. LYNN STARR	yes
2832/4526	☑	Sohel Sachak (c/o B. Dugan)	yes
x7423	☑	JOE LIN	yes
x3178	MAYBE	CARMEN NOT ATTENDING	NO
	☐	KARREN WILLIAMS	☐

OFFICE: (609) 730 2324 • FAX: (609) 730 3125
EMAIL: gpandina@janus.jnj.com

Bossie, Cyndi [JANUS]

Binder's comments

From: Binder, Carin [JOI]
Sent: Friday, October 11, 2002 3:37 PM
To: Bossie, Cyndi [JANUS]
Subject: FW: URGENT! FOR REVIEW: AACAP Poster

= Layout to all authors
= Check date presentation

Follow Up Flag: Follow up
Flag Status: Flagged

Cyndi,

Didn't have your email address - here's the draft.
Carin

----Original Message----
From: Binder, Carin [JOI]
Sent: October 11, 2002 3:35 PM
To: 'kzimmemn@exmedica.com'
Cc: Mehnert, Angelika [PGSMBE]; Binder, Carin [JOI]; Braendle, Daniel [JACCH]; Mannaert, Erik [PRDBE]; De Smedt, Goedele [PRDBE]; Caers, Ivo [PRDBE]; Lin, Joseph [JANUS]; Reyes-Harde, Magali [JANUS]; Rupnow, Marcia [JANUS]; Reyes-Harde, Magali [JANUS]; Kramer, Michelle [PRDUS]; Mielman, Olga [JANUS]; De Doncker, Piet [JanBe]; McIntyre, Todd [PRDUS]; Nys, Vincent [PGSMBE]; 'Cc: cbossie@janus.jnj.com'; Pandina, Gahan [JANUS]; Susan Conti (Business Fax)
Subject: FW: URGENT! FOR REVIEW: AACAP Poster

Karen,

My comments are attached. Please note I have a concern with some of the symptoms that have been classified as depressive or manic (i.e. physically attacking people) since these are not necessarily symptoms of mania or aggression. Request that a qualifier be inserted into the poster stating that with 60% comorbid ADHD, symptoms of overactivity speak to ADHD not only mania etc.

? Lisdexamfetamine

Regards,
Carin

----Original Message----
From: Karen Zimmermann [SMTP:KZimmemn@exmedica.com]
Sent: October 11, 2002 1:32 PM
To: amehnert@janbe.jnj.com; cbinder@joica.jnj.com; dbraendl@jacch.jnj.com; emannaer@janbe.jnj.com; gdsmedt@prdbe.jnj.com; icaers@janbe.jnj.com; JLin1@janus.jnj.com; mharde@janus.jnj.com; mrupnow1@janus.jnj.com; mharde@janus.jnj.com; mkramer@prdus.jnj.com; omielma@janus.jnj.com; pddoncke@janbe.jnj.com; tmcinty@janus.jnj.com; vnys2@janbe.jnj.com
Cc: cbossie@janus.jnj.com; gpandina@janus.jnj.com; Maha Radhakrishnan; Alissa Kubida; Susan Conti
Subject: URGENT! FOR REVIEW: AACAP Poster
Importance: High

Dear Janssen Reviewers:

Attached for your expedited review is the Biederman et al poster on risperidone for affective symptoms in children with disruptive behavior disorders, which will be presented at AACAP.

This document is being sent to you because you have been designated as a reviewer for Pediatrics publications. If this document was sent to you in error, or if there are reviewers who have not been included on this e-mail, please let me know.

We will need your comments by end of day on **MONDAY, OCTOBER 14,** to meet production deadlines. You can send your comments to me at the address below.

Thank you!

Karen

Karen L. Zimmermann
Group Director, Strategic Scientific Publications
Excerpta Medica
37 Watson Drive
Mount Laurel, NJ 08054
856-722-1340 (phone)
856-722-9137 (fax)
KZimmerm@exmedica.com <mailto:KZimmerm@exmedica.com> (e-mail)

Main Office:
105 Raider Blvd.
Suite 101
Hillsborough, NJ 08844

RIS-USA-93
effective poster (1...

From: Hsu, Irene [JANUS]
Sent: Tuesday, October 22, 2002 3:15 PM
To: Deloria, Carmen [JANUS]; Reyes-Harde, Magali [JANUS]; Lin, Joseph [JANUS]
Subject: FW: Follow-Up National Child and Adolescent Advisory Board Justification Document

Importance: High

Nov 02 Business Justification....

-----Original Message-----
From: Hsu, Irene [JANUS]
Sent: Tuesday, October 22, 2002 11:07 AM
To: Mallegol, David [JANUS]; Chester, Michael [JANUS]
Subject: RE: Follow-Up National Child and Adolescent Advisory Board Justification Document
Importance: High

Dave,

Here's the information:

The June meeting was held on June 14, 2002 (1-day meeting, from 7:00 am -- 4:30 pm)
12 KOLs (national advisors) attended
honorarium: $2500 each
Key issue presented: NCBRF item analysis, weight gain and prolactin data from CDMR datasets
Key issue discussed: Advisors provided specific recommendations on the re-analysis of these datasets to ensure that the data are presented in a clinically meaningful way to clinicians, eg. looking at outliers in weight gain, prolactin elevation (vs. group mean data as presented), whether there're any correlation of prolactin to weight gain, growth and development. The advisors urged us to complete these re-analysis as soon as possible as the safety information can be very reassuring for clinicians.
Carmen closed the meeting, and informed the advisors that we will get back to work on the re-analysis and share the findings with them when we convene them again in 2003. The advisors voiced their concerns re: 1-yr later, and wanted to re-convene before year's end.

Our clinical team had conducted these re-analysis, and we want to re-convene the same group to help us interpret the findings from these re-analysis. The group (Magali, Carmen, Gahan Pandina) discussed, and we believe this is an opportune time to convene the group (potential filing with RUPP datasets, post-AACAP), and would like to have this meeting before the holidays (in mid-late November).

As these are our top-tier KOLs (Joe Biederman, Peter Jensen, Gabrielle Carlson, etc.), we plan to offer $2500 as honorarium for the 1-day meeting (with arrivals the day prior).

Please let me know if I can answer any other questions that you may have. Attached please find the business justification document.

Thanks,
Irene
Irene Hsu, PharmD
Product Director, CNS
Janssen Pharmaceutica
1125 Trenton-Harbourton Road
Titusville, NJ 08560
tel: 609 730 2905

fax: 609 730 3092
email: ihsu@janus.jnj.com

-----Original Message-----
From: Mallegol, David [JANUS]
Sent: Tuesday, October 22, 2002 9:47 AM
To: Hsu, Irene [JANUS]
Subject: RE: Follow-Up National Child and Adolescent Advisory Board Justification Document

Irene, I spoke with legal on this idea of a follow up meeting. We need further discussion on this idea. Please include Mike Chester and myself. Dave M.

-----Original Message-----
From: Hsu, Irene [JANUS]
Sent: Monday, October 21, 2002 11:52 PM
To: Mallegol, David [JANUS]
Cc: Lin, Joseph [JANUS]
Subject: Follow-Up National Child and Adolescent Advisory Board Justification Document
Importance: High

Dear Dave,

Sorry to do this via email. I've been traveling and will be for the next few weeks, and so is Joe Lin (Joe is the new Product Director for Child and Adolescent in New Business, with Carmen). We want to conduct a follow-up meeting to the June National Ad Board – the advisors recommended that we conduct further re-analysis of our CDMR datasets, and convened the advisors together later this year to review the findings of the re-analysis, as they would like to see us get some of these data published.

We'd like to have this follow-up national advisory board meeting before year's end (in mid-late November), with 12-15 national advisors. The business justification document is attached. Please review and let me know any comments at your earliest convenience, as time is of the essence.

Thanks Dave.

Look forward to hearing from you.

Best,
Irene

<< File: Nov 02 Business Justification.doc >>

Irene Hsu, PharmD
Product Director, CNS
Janssen Pharmaceutica
1125 Trenton-Harbourton Road
Titusville, NJ 08560
tel: 609 730 2905
fax: 609 730 3092
email: ihsu@janus.jnj.com

From: Pandina, Gahan [JANUS]
Sent: Tuesday, November 12, 2002 5:36 PM
To: Seymour, Bob [JANUS]; Deloria, Carmen [JANUS]; Lin, Joseph [JANUS]
Cc: Gharabawi, Georges [JANUS]
Subject: Funds from McNeil Consumer for MGH initiative

Importance: High

Dear Bob, Carmen, and Joe,

I was recently contacted by Rhonda Peebles at McNeil. They would like to know how best to transfer 200,000 to be used towards this year's MGH initiative with PI Joe Biederman. The money for funding the entire center ($500K) was already paid by Janssen at year's end 2001 for calendar year 2002, and as such these funds could potentially be applied elsewhere in C&A (e.g., EMRP studies). McNeil also intends to fund $200K for the center for next year. They would like to know where/how to transfer funds. Rhonda can be reached at (215) 273-7453. Lets discuss before contacting Rhonda directly.

Gahan

Gahan J. Pandina, Ph.D.
Assistant Director, CNS Clinical Development
Janssen Pharmaceutica Products, L.P.
1125 Trenton-Harbourton Rd * Titusville, NJ 08560
OFFICE: (609) 730 2324 * FAX: (609) 730 3125
EMAIL: gpandina@janus.jnj.com

Annual Report 2002: The Johnson and Johnson Center for Pediatric Psychopathology at the Massachusetts General Hospital

Director: Joseph Biederman, MD
Co-Director: Stephen V. Faraone, PhD

Executive Summary

Overview

The mission of the Center is to create a common ground for a strategic collaboration between Johnson & Johnson (J&J) and the Pediatric Psychopharmacology Research Program an at the Massachusetts General Hospital (MGH). The Center provides an infrastructure for MGH researchers to collaborate with J&J researchers on comprehensive studies of pediatric psychopathology, including diagnostic, therapeutic, and neurobiologic studies. The formation of the Center has created a forum for multidisciplinary collaborative research in a number of key areas, with an initial focus on pediatric mood and disruptive behavior disorders.

An essential feature of the Center is its ability to conduct research satisfying three criteria: a) it will lead to findings that improve the psychiatric care of children; b) it will meet high levels of scientific quality and c) it will move forward the commercial goals of J&J. We strongly believe that the Center's systematic scientific inquiry will enhance the clinical and research foundation of child psychiatry and lead to the safer, more appropriate and more widespread use of medications in children. Considering that nearly all psychiatric medication use in children is off label, studies of safety and efficacy in children are essential for clinicians, parents and patients to feel comfortable using these medications in children. The Center is poised to test the effectiveness and safety of RISPERDAL, REDACTED and new products as the emerge from the pipeline.

Equally important to effective use of medications is the demonstration of the validity of disorders. Because parents, patients and clinicians are exposed to a media that frequently questions the validity of childhood disorders, genetic and brain imaging studies are needed to show the validity of these disorders as brain disorders that respond to medication. Epidemiologic studies are needed to show that childhood disorders are frequently chronic and severely debilitating. Without such data, many clinicians question the wisdom of aggressively treating children with medications, especially those like neuroleptics, which expose children to potentially serious adverse events. Epidemiologic studies also show the continuity of childhood and adult disorders. This provides an additional measure of validation for the childhood disorder and in some cases validates the disorder as a disorder of adulthood as we have seen for adult attention deficit hyperactivity disorder (ADHD).

Through the funding provided by J&J, we are creating a team of investigators focusing on the following issues.

Assessing the Efficacy and Safety of Medications for Child Psychopathology

We will generate and publish data on the efficacy and safety of medications for improving currently available treatment options for child psychopathology. This work is an essential precursor to the safe, appropriate and widespread use of medications given that most must be used off-label. Specific goals of this area of work include:

- Assessing the full range of symptoms treated by RISPERDAL by analyzing data from Janssen's study of RISPERDAL among conduct disordered/mentally retarded youth. This will allow us to extend Janssen's prior findings indicating efficacy for conduct disorder to mania, anxiety and other classes of psychopathology.
- Using MGH open-label studies to assess the differential effectiveness and safety of RISPERDAL and ZYPREXA in the treatment of pediatric bipolar disorder (BPD). For example, we have already shown that ZYPREXA leads to twice the weight gain as RISPERDAL.

- Using MGH open-label studies to demonstrate how combination pharmacotherapy can be used to treat complex cases. Examples include using RISPERDAL and CONCERTA to treat ADHD with BPD, REDACTED
- REDACTED

Resolving Complex and Controversial Diagnostic Issues

Many children with psychopathology never receive medical treatment due to controversies in the media and debates among professionals about the validity of psychiatric diagnoses in children. Additional under-treatment occurs due to lack of mental health screening in primary care clinics The Center seeks to address complex and controversial diagnostic issues through empirical research. This domain of work includes validating diagnostic methods, validating tools for screening and treatment monitoring and, if needed, creating new measures which will allow physicians to confidently screen for and diagnoses child psychopathology. Center investigators are now examining diagnostic and measurement issues for three disorders that have been particularly controversial: pediatric BPD, adult ADHD and pediatric psychosis. Specific goals of this area of work include:

- Analyzing databases at MGH to characterize pediatric BPD, adult ADHD and pediatric psychosis. This will help clinicians understand the nature of these disorders, which will facilitate their ability to diagnoses them in their practices.
- Developing and assessing the validity of screening tests for complex disorders such as comorbid ADHD, psychosis and pediatric BPD. Once appropriately validated, the use of these screening tests will alert physicians about disorders that exist which RISPERDAL and CONCERTA might treat. Currently, many children with psychosis and BPD and many ADHD adults are not identified as such so are not treated outside of specialty academic centers.
- Implementing training programs for screening tools in continuing medical education programs targeting pediatricians and general psychiatrists.
- Analyzing baseline data from Janssen funded studies to validate affective disorder sub-type in the conduct disorder subpopulation. Further validation of this group will alert physicians to the existence of a large group of children who might benefit from treatment with RISPERDAL.
- Analyzing data bases at MGH to clarify the continuity between childhood and adult disorders. Showing how pediatric mania evolves into what some have called mixed or atypical mania in adulthood, will provide further support for the chronic use of

RISPERDAL from childhood through adulthood. Such data will teach clinicians about how to identify these symptoms in adults.

- Using the classic criteria of Robins and Guze (1970) to validate diagnostic criteria for pediatric BPD, childhood psychosis and adult ADHD using studies of course, outcome, genetics, cognition and neuroimaging as described in the following sections.
- Using neuropsychological measures to accurately identify executive brain dysfunction and differentiate it from ADHD. Because executive brain dysfunction is seen in many ADHD children, there is some debate about whether it is a separate syndrome or another manifestation of ADHD. By clarifying this issue, we will demonstrate the need for clinicians to assess for executive brain dysfunction and consider potential medical treatments for this condition in their ADHD patients.
- REDACTED

Assessing the Severity and Chronicity of Child Psychopathology

We will study the natural course of pediatric psychopathology, the long-term incidence of the various dysfunctions and the long-term effects of pharmacologic and other interventions. This work validates childhood disorders by demonstrating how it evolves in adult manifestations of the same disorders. It shows clinicians that aggressive treatment is warranted because these disorders lead to substantial disability. By clarifying the chronicity of disorders, it further documents the necessity for the chronic treatment of some disorders by debunking myths which present childhood psychopathology as a normal phase of development. For example, in the past, ADHD was viewed as a remitting disorder and treatment was usually stopped during adolescence. Today, due to longitudinal studies the American Academy of Pediatrics now recommends treating ADHD as a chronic illness. Specific goals of this area of work include:

- Assessing the severity and chronicity of pediatric BPD using the same methods we have used for longitudinal studies of ADHD (Biederman et al., 1998b; Biederman et al., 2000).
- Characterizing the chronic, debilitating course of BPD to help people understand need for aggressive treatments such as RISPERDAL.
- Evaluating the effectiveness of medical and psychosocial treatments on long term outcomes in pediatric BPD using a naturalistic design.
- Evaluating the effect of RISPERDAL treatment on functioning in pediatric BPD in database studies and prospective short and long term studies.
- Assessing the disability associated with adult ADHD to help us understand the future of child ADHD and the need for chronic treatment. We are addressing this through a large longitudinal family study of ADHD and are also developing a day-long laboratory protocol to quantify the "real world" impairments associated with ADHD such as impaired driving skills and difficulty concentrating on work requiring sustained attention.

Clarifying the Biological Basis of Childhood Psychopathology

One of the main obstacles to the medical treatment of childhood disorders is the myth that they simply reflect problems of family and culture rather than dysfunctions of the brain. We will help dispel these myths using genetic and neuroimaging studies. These studies further validate childhood disorders as medical conditions and thereby give physicians more confidence in the use of medical treatments. By clarifying the causes of childhood disorders, these studies also lay

the ground work for the development of more efficacious treatments or the use of current treatments in a more effective manner. Specific goals of this area of work include:

Genetics

- Identifying genes that increase the susceptibility to child psychopathology with an initial emphasis on ADHD and BPD.
- Validating diagnostic criteria and assessing the validity of comorbidity using designs from genetic epidemiology.
- Creating a platform for collaboration between MGH and the J&J pharmacogenetics department by working with J&J to collect, DNA, safety data and efficacy data. The goal of this work is to discover genes which predict therapeutic response or adverse events during treatment with J&J medications.
- Collecting pharmacogenetic data in MGH studies of RISPERDAL, REDACTED REDACTED
- Studying children having a bipolar parent to develop rules for identifying pre-clinical cases. By accurately identifying children at risk for psychopathology, we will be able to develop early intervention and prevention treatment programs.

Neuroimaging

- Using magnetic resonance imaging to identify structural and functional patterns in the brain that characterize psychopathological subgroups, particularly controversial diagnoses such as pediatric BPD and adult ADHD.
- Initiating a prospective study of the efficacy and safety of RISPERDAL in pediatric BPD, including neuroimaging on a subset of patients.
- Using magnetic resonance spectroscopy to examine changes in NAA/CA, Choline, and other brain metabolites in response to RISPERDAL treatment.
- Using structural and functional magnetic resonance imaging in medication naïve patients to demonstrate that brain changes are associated with childhood disorders, not their treatment.

Disseminating Research Results and Educating Clinicians

To have an impact on clinical practice, research results from the Center must be disseminated through scientific publications, presentations and national and international meetings and continuing education programs. Our program of dissemination is as follows:

- Presenting findings and national meetings of the American Psychiatric Association, the American Academy of Pediatrics, the American Academy of Child and Adolescent Psychiatry, the American Psychological Association, Biological Psychiatry, NCDEU and the American College of Neuropsychopharmacology.
- Presenting findings at international meetings of the World Psychiatric Association, the World Congress of Psychiatric Genetics, the European College of Neuropsychopharmacology (ECNP) and the Collegium Internationale Neuro-Psychopharmacologicum (CINP).
- Developing and implementing a BPD continuing education program to teach pediatricians and psychiatrists how to screen for, diagnose and treat BPD

- Present continuing medical education programs at national and international professional meetings:
- Convening a yearly international conference for investigators studying pediatric BPD (this is possible through funding from Janssen and a grant from the National Institute of Mental Health to Dr. Biederman).
- Convening a yearly international conference for investigators studying the genetics of ADHD (this is possible through funding from the National Institute of Mental Health to Dr. Faraone).
- Preparing manuscripts for publication in psychiatric, pediatric and psychological journals.

Details of Center Activities in 2002

In 2002, we made progress in the following areas:

- At MGH, we identified a multidisciplinary team of psychiatrists, psychologists, psychiatric clinical nurse specialists, epidemiologists, and behavioral geneticists to participate in the Center
- We initiated several research projects
- We initiated data analyses of archival J&J and MGH data sets.
- We disseminated the results of our work and national and international meetings.
- We prepared initial manuscripts for publication.
- We supported junior faculty efforts to develop expertise in pediatric BPD.
- We developed and maintained a schedule of regular communication with J&J staff to facilitate collaborative efforts.
- We Initiated Yearly Meetings of Experts in Bipolar Disorder.

Creation of a Multidisciplinary Team

Table 1 lists the MGH investigators participating in the Center. These participants are each faculty members in the Harvard Medical School Department of Psychiatry at MGH. As Table 1 shows, they have experience using a wide range of methods and measurement tools. A comprehensive description of all the prior work in these areas of measurement is beyond the scope of this report, but an examination of the biographical sketches of the investigators (see Appendix A) shows the extent of their prior empirical work, most of which has used the methods and assessment measures to be used in the proposed Center.

Table 1: MGH Participants in Center Research

EXPERTISE	INVESTIGATOR
Psychosocial Treatment Outcome Designs	Stephen Faraone, PhD Ross Green, Ph.D Dina Hirschfeld, Ph.D.
Psychopharmacological Treatment Outcome Designs	Joseph Biederman, MD Tom Spencer, MD Tim Wilens, MD
Epidemiological Designs	Stephen Faraone PhD Eric Mick, Sc.D.
Molecular and Statistical Genetics	Stephen Faraone, PhD James Gusella, PhD Paul Van Eerdewegh, PhD
Psychiatric Assessment, Diagnosis and Treatment-Outcome	Joseph Biederman, MD Tom Spencer, MD Tim Wilens, MD Janet Wozniak, MD
Psychological and Psychosocial Assessment	Stephen Faraone, Ph.D. Ross Green, Ph.D Dina Hirschfeld, Ph.D.
Neuropsychological Assessment	Larry Seidman, PhD Alysa Doyle, Ph.D
Neuroimaging	Larry Seidman, PhD
Statistical Analysis Analysis	Stephen Faraone PhD Eric Mick, Sc.D.
Data Base Programming; Computer Hardware; Networking; Data Quality and Security	Eric Mick, Sc.D.
Biostatistics	Stephen Faraone PhD Eric Mick, Sc.D.

Through this multidisciplinary faculty, the Center has access to the systematic assessments needed for screening, study recruitment and study implementation. Table 2 shows the domains of assessment expertise available to the Center. Most studies need structured interviews for psychiatric diagnostic assessments. Treatment protocols also require measurement in domains of functioning at baseline that might be predictive of subsequent treatment response as well as measures of psychopathology and functioning that will be sensitive to the clinically meaningful changes that will occur with treatment. The Center maintain assessment tools that allow for the assessment of functioning in multiple domains: psychiatric, psychosocial, neuropsychological, quality of life, and the utilization of health services.

Table 2: Measurement Domains Available to the Center

	Type of Study		
	Diagnostic Studies	Treatment Studies	Etiology Studies
Psychiatric Symptoms			✓
Structured Diagnostic Psychiatric Interview	✓	✓	✓
Substance Use Assessments		✓	✓
Clinical Rating Scales	✓	✓	✓
Social Functioning	✓	✓	✓
Family Environment Scale		✓	✓
Expressed Emotion		✓	✓
Family Burden		✓	
Neuropsychological Functioning			
Health Services Utilization	✓	✓	

Because much of the under-treatment of psychiatric disorders in children is due to concerns about the accuracy and validity of diagnostic measures, the ability to validate measures of childhood psychopathology is an essential component of the Center. The availability and use of good measurement technologies leads to improved acceptance of research results by the FDA, physicians, patients, their parents and the general public.

Center investigators have completed many methodological studies that validate the use of these assessment tools in pediatric populations. Examples include:

- Showing that parent-based diagnoses of ADHD are predictive of teacher-based diagnoses (Biederman et al., 1993b; Biederman et al., 1990a). This work has facilitated drug development for ADHD, when teacher reports are lacking. This makes adolescent studies feasible and also provides reassurance to clinicians when they must diagnose children without information from teachers.
- Using clinical trials data to show that parent reports are sufficient for detecting efficacy in studies of long-acting medications for ADHD (Biederman et al., submit). This work provides reassurance to clinicians when they must titrate medications without feedback from teachers
- Demonstrating that structured interview diagnoses of child psychopathology show high reliability and diagnostic efficiency (Faraone et al., 1995). This type of work clarifies the objective nature of diagnosis, which helps clinicians understand the value of applying them in pediatric settings.
- Supporting the validtity of adult ADHD diagnoses by showing that parental ADHD does not bias reports of ADHD in children (Faraone et al., in press), that symptom reports by ADHD adults are not influenced by the presence of ADHD in their children (Faraone et al., 1997) and that adult relatives of ADHD children have high rates of ADHD and that family study methods show adult ADHD to be a valid diagnosis (Faraone et al., 2000a). By demonstrating the validity of adult ADHD diagnoses, this and other work has led to a more widespread acceptance of the diagnosis, including acceptance by the FDA, which previously doubted its validity but has now given Lilly an adult ADHD indication for STRATTERA.
- Creating a method for assessing medication efficacy in a naturalistic setting by applying structured assessments to medical records (Biederman et al., 1999). This provides a simple method for assessing efficacy. As we have shown for the RISPERDAL treatment of bipolar disorder (Biederman et al., 1999), this method provides a quick assessment of whether a currently available medication is worth pursuing in a clinical trial.
- Using multiple definitions of remission to assess course and outcome (Biederman et al., 2000) and creating an assessment and analysis scheme for defining normalized functioning in children (Biederman et al., 1998b) we have been able to quantify the chronicity and severity of disorders and, thus, the need for chronic, aggressive medical treatment.
- Demonstrating the validity of the Social Adjustment Scale for Children and Adolescents (Biederman et al., 1993a) provides a useful tool for assessing the efficacy of medications in this "real world" domain of dysfunction affected by many psychiatric disorders.
- Creating new designs to clarify psychiatric comorbidity using the family study method has validated comorbid conditions and strengthened the rational for treating them (Faraone et al., 1999).

- Showing that exclusive reliance on youth self-reports may identify a mild form of depression associated with limited morbidity and disability compared with that identified by parental reports (Braaten et al., 2001) and showing that the potential distortion of indirect interviews by depressed mothers may be stronger in community than in clinical settings and does not account for the increased risk for MD in referred adolescents with ADHD (Mick et al., 2000) This work will lead to better methods of identifying depression in children.
- Documenting substantial stability of Child Behavior Checklist (CBCL) scales over time for ADHD patients to support the informativeness of the CBCL as a useful measure of longitudinal course in clinical samples of youth with ADHD (Biederman et al., 2001b). This work provides further evidence that the CBCL is a useful tool for screening and monitoring the progression of disorders.
- Developing new methodologic approaches for prevention protocols (Faraone et al., 2002). This work will, in the long-term, lead to psychopharmacologic protocols aimed at the primary prevention of childhood psychiatric disorders

The Center also includes substantial expertise in data management and analysis, which allows it to provide methodological, statistical and data base management assistance to participating investigators. To facilitate study efficiency and data sharing the Center has implemented a common data analytic infrastructure. This infrastructure has enabled the design of shared databases for analytic efforts of data collected across various studies.

Eric Mick, ScD heads the Center's data management efforts. As an epidemiologist, he is highly experienced in the collection, editing and management of large complex data sets from psychiatric studies, including longitudinal and family studies. He and our data base developer, Ellie Remskar, are responsible for setting-up and maintaining the central data management system. To achieve the goals of central data management, he plans for the software and hardware needs of the central system and supervises the day to day work of the central data management staff. He also assures the integrity of data management for each Center project.

Stephen Faraone, Ph.D. heads the Center's data management efforts by coordinating group of two junior faculty and three masters level statisticians well versed in a variety of statistical techniques. This resource is available to participating investigators (i.e., developing and established scientists), clinicians planning to become investigators and students (including graduate students, interns, residents and fellows). The data analysis efforts at the Center also include the development of new methods to deal with new issues that arise in the Center's research program. Prior examples of methods development include:

- The use of analytic mathematics and simulations to choose among methods for analyzing autocorrelated binary data (Faraone and Dorfman, 1987);
- The development of a method to assess inter-observer agreement in the presence of autocorrelation (Faraone and Dorfman, 1988);
- Creation of a method to render radioreceptor assay results comparable between different neuroleptic medications (Young et al., 1989).
- The use of simulations to choose among methods of morbidity risk estimation (Faraone et al., 1994) and to assess the statistical power of linkage studies (Chen et al., 1992).
- The use of multidimensional scaling to clarify diagnostic confusability and reliability (Faraone et al., 1996).
- The use of mathematical genetic considerations to choose phenotypes for genetic analysis (Faraone et al., 2000b).

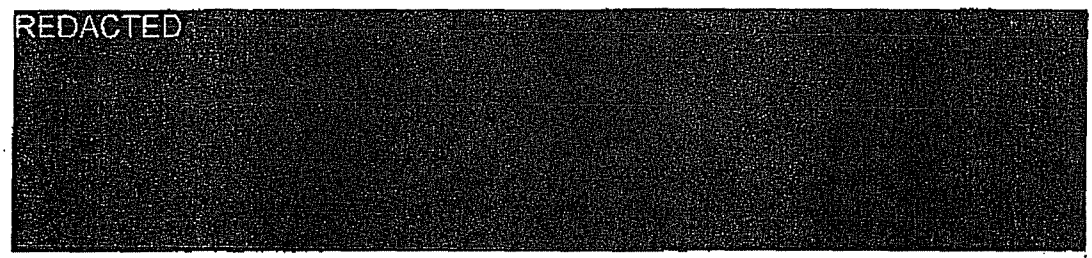
- The use of latent class methods to measure diagnostic accuracy in the absence of a gold standard (Faraone and Tsuang, 1994).
- An analytic demonstration of the effects of fixed-dose, clinical-dose and reduced-dose treatment designs on outcome measures (Faraone et al., 1992).
- The development of a receiver operating characteristic (ROC) based method to optimize the validity of psychiatric diagnoses (Faraone et al., 1993).
- The development of an ROC based method to comprehensively describe differences in efficacy between drug and placebo or between two drugs (Faraone et al., 2000c).
- Comprehensive reviews of ascertainment and statistical methods in psychiatric genetics (Faraone and Santangelo, 1992; Faraone et al., 1999; Faraone and Tsuang, 1995).

Data Collection Efforts Initiated in 2002

Treatment Studies

We will add descriptions of these.

Comparative Effectiveness and Tolerability of RISPERDAL with SEROQUEL, GEODON, ZYPREXIA



RISPERDAL and CONCERTA for ADHD in Children and Adults with Bipolar Disorder

MR spectroscopy study of children before and after RISPERDAL

Development of driving simulator for adults with ADHD

Sleep apnea and ADHD in adults

Treatment of Psychiatric Comorbidity in Bipolar Disorder.

Bipolar youth frequently present with one or more of the following comorbid disorders: ADHD, oppositional defiant disorder, pervasive developmental disorder, anxiety, and major depression. These disorders complicate treatment planning for two reasons. First, little is known about how to sequence the treatments for co-occurring conditions. In addition, the standard treatments for some comorbid conditions (e.g. stimulants for ADHD, SSRIs for depression) may exacerbate mania. Our plan is to develop open label trials targeted at these comorbid conditions to get an early signal regarding the effectiveness of these therapies. Those that look promising will be further developed by pursuing external funding for large scale clinical trials. We have currently initiated the following studies of comorbidity:

- Open-label study of RISPERDAL for pediatric BPD. This study serves as an ascertainment source for cases of BPD with ADHD, which can then be enrolled in a

study assessing the effectiveness of CONCERTA for ADHD in RISPERDAL treated BPD children.

- REDACTED

Pharmacokinetics and Drug-Drug Interactions.

Because many of the medications we are studying have not been used extensively in pediatric populations, it is essential that we collect pharmacokinetic data. Moreover, some of our protocols use more than one compound. Thus, a key component of our program is to evaluate potential drug-drug interactions associated with combined treatments using appropriate pharmacokinetic and pharmacodynamic protocols. Current pharmacokinetic studies are as follows:

- Pharmacokinetics of RISPERDAL in Pediatric ADHD
- REDACTED
- Pharmacokinetics of RISPERDAL and CONCERTA in Children with BPD and ADHD

Olanzapine plus Topiramate.

Topiramate has been used to offset weight gain associated with atypical neuroleptics in clinical practice but has not been systematically evaluated. Thus, the objective of this study is to evaluate the safety and effectiveness of added topiramate to minimize iatrogenic weight gain approaches to the treatment of BPD in children and adolescents.

Initial Treatment Studies of Bipolar Depression.

Since depression is a highly morbid state of bipolar disorder and since antidepressants can exacerbate manic symptoms, the evaluation of safe and efficacious treatments for bipolar depression remains uncertain. To this end, we initiated a clinical trial comparing the effectiveness of buproprion and paroxetine for the treatment of bipolar children with active symptoms of depression. These are potentially useful options to evaluate in this population since they have each been shown to have a low manicogenic risk in adults.

Epidemiologic and Genetic Studies of Pediatric Psychopathology.

Genotyping Efforts and Genetic Databank Development

We have been collecting blood samples from each member of the nuclear family of children with bipolar disorder. This blood is stored so that DNA may be extracted in the future in order to conduct linkage, association or pharmacogenetic analyses.

Phenotypic characterization of velo-cardio-facial (VFC) Syndrome

Since VCF has been associated with bipolar disorder in some studies, we are collecting digital photographs of children with bipolar disorder in order to test the hypothesis that hemizygous deletion of chromosome 22q11 may result in bipolar affective disorder. This finding may eventually lead towards the identification of candidate genes for early onset bipolar disorder.

Studies of Temperamental Risk Factors for Pediatric Bipolar Disorder.

Another major research interest of our group has been the study of temperament as a risk factor for subsequent psychopathology in at-risk children. We currently have a large program which has shown that behavioral inhibition is an early onset precursor of subsequent anxiety disorders

(Biederman et al., 2001a; Biederman et al., 1993c; Biederman et al., 1990b). If the new Center is funded, we plan to create a research program aimed at identifying temperamental risk factors for pediatric bipolar disorder. In particular, we intend to follow-up on some intriguing leads from our pilot studies, which suggest that behavioral disinhibition may be a very early onset risk factor for pediatric bipolar disorder.

Longitudinal Family Study of Pediatric Bipolar Disorder.

Longitudinal studies of pediatric bipolar disorder hold the promise of settling controversies that have plagued the field. If bipolar disorder is a valid diagnosis in children, signs of the disorder should remain evident at follow-up assessments. Equally important will be determining the course of comorbidity in pediatric bipolar disorder to see if they have a course and outcome that parallels that which has been seen for the comorbid disorder when it occurs in the absence of bipolar disorder. Dr. Wozniak collected 110 families ascertained via pediatric bipolar patients through her NIMH Career Development Award. With J&J funding, we have been able to initiate a follow-up study of this sample.

Follow-Up of Preschoolers with Bipolar Disorder.

In light of extensive media attention devoted to a recent pharmacoepidemiological analysis which asserted that large number of preschool children are inappropriately treated with pharmacotherapy and since children with bipolar disorder frequently present to clinics at very young ages with a very severe clinical picture, we are following preschoolers (age<6 years) who meet criteria for bipolar disorder to systematically evaluate the longitudinal course of this disorder in this age group.

Children at High Risk for Bipolar Disorder

We will add descriptions of this.

Neuropsychology and Neuroimaging of Pediatric Psychopathology

Magnetic Resonance Imaging of BPD+ADHD Adults

We will add descriptions of this.

MR Spectroscopy of BPD children before and after treatment with RISPERDAL

Analyses of Archival Data Sets

Data Sets Available Through MGH

Clinic Data

For the past decade we have systematically collected data on consecutive admissions to our pediatric psychopharmacology clinic. As a result, we have extensive clinical data (e.g., structured interviews, rating scales, psychometric tests) on more than 2000 patients not selected for a specific disorder. We also have the capability of completing systematic chart reviews using the methodology developed by Biederman et al. (Biederman et al., 1998a; Biederman et al., 1999). Ongoing analyses of these data are as follows:

- Clinical Features of Pediatric BPD
- Gender and Psychiatric Comorbidity in Adult ADHD
- Clinical Features of Children with Psychosis

Longitudinal Family Study of ADHD

Over the past twenty years, Drs. Biederman and Faraone have, with funding from NIMH, been following families of 140 ADHD boys, 140 ADHD girls and more than 200 gender and age matched control families from childhood to adulthood. Baseline and follow-up studies (which have also included family members) have provided a wealth of data about the course, outcome, clinical correlates and familial aggregation of ADHD. These data sets have allowed for the following analyses:

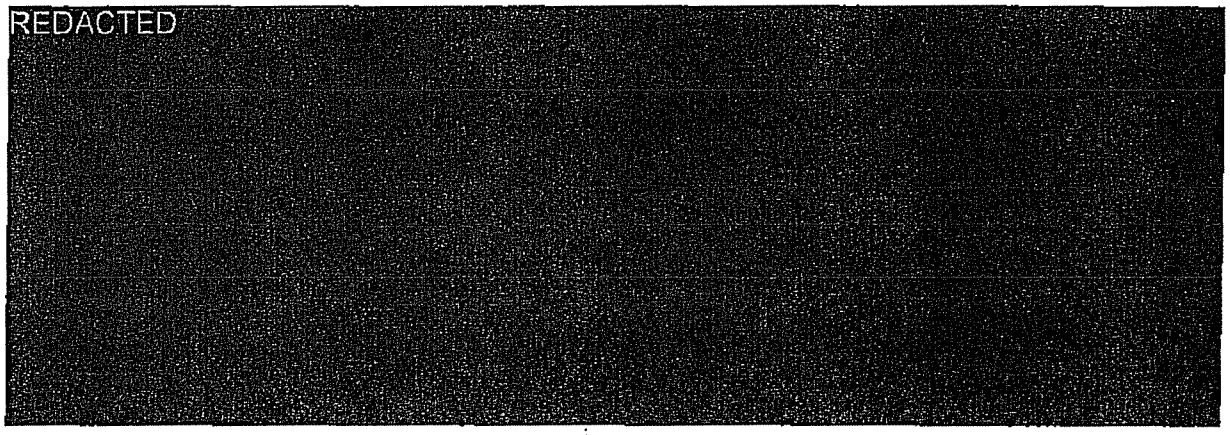
- Comorbid Anxiety Disorders Among Children with BPD
- Exposure to Parental Bipolar Disorder as a Risk Factor.
- Follow-up Study of ADHD children with BPD

Data Sets Available Through J&J

Double-Blind Trial of RISPERDAL in Children with Conduct Disorder and Mental Retardation

This data set contains the results of Janssen's clinical trial of RISPERDAL for conduct disorder and mental retardation. It also includes outcome ratings on a wide variety of symptoms, which makes it useful for assessing the efficacy of RISPERDAL for other conditions in this population and for assessing psychometric features of the measures. Analyses completed to date are:

- Efficacy of RISPERDAL for manic symptoms
- Replication of Factor Analysis of BPD Symptoms



Other Data Sets

Bipolar Genetic Linkage Data.

We have access to the NIMH bipolar disorder genetic linkage data set, which is a public resource available through the NIMH Genetics Initiative Program. We are using this data set for the following:

- Linkage analysis of the age at onset of manic symptoms

- Factor analysis of manic symptoms
- Published Data

We have found meta-analysis to be very useful for clarifying issues in pediatric psychopathology. We have already applied this methodology to studying the DRD4 gene in ADHD (Faraone et al., 2001), the efficacy of ADHD medications (Faraone and Biederman, 2002; Faraone et al., 2002) and to studying the effects of stimulant medications on substance abuse in ADHD (Wilens et al., in press). We are currently using meta-analysis of published data as follows:

- Meta-analysis of multiple studies using CBCL to validate profiles
- Meta-analysis of the DAT gene in ADHD (through collaboration with the ADHD Genetics Network, S. Faraone (PI)).
- Meta-analysis of the DRD5 gene in ADHD (through collaboration with the ADHD Genetics Network, S. Faraone (PI)).

Support of Junior Faculty to Develop Expertise in Pediatric Psychopathology Research

Perhaps the most enduring impact of our Center will be the work of trainees and junior investigators whom we have attracted to the study of pediatric psychopathology. By doing so, we will create a new generation of investigators committed to studying the causes of and treatments for childhood psychopathology.

Table 3 describes the young investigators supported by our research program. The table shows that we have been creating a team of new investigators who have a wide range of expertise including psychopharmacology, psychosocial treatment, substance abuse, neuroimaging and pharmacology. Although each of these new investigators has a specific expertise, our approach to training requires that they study pediatric bipolar disorder within the broader context of childhood psychopathology. For example, we have not set up a bipolar disorder specialty clinic. Instead, clinicians are taught to diagnose bipolar disorder and all comorbid psychopathology. This makes it easier to recognize comorbidity and to devise research protocols aimed at understanding its causes or devising methods for its treatment.

Table 3: Young Investigators Being Trained in the MGH Pediatric Psychopharmacology Research Program

Investigator	Speciality	Projects
Janet Wozniak, MD	Pediatric BPD	Clinical trials and longitudinal family study of BPD.
Ross Greene, PhD	Psychosocial Treatment	Clinical Trials of Psychosocial Therapies for Children with Bipolar Disorder.
Louise Cohen, PharmD	Pharmacokinetics	Developmental Pharmacokinetics of Psychotropic Drugs
Dina Hirshfeld, PhD	Anxiety Disorders	Temperament as a Risk Factor for Psychopathology
REDACTED		
Eric Mick, ScD	Methodology	Methods Development and Applications
Aude Henin, Ph.D.	Children at Risk	Children at Risk for Bipolar Disorder
Alysa Doyle, Ph.D.	Neuropsychology	Cognition and Genetics of ADHD
Dan Geller, MD	Obsessive Compulsive Disorder	Treatment and Epidemiologic Studies of OCD
Eve Valera, Ph.D	Neuroimaging	Structural and Functional MRI of ADHD

Our training program also encourages cross-fertilization among disciplines, a process that is facilitated by the fact that the Center Director, Dr. Biederman, is a psychiatrist, his Co-Director, Dr. Faraone, is a psychologist and the Scientific Coordinator, Dr. Mick, is an epidemiologist. On a practical, training level, cross-fertilization means that junior investigators must learn about

concepts and methods outside their main area of inquiry. Moreover, they must incorporate these into their research protocols.

Communication With J&J Staff to Facilitate Collaborative Efforts
We will add descriptions of this.

Initiation of Yearly Meetings of Experts in Bipolar Disorder

To address the controversy about pediatric bipolar disorder, we initiated a multi-year conference series which seeks to establish a forum for researchers and clinicians to improve dialogue and foster collaborative studies about children who present with extreme temper tantrums and dysregulated mood. Preceding roundtables on pediatric bipolar disorder had stressed the pressing need to advance the scientific knowledge of this severe mental disorder and had recognized the paralyzing effects of the ongoing controversy surrounding pediatric bipolar disorder and bipolar spectrum disorders. This controversy led to a vicious circle of diagnostic skepticism, void of scientific information, and therapeutic nihilism with its detrimental impact on patients and their families.

Fostering dialogue among scientists and clinicians is a key step to better defining the clinical and scientific questions and fostering necessary collaborative research critical to building a scientific foundation for the understanding and treatment of pediatric bipolar disorder. When collaborations are considered, they frequently face hurdles that cannot be easily surmounted. For example, clinical traditions at different centers often clash regarding diagnostic conceptualizations as well as over which clinical and research strategies are best suited to answering important research questions. Thus, the main goal of the conference series on pediatric bipolar disorder is to build consensus through a network of clinicians and investigators who are studying or are planning to study pediatric bipolar disorder. Sub-goals of these conferences are:

- To define the boundaries of the bipolar spectrum phenotype and determine if children who technically meet criteria for bipolar disorder actually have this disorder or are affected with another condition.
- To standardize data collection methods across different centers to facilitate pooling of diagnostic data.
- To facilitate joint submissions of large collaborative projects that will enable the study of a broad spectrum of scientific questions including genetic, imaging and therapeutic protocols.
- To create a mechanism for pooling samples so that potential findings from one group may be cross-validated on pooled data from remaining groups

The first meeting was held in March, 2002, through an unrestricted educational grant by Janssen Pharmaceuticals. The proceedings of the first meeting will be published in Biological Psychiatry (See www.mgh.harvard.edu/depts/pediatricpsych/bipolar_2002.htm to view the slide presentations). A list of the presentations follows:

- Phenotypes of Inpatient Children with Mania: Gabrielle Carlson, MD
- Convergence between Structured Interviews and Clinician Assessments of BPD: Janet Wozniak, M.D.
- High Risk Studies of Children at Risk for BPD: Kiki Chang, PhD.
- Dysphoric Conduct Disorder: The overlap between conduct disorder and BPD: Joseph Biederman, MD
- Proposed Cross Natural Study of Diagnosis of Pediatric Mania: Richard Harrington, MD

- Genetics of Pediatric Bipolar Disorder and Its Comorbidities: Steven Faraone, Ph.D.
- Magnetic Resonance Imaging Studies of Pediatric BPD: Jean Frazier, MD
- Combination Pharmacotherapy in Children and Adolescents with Bipolar Disorders: Robert Kovatch, MD
- Temperament and Mood DisordersóBehavioral Disinhibition: Dina Hirshfeld-Becker, Ph.D.
- Parent Advocacy Perspective: Martha Hellander
- Multifamily Psychoeducation Groups for Pediatric Bipolar Disorder: Mary Fristad, MD
- Defining Clinical Phenotypes of Juvenile Bipolar Disorder: Ellen Leibenluft, MD
- Systematic Treatment Enhancement Program for Bipolar Disorder (STEP-BD): Andrew Nierenberg, MD
- Children and Adolescents with Bipolar Disorder: Methodological Issues: Boris Birmaher, MD
- Methodological Issues in Pediatric BPD: Eric Mick, Sc.D.
- Retrospective, unblinded chart review of pediatric BPD. Luis Rohde, MD
- BPD Among ADHD Children. Philip Hazell, MD

Plans for the Future

Table 4 presents our original timeline for research at the J&J Center for Psychopathology Research at MGH.

Table 4: Project Timeline for the J&J Center for Psychopathology Research at MGH						
	Yr 0	Yr 1	Yr 2	Yr 3	Yr 4	Yr 5
Treatment Research						
Efficacy of RISPERDAL for Pediatric BPD	X	XP	XP			
Pediatric BPD RISPERDAL PK Study		XP	XP			
Meridia for weight gain in Risp treated patients		XP	XP			
REDACTED						
PK study of stimulants and RISPERDAL		XP	XP			
Efficacy of adding Wellbutrin or Paxil for depression to RISPERDAL treated BPD patients		XP	XP			
PK study of Wellbutrin/Paxil and RISPERDAL		XP	XP			
Cabergolinefor hyperprolactinemia in Risp treated patients		XP	XP			
Efficacy of galantamine for executive dysfunction in BPD			XP	XP		
Efficacy of RISPERDAL for BPD in PDD Children				XP	XP	
Efficacy of RISPERDAL for BPD in OCD Children				XP	XP	
Efficacy of Multimodal treatment of BPD using risperdone and cognitive behavior therapy				XX	XP	XP
Long term follow-up of Efficacy Studies to assess psychosocial outcome, cognitive outcome, symptomatic outcomes and substance use outcomes				XP	XP	XP
Etiologic Research						
Structural MRI of BPD adults with and without ADHD		XX	XP			
Structural MRI of BPD children with and without ADHD	XX			XX	XP	
Pharmacogenetic studies of BPD trials	XX	XX	XP	XP	XP	
Velo-Cardio Facial Syndrome and BPD			XX	XP		
Candidate gene studies of Pediatric BPD			XX	XP	XP	XP
Longitudinal Research						
Validation of affective-type conduct disorder with family study	XX	XX	XX	XP	XP	XP
Follow-up of BPD Children		XX	XX	XP	XP	XP
Follow-up of children at risk for BPD		XX	XX	XP	XP	XP
Analysis of Existing Data						
Efficacy of RISPERDAL for affective-type conduct disorder in Janssen clinical trial	XP	XP				
Use MGH follow-up and family study data to define and validate antisocial and non-antisocial subtypes of BPD	XP	XP				
Use MGH follow-up data to define risk factors and developmental trajectories of BPD			XP			
Use MGH follow-up and family study data to define CBCL screening rules for pediatricians			XP			
Use MGH follow-up and family study data to define executive dysfunction measure for galantamine study		XP				
Educational Initiatives						
Yearly Pediatric BPD Conference	X	X	X	X	X	X
Development of BPD CME Program	X	XX				
Implementation of BPD CME Program	X		XX	XX	XX	XX
BPD Programs at national and international professional meetings: NCDEU, AACAP, Biological Psychiatry, ACNP, APA, AAP, ECNP, CINP, WPA		XX	XX	XX	XX	XX

Appendix A: Biographical Sketches of MGH Investigators

APPENDIX B: Presentations at National and International Meetings in 2002 By MGH Pediatric Psychopharmacology Research Program

APPENDIX C: Preparation of Manuscripts for Publication in 2002 By MGH Pediatric Psychopharmacology Research Program

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Extramural Research Grant Agreement

December 12, 2002

Joseph Biederman, MD
Massachusetts General Hospital
Pediatric Psychopharmacology Research
Warren 705
55 Fruit Street
Boston, MA 02114

Re: **RIS-USA-T331** – Proton Magnetic Resonance Spectroscopy in Manic Children and Adolescents

Dear Dr. Biederman:

Janssen Pharmaceutica Products, L.P has approved an extramural research grant with the Massachusetts General Hospital in the amount of $181,500.00 for your proposal entitled "Proton Magnetic Resonance Spectroscopy in Manic Children and Adolescents" (hereinafter the "Study"). In conducting the Study, you will be acting as the Principal Investigator. Please review the following and if agreeable to you, please have both copies signed by an authorized representative of the Institution and sign both letters as Principal Investigator, retain one copy for your files and return the other to Robert Jones, Assistant Director, EmRP, Janssen Pharmaceutica Products, L.P.

The term of this letter Agreement shall begin on the date that this letter agreement is fully executed by all parties and shall extend through completion of the study unless earlier terminated as provided for herein.

1. Parties to this Agreement will be Janssen Pharmaceutica Products, L.P. (hereafter "Janssen") and Massachusetts General Hospital (hereafter "Institution").

2. All proprietary information received from Janssen in writing or orally conveyed will be deemed confidential and proprietary of Janssen. Information developed from the Study, except known previously by you, Institution or the public, shall be considered confidential as provided in this Agreement and is the joint property of Institution and Janssen. When you or Institution wish to publish the scientific data developed from the Study, a manuscript or poster will be provided to Janssen thirty (30) days prior to submission for publication and abstracts will be provided two weeks prior to submission for review. If Janssen believes that the proposed publication contains information relating to patentable items, the disclosure of such proposed publication shall be delayed for an additional sixty (60) days to allow for filing patent applications.

3. Janssen retains the rights to any patentable discoveries made in the performance of this Study. You and Institution agree to cooperate with Janssen in the preparation and filing of any patent applications relating to such discoveries and execute any assignment documents and other documents relating to the filing and prosecuting of any such patent applications. Janssen shall have the unrestricted right to use any results, reports or information generated hereunder.

4. You agree to update Janssen on the Study status on a monthly basis.

5. Janssen reserves the right forthwith to discontinue our support for this Study at any time. Upon termination, Janssen shall be obligated to pay Institution only for work performed to date and cost of materials for which Institution has become obligated. (e.g. IRB fee) in connection with the contemplated services up to the date of such discontinuance.

   Institution reserves the right to terminate the study at any time. Institution shall be obligated to refund Janssen for any monies owed due to early termination.

6. You expect to enroll 20 valid subjects and complete this study in one year from the effective date of the Agreement.

7. You and Institution agree that neither Janssen, nor any of its subsidiaries or affiliates, their respective officers, directors, or employees will bear any responsibility or liability for claims, losses, injuries, or other damages arising out of your project, research, and/or meetings, discussions or publications regarding same, and that you and Institution will hold Janssen and its respective subsidiaries and affiliates, and their respective officers, directors and employees harmless from such liability, except to the extent any liability arises from an act or omission of Janssen in the manufacture of Risperdal which has been provided to you in connection with this Study, if any. In addition, you and Institution will be entirely responsible for all regulatory and other obligations arising in connection with the proposed research described above, your project, and this grant.

8. The Institution's and your signatures below also indicate that Institution and you understand that our giving of this independent grant was not conditioned in any way on any pre-existing or future business relationships between or among any or all of us, nor was it conditioned on any business or other decisions you have made or may make in the future relating to Janssen.

9. You agree to the following payment schedule:

Milestone	Anticipated Delivery Date	Payment ($)
Receipt by Janssen of fully-executed contract	December 15, 2002	25,000.00
Enrollment of first 10 subjects	February 15, 2003	25,125.00
Enrollment of second 10 subjects	April 1, 2003	25,125.00
Completion of data collection/analysis	August 1, 2003	35,416.66
Receipt by Janssen of abstract/poster suitable for presentation	September 15, 2004	35,416.67
Receipt by Janssen of study report/manuscript	December 15, 2003	35,416.67
Total		$181,500.00

Failure to meet timelines may result in termination of this Agreement.

10. Payment will be directed as follows:

Payee: General Hospital Corporation
Attention: Diane Spiliotis Research Management
Address: 50 Staniford Street
Suite 1001
Boston, MA 02114
Tax ID #: 04-2697983

On behalf of Janssen Pharmaceutica Products, L.P., thank you for your interest in studying Risperdal. We look forward to seeing the results of this interesting study. If you have any questions, please call Randall L. Morrison, PhD, Director, EmRP, CNS, Medical Affairs at 609.730.3334.

Janssen's commitment to fund this proposal is valid for 30 days from the date of Janssen signature below.

Sincerely,

Christine Côté, M.D.
Vice President, Medical Affairs
Janssen Pharmaceutica Products, L.P.
Janssen Pharaceutica Inc.

_____
Date

General Partner

I ACKNOWLEDGE AND AGREE TO THE TERMS SET FORTH IN THIS AGREEMENT

INSTITUTION OFFICIAL

_____ _____

Name Date
Title

_____ _____

Joseph Biederman, MD Date

Key points from 2003 Child & Adolescent Business Planning Session 2 –6/12/02

Sales & Marketing

Current Projects:

- Findling et al : Teletooics
- Riddle, Armenteros, Findling: 7/21/02 National Live Satellite Conference with audio cassettes going to 5,000 physicians
- 6 Institutional Centers of Excellence around the US to be attended by 25-50 invited pediatric psychiatrists; a one-day professional preceptorship with case studies; monograph to follow. RBD's will submit invite lists.
- Leasers include Peter Jensen, James McCracken, Robert Findling, Jorge Armenteros, Graham Emsley. Larry Scahill.
- Direct mail CME poster book
- Textbook/Handbook, "Growing Up Whole" by Riddle, Labalarte: Hand out at AACAP?
- International Bipolar Conference Monograph by Joseph Biederman

KEY: Need to train KOL's to handle the media; need a proactive media plan

- J&J Center for the Study of Pediatric Psychopathology –joint effort by Janssen, OMP, and McNeil Consumer –in Boston with Joe Biederman
- International Pediatric Bipolar Conference in Boston: will produce 2 articles for AJ Psychiatry and for Am J of Child & Adolescent Psychiatry
- NYC Schizophrenia Prodrome Workshop held last April with Pat McGorry

KEY: Need consensus guidelines for appropriate use of psychotropic drugs in children including ADHD consensus guidelines with OMP

KEY: Need allied professional and lay education via advocacy groups

KEY: Need data generation and dissemination including post hoc analyses of currently available data

KEY: Need to poll KOL's for a specific needs analysis

New Initiative!
J&J Pediatric Research Center at Mass General Hospital

Gahan J. Pandina, Ph.D.

Pharmacologic Treatment of Children & Adolescents

- Pharmacologic treatment of child & adolescent psychiatric disorders is widespread
- Most use is off-label with limited data to guide treatment
- Recent legislation from FDA has resulted in increased research in this area
- Future legislation becoming more specific in the need to obtain data children & adolescents where product use is expected
- Strong need for expert collaboration to inform pediatric initiatives

Risperidone Treatment in Children & Adolescents

- RIS is widely used to treat psychiatric disorders in children & adolescents
  - Children & adolescents ~ 21% of RIS market
- Behavioral disorders, affective disorders, & autism are primary disorders treated with RIS
- Limited scientific data is available in diagnosis & treatment of affective disorders
  - *especially* bipolar disorder
- Treatment with RIS in this population continues despite lack of well-controlled clinical research
- Limited available data results in potential for medical mis-use

J&J Pediatric Research Ctr. At MGH Background *(continued)*

- Dr. Joseph Biederman is recognized as a global expert in the diagnosis & treatment of Bipolar Disorder and ADHD
- Dr. Biederman has a large research team, with multiple collaborations at MGH, McClean Hospital, & Harvard University
- This group was identified as one of the most important international scientific research centers by JPI
- Other J&J companies have conducted pilot research at MGH, with no coordinated effort to date

J&J Pediatric Research Ctr. at MGH Background *(continued)*

- With marketing, held initial discussions with MGH to discuss collaboration re: specific extramural research with risperidone
- Discussed the concept of a J&J center at MGH, reviewing specific scientific questions related to key business areas
- Discussed partnerships with J&J sister companies (OMP, McNeil) to coordinate support of MGH collaboration
- Designed a model methodology for collaboration, with specific scientific deliverables and timelines for delivery

J&J Pediatric Research Ctr. at MGH Goals

- Support a broader range of scientific activities than would be possible from JPI alone
- Utilize state-of-the-art scientific methodology (e.g., neuroimaging, genetics) and link to diagnosis and treatment
- Reinforce J&J image as a CNS company with strong scientific commitment
- Provide a model for J&J sister-company partnerships with key opinion leaders
- Ensure timely delivery of scientific outputs
- Coordinate data and messaging related to compounds from sister companies

J&J Pediatric Research Ctr. at MGH
Sample of Deliverables

Put timeline of deliverables from Steve Faraone about here

Company Partners & Key Contributors

- **Janssen key contributors**
  - **Kent Bockes**
  - **Georges Gharabawi**
- **McNeil Consumer**
  - **Diana Bacci**
  - **Tom West**
  - **Mary Joan Denisco**
  - **Peter Bell**
  - **Patrick E. Ciccone**
- **ORTHO-McNeil Pharmaceutical**
  - **Paul Short**
  - **Joe Lofft**
  - **Ceceila Mavica Ingraham**
  - **Dan Van Kammen**

From: Berry, Sally [PRDUS]
Sent: Wednesday, July 16, 2003 6:58 PM
To: Reyes-Harde, Magali [JANUS]
Subject: RE: MGH

We really need sites. Your contacts for site recommendations are Diane Hoffman and Nicole Cavallero.
Regards,
S

-----Original Message-----
From: Reyes-Harde, Magali [JANUS]
Sent: Wednesday, July 16, 2003 2:04 PM
To: Berry, Sally [PRDUS]
Subject: RE: MGH

Thanks Sally - I'm hoping to use all of these relationships for OUR good now too. I also met with Dr. Gonzalex-Heinrich in Boston from the Children's Hospital. He has MANY bipolar children in his practice and works with Dr. Biederman closely. This could be a potential site for our trials.

Magali

-----Original Message-----
From: Berry, Sally [PRDUS]
Sent: Wednesday, July 16, 2003 1:30 PM
To: Reyes-Harde, Magali [JANUS]; Pandina, Gahan [JANUS]
Subject: RE: MGH

Magali and Gahan,

I just wanted to thank both of you for this as well. I remember when our relationship with MGH was strained at best. It seems that most of our business boils down to relationships and you two are experts at developing relationships. (For this, I hope you give some credit to your parents.)

The other piece is the ability to digest detailed scientific data, a task that many of our colleagues are not prepared to do and many others do not expend the necessary energy, preparation and dedication to do so. Like Karren, I too am proud to be associated with you.
Kind regards,
Sally

Sally A. Berry, MD, PhD
Global Medical Leader, Risperdal
J&JPRD
1125 Trenton-Harbourton Road
Titusville, NJ 08560-0200
609-730-3374 phone
609-730-4417 fax
609-865-6816 cell
sberry@prdus.jnj.com
Office: E12508

-----Original Message-----
From: Reyes-Harde, Magali [JANUS]
Sent: Wednesday, July 16, 2003 1:14 PM
To: Jacoppi, John [JANUS]; Berry, Sally [PRDUS]
Subject: FW: MGH

Dear John and Sally,

Thought you both might want to see this. These are important relationships for both PRD and JPI.

Magali

-----Original Message-----
From: Williams, Karren [JANUS]
Sent: Tuesday, July 15, 2003 10:02 PM
To: Pandina, Gahan [JANUS]; Reyes-Harde, Magali [JANUS]
Cc: Wojtowicz, Jeffrey [JANUS]; Gharabawi, Georges [JANUS]; Kalmeijer, Ronald [JANUS]
Subject: MGH

Gahan and Magali,

I wanted to again tell you both how very appreciative I am of your coming up to MGH today to meet with the neuroendocrine group at MGH and also with Jerry Rosenbaum. I received emails from both Anne Klibanski tonight and Jerry Rosenbaum telling me that during conversations both had (Jerry and Anne) following our meeting, they were very impressed with our/Janssen's committment to MGH and to our work within our scientific team-but mostly with both of your professionalism and obvious solid science background and grasp of the data that was presented. Being a relatively new MSL, working with people of both of your caliber has made my job easy. Quite frankly, I am proud to be associated with both of you.

I look forward to future collaborations,

Karren

Karren R. Williams, Ph. D
Manager, CNS-Medical Science Liaison
Boston Region

11 South Angell Street
Providence, RI 02906

Office: 401-277-9677
Fax: 401-277-9676
Cell: 401-487-5273
Voice Mail: 888-870-6200 X6726

RISPERDAL®

Child and Adolescent Market Segment

2003 Business Plan Summary

Table of Contents

RISPERDAL – Child and Adolescent

Appendices

RISPERDAL®
2002 Business Plan Summary
Child & Adolescent

I. INTRODUCTION:

The child and adolescent market continues to represent an area of great scientific interest and opportunity for RISPERDAL (risperidone). The mental health needs of children and their families in the United States are well documented. The U.S. Surgeon General estimates that 1 in 10 children in this country suffer from a serious mental health problem. However, less than a third of these children receive any care – and even less receives appropriate care. Despite this, the use of pharmacological therapies in the treatment of children and adolescents with mental illness has grown dramatically over the last decade. This is particularly true for atypical antipsychotics, as total prescriptions for this class have grown at an annual rate of 20% over the past 5 years. RISPERDAL is the most prescribed of the atypical antipsychotics; however, as is the case with the other atypicals, RISPERDAL is not currently indicated for use in children or adolescents. This business plan will focus on continued market understanding, medical education efforts, the drug commercialization efforts necessary to capitalize on the market opportunities for the brand in the child and adolescent segment.

The clinical development program for RISPERDAL has yielded important new efficacy and safety data in the child and adolescent area. These efforts have previously been focused in the area of Disruptive Behavior Disorders and Subaverage IQ. Several trials, RIS–USA–93 and RIS–CAN– 19 (as well as the open label, 48 week follow up trials, USA-97 and CAN-20), initially designed to support filing for an FDA indication, have been completed and have yielded an impressive volume of new efficacy and safety data. Unfortunately, the FDA determined that Disruptive Behavior Disorder lacks the diagnostic specificity necessary to receive an approved indication. Nevertheless, these studies have contributed significantly to the clinical knowledge of RISPERDAL in the child and adolescent population, and provide a basis for ongoing medical education activities. Going forward, regulatory and clinical development efforts will include the evaluation of the NIMH RUPP Risperidone in Autism database to support filing for potential autism indication, adolescent schizophrenia indication, and the fulfillment of the FDA Written Request requirement for additional 6 month patent exclusivity. It is expected that the request will include the following requirements:

- Pediatric PK trial;
- Adolescent schizophrenia trial; and
- Pediatric bipolar trial.

The child and adolescent market offers several unique challenges not found in other areas where RISPERDAL is used. First and foremost, the sensitivity towards medications and their use in children shapes this segment. This issue is prominent in medical as well as lay press and public discussions regarding pediatric psychopharmacology. This results in many stereotypes and stigmas that prevent some children from receiving appropriate treatment. Additionally, the child and adolescent market is not driven by diagnosis, but rather by treatment of symptoms such as aggression, agitation, self – injurious behavior, and explosive rage. This lack of consistent diagnosis stems from a reluctance to "label" children at an early age, as well as a fundamental lack of consensus regarding the actual underlying disease states causing this symptomatic behavior. As a result, multiple diagnoses and comorbidities are the rule, rather than the exception in this area. These issues have influenced the clinical development process and limited the ability to achieve an FDA approved indication for RISPERDAL in children.

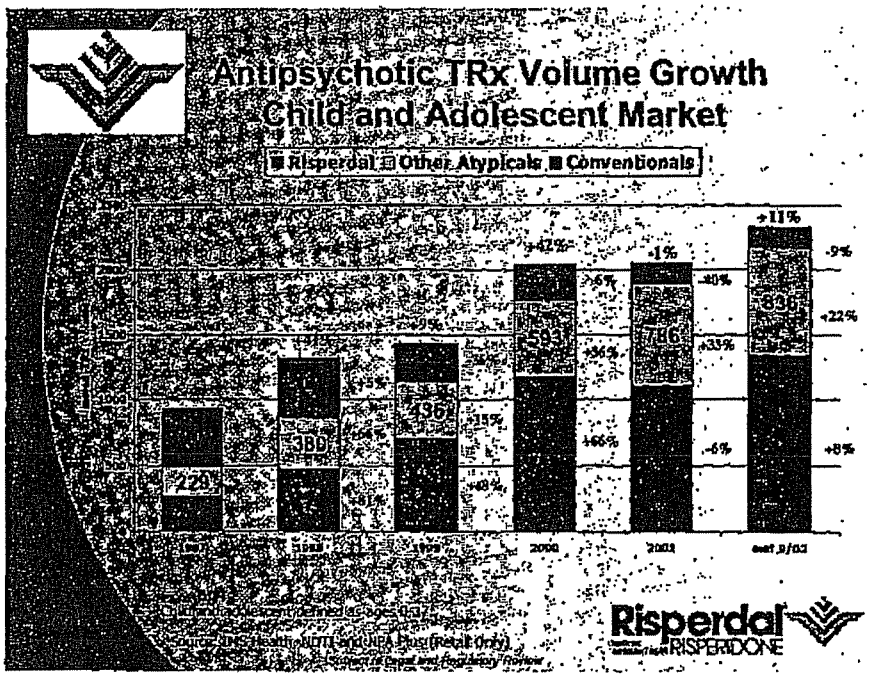
Johnson & Johnson has a unique opportunity in the child and adolescent psychopharmacology marketplace due to its product offerings across multiple operating companies. In addition to RISPERDAL, TOPAMAX (topiramate) and CONCERTA (methylphenidate HCl) are all used with this patient population. In addition to this product offering, Johnson & Johnson can also draw upon the expertise of the Johnson & Johnson Pediatric Institute to assess this complex marketplace.

II. SITUATION DIAGNOSTIC/ANALYSIS

Market Overview:

The U.S. Child and Adolescent antipsychotic market (defined as patients ≤ 17 years of age; in previous years, this has been defined as ≤ 19 years of age) is valued at over $400 million (IMS Health & NDTI). In terms of total prescriptions, this market has been growing steadily over the past several years, with the exception of 2001, where the market actually declined by 1%. Possible explanations for this decline include: 1) negative publicity directed at pediatric psychopharmacology, leading to reluctance on the part of some physicians to prescribe antipsychotics for children, and 2) education regarding appropriate use of these drugs that resulted in a decrease in the average dose of antipsychotic used (see Figure 1). In 2002 YTD, growth in the child and adolescent antipsychotic market has returned at a robust rate of 11%. This market represents approximately 18% of all RISPERDAL drug uses in the U.S., twice that of the 9% of uses reported for antipsychotics as a class.

Figure 1:



The bulk of RISPERDAL use in the child and adolescent market is for mood and anxiety related diagnoses (keeping in mind the limitation previously mentioned regarding diagnosis vs. symptomatic treatment). Bipolar Disorder with 18% of uses leads the way in this area followed by Depression with 10% and Anxiety with 3% (see Figure 2). This represents an overall mood and anxiety use of 31% of the total atypical drug use for children. ADHD/Conduct Disorder makes up the next largest market segment with 20% of total drug uses, followed by schizophrenia/psychosis at 15%, and autism at 14%. These usage patterns are consistent with those for all atypical antipsychotics in aggregate. However, it is challenging to interpret these data diagnostically, as children may have comorbid conditions that are not fully reflected in the NDTI audit.

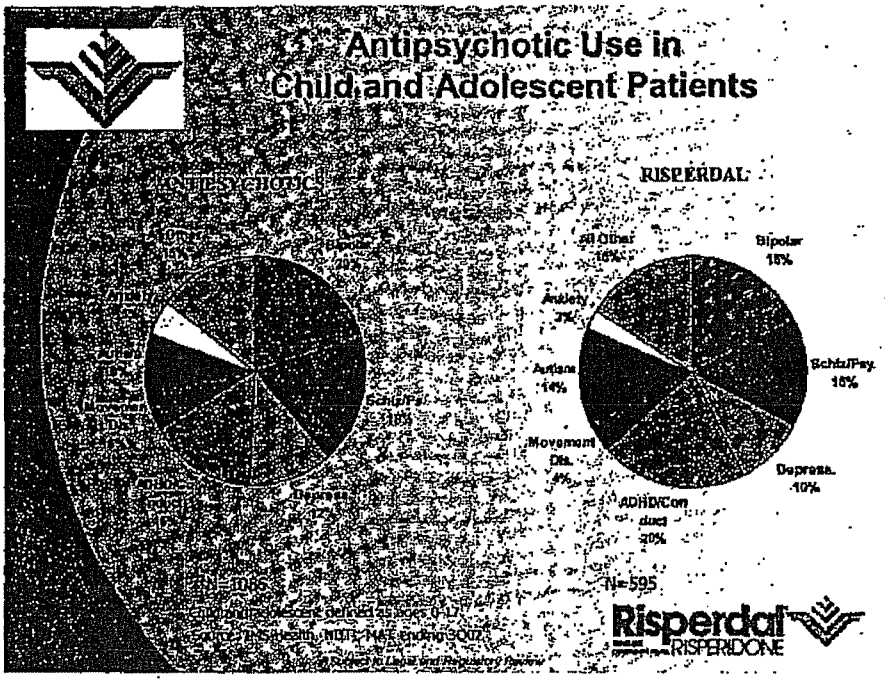


Figure 2:

Within the child and adolescent market, it is useful to look at the breakdown of drug use by age group. RISPERDAL drug use occurs 36% of the time in the 13-17 age group (adolescent), 45% of the time in the 7-12 age group (child), and approximately 19% of the time in the ≤ 6 age group. The use in younger children is primarily limited to autism spectrum and disruptive behavior disorders, or to the treatment of focused symptoms of aggression, which are more easily diagnosed at an earlier age than other major psychiatric illnesses such as schizophrenia or bipolar disorder.

Competitive Overview:

RISPERDAL remains the most widely prescribed antipsychotic in the child and adolescent market segment (55% market share – see Figure 3). However, there is growing competition from the other atypical antipsychotics. Following is an overview of major competitors:

Product/ Company	% Share* 2002 YTD	Strengths (+) Weaknesses (-)
Zyprexa (olanzapine) Eli Lilly	15%	+ Experience in adult market in schizophrenia and acute mania - Limited clinical data in children and adolescents - High weight gain relative to other compounds in the class; metabolic disregulation
Seroquel (quetiapine) AstraZeneca	16%	+ Relatively benign side effect profile + Sedative properties perceived as advantageous - Limited of clinical data in children and adolescents - Inconsistent efficacy and dosing variability
Geodon (ziprasidone) Pfizer	9%	+ Relatively benign side effect profile, including perceived low weight gain - Limited of clinical data in children and adolescents - Spillover of QTc prolongation concerns

* Share of total antipsychotic market, including conventionals

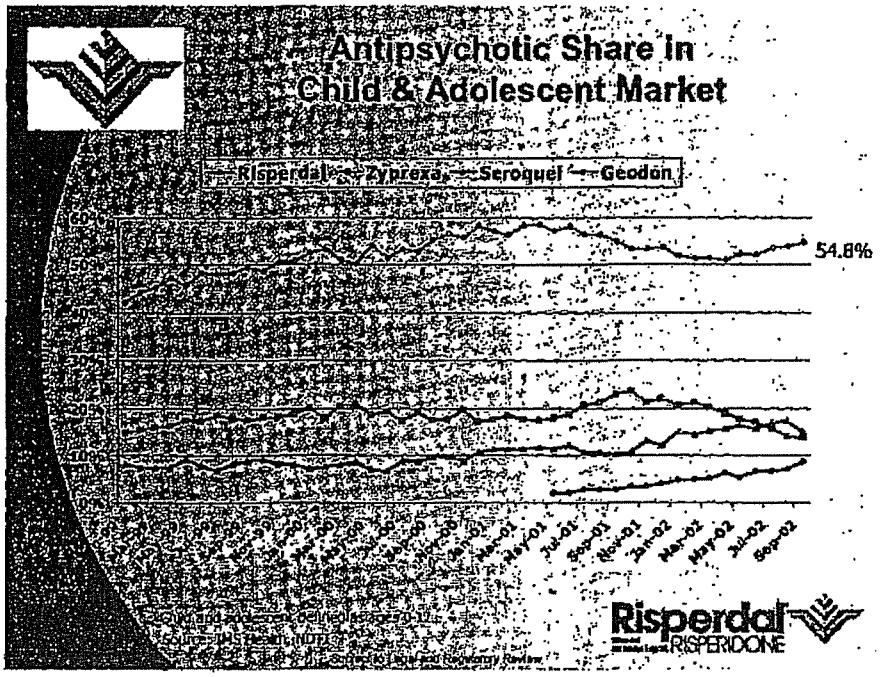


Figure 3:

All competitive products in this market have clinical development programs underway. Competitive intelligence in this segment indicates that Bipolar Disorder (specifically Pediatric Mania) is a major area of focus of all competitors. However, no competitor is likely to gain FDA approval in this market segment prior to late 2004. Barring an unforeseen setback, Seroquel will most likely be the first competitor to gain this indication. It is also important to note that Abilify (aripiprazole) will be launched very shortly. Given the expected positioning of this new product (comparable efficacy, better safety profile, unique mechanism of action), it is anticipated that Abilify will make early inroads into the child and adolescent market.

Customer Segment Overview:

Psychiatrists account for almost 70% of all RISPERDAL prescriptions, followed by pediatricians at 18%, neurologists at 10%, and primary care physicians at 3%. It is notable that pediatricians and neurologists are accounting for an increasing share of prescriptions for RISPERDAL. Psychiatrists are responsible for managing the majority of patients as well as the more difficult to treat illnesses such as psychosis and mood disorders. In general, pediatricians and primary care physicians are more likely to follow patients already diagnosed and treated. The exception to this is in geographic areas where these primary care physicians have become the de facto child psychiatrist for the area. This is fairly common due to the overall shortage of child psychiatrists in the United States. There are an estimated 6500 child psychiatrists practicing in the U.S. The American Academy of Child and Adolescent Psychiatry (AACAP) estimates that at least 20,000 child psychiatrists are needed to provide adequate care to all children in need of mental health treatment.

Parents and teachers also play a very important role in this market. Parents of children with illnesses such as autism and bipolar disorder are often strong advocates of clinical trials and drug therapy, and are active members of advocacy groups such as National Association of Mental Illness (NAMI), National Mental Health Association (NMHA), Child and Adolescent Bipolar Foundation (CABF), and Cure Autism Now (CAN). Teachers are often the first to see symptoms that necessitate treatment in these children. This information is typically shared with the parents when it becomes a "problem" for the teacher in the classroom environment. Social workers will occasionally play a similar role, especially with children in the criminal justice system.

III. 2002 PRODUCT PERFORMANCE SUMMARY

RISPERDAL did not have a 2002 forecast for the child and adolescent segment due to the lack of an FDA approved indication. However, qualitative goals were established for 2002, and are summarized below:

2002 Qualitative Objective	Results
❑ Remain the gold standard in the child and adolescent market by being recognized as the antipsychotic with the strongest clinical efficacy and safety data.	❑ 4 significant publications in 2002 (3 conduct disorder studies, and NIMH RUPP Autism Study in NEJM) ❑ New data postered at APA, AACAP ❑ Positive feedback from HOVS, Regional and National Advisory Board Meetings
❑ Ensure that clinicians recognize the appropriateness of antipsychotic therapy as part of the overall therapeutic approach to patient care	❑ Positive feedback from HOVS, Regional and National Advisory Board Meetings
❑ Work synergistically with J&J Pediatric Institute	❑ Ensured participation of members of J&J Pediatric Institute in C&A Core Team Meetings

Lessons Learned:

- Child and Adolescent market is large and growing
- Increasingly competitive market, and increased comfort with newer agents
- Prolactin, EPS, TD, and weight gain continue to be important issues (particularly long-term implications); safety is the driving factor in determining atypical drug use
- Competitors are driving negative safety and tolerability perceptions of RISPERDAL
- Advocacy seeking to define a public position regarding C&A use of antipsychotics
- A proactive approach to education and public relations are necessary to break down barriers and eliminate stigmas that exist in this area
- FDA approval is necessary in order to maximize educational efforts and initiate promotional opportunities
- Pediatricians and Neurologists are playing an increasingly important role in this market
- Pediatric bipolar is area of major focus of clinical study for scientific community and competitors

IV. SWOT ANALYSIS, KEY ISSUES

Strengths	Weaknesses
❑ APS market leader in this area ❑ Low dose availability; positive experiences ❑ Trust/experience with RISPERDAL ❑ Proven/strong efficacy; strong clinical data available ❑ Perceived side effect advantages relative to other APS ❑ Early onset of action ❑ Thought leader support	❑ Safety perceptions – Prolactin, EPS, TD, weight gain ❑ Lack of indication ❑ No ability to promote ❑ Limited clinical development program ongoing ❑ Lack of sedation relative to other APS ❑ Lack of awareness of appropriate dosing

Opportunities	Threats
❑ Poor perception/experience with other APS (Zyprexa – metabolic issues) ❑ External data sources (NIMH – RUPP) ❑ Clinical partnerships (Mass General) ❑ Potential J&J Pediatric synergies (MCC, OMP, Alza) ❑ Under-serviced/unsatisfied market ❑ Advocacy partnering for educational initiatives ❑ Better diagnosis (DSM-V, consensus guidelines – TRAAY) ❑ RISPERDAL ODT	❑ Negative public relations/media reporting – effect on patients, providers, and company ❑ Lack of consensus – no diagnostic specificity ❑ Migration to other classes of drugs ❑ Further delay of labeling/exclusivity ❑ Perceived legal liability by prescribers ❑ Emerging clinical data for Geodon, Seroquel, Zyprexa ❑ Increased focus of competition on C&A market (aripiprazole launch) ❑ Sensitivity regarding use of APS in C&A

KEY ISSUES:

- Use of psychotropic medications in children and adolescents remains controversial
- Limited education and awareness of appropriate use of APS
- Physician misperception of RISPERDAL safety profile, driven primarily by increasingly competitive market
- Lack of indication

V. 2003 STRATEGIC OBJECTIVES:

Quantitative:

There are no quantitative objectives for this segment due to the lack of indication for child and adolescent use.

Qualitative:

- Raise awareness regarding prevalence, economic and emotional burden of untreated C&A mental illness
- Develop educational platform to establish the role of APS in the treatment of C&A mental illness
- Establish RISPERDAL as having a favorable risk-benefit ratio relative to other compounds
- Partner with JJPRD and Pediatric Drug Development to facilitate development plans

VI. KEY BUSINESS STRATEGIES:

KEY BUSINESS STRATEGIES
❑ Partner with scientific community and patient/family advocacy organizations to raise awareness regarding prevalence, economic and emotional burden of untreated C&A mental illness.
❑ Educate health care providers on therapeutic options for treating mental illness in children.
❑ Educate health care providers on the safety profile of RISPERDAL.
❑ Clarify FDA requirements for pediatric exclusivity and support efforts to obtain child and adolescent labeling.

VII. KEY PROGRAMS AND TACTICS:

The overall tactical budget for the child and adolescent programs is $6.4 million. The breakdown of tactics by strategy and budget are listed below.

Strategy 1: Partner with scientific community and patient/family advocacy organizations to raise awareness regarding prevalence, economic and emotional burden of untreated C&A mental illness

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Public Relations	C&A Mental Health Media Briefing Ongoing Public Affairs activity	Ongoing Public Affairs activity	Ongoing Public Affairs activity	Ongoing Public Affairs activity
Other	Ongoing support for advocacy	Ongoing support for advocacy	Ongoing support for advocacy	Ongoing support for advocacy

Strategy 2: Educate health care providers on therapeutic options for treating mental illness in children

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Postered Data		CDMR data reanalysis	CDMR data reanalysis	
Publications	RIS-USA-97		RIS-INT-41	
Educational/CME	"Branded" Pediatric Educational Institute	Psychlink/Teletopics "Branded" Pediatric Educational Institute AAP Symposium C&A CME Conference	Psychlink/Teletopics "Branded" Pediatric Educational Institute AACAP Symposium	Psychlink/Teletopics "Branded" Pediatric Educational Institute
Advisory/Meetings	CNS Summit	National Ad Board HOV (2) Regional Ad Board (2)	HOV (2) Regional Ad Board	HOV (2)

Strategy 3: Educate health care providers on the safety profile of RISPERDAL

	1st Quarter	2nd Quarter	3rd Quarter	4th Quarter
Postered Data		CDMR data reanalysis	CDMR data reanalysis	
Publications	RIS-USA-97		RIS-INT-41	
Educational/CME	"Branded" Pediatric Educational Institute	Psychlink/Teletopics "Branded" Pediatric Educational Institute AAP Symposium C&A CME Conference	Psychlink/Teletopics "Branded" Pediatric Educational Institute AACAP Symposium	Psychlink/Teletopics "Branded" Pediatric Educational Institute
Advisory/Meetings	CNS Summit	National Ad Board HOV (2) Regional Ad Board (2)	HOV (2) Regional Ad Board	HOV (2)

Strategy 4: Clarify FDA requirements for pediatric exclusivity and support efforts to obtain child and adolescent labeling

- Explore potential indication for autism by utilizing NIMH RUPP Autism database
- Support fulfillment of FDA Written Request for pediatric exclusivity (schizophrenia, bipolar disorder, and PK studies)
- Support adolescent bipolar study as required by FDA Pediatric Rule

Tactical Highlights:

1. **Children's Mental Health and Media Summit**
   Description: One day meeting of key scientific opinion leaders, advocacy organizations, and medical/mass media. Case study of negative media reporting will be presented, followed by presentations from scientific opinion leaders and advocacy on impact of these reports on research, diagnosis, and treatment of children with mental illness.

   Cost: $0.4 million

   Measurement: Success of program will be assessed by routine monitoring of media, with specific focus on frequency of fair balanced media reports regarding childhood mental illness. Additionally, the decrease in the number of factually incorrect stories that are reported will also be an indication of program success.

2. **"Branded" Pediatric Educational Institute**
   Description: Multi-medium, comprehensive, branded educational campaign on the role of APS in the treatment of C&A mental health. To include Centers of Excellence, regional CME symposia, monographs, and newsletters. Opportunities to incorporate other products from other J&J operating companies will be identified (Concerta).

   Cost: $1.8 million

   Measurement: Success of program will be assessed via standardized CME metrics (program redemption, educational impact, satisfaction, etc.).

3. **National and Regional Advisory Boards, HOVs**
   Description: C&A Advisory Boards are designed to enhance understanding of key market dynamics, clinical issues related to efficacy, safety, and dosing, competitive activity, and data needs. In addition to the actual advisory boards a web-based communications platform will be developed to rapidly communicate with all advisors on an ongoing basis. There will be one National Advisory Board for Key Academic Thought Leaders, three Regional Advisory Boards for Regional Thought Leaders and six Home Office Advisory Boards for – separated by region due to differing regional issues.

   Cost: $2.1 million

   Measurement: Program success will be measured by the refinement of the clinical development plan, new extramural research ideas, and other educational and advocacy related initiatives.

Budget Summary:

Description	2002 PME ($K)	Proposed 2003 PME ($K)	2003 PME %
Medical Marketing/Education	**$3,890**	**$3,300**	**52%**
CME Branded Initiative		1,800	
PsychLink/Teletopics		450	
Symposia (2)		350	
Publications		500	
National Ad Board		200	
Advisory Boards (RAB/HOV)	**$1,800**	**$1,900**	**30%**
Public Relations	**$325**	**$500**	**8%**
C&A Summit		$400	
Other		$100	
Grants	**$160**	**$300**	**5%**
Other	**$225**	**$400**	**6%**
TOTAL C&A	**$6,400**	**$6,400**	**100%**

VIII. SUCCESS PREDICTORS:

The success of the child and adolescent program will depend on several factors:

- The extent to which new or reanalyzed data is generated and disseminated via educational and advisory venues;
- The ability to satisfy requirements for pediatric exclusivity, FDA pediatric rule; full assessment of NIMH RUPP database for potential autism indication; and
- The change in public dialogue and perception of psychopharmacology as an appropriate means of addressing severe childhood mental health problems.

Appendices

RISPERDAL Child & Adolescent
SUMMARY
1

	1999	2000	2001	YTD 2002
Market Size ($MM)	$178	$277	$344	$280*
% Growth		55.4%	24.2%	
Net Trade Sales ($MM)	$102	$160	$157	$151*
% Growth		57.9%	-2.1%	
Drug Uses Market Share (%)	50.9%	58.7%	53%	54.8%*
Average Price/Day (AWP)	$5.87	$5.78	$6.20	$6.52*
Average Dose/Day (mg/day)	1.8	1.7	1.8	1.9*

* Based on NDTI Mat Sep02 data & YTD Aug02 dollars

COMPETITIVE OVERVIEW
2

	1999	2000	2001	2002YTD
Product Uses Market Share (%)				
RISPERDAL	50.9%	58.7%	53%	54.8%*
Zyprexa	18.8%	16.9%	23%	13.7%*
Seroquel	8.1%	10.5%	12.4%	15.1%*
Geodon	-	-	3.9%	8.7%*
Avg. Price/Day (AWP)				
RISPERDAL	$5.87	$5.78	$6.20	$6.52*
Zyprexa	$8.41	$8.64	$10.49	$11.70*
Seroquel	$10.73	$6.89	$7.70	$6.37*
Avg. Dose/Day (mg/day)				
RISPERDAL	2.1	1.7	1.8	1.9*
Zyprexa	7.5	6.9	8.0	8.6*
Seroquel	321.0	212.0	263.1	198.2*

* Based on NDTI Mat Sep02 data & YTD Aug02 dollars

MARKET RESEARCH PLAN
3

Program	Objective	Target	Timing (Start/Finish)
RISPERDAL Annual Tracking Study	Evaluate attribute importance and APS product perceptions across disease states and customer segments	Psychs, PCP	2Q03
Child and Adolescent Landscape Study	Assess treatment patterns, decision making processes, attitudes and usage of APS in child and adolescent segment	Psychs, Peds, PCP	Q103
TBD - based on identified needs and evolution of clinical development plans	TBD	Psychs, Peds, PCPs	Q403

Child and Adolescent & Other New Business

2003 Business Plan

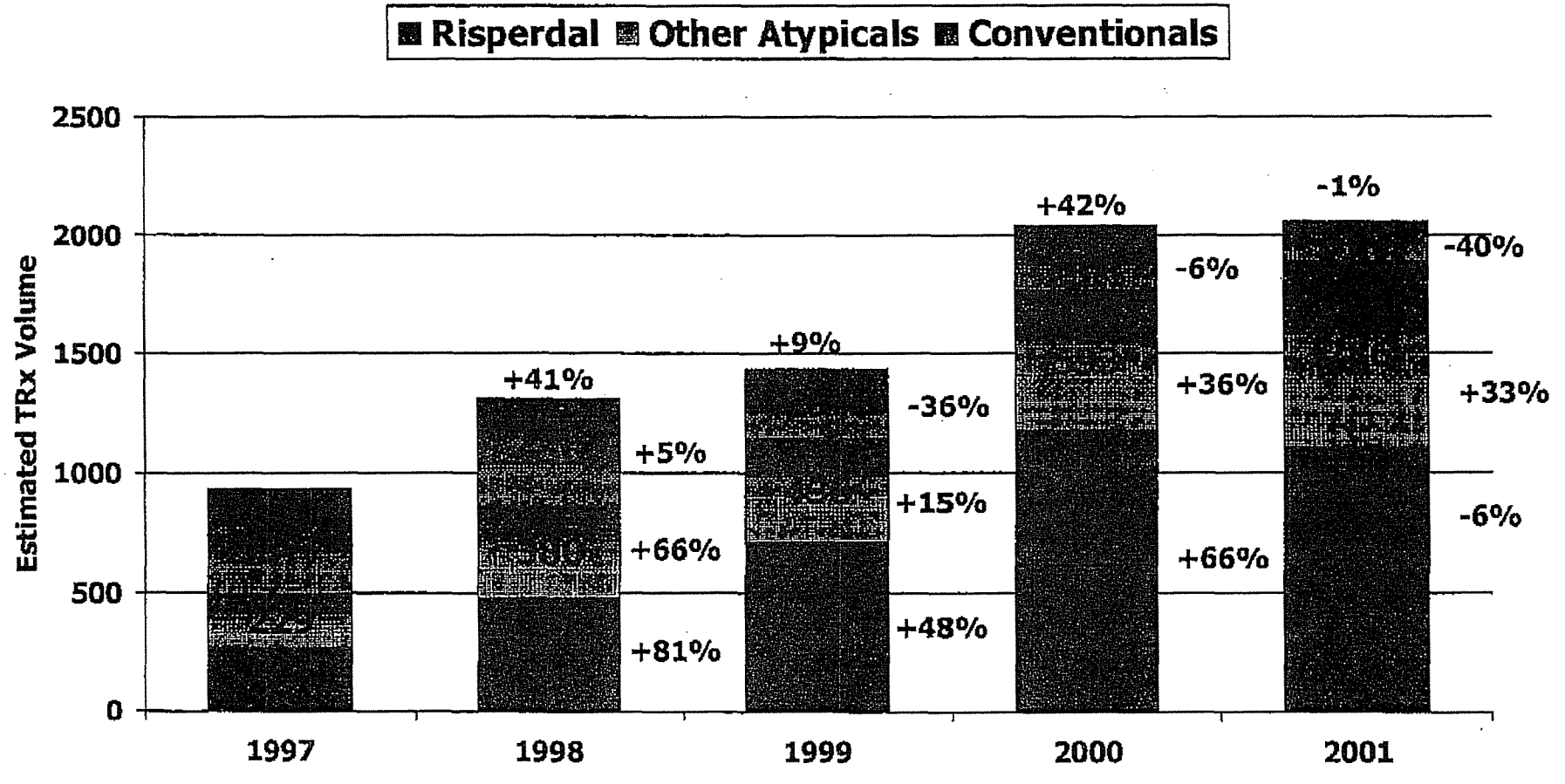
July 29, 2002

Child and Adolescent Business Planning Team

- Tom Gibbs
- Paul Mullen
- Adrian Bing-Zaremba
- Barbara Mieczkowski
- Rob Lisicki
- Jennifer Boehmer
- Rose Psomas
- Carol Szwarc
- Matt Murphy
- Marcia Rupnow
- Pat Wilkinson
- Giovanna Perot-Averill
- Gahan Pandina
- Georges Gharabawi
- Melissa Katz
- Dennis Meletiche
- Irene Hsu

Subject to legal and regulatory review

APS TRx Volume Growth
Child and Adolescent Market

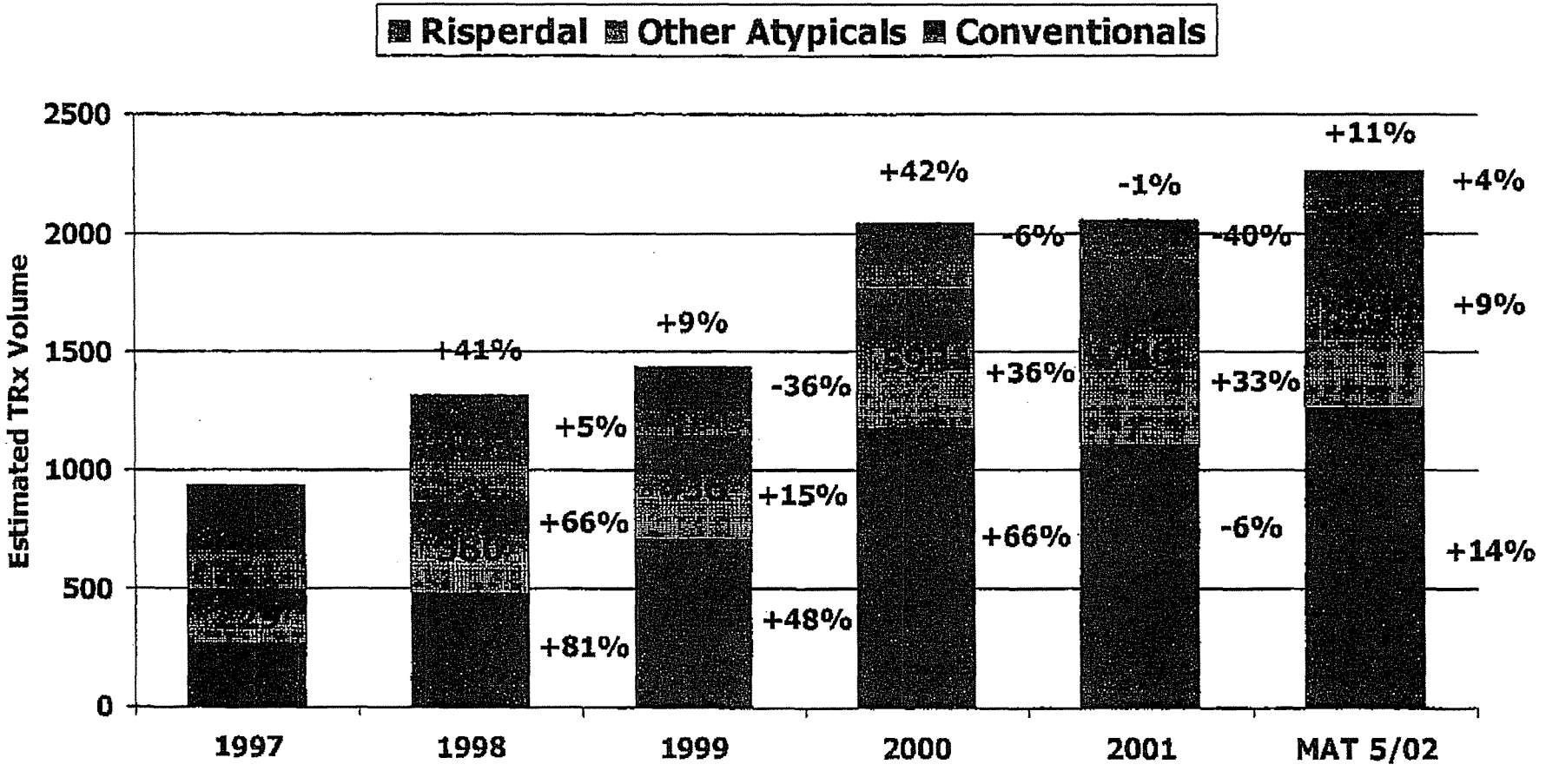


Source: IMS Health, NDTI and NPA Plus (Retail Only)

Child and adolescent defined as ages 0-17.

Subject to legal and regulatory review

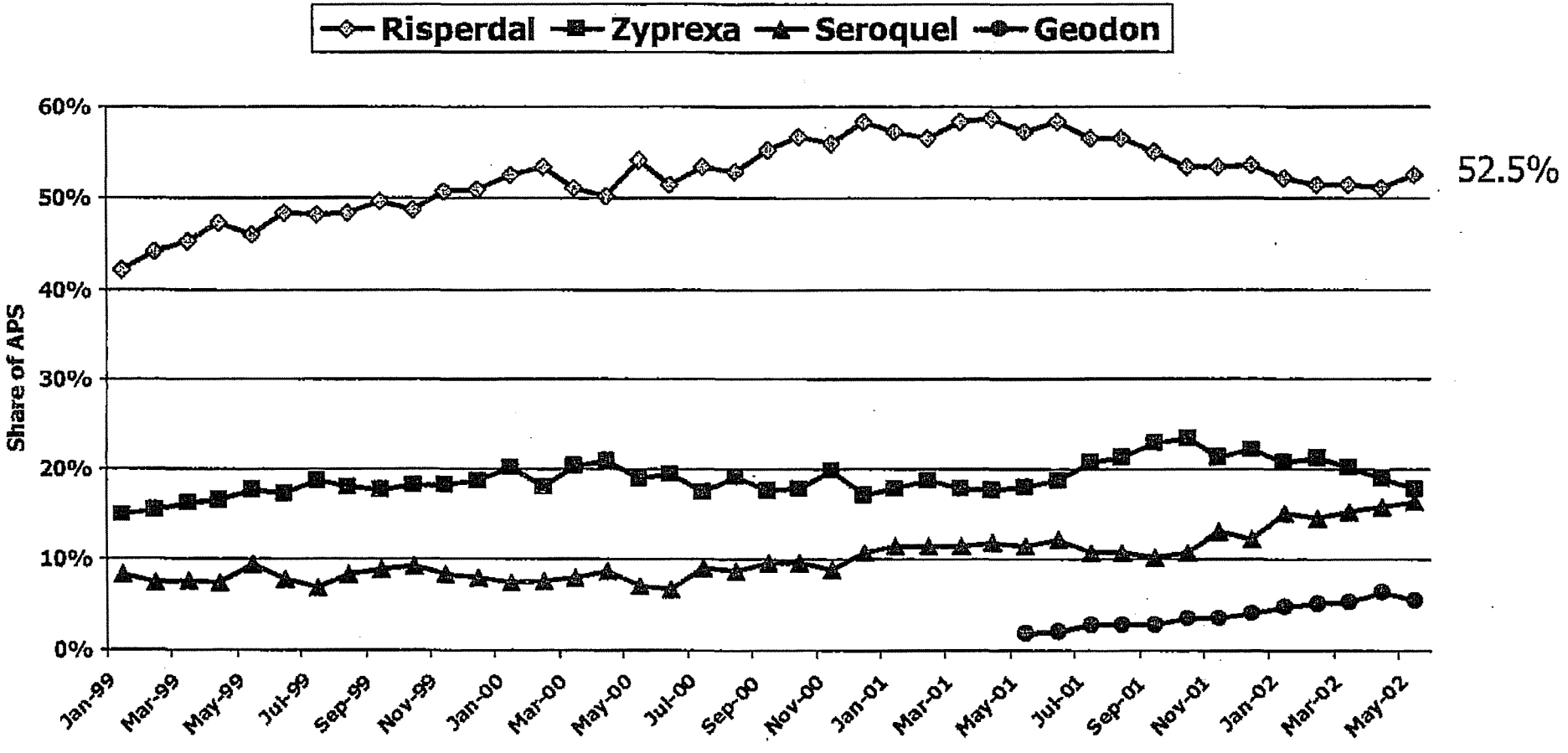
APS TRx Volume Growth
Child and Adolescent Market



Source: IMS Health, NDTI and NPA Plus (Retail Only)
Child and adolescent defined as ages 0-17.

Subject to legal and regulatory review

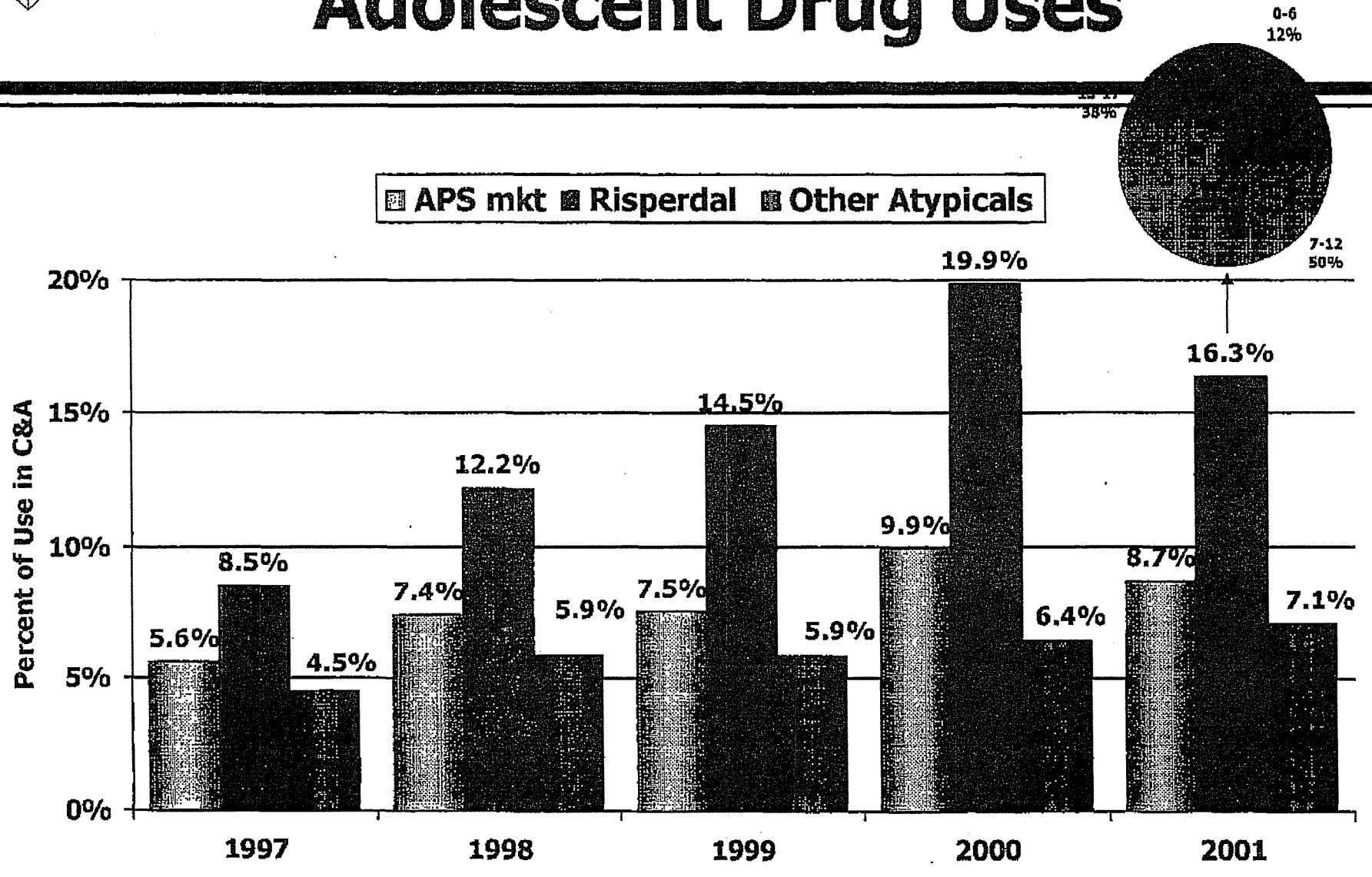
Antipsychotic Share in Child & Adolescent Market



Subject to legal and regulatory review

Source: IMS Health, NDTI
Child and adolescent defined as ages 0-17.

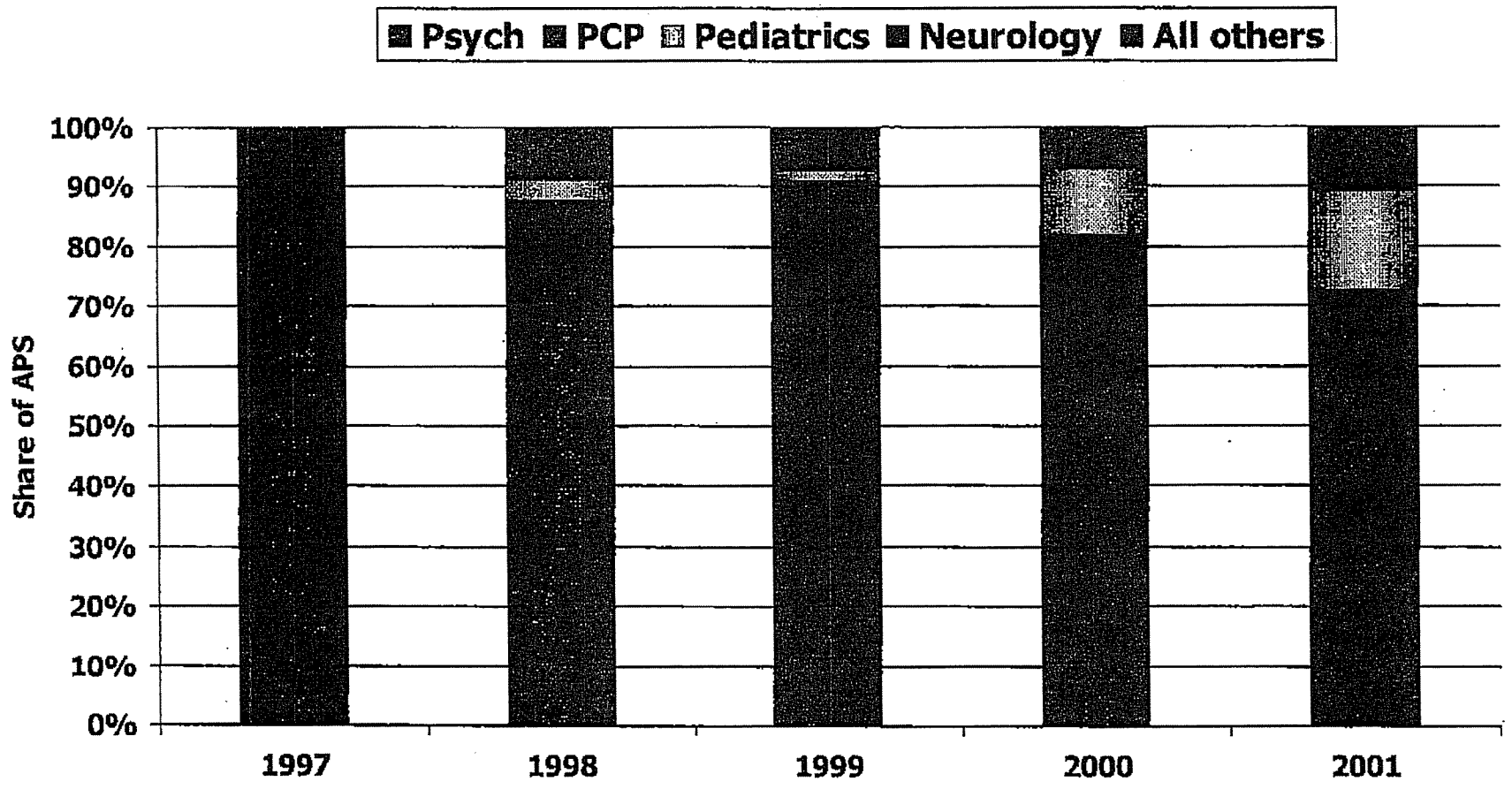
Percent of APS Child & Adolescent Drug Uses



Subject to legal and regulatory review

Source: IMS Health, NDTI MAT ending 1Q02
Child and adolescent defined as ages 0-17.

Risperdal Child & Adolescent Trends by Specialty



Subject to legal and regulatory review

Source: IMS Health, NDTI MAT ending 1Q02
Child and adolescent defined as ages 0-17.

Child and Adolescents: Opportunities and Requirements

Pediatric Exclusivity	Pediatric Rule	Schizo-phrenia	Autism
• 6-month patent extension • Awaiting written request from FDA • Lilly has received request	• Bipolar trials will be required • Informed FDA that we will not act until exclusivity requirements are elucidated	• Pivotal trial is ongoing • Will likely be part of exclusivity requirements • Indication projected 2005+	• Awaiting NIMH RUPP trial database • JJPRD/JPI will evaluate options for registration

Subject to legal and regulatory review

Key Publication Dates

Study	Disease	Journal	Date
RUPP	Autism	NEJM	Aug. 2002
RIS USA 93	CDMR ST	Am J Psych	Aug. 2002
RIS CAN 19	CDMR ST	JAACAP	Sept. 2002
RIS CAN 20	CDMR LT	Pediatrics	Oct. 2002
RIS USA 97	CDMR LT	Am J Psych	3Q2002 Sub.
RIS INT 41	CDMR LT	TBD	4Q2002 Sub.

Subject to legal and regulatory review

ST=Short Term
LT= Long Term

Lessons Learned

Lessons Learned

- C&A market is becoming increasingly competitive: increased comfort with newer agents
- Prolactin, EPS, TD and weight gain continue to be important issues (especially long-term implications)
- Competitors are driving negative safety and tolerability perceptions for Risperdal (e.g., prolactin)
- C&A market growth has flattened
- Advocacy is seeking to define a public position regarding C&A use of antipsychotics

Implications

- Generation and dissemination of current and future data is essential
- Dissemination of re-analyses of safety databases is critical
- Stigma and lack of education regarding appropriate use of APS in C&A must be addressed
- Opportunities exist for partnerships with advocacy

SWOT Analysis

STRENGTHS

- **APS market leader in C & A market**
- **Perceived efficacy advantage:**
  - **trust and experience with product**
- **Most data (Relative to Other APS)**
- Low dose availability/oral Solution
- KOL support
- Early onset of action

WEAKNESSES

- **Safety perceptions (Prolactin, EPS, TD, Weight Gain)**
- **Lack of awareness of appropriate dosing**
- Lack of promotional platform/indication
- Lack of sedation relative to other APS

OPPORTUNITIES

- **External data sources (e.g., RUPP)**
- **Clinical partnerships (e.g., Mass General)**
- **Under serviced market/unsatisfied market**
- Zyprexa safety profile (e.g., metabolic)
- JNJ "pediatric" synergy (MCC, OMP, Alza)
- Better diagnosis (DSM - V, consensus guidelines)
- Advocacy is seeking partnership
- Quicksolv

THREATS

- **Further delay of labeling/exclusivity**
- **Negative PR regarding use of APS in C&A**
- **Increased focus of competition on C&A market**
- Perceived legal liability by prescribers
- Sensitivity regarding use of APS in C&A
- Emerging clinical data with other APS
- Migration to other classes of drugs

Subject to legal and regulatory review

Key Issues

- Use of psychotropic medications in child and adolescents remains controversial
- Limited education and awareness of appropriate use of APS
- Physician misperception of Risperdal safety profile: driven primarily by increasingly competitive market
- Lack of indication

Key Issues and Strategies

Use of psychotropic medications in C&A remains controversial

Limited education and awareness of appropriate use of APSs

Physician misperception of RIS safety profile: driven primarily by increasingly competitive market

Lack of indication

Core Strategies

- Raise awareness regarding prevalence, economic and emotional burden of untreated C&A mental illness
- Develop educational platform to establish the role of APSs in the treatment of C&A mental illness
- Establish Risperdal as having a favorable risk-benefit ratio relative to other compounds
- Partner with JJPRD and Pediatric Drug Development to facilitate development plans

Subject to legal and regulatory review

Strategic Initiatives

Use of psychotropic medications in C&A remains controversial	*Limited education and awareness of appropriate use of APSs*	*Physician misperception of RIS safety profile*	*Lack of indication*
Raise awareness regarding prevalence, economic and emotional burden	***Develop educational platform***	***Establish Risperdal as having a favorable risk-benefit ratio***	***Partner with JJPRD to facilitate development plans***
• Partner with advocacy to drive caregiver education • Generate and disseminate data supporting clinical rationale and utility of APS in C&A • Leverage CAPRI initiative with NIMH • Leverage J&J-MGH Pediatric Psychopathology Center to drive awareness	• Partner with McNeil to drive and leverage educational program • Targeted medical education to pediatricians and neurologists • Leverage J&J-MGH Pediatric Psychopathology Center to drive educational needs	• Neutralize safety and tolerability concerns • Leverage current datasets • Develop EMRP plan addressing datagaps: ADHD, bipolar disorder, autism, acute agitation, Tourette's • Maximize RUPP autism publication	• Work to expedite enrollment in ongoing Schizophrenia trial • Assist in development of adolescent bipolar trial • Expedite transfer and analysis of RUPP database • Work with JJPRD and Pediatric Development Group to expedite receipt of written request

Use of psychotropic medications in children is controversial

- Raise awareness regarding prevalence, economic, and emotional burden of untreated C&A mental illnesses and the long-term implications

Key Tactic: C&A Mental Health Summit

Description

One day national summit which addresses current issues in mental illnesses in children and adolescents

Audience

Advocacy, KOLs, AACAP, NIMH

Limited education and awareness of appropriate use of APS

- Develop educational platform to establish the role of APSs in the treatment of C&A mental illness

Key Tactic#1: "Branded" educational initiative

Description

Multi- medium, comprehensive branded educational campaign on the role of APS in the treatment of C&A mental health: Centers of excellence, Regional CME symposia, monographs

Audience

National and regional key opinion leaders, community based physicians

Key Tactic#2: Academic collaboration (MGH and CAPRI)

Physician misperception of Risperdal safety profile

- Establish Risperdal as having a favorable risk-benefit ratio relative to other compounds
  - Leveraging current datasets
  - Generating new data to address identified gaps

Key Tactics #1: Re-analysis and dissemination of CDMR database addressing: prolactin, EPS/TD, weight gain, development, PK

Key Tactic #2: Conduct selected EMRP studies targeting:

- Treatment-refractory ADHD
- Bipolar disorder
- Acute agitation
- Autism
- Tourette's

Subject to legal and regulatory review

Lack of indication

- Partner with JJPRD and J&J Pediatric Institute to facilitate current development plans
  - RUPP (autism)
  - Schizophrenia
  - Bipolar Disorder
  - Exclusivity

❑ INSERT MEDICAL AFFAIRS SLIDE

Subject to legal and
regulatory review

Market Research Plan

Program	*Objectives*	*Timing/Cost*
C&A Landscape Study	Determine diagnostic and treatment trends in C&A mental health market by specialty	1Q03/$150k
TBD based on identified needs and final clinical development plans	TBD	TBD

Risperdal C&A 2003 PME's

Description	2002 PME ($K)	Proposed 2003 PME ($K)	2003 PME (%)
Medical Marketing/Education	**3,890**	**3,300**	**51.6%**
CME Branded Initiative		1,800	
PsychLink/Teletopics		450	
Symposia (2)		350	
Publications		500	
National Ad Board		200	
Advisory Boards (RAB/HOV)	**1,800**	**1,900**	**29.7%**
Public Relations	**325**	**500**	**7.8%**
C&A Summit		400	
Other		100	
Grants	**160**	**300**	**4.6%**
Other	**225**	**400**	**6.3%**
Total PME	**$6,400**	**$6,400**	**100%**

Subject to legal and regulatory review

Critical Success Factors

- Maximize existing clinical data including dissemination and re-analyses
- Generate new data in key diagnostic/symptom areas
- Neutralize misconceptions about Risperdal's safety profile
- Gaining acceptance of the usage of APS in C&A
- Build new and strengthen existing internal and external partnerships
- Finalize clinical development plan (i.e., exclusivity, labeling)

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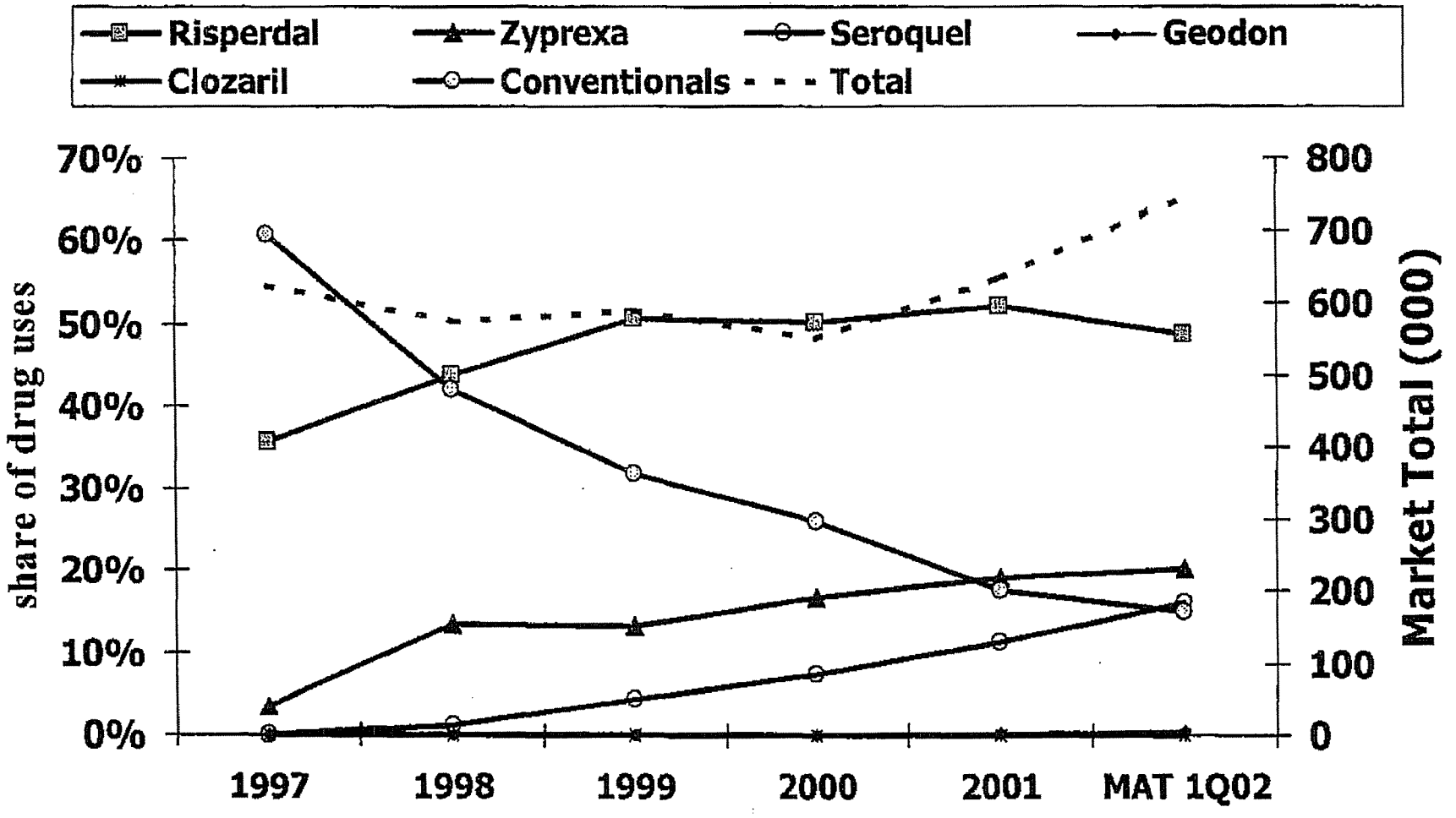
"Quicksolv" Opportunity

- Opportunity for expanded product differentiation
  - Convenience (unit dose, no mixing, no water, etc.)
  - Difficulty swallowing
  - Compliance (cheeking)
- Segmentation
  - Special patient populations
    - Geriatrics
    - Pediatrics (upon approval)
  - Treatment settings
    - Acute care/Institutions
    - Long-term care

Critical Ongoing/Next Steps

- Market research
  - Back-up tradename generation/testing: completed
  - Pricing research: ongoing
  - Message/flashcard testing: ongoing
- Development of promotional platform
  - Integration in acute care and long term care strategies
  - Complimentary positioning with oral solution
- Medical Affairs clinical plan
  - EMRP
  - Incorporation in acute care study vs. Zyprexa IM

Antipsychotic Market Dementia Share Trends



Subject to legal and regulatory review

Source: IMS Health, NDTI

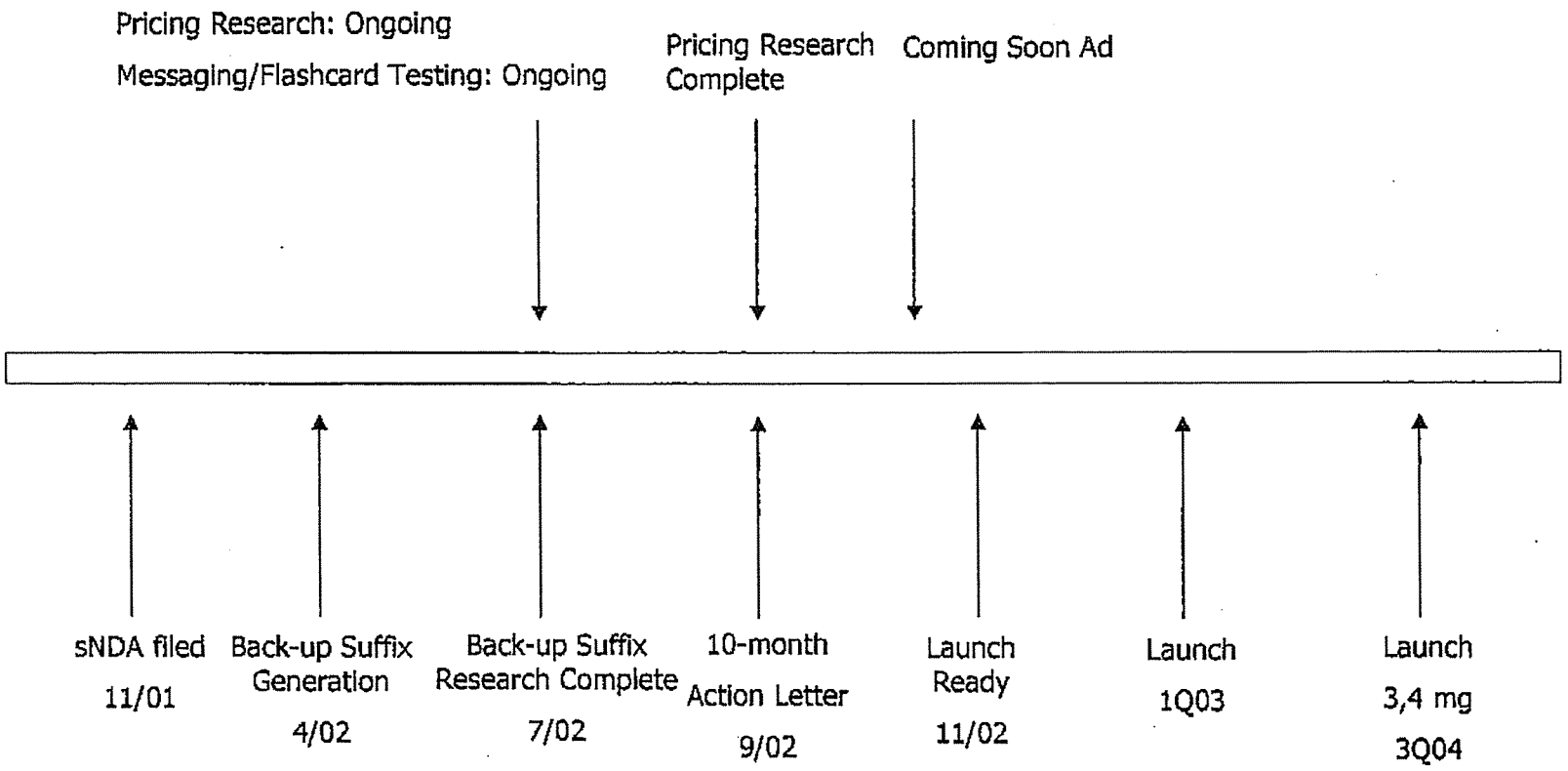
2003 Business PLan

Dementia - BPSD

- sNDA file planned for mid-2003; anticipated launch 1Q05
- Zyprexa anticipated launch date tracking with Risperdal
- Management of "CVA issue" ongoing
- 2003 efforts will focus on medical marketing programs

Back-Up

Quicksolv Timeline of Key Activities



Subject to legal and regulatory review

Risperdal LTC Share Change by LTC Pharmacy Provider

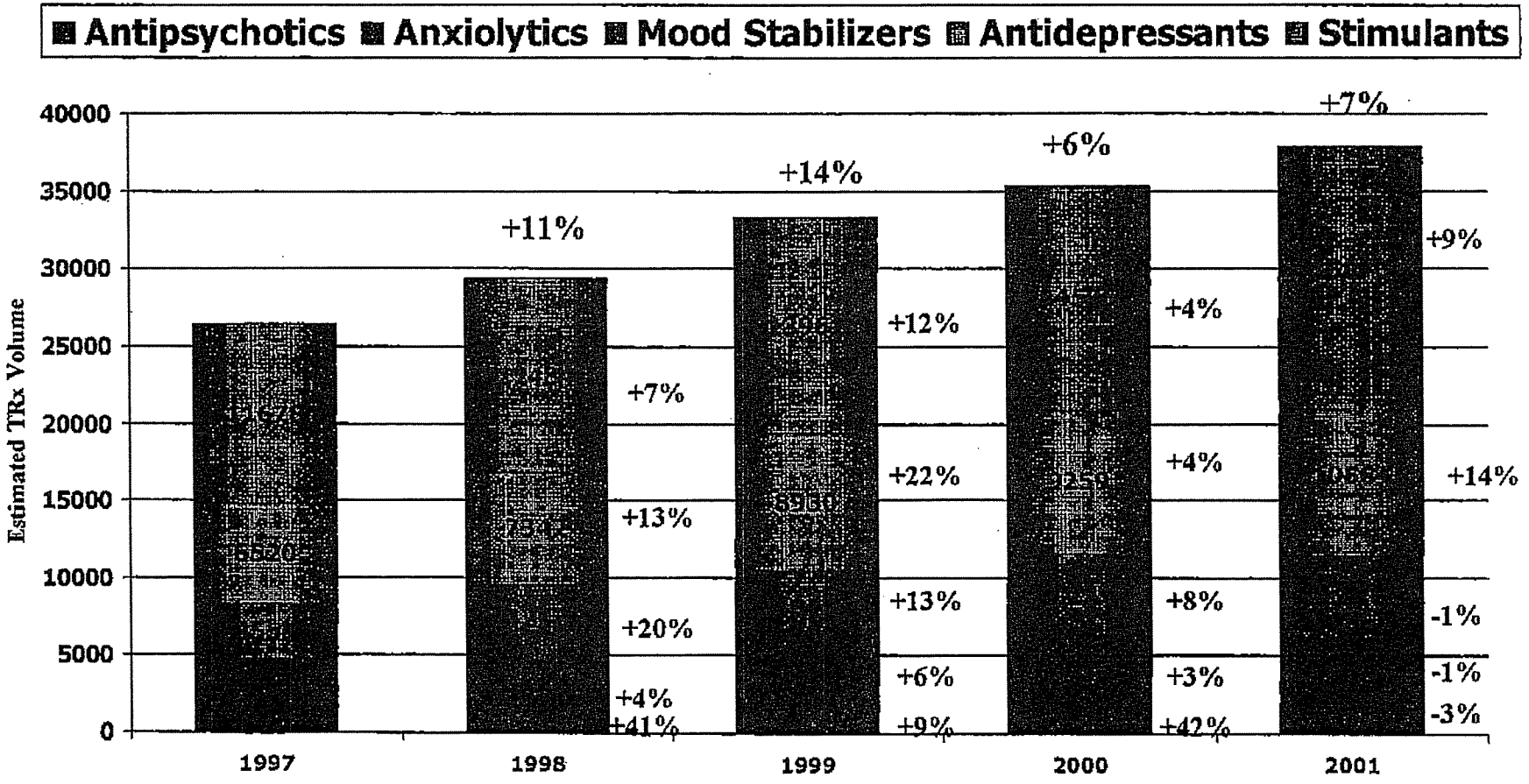
2001 LTC account trends mirror NPA LTC share loss

Provider	4Q00	4Q01	Change
IMS NPA LTC	36.8%	34.7%	-2.1
Omnicare	57.0%	54.7%	-2.3
PharMerica	52.2%	50.6%	-1.6
NCS	55.1%	50.6%	-4.5
NeighborCare	53.6%	49.9%	-3.6
APS	55.8%	51.6%	-4.1
SunScript	45.6%	45.9%	+0.4

Subject to legal and regulatory review

Source: IMS Health; JJHCS Internal Database

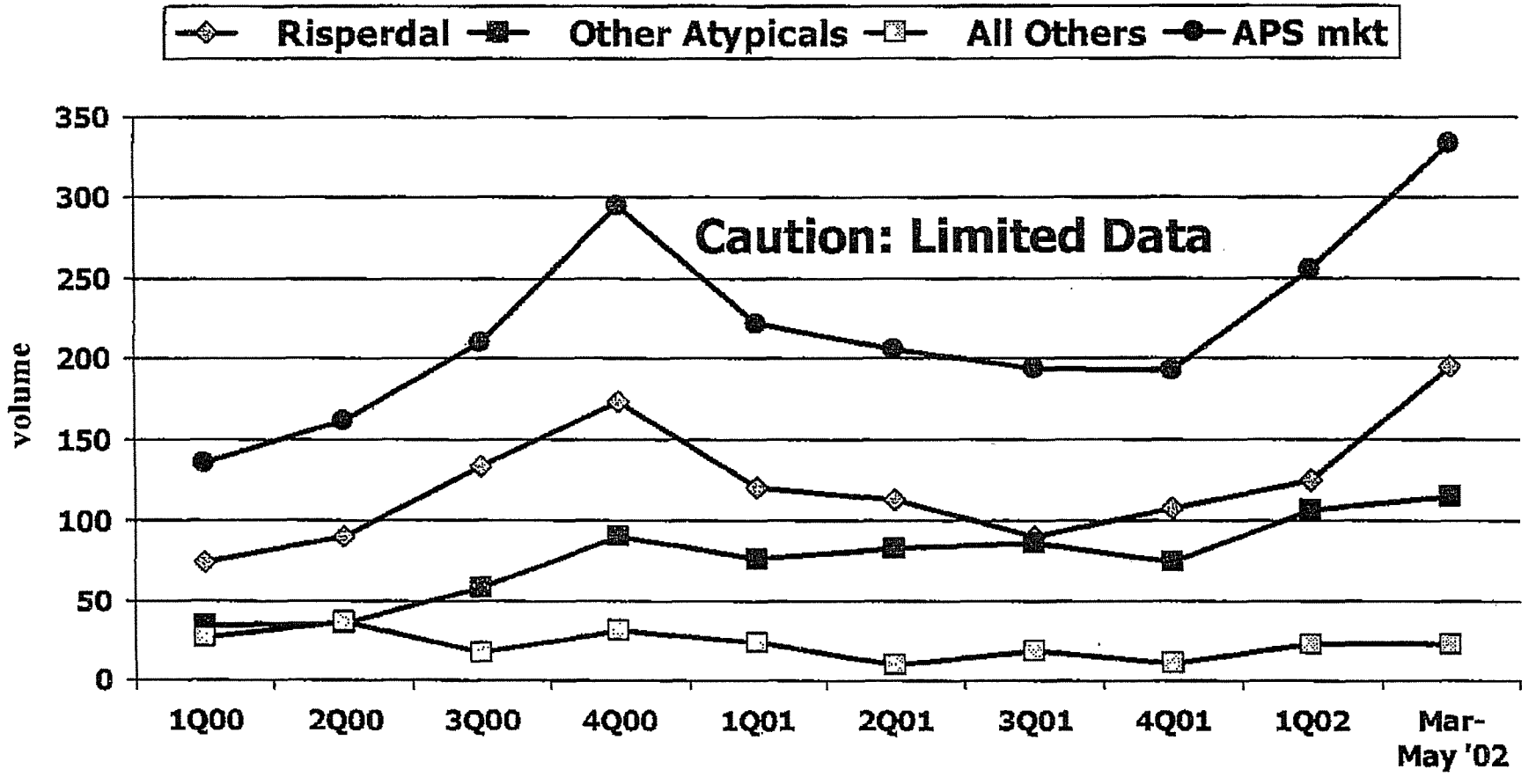
CNS TRx Volume Growth
Child and Adolescent Market



Source: IMS Health, NDTI and NPA Plus (Retail Only)
Child and adolescent defined as ages 0-17.

Subject to legal and regulatory review

Antipsychotic Volume in C&A Market By Quarter

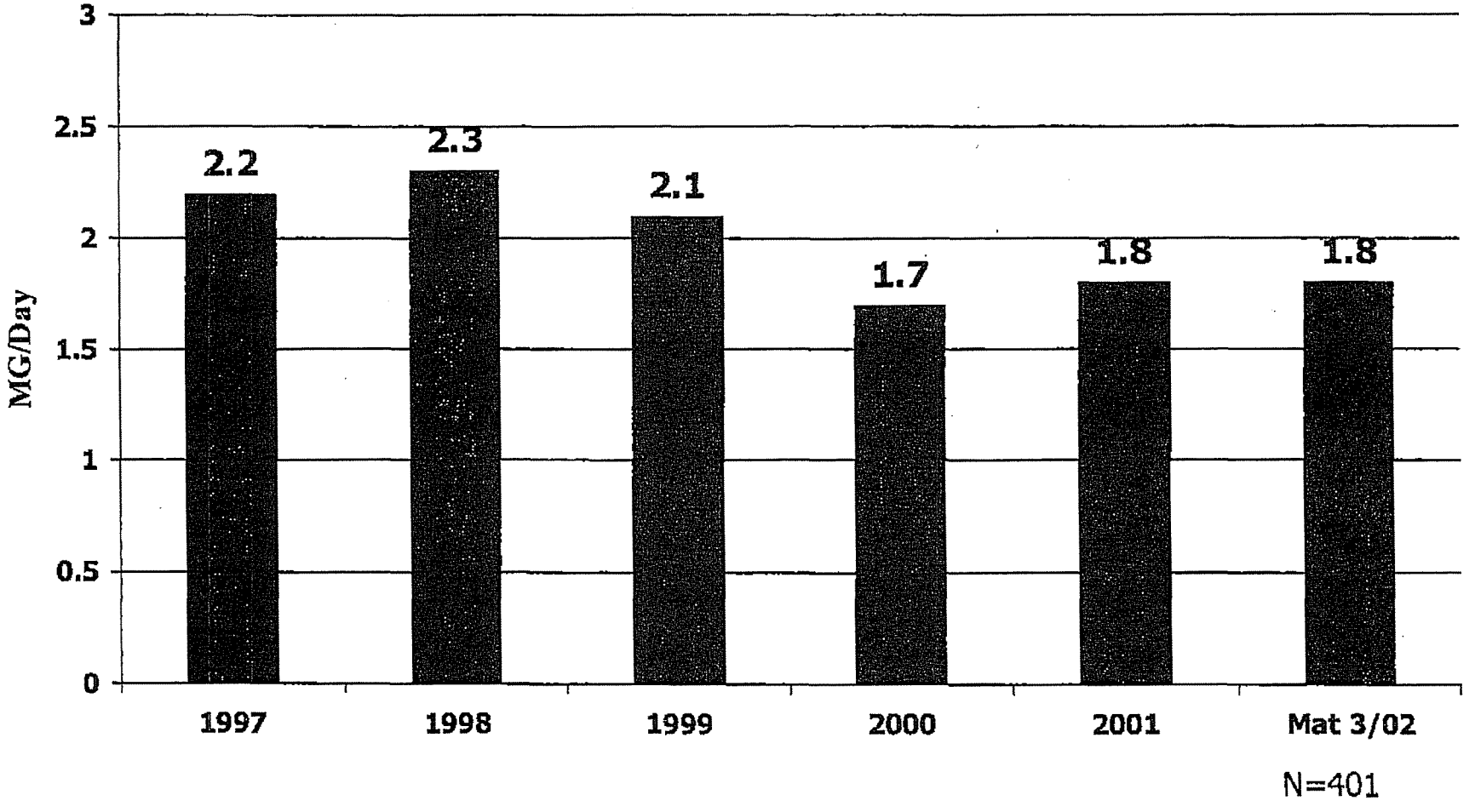


Source: IMS Health, Quarterly NDTI data

Child and adolescent defined as ages 0-17.

Subject to legal and regulatory review

Risperdal
C&A Dosing Trends



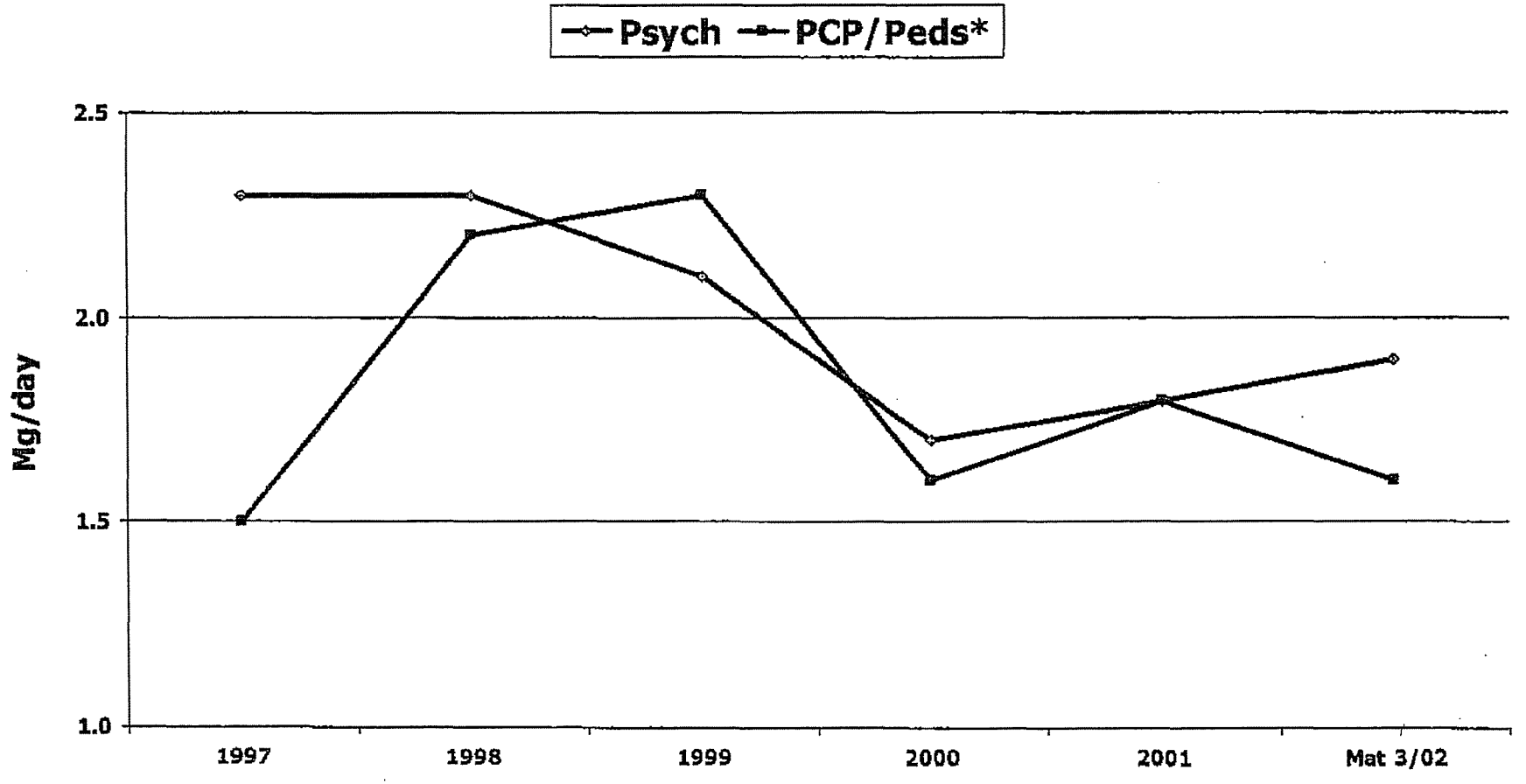
N=401

Subject to legal and regulatory review

Source: IMS Health, NDTI, MAT ending 1Q02

Child and adolescent defined as ages 0-17

Risperdal C&A Dosing Trends by Specialty

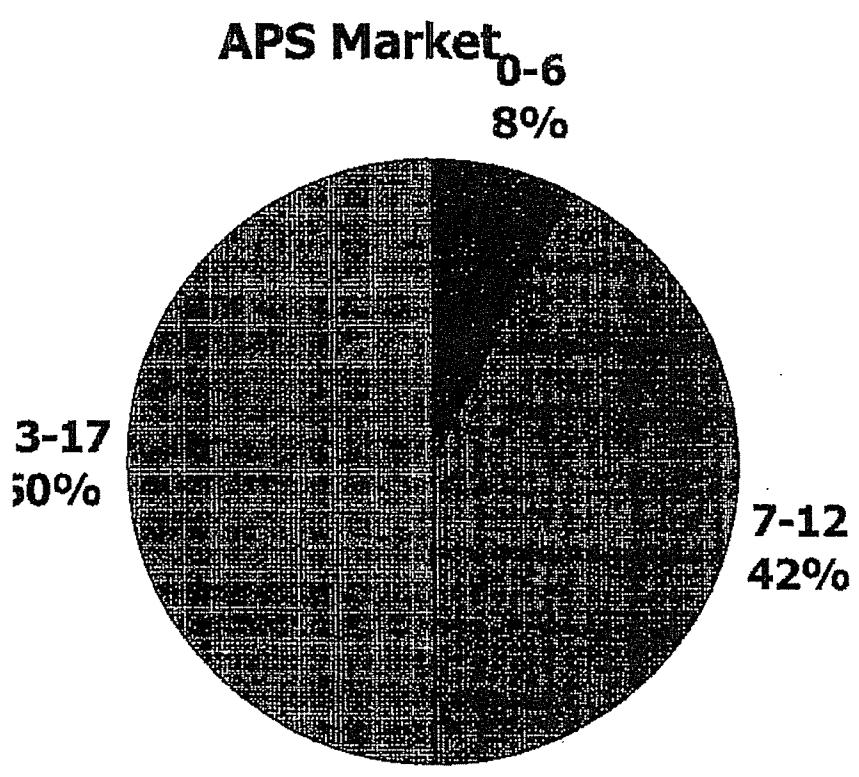


Source: IMS Health, NDTI, MAT ending 1Q02, *PCP/ Peds includes FP, GP, IM, DO, Peds

Subject to legal and regulatory review

Child and adolescent defined as ages 0-17

Child and Adolescent Age Breakdown



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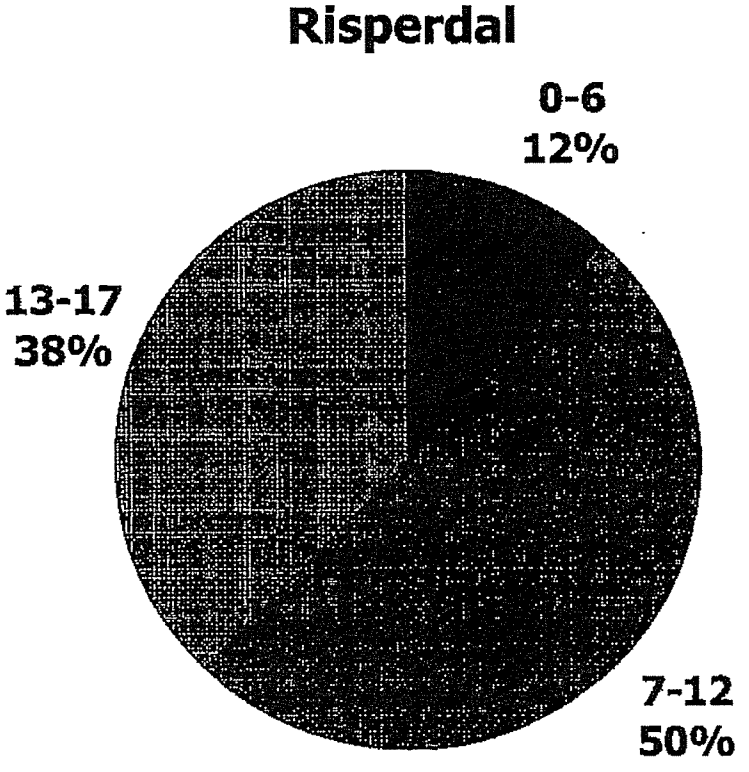
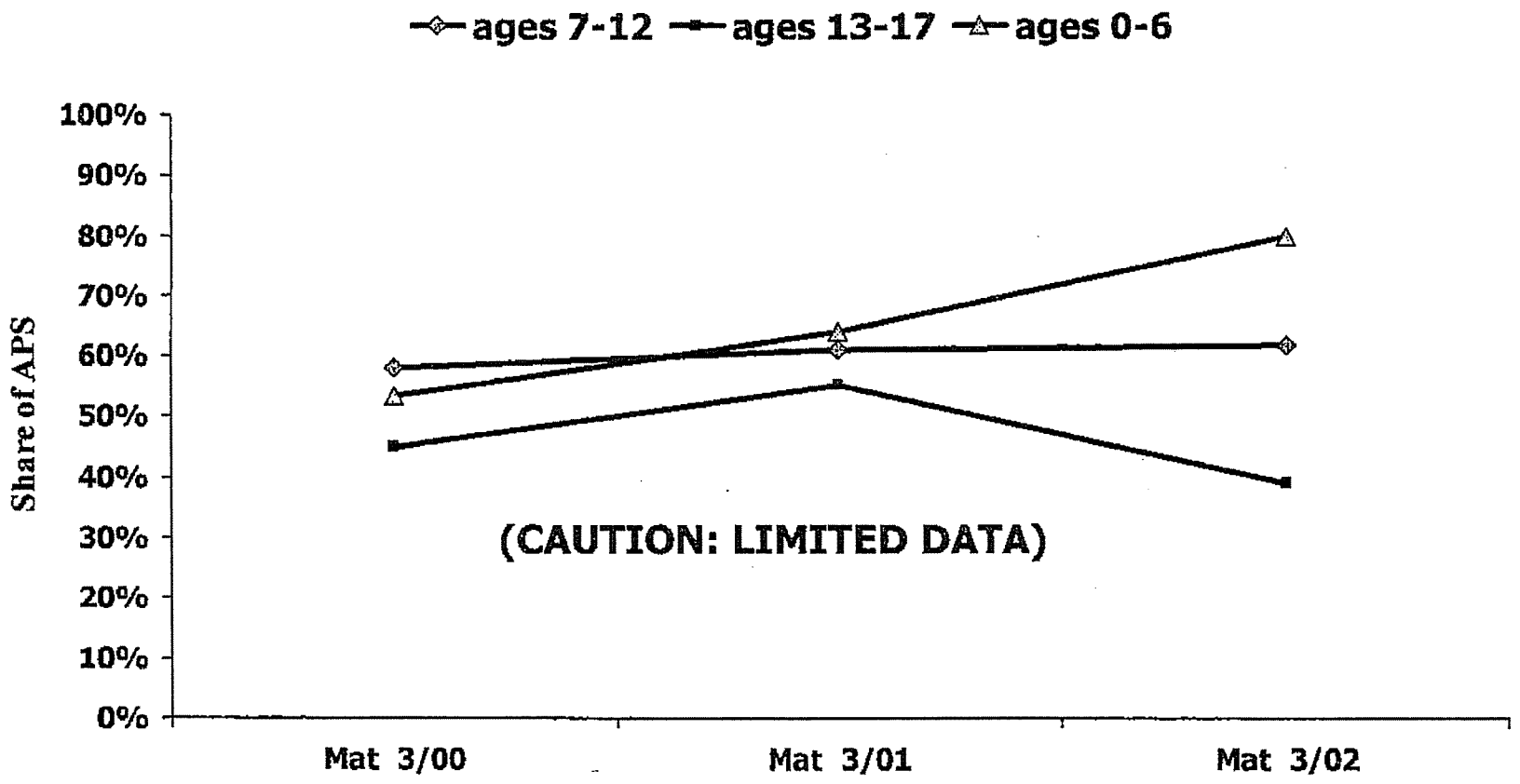


N=430

Source: IMS Health, NDTI MAT ending 1Q02

Child and adolescent defined as ages 0-17

Risperdal Share of C&A Age Groups

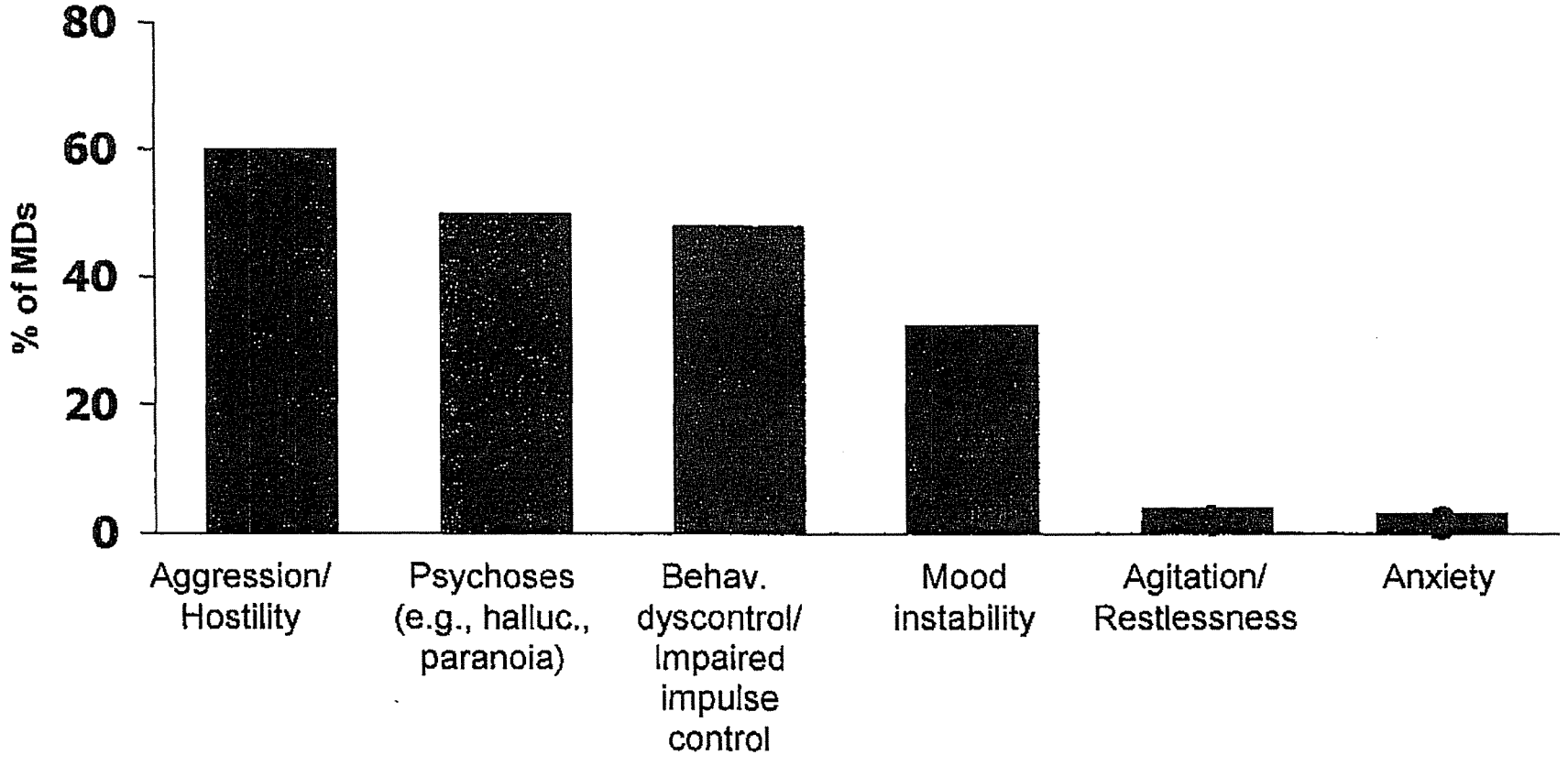


Source: IMS Health, NDTI MAT ending 1Q02

Child and adolescent defined as ages 0-17

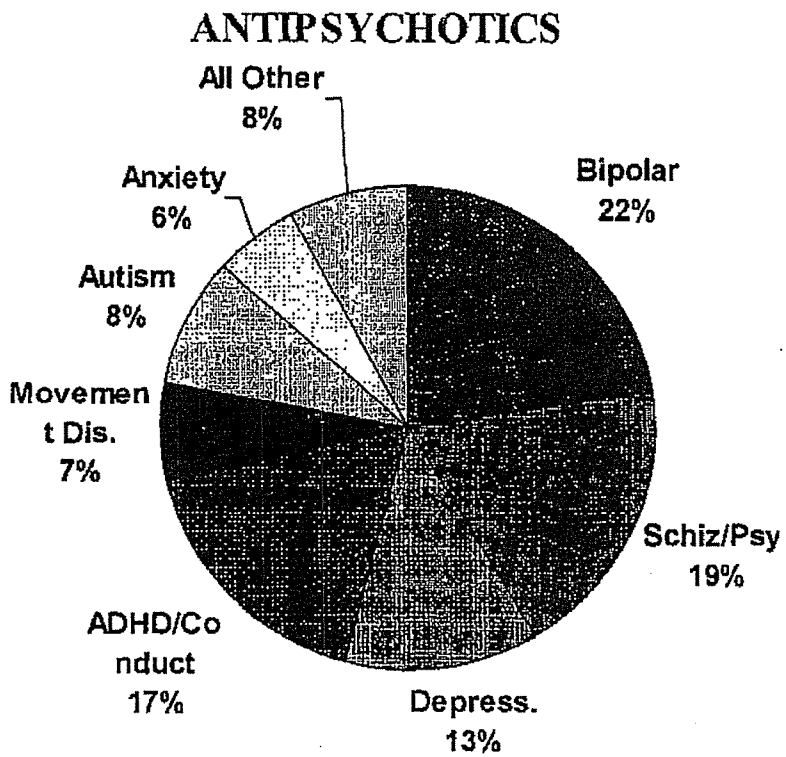
Subject to legal and regulatory review

TOP TWO C&A SYMPTOMS ADDRESSED WITH ANTIPSYCHOTICS



Subject to legal and regulatory review

Antipsychotic Use In C&A Patients



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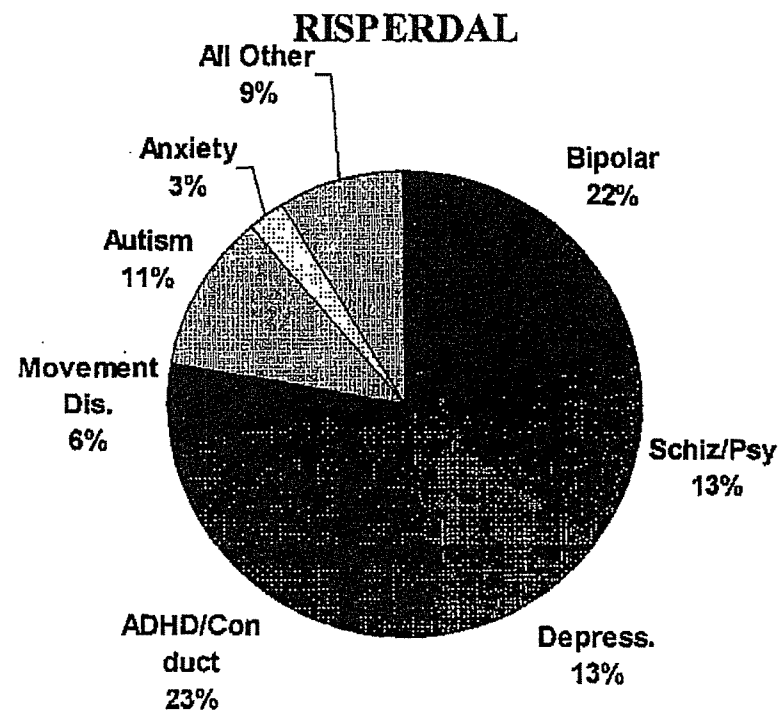


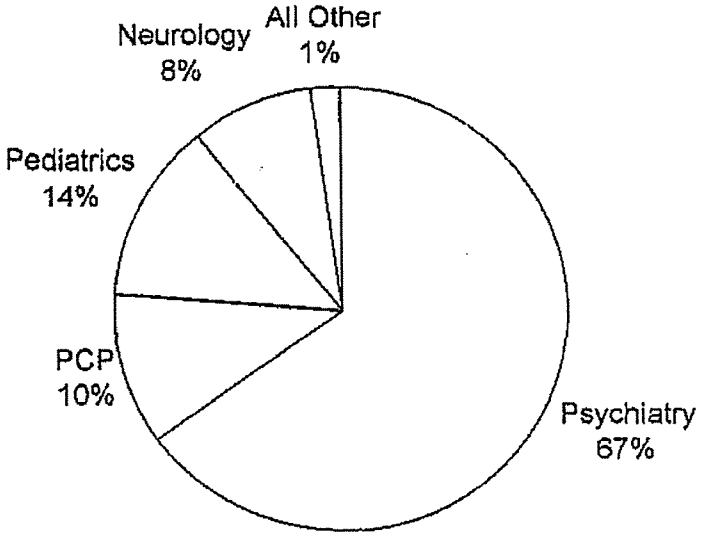
N=436

Subject to legal and regulatory review

Source: IMS Health, NDTI, MAT ending 1Q02
Child and adolescent defined as ages 0-17.

Antipsychotic use by specialty in C&A patients

ANTIPSYCHOTICS



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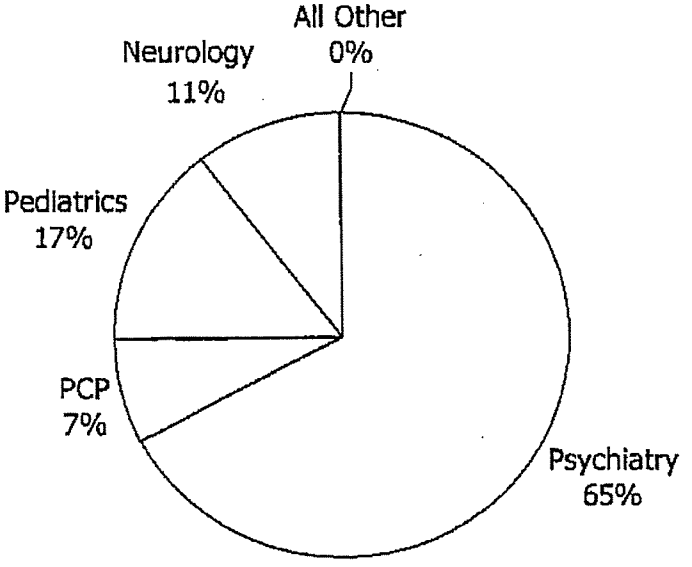
RISPERDAL



N=459

Subject to legal and regulatory review

Source: IMS Health, NDTI, MAT ending 1Q02

Child and adolescent defined as ages 0-17

Market Analysis
Child Psychiatry Opportunity

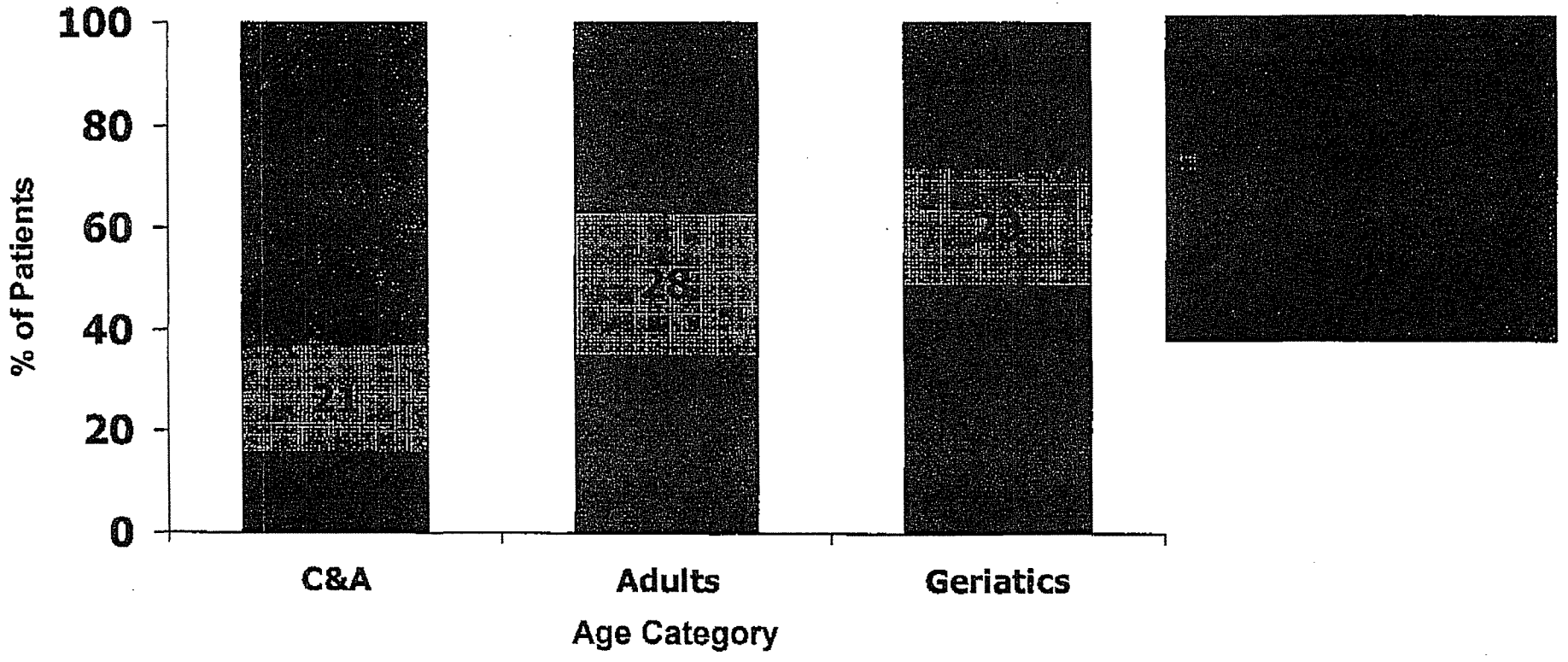
- Number child psychiatrists 5,192
- Cross Matched to APS Decile 20-90 (56.4%) 2,926
- Cross Matched to APS Decile 50-90 (13.8%) 717
- Received call last 12 months (63.7%) 3,307
  - 1,985 received more than 12 calls (38.2%)
  - 30 APS 50 90 CHPs received no calls
- Total APS Sales (Mar '01 - Feb '02) $311 MM

Product	$ Sales	NRx Share
Risperdal	$132 Million	42.5%
Zyprexa	$69 Million	22.2%
Seroquel	$53 Million	17.1%
Geodon	$10 Million	3.2%
Conventionals	$47 Million	15.1%

Subject to legal and regulatory review

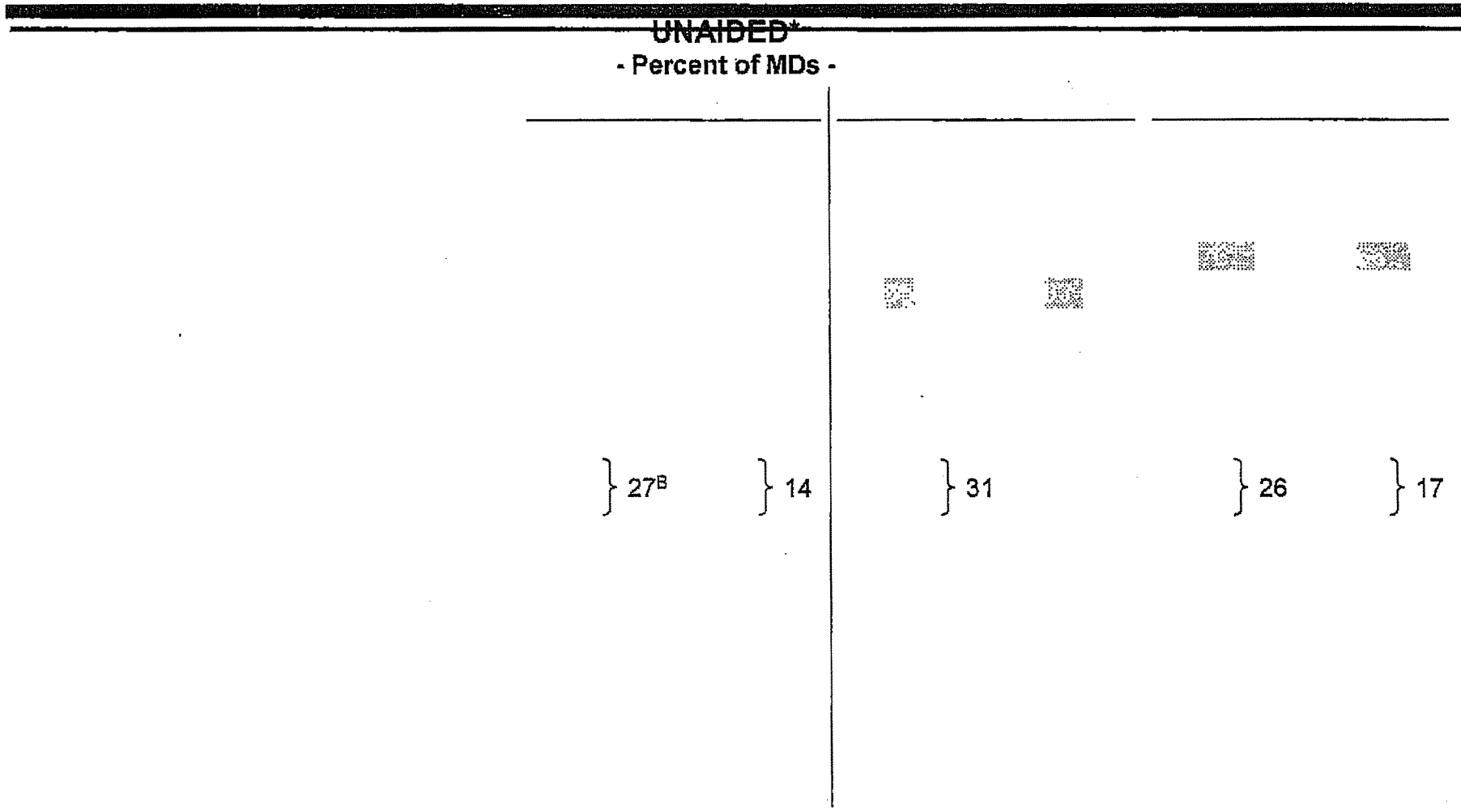
Source: Powerplay cubes (Sales Force Optimization – Jan02 Decile Update), Janssen dollar sales

PCPs' Rate of Initiating/Changing Antipsychotic Treatment



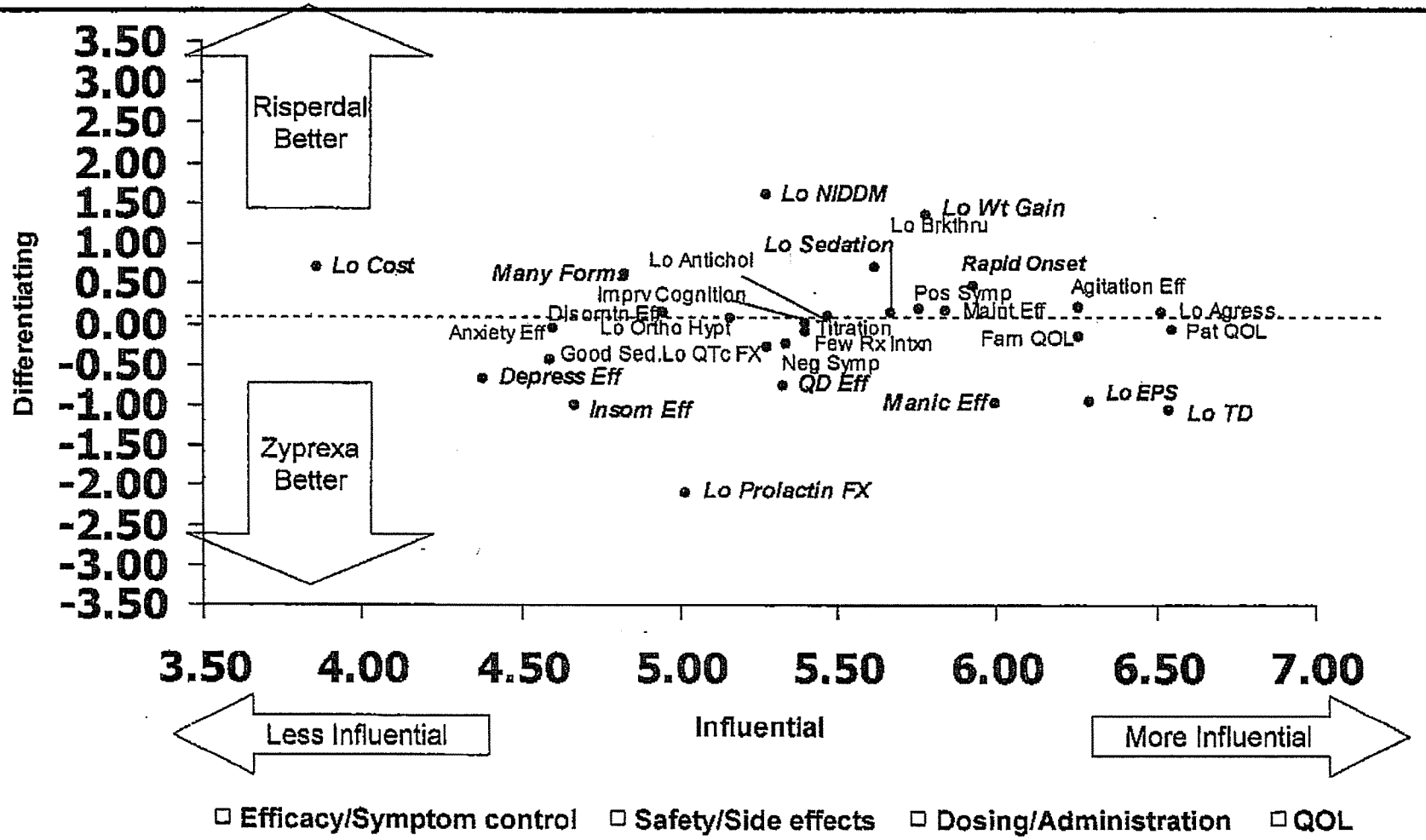
Subject to legal and regulatory review

Top Three Diagnoses for APS RxING in C&A Disorders



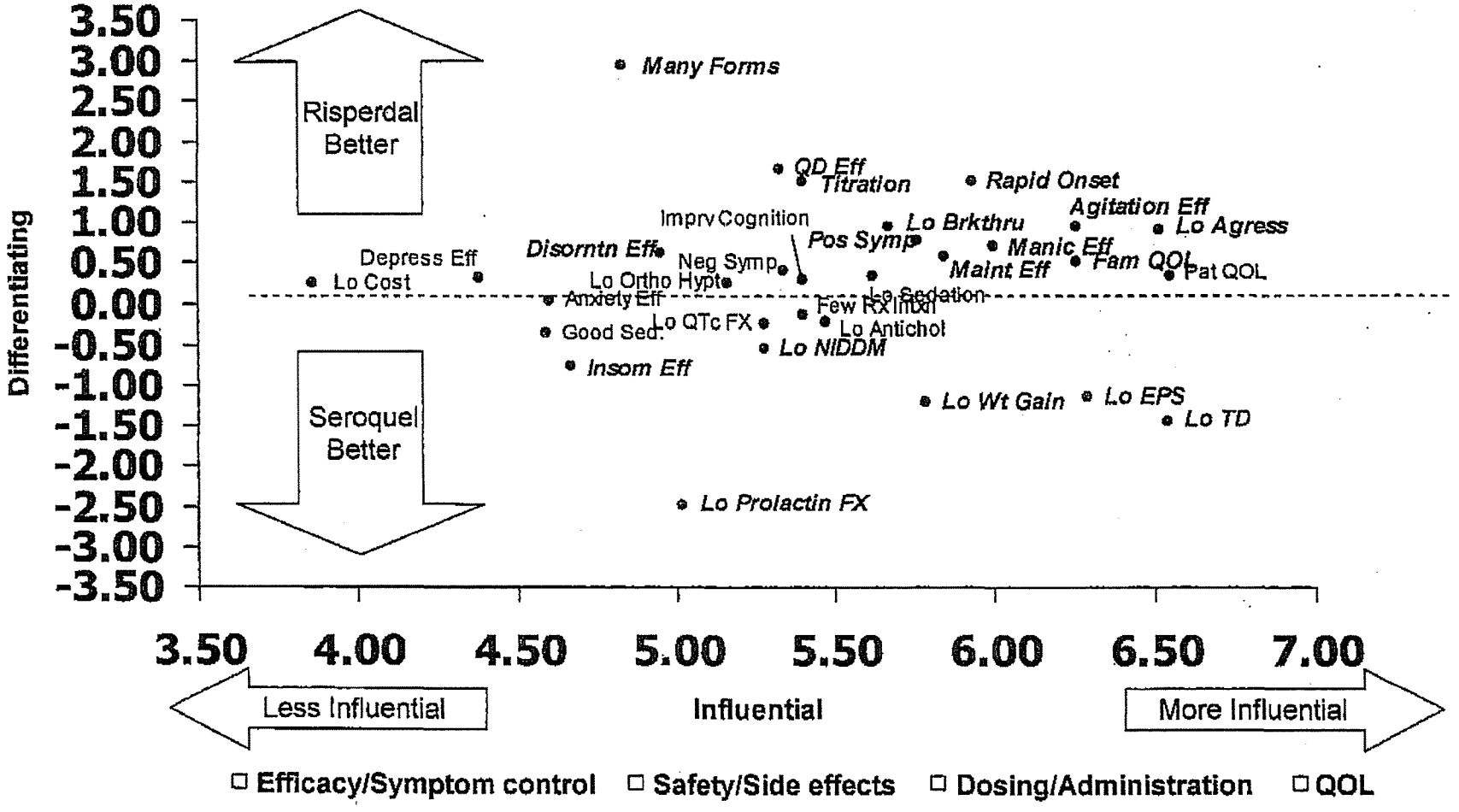
24; Base: Children/adolescents comprise at least 10% of their patients on antipsychotics
Mentioned by at least 5% of MDs **Caution, small sample size

RISPERDAL vs ZYPREXA For C&A Disorders 2002 - Psychiatrists



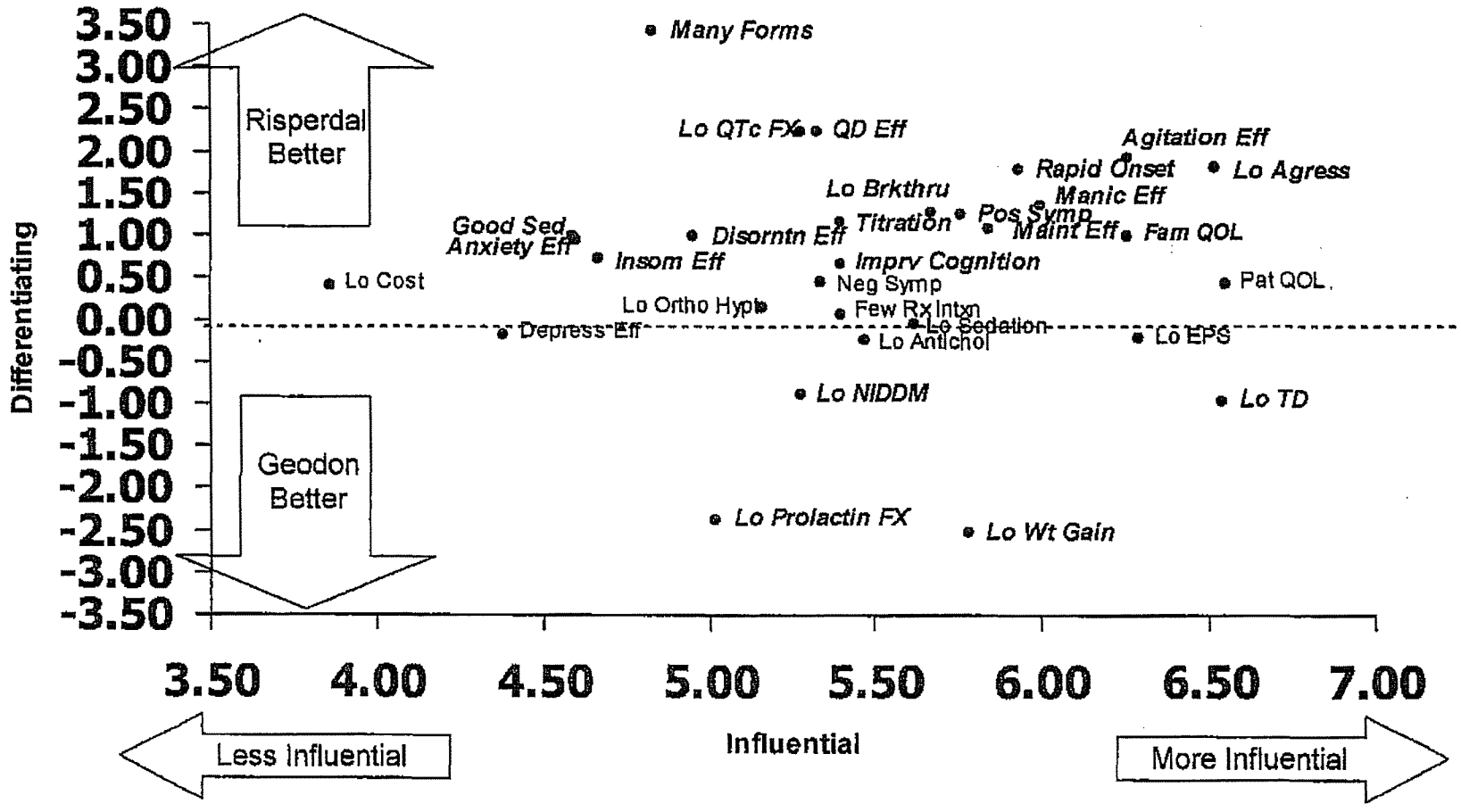
Attribute is bolded and italicized if significant difference between drugs.

RISPERDAL v SEROQUEL For C&A Disorders 2002 - Psychiatrists



Attribute is bolded and italicized if significant difference between drugs.

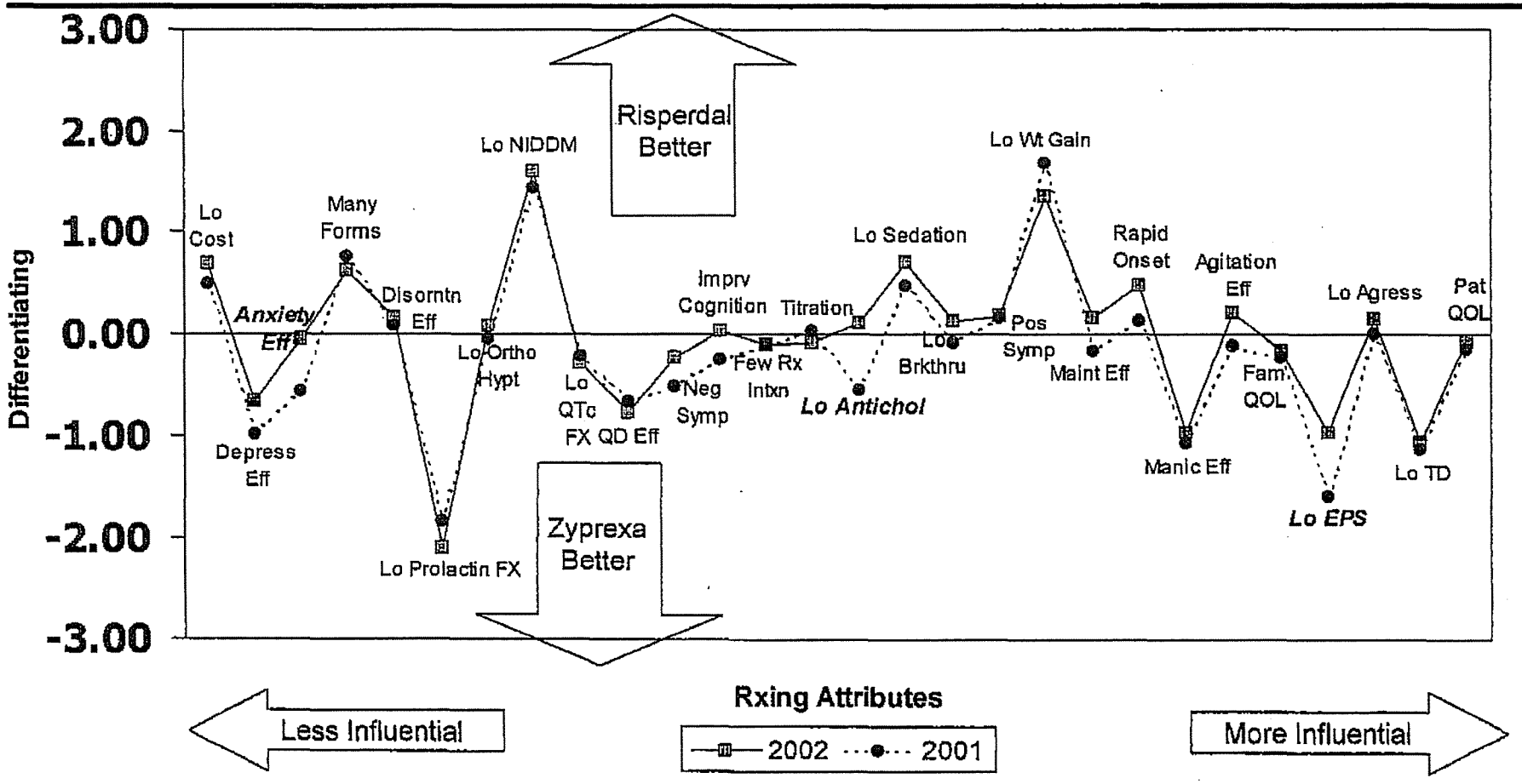
RISPERDAL v GEODON FOR C&A Disorders 2002 - Psychiatrists



Attribute is bolded and italicized if significant difference between drugs.

Subject to legal and regulatory review

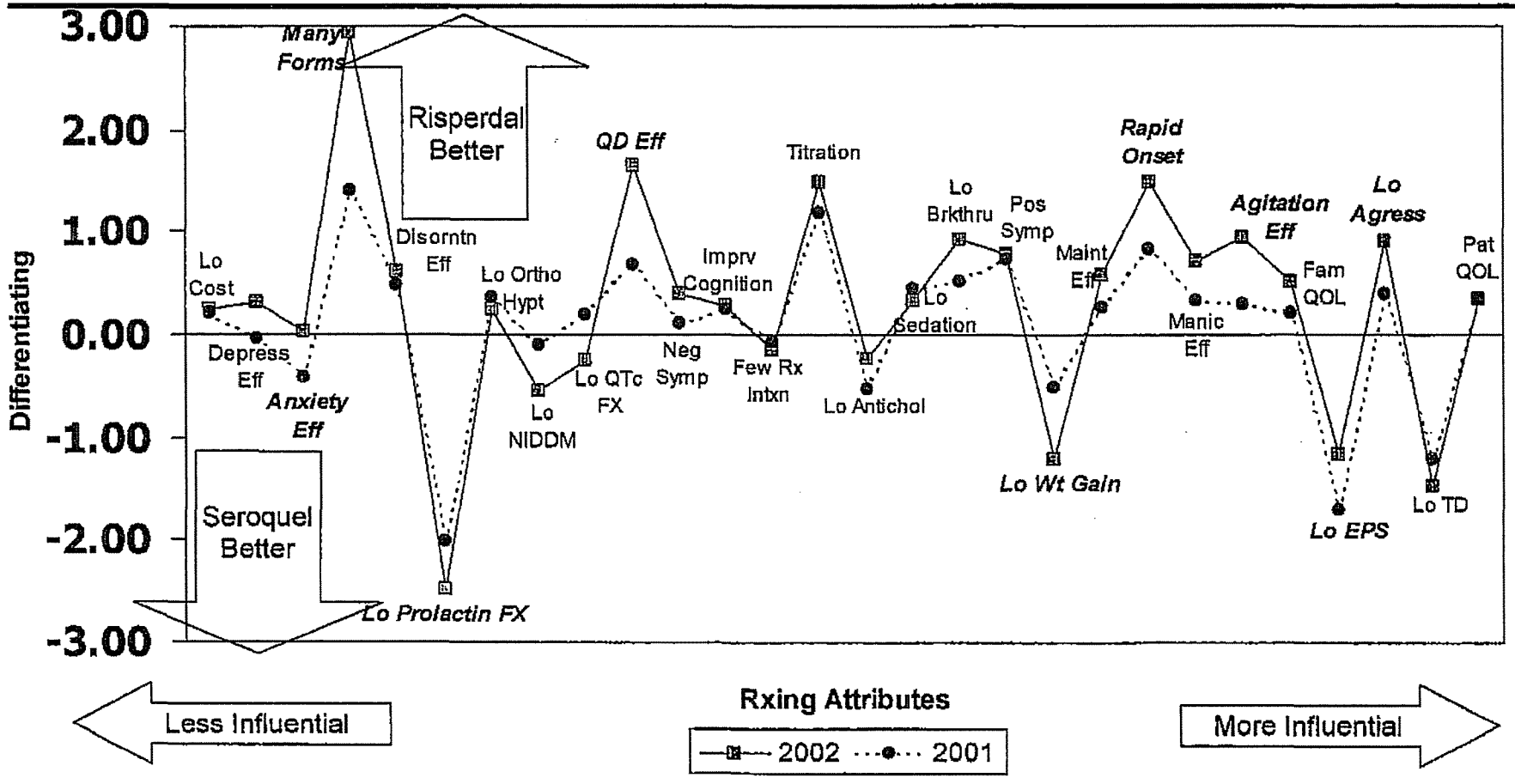
RISPERDAL v ZYPREXA FOR C&A
Disorders – 2001 v 2002 Psychiatrists



*Subject to legal and regulatory review

Bolded and italicized if significant wave difference

RISPERDAL v SEROQUEL FOR C&A Disorders – 2001 vs 2002 - Psychiatrists



*Attribute is bolded and italicized if significant wave difference

Subject to legal and regulatory review

Jones, Robert [JANUS]

From: Pandina, Gahan [JANUS]
Sent: Tuesday, May 27, 2003 9:52 AM
To: Williams, Karren [JANUS]; Lin, Joseph [JANUS]
Cc: Morrison, Randy [JANUS]; Jones, Robert [JANUS]; Steffe, Carrie [JANUS]; Schubert, Lauren [JANUS]
Subject: RE: Biederman

Dear Karren,

We need to discuss as a team, and it is too difficult via email. I appreciate the difficulties arising here, and am concerned. I also spoke with Dr. Biederman regarding this issue, and he was concerned regarding his pharmacy bill, but otherwise would not elaborate. As to the consent issue, this is an investigator-initiated protocol, and while we have guidelines that require certain GCP processes, I defer to Randy for specifics here. While we did speak at APA, Dr. Biederman informed me that he had completely enrolled the risperidone open-label study **before** the approval for the MRS study add-on funds were approved, and as such has begun enrollment (already approximately half enrolled) anticipating our supply of drug as the only additional cost to be incurred above and beyond the MRS funds supplied.

Can we discuss as a group (or sub-group) later this week? I will be at Future Leaders on Thursday afternoon and Friday, but otherwise am available.

Gahan

-----Original Message-----
From: Williams, Karren [JANUS]
Sent: Friday, May 23, 2003 2:23 PM
To: Pandina, Gahan [JANUS]; Lin, Joseph [JANUS]
Cc: Morrison, Randy [JANUS]; Jones, Robert [JANUS]; Steffe, Carrie [JANUS]; Schubert, Lauren [JANUS]
Subject: Biederman
Importance: High

Gahan,

I just got off the phone with Joe Biederman. I desperately need to speak with you and hear the outcome of your meeting with him at APA. When your time permits, could you call me on my cell phone?

Per my discussion with Joe today:

1. For the adolescent mania study, he did not use Janssen consents for this study. He used the 'generic' consent forms that he is using for his large Stanley Foundation grant. I asked if the 30 subjects were 'different' then the ones he is recruiting for the Stanley Foundation-he said that they were, but that his staff did not use Janssen specific consents for this study. He said that the 30 subjects are complete and that we have had the data from this study available and presented. He said that no additional subjects need to be completed for this study-that the study is complete.

2. Because Joe's staff did not use Janssen consents for the study-he said that at his cost, he will run another 30 subjects using the 'correct' consents. We did not discuss how this would affect his data or the published data as it would be an entirely different dataset. Is this something that is a violation of IRB or our contract-that the consent was not used?

3. He agreed that he would only receive from Janssen drug for the 30 patients for our study. He is going to send a listing by patient by dose for us to send to his pharmacy. He agreed that this amount in no way would reflect the LARGE amount requested before from his staff. He has no patients in our study currently so there is not an immediate need.

4. He wants drug also for the MRA study. I pushed back that as per my conversation with you, I understand-and also as the contract is written, the MRA study was a SUB STUDY of the adolescent bipolar study. He said that you and he talked at APA and that you both agreed that they are 2 different studies. Was that the outcome of your discussion? I was just going by our earlier discussion. I spoke to Randy today and the contract that we signed was not set up as a separate study and did not specify additional drug.

5. If we want Joe to do another 30 patients using Janssen consent-he will do 'free' for us but will not supply the drug. We would have to give him additional drug above the 30 he used for his non-Janssen consented study.

6. He commented that he had received a fax from Carrie asking for information about this study. I would suggest that I be the contact with Joe about this so that we can coordinate our actions and alleviate any cross talk. He is preparing for me as requested specifically from Randy-the dose per patient for us to replace in the pharmacy.

7. Joe commented to me that he 'dismantled' the Stanley grant into 3 separate arms. Ol, Ser, and Ris. Each is funded also by pharma and has pharma supplying drug. Draw your own conclusions.

Summary:

The 30 patient data from the adolescent bipolar study were not consented with a Janssen consent for this specific study-they were consented with the Stanley Foundation Consent. I need to know if we are going to require Joe to do another 30 patients-if so, what does that do to our data and paper that is in progress? And if so, we will need to supply more drug for him, that is his 'terms'.

He is under the impression following the meeting at APA that the MRA is a distinct study. That is not how the contract is specified. Randy, how do you want to handle this? Also, he is requesting drug for this study also.

Please advise ASAP as Joe is pushing me hard.

Karren

Karren R. Williams, Ph. D
Manager, CNS-Medical Science Liaison
Boston Region

11 South Angell Street
Providence, RI 02906

Office: 401-277-9677
Fax: 401-277-9676
Cell: 401-487-5273
Voice Mail: 888-870-6200 X6726

Jones, Robert [JANUS]

From: Williams, Karren [JANUS]
Sent: Friday, May 16, 2003 3:46 AM
To: Morrison, Randy [JANUS]; Jones, Robert [JANUS]; Pandina, Gahan [JANUS]
Cc: Lin, Joseph [JANUS]; Schubert, Lauren [JANUS]
Subject: FW: Risperdal Drug Supply/Dr. Biederman

IANSSEN Risperda Supply

Hi all,

Round 5! I received this from one of Biederman's study coordinators. I had asked, per my conversation with Randy, that we have a list from the pharmacy-but this is what was sent to me. I talked to Biederman today after his symposia-and he said that he needs drug for both the MR study and the Mania study. He also mentioned that he is not receiving support for drug for his Stanley grant-no indication that he is requesting that, at least not right now. He mentioned today that the pharmacy has charged him $100,000 for the drug that was dispensed to him so far-so now we have that figure. I mentioned to him that for our guidelines; we needed the supply to be tied to the mania study and also by dose. I do not understand the 'accounting' that is attached. From my read of the study progress-this quantity does not match. The amount requested is in excessive of the study. Gahan, as we discussed, Joe is under the assumption that the MR study is separate and he wants drug for that also-will you be talking to him for clarification?

Please review and let me know what you would like for me to do/request from Biederman?

Thanks!

FYI-Joe let me know that the new data from his mania study reflects significant decrease in symptoms as early as 3 weeks. He mentioned that he will be discussing at the meeting with everyone at APA. He is going to push for us to fund a double-blind study to 'further demonstrate' this finding. He stressed that we should move forward "immediately"-just a heads up.

Karren

Karren R. Williams, Ph. D
Manager, CNS-Medical Science Liaison
Boston Region

11 South Angell Street
Providence, RI 02906

Office: 401-277-9677
Fax: 401-277-9676
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>

-----Original Message-----
From: Clark, Maureen E [mailto:MECLARK@PARTNERS.ORG]
Sent: Thursday, May 15, 2003 4:50 PM
To: 'KWillia7@Janus.jnj.com'
Subject: Risperdal Drug Supply/Dr. Biederman

Dr. Williams,
Attached please find a spreadsheet of dosages and quantities of Risperdal samples received from Janssen since November 2001. We received a total of approximately 6,300 pills however Janssen funded a study for 30 subjects for a one year period. In our calculations, the pill supply needed for 30 subjects for a one year period is approximately 32,400 (depending on dose and length of time enrolled in the study).
The calculation of the medication supply needed for 30 subjects through one year (32,400) minus what we have received from Janssen (6,300) leaves a discrepancy of approximately 26,000 pills which we would like to respectfully ask for at this time.
If Janssen can send us the supply of Risperdal needed and we receive the study medication in a bulk supply as opposed to samples, we can be retroactively reimbursed by the Pharmacy at MGH for the medication we were charged for in addition to providing the Pharmacy with enough study medication for us to complete the study.
Please contact use with any questions or concerns.
Thank you very much for your assistance with this matter.
Maureen Clark
<<JANSSEN Risperdal Supply>>

> Maureen Clark, M.S.
> Manager, Clinical Trials
> Pediatric Psychopharmacology
> Massachusetts General Hospital
> Tel 617-503-1009
> Fax 617-503-1060
>
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Janssen Pharmaceutica
Selling, Marketing, and Medical Affairs
As of July 21, 2003

Vendor Name	Spent/Committed 2003 YTD	Spent 2002 Act
FANIZZI ASSOCIATES INC Total	18,739,875	12,172,786
DISCOVERY INTERNATIONAL Total	16,745,831	10,279,112
SYNDICATED DETAILING SERVICES LLC Total	14,152,857	4,904,341
PHARMACEUTICAL RESEARCH Total	13,070,428	6,479,717
KALLIR PHILIPS ROSS INC Total	12,707,618	12,237,857
VERISPAN LLC Total	12,006,144	7,471,316
INGENIX PHARMACEUTICAL SERVICES Total	10,632,243	5,859,451
IMS HEALTH INC Total	10,164,008	5,891,981
SYNAVANT INC Total	8,785,452	3,095,697
TRAVEL DESTINATIONS MANAGEMENT Total	8,462,752	8,126,887
COVANCE PERIAPPROVAL SERVICES INC Total	8,346,042	5,152,815
QUINTILES INC Total	8,029,381	1,302,489
HYATT REGENCY PRINCETON Total	7,019,366	2,319,851
ALLIANCE FOR SCIENTIFIC Total	6,463,067	10,125,351
THE LASH GROUP INC Total	6,369,889	6,079,344
QUINTILES PACIFIC INC Total	6,082,746	-
PHASE V COMMUNICATIONS Total	5,111,452	6,555,404
XEROX CORPORATION Total	4,853,114	1,858,671
CLINICAL CONNEXION LLC Total	4,663,559	2,294,718
CLINE DAVIS AND MANN INC Total	4,256,895	1,535,799
OCC NORTH AMERICA INC Total	4,213,953	4,074,414
PHASE FIVE COMMUNICATIONS INC Total	4,051,738	-
COMMONHEALTH Total	3,844,932	5,903,737
DISCOVERY EAST Total	3,442,557	959,520
HYATT REGENCY Total	3,244,170	413,472
EXCERPTA MEDICA INC Total	3,052,289	2,566,075
THOMAS DIRECT SALES INC Total	2,969,177	3,708,302
KELLY SERVICES INC Total	2,896,577	2,513,698
DERSE EXHIBITS Total	2,787,431	3,391,366
MEDICOM WORLDWIDE INC Total	2,769,280	5,181,432
C3I INC Total	2,640,490	2,938,428
DIRECT MEDICAL RESOURCES Total	2,515,950	1,121,354
JACK MORTON WORLDWIDE Total	2,405,000	-
WYNDHAM ANATOLE Total	2,321,791	-
PROMOTIONS BY DESIGN INC Total	2,275,505	1,681,603
BUSINESS INCENTIVES INC Total	2,119,127	287,962
COMPREHENSIVE NEUROSCIENCE Total	1,863,260	1,109,739
WESTIN HOTEL COMPANY Total	1,856,682	35,255
PROCLINICAL INC Total	1,844,032	1,707,933
OVATION RESEARCH GROUP Total	1,722,000	445,000
CARLSON MARKETING GROUP Total	1,720,247	612,825
HEALTH RESOURCE Total	1,720,000	2,580,000
APPLIED RESEARCH Total	1,654,726	806,832
TOTAL EVENT PRODUCTIONS INC Total	1,613,840	2,368,328
MARKET RX INC Total	1,569,360	320,000
MANSFIELD PRESS INC Total	1,534,359	2,050,615
EAST WEST CONNECTION Total	1,527,154	1,894,507
DELTA CORPORATE SERVICES INC Total	1,395,828	757,565
SCIREX CORPORATION Total	1,390,022	1,114,237
AMERICAN GASTRO ASSOCIATION Total	1,353,500	389,974
HEALTH RESEARCH ASSOCIATION Total	1,314,684	1,143,209
FLIK INTERNATIONAL CORP Total	1,313,719	1,028,768
BUCOM INTERNATIONAL INC Total	1,312,344	1,060,241
MCKESSON HEALTH SOLUTIONS Total	1,286,160	2,446,289
LAKESHORE TOWERS LTD PHASE II Total	1,272,315	476,492
DIGESTIVE DISEASES EDUCATION CO INC Total	1,235,000	267,000
MJM CREATIVE SERVICES INC Total	1,221,425	1,199,623
TORRE LAZUR COMMUNICATIONS INC Total	1,220,046	32,960
PHARMA COMMUNICATIONS INC Total	1,158,986	400
PHYSICIANS POSTGRADUATE PRESS INC Total	1,114,792	988,459
DIGESTIVE DISEASES CONSULTING Total	1,060,000	1,305,000
RODALE INC Total	1,039,280	-
TRIPLE I Total	1,025,441	274,253
HELIX MEDICAL COMMUNICATIONS Total	1,023,299	460,141
DAMKTG INC Total	976,031	551,131
CME OUTFITTERS LLC Total	948,814	-
NCM PUBLISHERS INC Total	938,756	-

EDEN COMMUNICATIONS GROUP Total	373,835	-
DOT COM ADVISORS Total	372,335	610,000
PRINCETON PARTNERS INC Total	370,909	88,744
THOMAS JEFFERSON UNIVERSITY Total	365,832	286,010
DEGGE GROUP LTD Total	364,612	262,388
AMERICAN PSYCHIATRIC Total	361,671	451,472
MCKINSEY AND COMPANY INC Total	361,000	768,750
PPS MEDICAL MARKETING Total	356,151	-
INTERNATIONAL BUSINESS Total	345,824	355,982
MEDICAL ECONOMICS DATA Total	345,506	46,860
ALLIANCE CONSULTING GROUP Total	345,000	-
MASSACHUSETTS GENERAL HOSPITAL Total	345,000	631,600
RESEARCH BY DESIGN Total	344,832	814,520
BARNES HOLLANDER INC Total	342,565	2,635
TMT THREE MAROON CIRCLE INC Total	336,362	23,734
BRIGHT HORIZONS FAMILY Total	333,048	214,763
AMERICAN SOCIETY OF CONSULTANT Total	332,105	439,374
DOUBLETREE HOTEL Total	328,107	443,031
PHARMACEUTICAL SALES SOLUTIONS LLC Total	326,060	9,597,679
STRATEGIC MARKETING INCORPORATED Total	326,000	-
STEEL BEACH PRODUCTIONS INC Total	325,000	295,000
DANNEMILLER MEMORIAL Total	324,557	1,385,259
KELLY MANAGEMENT SERVICES Total	323,342	376,658
EPOCRATES INC Total	322,500	493,000
INNOVATIVE SYSTEMS Total	318,782	253,889
JADA CREATIVE COMMUNICATIONS Total	312,362	304,265
CONTEXT INTEGRATION INC Total	311,300	498,075
MARRIOTT INTERNATIONAL Total	310,081	248,186
ACME DESIGN GROUP INC Total	301,730	248,453
DISNEYLAND RESORT Total	301,620	-
LEWIN GROUP INC Total	301,165	491,569
DESIGNWRITE INC Total	300,000	-
MEDIMEDIA USA INC Total	298,875	809,266
DUKE UNIVERSITY Total	297,970	971,827
HYBRID PUBLISHING Total	297,660	-
PHARMASTAR LLC Total	295,170	259,030
AMERICAN PSYCHIATRIC ASSOCIATION Total	291,900	120,900
NETWORK FOR CONTINUING MEDICAL Total	287,338	282,608
AMERICAN MEDICAL DIRECTORS Total	285,000	-
COVANCE CLINICAL AND Total	280,830	276,170
CHRIS KOZMA PHD Total	280,162	169,478
LASH GROUP HEALTHCARE Total	275,594	1,010,320
COGTEST *PLC Total	271,918	453,953
KRAMER CONSULTING SOLUTIONS INC Total	271,065	382,030
DIGEX INCORPORATED Total	266,630	196,215
MAROON OFFICE PARTNERS III LLC Total	264,515	410,648
EFORCE INC Total	264,200	105,500
PRINT PROMOTIONS INC Total	263,666	515,336
WILSON LEARNING CORPORATION Total	261,994	244,429
UNIVERSITY OF KANSAS MEDICAL Total	260,629	257,988
DRURY DESIGN DYNAMICS Total	259,158	230,279
COGNOS CORPORATION Total	258,851	376,306
HYBRID MEDICAL PUBLISHING Total	258,700	396,700
HEALTH TECH SOLUTIONS Total	258,000	-
UNIVERSITY OF TEXAS SOUTHWESTERN Total	257,936	-
DECISION POINTS INTERNATIONAL Total	254,313	184,617
HEALTH PRODUCTS RESEARCH INC Total	251,250	298,650
MG&G ADVERTISING INC Total	250,999	193,001
NOP WORLD HEALTH DBA Total	247,645	180,355
TEXANS CREDIT UNION Total	247,607	202,098
MEDICAL BROADCAST LIMITED Total	246,000	-
B I PERFORMANCE SERVICES Total	245,638	48,953
ANNENBERG CENTER AT EISENHOWER Total	244,140	418,850
IPROSPECT Total	243,359	71,494
NDCHEALTH Total	242,500	54,750
DOCUMENTUM INC Total	240,502	153,125
THOMSON HEALTHCARE INC Total	239,200	1,107,381
NATIONAL ALLIANCE FOR THE Total	237,349	653,341
COMPLETE HEALTHCARE Total	236,508	-
THE GMR GROUP INC Total	232,742	140,278
BELL MEDICAL SERVICES INC Total	231,868	329,287
YALE MARKETING LLC Total	231,596	32,938
PRI-MED Total	229,220	74,340
PRINTING METHODS INC Total	228,272	-

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- **Genetics Core:**
  - Coordinates the collection of DNA data across all center projects
  - Capitalize from pooling data from multiple studies to enhance statistical power
  - Facilitates the development of new genetic markers
  - Pilot projects

[redacted]

  - Pharmacogenetics of Risperdal

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- **Neuroimaging Core:**
  - Develop automated segmentation and brain parcellation methods
  - Coordinate imaging assessments across Center projects
  - Ability to rapidly process imaging data

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

- **Neuroimaging Core:**
  - Access to Dr. Nikos Makris at the Center For Morphometric Analysis at MGH
  - Collaboration provides access to automated methodology which will improve and expedite analysis of brain images

Johnson & Johnson Center for Pediatric Psychopathology Research

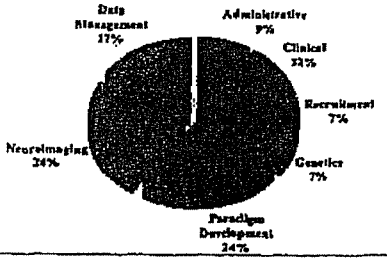
Massachusetts General Hospital

- **Paradigm Development Core:**
  - Develop new methods to address priority research areas for the Center
  - Paradigm Development
    - Driving
    - Laboratory workplace

Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

Allocation of Funds by Cores-2003



Johnson & Johnson Center for Pediatric Psychopathology Research

Massachusetts General Hospital

Allocation of Funds-2003

Total	$425,000
Recruitment/Assessment	$30,000
Genetics	$30,000
Administrative	$40,000
Clinical	$50,000
Data Management	$75,000
Neuroimaging	$100,000
Paradigm Development	$100,000

Final

Autism Treatment KOL Study

August 30, 2004

Last Revised: September 22, 2004 Deleted: 22

Estimated Survey Length: 10 min Deleted: 15

[Page]

KOL for Pharmacological Treatment of Children and Adolescents with Autism using Psychotropic Medications

SurveyRx is interested in identifying physicians who influence the opinions of other practitioners in treating Autism. We wish to identify physicians whose opinions are frequently sought by their peers.

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The following survey will require you to identify the names of physicians on national and regional levels who are key opinion leaders for the pharmacological treatment of children and adolescents with Autism using psychotropic medications. As consideration for your time to participate in our survey, you will receive an honorarium as stated in our invitation to this survey. However, please note that the honorarium will be credited only if real names are provided.

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The survey should take about 10 minutes to complete. All results are reported in the aggregate, for research purposes only, in accordance with Council of American Survey Research Organization guidelines.

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[Screener Questions]

S1. Which of the following best describes your primary specialty? *(Please select one.)*

[ ] Pediatrician
[ ] Child Psychiatrist
[ ] General Psychiatrist
[ ] Child Neurologist
[ ] General Neurologist
[ ] Other (Please specify) _____

S2. In a typical month, how many patients do you see for any condition? *(Please enter a number)*

_____ patients per month **[Range 0-1000, If it is less than 50, terminate]**

S3. Of these **[insert answer from S2]** patients seen in a typical month, how many patients do you see specifically for **Autism**? *(Please enter a number)*

_____ patients seen for **Autism [<= response in S2. If it is equal to 0, terminate]**

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[Begin Survey]

Q1. Do you refer the patients you see for **Autism** out to other physicians?
Yes, for at least some patients
No

[If Q1 = No, Skip Q2 and Q3]

Q2. Please indicate for what reason(s) do you refer out patients that you see for **Autism** to other physicians? *(Please select all that apply)*

[ROTATE ITEMS, Others is always the last item]

[ ] Referred to physician has more experience and/or treats more patients for **Autism**
[ ] Referred to physician is a specialist in the field of **Autism** treatment
[ ] Recommended by other colleagues
[ ] I don't have enough information about **Autism** and its treatment options
[ ] Patient fails to improve
[ ] **Autism** is not a part of my standard practice
[ ] Other (Please specify) _____

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Q3. Which physician(s) do you refer them to?
(If you do not know one of the requested items for any physician, you may leave that space blank.)

[First Name, Last Name and State is mandatory for at least one physician. These three fields (First Name, Last Name and State) are mandatory if the respondent enters information in Physician 2 fields]

Physician 1:
First Name _____
Last Name _____
City _____
State _____
Affiliation (Hospital, University, etc.) _____

Physician 2:
First Name _____
Last Name _____
City _____
State _____
Affiliation (Hospital, University, etc.) _____

[Page]

[NEXT SCREEN]

Now, we'd like to ask you about physicians who are nationally recognized for the pharmacological treatment of children and adolescents with Autism using psychotropic medications

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Q4. Please provide the names of three **nationally recognized** physicians who are most likely to influence your approach when treating Autism using medication.
(If you do not know one of the requested items for any physician, you may leave that space blank.)

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[First Name, Last Name and State is mandatory for at least one physician. These three fields (First Name, Last Name and State) are mandatory if the respondent enters information in Physician 2 or Physician 3 fields]

Physician 1:
First Name _____
Last Name _____
City _____
State _____
Affiliation (Hospital, University, etc.) _____

Physician 2:
First Name _____
Last Name _____
City _____
State _____
Affiliation (Hospital, University, etc.) _____

Physician 3:
First Name _____
Last Name _____
City _____
State _____
Affiliation (Hospital, University, etc.) _____

[NEXT SCREEN]

[Repeat Q5-Q7 separately for each physician mentioned in Q4 where First Name and Last Name fields have been filled] [Show Q5-Q7 on one screen for each physician]

Earlier you identified [Insert First Name, Last Name of physician named in Q4] as a nationally recognized physician for the pharmacological treatment of children and adolescents with Autism using psychotropic medications

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Q5. Please indicate the number of times within the past 3 years you attended an event at which this physician presented or spoke. **[Numeric Range 0 - 100]**

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_____

Q6. Please rate the influence this physician has had on your treatment practices for Autism. Please use a 7-point scale, where 1 means the physician "has not influenced my treatment at all" and 7 means the physician "has influenced my treatment greatly".

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Has not influenced my treatment at all						Has influenced my treatment greatly
1	2	3	4	5	6	7

Q7. Please indicate whichever option(s) best explain the reason(s) for classifying this physician as a national KOL. (*Please select all that apply*)

[ ] Involvement in Clinical Trials
[ ] Years of Experience in Treatment Area
[ ] Recommended by Other Colleagues
[ ] Published Articles
[ ] Case Studies from practice
[ ] Participation in Speaker Programs / Conferences

[NEXT SCREEN]

Next, we'd like to ask you about physicians who are regionally recognized for the pharmacological treatment of children and adolescents with Autism using psychotropic medications

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Q8. Please provide the names of 3 **regionally recognized physicians**, who are most likely to influence your approach when treating Autism. Here region refers to physicians practicing within your state or nearby states.
(If you do not know one of the requested items for any physician, you may leave that space blank.)

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[First Name, Last Name and State is mandatory for at least one physician. These three fields (First Name, Last Name and State) are mandatory if the respondent enters information in Physician 2 or Physician 3 fields]

Physician1:
First Name _____
Last Name _____
City _____
State _____
Affiliation (Hospital, University, etc.) _____

Physician2:
First Name _____
Last Name _____
City _____
State _____
Affiliation (Hospital, University, etc.) _____

Physician3:
First Name _____
Last Name _____
City _____
State _____
Affiliation (Hospital, University, etc.) _____

[Page]

[NEXT SCREEN]

[Repeat Q9 – Q12 separately for each physician mentioned in Q8 where First Name and Last Name fields have been filled] [Show Q9-Q12 on one screen for each physician]

Earlier you identified [Insert First Name, Last Name of physician named in Q.8] as a regionally recognized physician for the pharmacological treatment of children and adolescents with Autism using psychotropic medications

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Q9. Please indicate the number of times within the past 3 years you attended an event at which this physician presented or spoke. . **[Numeric Range 0-100]**

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_____

Q10. Please indicate the number of times you have spoken to or consulted with this physician over the past year, regarding a patient suffering from autism. **[Numeric Range 0-300]**

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_____

Q11. Please rate the influence this physician has had on your pharmacological treatment of children and adolescents with Autism using psychotropic medications. Please use a 7-point scale, where 1 means this physician "has not influenced my treatment at all" and 7 means the physician "has influenced my treatment greatly".

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Has not influenced my treatment at all						Has influenced my treatment greatly
1	2	3	4	5	6	7

Q12. Please indicate whichever option(s) best explain the reason(s) for classifying these physicians as regional KOLs. (Please select all that apply)

[ ] Involvement in Clinical Trials
[ ] Years of Experience in Treatment Area
[ ] Recommended by Other Colleagues
[ ] Published Articles
[ ] Case Studies from practice
[ ] Participation in Speaker Programs / Conferences

Q13. Please consider the following **specific** factors that may influence your prescribing for the pharmacological treatment of children and adolescents with **Autism** using psychotropic medications. Of course, many other factors will influence your prescribing, but we are interested in the relative influence of these particular factors.

Step1: Please read through the list of factors and assign **100 points to the one factor** that is most influential.

Step2: For each of the remaining factors, assign a value between 0 and 99 to indicate how important it is relative to the most influential factor. A value of 0 would indicate that you do not consider that factor at all, and value of 99 would indicate that it is nearly as important as the most influential factor. Please ensure that no two factors are assigned the same value.
(Please be sure to fill in a value for each factor.)

[ROTATE ITEMS]
[All values should be unique, one option has to be =100, Range 0-100]

	Points
Peer Interaction	
Patient Requests for Specific Drugs	
Availability of coupons and /or vouchers	
Sales Representative Messages	
Influence of Opinion Leaders	
Peer-Reviewed Journal Articles or Studies	
Medical Education	
Formulary Status	
Regulatory/Liability concerns	
Price of drugs	

Q14. From the following list of physicians, please identify the physicians whom you recognize as key opinion leaders for the pharmacological treatment of children and adolescents with **Autism** using psychotropic medications.

[Insert the following two tables with a check box against each name. These two tables shall appear side by side to accommodate all the names on the same screen. The survey participant will need to check boxes for only those names that he/she recognizes.]

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Michael Aman, Ohio Sta
Jorge Armenteros, Univ
Robert Asarnow, UCLA
David Beversdorf, OSU
Joseph Biederman, Mas
Tyrone Cannon, UCLA
Gabrielle Carlson, SUN
Kiki Chang, Stanford Un
Diane Chugani, Wayne
Daniel Connor, Universi
Barbara Cornblatt, Zuck
Graham Emslie, Univers
Paul Eslinger, Penn Stat
Robert Findling, Case W
Jean Frazier, McLean H
Barbara Gellar, Washin
Laurence Greenhill, Col
Robert Hendren, Univer
Michael Henry, McLean
Eric Hollander, Mt. Sinai
Peter Jensen, Columbia
Stuart Kaplan, The Milto
Jean King, University of
Deleted: Robert Kowalch, Univer

Michael Aman, Ohio State University
Jorge Armenteros, University of Miami School of Medicine
Robert Asarnow, UCLA Medical Center
David Beversdorf, OSU
Joseph Biederman, Massachusetts General Hospital
Tyrone Cannon, UCLA
Gabrielle Carlson, SUNY @ Stonybrook
Kiki Chang, Stanford University School of Medicine
Diane Chugani, Wayne State University
Daniel Connor, University of Massachusetts Medical School
Barbara Cornblatt, Zucker Hillside Hospital, Albert Einstein College of Medicine
Graham Emslie, University of Texas Southwestern Medical Center
Paul Eslinger, Penn State
Robert Findling, Case Western Reserve University School of Medicine
Jean Frazier, McLean Hospital
Barbara Gellar, Washington University
Laurence Greenhill, Columbia University
Robert Hendren, University of California, Davis/MIND Institute
Michael Henry, McLean Hospital
Eric Hollander, Mt. Sinai
Peter Jensen, Columbia University
Stuart Kaplan, The Milton Hershey Medical Center
Jean King, University of Massachusetts Medical School
Robert Kowatch, University of Cincinnati College of Medicine

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Harvey Kranzler, Bronx Psychiatric Center - Children's Hospital, Albert Einstein College of Medicine	Harvey Kranzler, Bronx
Sanjiv Kumra, Zucker Hillside Hospital, Albert Einstein College of Medicine	Sanjiv Kumra, Zucker H
Bennett Leventhal, University of Chicago	Bennett Leventhal, Univ
Mark Lewis, University of Florida Brain Institute	Mark Lewis, University c
Jeff Lieberman, University of North Carolina @ Chapel Hill	Jeff Lieberman, Univers
Thomas Lowe, University of California San Francisco	Thomas Lowe, Universit
Joan Luby, Washington University	Joan Luby, Washington
Andres Martin, Yale University School of Medicine	Andres Martin, Yale Uni
James McCracken, UCLA Medical Center	James McCracken, UCI
Christopher McDougle, Indiana University School of Medicine	Christopher McDougle, I
Tanya Murphy, University of Florida College of Medicine	Tanya Murphy, Universit
Mani Pavuluri, University of Illinois @ Chicago	Mani Pavuluri, Universit
David Pruitt, Univeristy of Maryland	David Pruitt, Univeristy c
Jeffrey Rausch, Medical College of Georgia	Jeffrey Rausch, Medical
Mark Riddle, Johns Hopkins Medical Center	Mark Riddle, Johns Hop
Floyd Sallee, University of Cincinnati College of Medicine	Floyd Sallee, University
Larry Scahill, Yale University School of Medicine, Yale Child Study Center	Larry Scahill, Yale Unive
Jon Shaw, University of Miami School of Medicine	Jon Shaw, University of
Hans Steiner, Stanford University School of Medicine	Hans Steiner, Stanford U
Gunvant Thaker, University of Maryland	Gunvant Thaker, Univer
Benedetto Vitiello, National Inst. of Mental Health	Benedetto Vitiello, Natio
Karen Wagner, The University of Texas Medical Branch	Karen Wagner, The Uni
John Walkup, Johns Hopkins Medical Center	Deleted: John Walkup, Johns Ho

[Page]

Thank you for your participation and insights!
Your survey information has been processed successfully!

[Page]

Kovacs, Clare [JANUS]

From: Kovacs, Clare [JANUS]
Sent: Wednesday, December 15, 2004 2:44 PM
To: 'Thiboutot, Debra A.'; Gross, Marilyn J.
Cc: Biederman, Joseph,M.D.; Aleardi, Megan M.; Pandina, Gahan [JANUS]
Subject: RE: 2004 payment

Debra, Marilyn,

Check #471364, dated December 13, for $250,000.00 for payment in full for the Year 2004 MGH Center for Pediatric Psychopharmacology Research activities will go out tonight (12/15/04) by 2-day Fedex to:

Marilyn Gross
General Hospital Corporation
50 Staniford Street, 10th Floor
Boston, MA 02114
Fedex Tracking #: 7903 6799 0454

Clare E. Kovacs

Senior Administrative Associate to
Georges M. Gharabawi, M.D., Gahan J. Pandina, Ph.D., Cynthia A. Bossie, Ph.D., Jacqueline D. Morein, Courtney A. Lonchena

Janssen Medical Affairs, LLC - Clinical Development

Phone: 609-730-3482; Fax: 609-730-3125

E-mail: ckovacs1@janus.jnj.com

-----Original Message-----
From: Thiboutot, Debra A. [mailto:DTHIBOUTOT@PARTNERS.ORG]
Sent: Thursday, December 09, 2004 12:46 PM
To: 'Pandina, Gahan [JANUS]'; Kovacs, Clare [JANUS]
Cc: Biederman, Joseph,M.D.; Aleardi, Megan M.; Gross, Marilyn J.
Subject: RE: 2004 payment

Dear Dr. Pandina and Ms. Kovacs,

The payee and address that you have is correct. Please send the payment to the attention of Marilyn Gross and reference fund number 020332. I would assume that the previously used supplier ID for these payments would remain the same. Please let me know if you need additional information. Thank you for your assistance.

12/15/04

Sincerely,
Deb Thiboutot

-----Original Message-----
From: Pandina, Gahan [JANUS] [mailto:GPandina@JANUS.JNJ.com]
Sent: Thursday, December 09, 2004 12:39 PM
To: Thiboutot, Debra A.; Kovacs, Clare [JANUS]
Subject: RE: 2004 payment
Importance: High

Dear Ms. Thiboutot,

I am working with my assistant, Clare Kovacs, to assure that the payment is remitted to you promptly.. I have one final question, and that is do you know to whom the check is to be paid, and what supplier ID (one previously used by Janssen) will be used? Our previous payment had been made to:

General Hospital Corp
50 Staniford Street 10th Floor
Boston MA 02114

Is this correct?

Please let both myself and Clare know as soon as possible. I will be leaving the office at 2:30 today, so if you need to discuss in more detail, please contact Clare at 609-730-3482.

Sincerely,

Gahan Pandina

-----Original Message-----
From: Thiboutot, Debra A. [mailto:DTHIBOUTOT@PARTNERS.ORG]
Sent: Wednesday, December 08, 2004 10:23 AM
To: 'Pandina, Gahan [JANUS]'
Subject: RE: 2004 payment

Dear Dr. Pandina,

Thank you for the update. We'll look forward to hearing from you as things progress.

Regards,
Deb

-----Original Message-----
From: Pandina, Gahan [JANUS] [mailto:GPandina@JANUS.JNJ.com]
Sent: Wednesday, December 08, 2004 10:16 AM
To: Thiboutot, Debra A.

Subject: RE: 2004 payment

Dear Ms. Thiboutot,

I am working closely with finance to remit this payment as soon as possible. I will let you know when I have a firm date for payment. Please feel free to contact me with any questions at the number below, or via email.

Sincerely,

Gahan Pandina

Gahan J. Pandina, Ph.D.
Associate Director, CNS Clinical Development
Janssen Medical Affairs, LLC
1125 Trenton-Harbourton Rd ☕ Titusville, NJ 08560
OFFICE: (609) 730 2324 ✉ FAX: (609) 730 3125
EMAIL: gpandina@janus.jnj.com

-----Original Message-----
From: Thiboutot, Debra A. [mailto:DTHIBOUTOT@PARTNERS.ORG]
Sent: Tuesday, November 30, 2004 10:13 AM
To: 'GPandina@JANUS.JNJ.com'
Subject: FW: 2004 payment

Dear Dr. Pandina,

I wondered if you might have had a chance to check into the payment for Dr. Biederman? He is anxious to learn of the status of the payment. Thank you for your attention to this request.

Deb Thiboutot

> -----Original Message-----
> From: Thiboutot, Debra A.

12/15/04

> Sent: Tuesday, November 23, 2004 12:57 PM
> To: 'gpandina@janus.JNJ.com'
> Subject: 2004 payment
>
> Dear Dr. Pandina,
>
> By way of introduction, I am temporarily filling in as Joe Biederman's
> business manager. Joe has asked me to contact you regarding a payment of
> $250,000 for his Johnson and Johnson Center for the Study of Pediatric
> Psychopharmacology at Mass. General Hospital. A payment of $250,000 was
> received in January, 2004 and an additional equivalent payment was anticipated
> for 2004 Center activities. Can you let me know the status of this payment?
> Please let me know if you require any additional information in order to
> respond to this inquiry. Thank you for your assistance.
>
> Deb
> Deb Thiboutot
> Acting Manager, Pedi Psychopharmacology
> Warren 7
>
>
> "The information transmitted in the email is intended only for the person or
> entity to which it is addressed and may contain confidential and/or privileged
> material. Any review, retransmission, dissemination or other use of or taking
> of any action in reliance upon this information by persons or entities other
> than the intended recipient is prohibited. If you receive this email in
> error, please contact the sender and delete the material from any computer."
>

Exhibit B attached to
Exhibit B

SUBMITTED UNDER SEAL
ENCLOSED DOCUMENTS SUBJECT TO STIPULATED PROTECTIVE ORDER

WEITZ & LUXENBERG, P.C.
A New York Professional Corporation
210 Lake Drive East, Suite 101
Cherry Hill, New Jersey 08002
(856) 755-1115

SUPERIOR COURT OF NEW JERSEY LAW DIVISION
MIDDLESEX COUNTY

In re: Risperdal/Seroquel/Zyprexa Litigation
Case Code 274

FILED UNDER SEAL

Alma Avila, as Next Friend of Amber N. Avila, an Individual Case,

Plaintiffs,

DOCKET NO.: L-6661-06

CIVIL ACTION

JOHNSON & JOHNSON COMPANY, JANSSEN PHARMACEUTICA PRODUCTS, L.P. a/k/a/ Janssen, L.P. a/k/a/ Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc., JOHN DOE Nos. 1 through 20 and JANE DOE Nos. 1 through 20.

Defendants.

CERTIFICATION OF TERESA CURTIN IN SUPPORT OF MOTION TO DESEAL

AFFIDAVIT OF RHONDA RADLIFF

STATE OF TEXAS §
§
COUNTY OF HARRIS §

ON THIS DAY, RHONDA RADLIFF appeared before me, the undersigned notary public. After I administered an oath to her, upon her oath, she said:

1. "My name is Rhonda Radliff. I am competent to make this affidavit. The facts stated in this affidavit are within my personal knowledge and are true and correct.

2. I am employed as a research project manager for the law firm of Bailey Perrin Bailey, located in Houston, Texas. I have been employed by the firm in that capacity since August 1, 2006. I have approximately 22 years work experience as a project manager, including the review of documents in mass tort and other complex litigation.

3. I am the project manager primarily responsible for coordinating the receipt, review, and preliminary analysis of the documents produced by Janssen Pharmaceutica, Inc., *et al.* ('Janssen') in the above-captioned cases, and have worked in that capacity on such cases since August 1, 2006. To date, the firm has received more than 2.5 million documents (19,623,569 pages) from Janssen, both in paper and electronic form (CDs and DVDs). To date, the firm and/or its representatives or agents have reviewed about a third of those documents. In addition, some documents remain to be loaded into the system, reviewed and analyzed. The firm is still receiving new document productions from Janssen, the last having been received in May 2008.

4. In the course of the firm's review of Janssen's document production, serious complications and shortcomings have been encountered with the production that, at best, have added months to time necessary to review the documents and, at worst, have made it impossible or prohibitively difficult to properly evaluate the production as a whole for completeness. In particular:

(a) Enormous amounts of document duplication is present in the production, seriously adding to the time and expense of document review and making it more difficult to determine production completeness;

(b) Large segments of produced documents do not contain any metadata regarding the source of the documents;

(c) Large segments of produced documents do not contain any optical character recognition ('OCR') capability, or have defective or limited OCR capability, rendering such documents unsearchable;

(d) Portions of the Food & Drug Administration ('FDA')-related data was provided in portable document format ('PDF') on separate disks, not in the Tagged Image File ('TIFF')/Meta data/OCR format that was typical of the remaining production, rendering it unsearchable in conjunction with the entire dataset and thus more difficult and time consuming to review;

(e) More Bates number prefixes than simply the 'JJRP,' 'JJRIS,' and 'JJRE' prefixes identified in the Fidurski Affidavit, which is attached to Janssen's Motion to Preclude Further Discovery or for Cost Shifting as Exhibit B, appear in the production and are not discussed or defined;

(f) The redaction of documents is very inconsistent and the noted reasons for redaction of documents is often vague; for example, non-responsive; and versions of redacted documents have been located in other parts of the production as unredacted.

(g) The metadata produced is at best incomplete. For example, very few, if any, blind-carbon ('bcc') email information has appeared in the production;

(h) Because of the haphazard manner in which the rolling production occurred, it has been impossible or prohibitively difficult so far to detect omissions from production, though we are recently (this month) attempting as best as possible to conduct such analysis;

(i) Without explanation, some documents have been provided only in hardcopy format;

(j) In some cases, documents are referenced within emails that we have been unable to locate in the data produced by Janssen;

(k) The list of custodians/employee sources of documents is very large, but we have been unable to determine whether it is complete because we have not been provided information by Janssen as to how it was derived; because documents continue to be delivered, we have not been able to determine the time frame that each custodian's/employee's documents were collected; we are unable to determine if there are gaps in date ranges for documents, including emails for example, until the production and review are complete; it is impossible to determine whether 'lower level' employees were excluded from the production as the organizational charts provided often do not include 'lower level' employees; analysis of teams and members of teams within Janssen will require additional time and may require 30(b)(6) depositions to determine completeness of the custodial/employee production."

5. As of June 20, 2008, per the meta data supplied by the defense, the number of confidential documents is 2,533,740, or just over 78% of the total number of documents (2,648,399). Considering the rolling production of documents has only recently subsided, my initial evaluation of the database as a whole has just begun. After many hours of searches, viewing random samples of selected sorts and search results, I estimate that the number of 'confidential' documents is about 95%.

FURTHER AFFIANT SAYETH NOT.

Rhonda Radliff

RHONDA RADLIFF

SWORN TO and SUBSCRIBED before me by RHONDA RADLIFF on June 20, 2008.

TEGAN R. BAKER
Notary Public, State of Texas
My Commission Expires
November 03, 2010

TEGAN BAKER, Notary Public in and for the State of Texas

Exhibit C attached to
Exhibit B

From: Peck, Jeffrey A (FP) [Jeffrey.Peck@dbr.com]
Sent: Wednesday, June 25, 2008 6:56 AM
To: Pennock, Paul
Subject: FW: Documents

Here it is.

Sent by Good Messaging
(www.good.com)

----Original Message----
From: Peck, Jeffrey A (FP)
Sent: Monday, June 23, 2008 05:07 PM Eastern Standard Time
To: 'Pennock, Paul'; Campion, Thomas F
Cc: kbailey@bpblaw.com
Subject: RE: Documents

Paul,

Pursuant to the Stipulated Protective Order entered on 8/6/07, and with the assumption that the attached documents will be used solely for purposes appropriate to this litigation, and in accordance with Rule 4:10 et. seq., Janssen does not object to their declassification.

From: Pennock, Paul [mailto:PPennock@weitzlux.com]
Sent: Thursday, June 19, 2008 11:18 AM
To: Campion, Thomas F; Peck, Jeffrey A (FP)
Cc: kbailey@bpblaw.com
Subject: Documents

Attached are the documents that we would like "declassified". Please have a look. I'm of course available to confer on this. Since it shouldn't take you very long to look these over, let's speak Monday. Let me know if some time around 2pm is okay on Monday. Ken will not need to be on the phone with me, so just let me know who needs to be on from your office and I'll call them.

Exhibit D attached to
Exhibit B

The New York Times
nytimes.com

June 8, 2008

Researchers Fail to Reveal Full Drug Pay

By GARDINER HARRIS and BENEDICT CAREY

A world-renowned Harvard child psychiatrist whose work has helped fuel an explosion in the use of powerful antipsychotic medicines in children earned at least $1.6 million in consulting fees from drug makers from 2000 to 2007 but for years did not report much of this income to university officials, according to information given Congressional investigators.

By failing to report income, the psychiatrist, Dr. Joseph Biederman, and a colleague in the psychiatry department at Harvard Medical School, Dr. Timothy E. Wilens, may have violated federal and university research rules designed to police potential conflicts of interest, according to Senator Charles E. Grassley, Republican of Iowa. Some of their research is financed by government grants.

Like Dr. Biederman, Dr. Wilens belatedly reported earning at least $1.6 million from 2000 to 2007, and another Harvard colleague, Dr. Thomas Spencer, reported earning at least $1 million after being pressed by Mr. Grassley's investigators. But even these amended disclosures may understate the researchers' outside income because some entries contradict payment information from drug makers, Mr. Grassley found.

In one example, Dr. Biederman reported no income from Johnson & Johnson for 2001 in a disclosure report filed with the university. When asked to check again, he said he received $3,500. But Johnson & Johnson told Mr. Grassley that it paid him $58,169 in 2001, Mr. Grassley found.

The Harvard group's consulting arrangements with drug makers were already controversial because of the researchers' advocacy of unapproved uses of psychiatric medicines in children.

In an e-mailed statement, Dr. Biederman said, "My interests are solely in the advancement of medical treatment through rigorous and objective study," and he said he took conflict-of-interest policies "very seriously." Drs. Wilens and Spencer said in e-mailed statements that they thought they had complied with conflict-of-interest rules.

John Burklow, a spokesman for the National Institutes of Health, said: "If there have been

violations of N.I.H. policy — and if research integrity has been compromised — we will take all the appropriate action within our power to hold those responsible accountable. This would be completely unacceptable behavior, and N.I.H. will not tolerate it."

The federal grants received by Drs. Biederman and Wilens were administered by Massachusetts General Hospital, which in 2005 won $287 million in such grants. The health institutes could place restrictions on the hospital's grants or even suspend them altogether.

Alyssa Kneller, a Harvard spokeswoman, said in an e-mailed statement: "The information released by Senator Grassley suggests that, in certain instances, each doctor may have failed to disclose outside income from pharmaceutical companies and other entities that should have been disclosed."

Ms. Kneller said the doctors had been referred to a university conflict committee for review.

Mr. Grassley sent letters on Wednesday to Harvard and the health institutes outlining his investigators' findings, and he placed the letters along with his comments in The Congressional Record.

Dr. Biederman is one of the most influential researchers in child psychiatry and is widely admired for focusing the field's attention on its most troubled young patients. Although many of his studies are small and often financed by drug makers, his work helped to fuel a controversial 40-fold increase from 1994 to 2003 in the diagnosis of pediatric bipolar disorder, which is characterized by severe mood swings, and a rapid rise in the use of antipsychotic medicines in children. The Grassley investigation did not address research quality.

Doctors have known for years that antipsychotic drugs, sometimes called major tranquilizers, can quickly subdue children. But youngsters appear to be especially susceptible to the weight gain and metabolic problems caused by the drugs, and it is far from clear that the medications improve children's lives over time, experts say.

In the last 25 years, drug and device makers have displaced the federal government as the primary source of research financing, and industry support is vital to many university research programs. But as corporate research executives recruit the brightest scientists, their brethren in marketing departments have discovered that some of these same scientists can be terrific pitchmen.

To protect research integrity, the National Institutes of Health require researchers to report to universities earnings of $10,000 or more per year, for instance, in consulting money from

makers of drugs also studied by the researchers in federally financed trials. Universities manage financial conflicts by requiring that the money be disclosed to research subjects, among other measures.

The health institutes last year awarded more than $23 billion in grants to more than 325,000 researchers at over 3,000 universities, and auditing the potential conflicts of each grantee would be impossible, health institutes officials have long insisted. So the government relies on universities.

Universities ask professors to report their conflicts but do almost nothing to verify the accuracy of these voluntary disclosures.

"It's really been an honor system thing," said Dr. Robert Alpern, dean of Yale School of Medicine. "If somebody tells us that a pharmaceutical company pays them $80,000 a year, I don't even know how to check on that."

Some states have laws requiring drug makers to disclose payments made to doctors, and Mr. Grassley and others have sponsored legislation to create a national registry.

Lawmakers have been concerned in recent years about the use of unapproved medications in children and the influence of industry money.

Mr. Grassley asked Harvard for the three researchers' financial disclosure reports from 2000 through 2007 and asked some drug makers to list payments made to them.

"Basically, these forms were a mess," Mr. Grassley said in comments he entered into The Congressional Record on Wednesday. "Over the last seven years, it looked like they had taken a couple hundred thousand dollars."

Prompted by Mr. Grassley's interest, Harvard asked the researchers to re-examine their disclosure reports.

In the new disclosures, the trio's outside consulting income jumped but was still contradicted by reports sent to Mr. Grassley from some of the companies. In some cases, the income seems to have put the researchers in violation of university and federal rules.

In 2000, for instance, Dr. Biederman received a grant from the National Institutes of Health to study in children Strattera, an Eli Lilly drug for attention deficit disorder. Dr. Biederman reported to Harvard that he received less than $10,000 from Lilly that year, but the company told Mr. Grassley that it paid Dr. Biederman more than $14,000 in 2000, Mr. Grassley's letter

stated.

At the time, Harvard forbade professors from conducting clinical trials if they received payments over $10,000 from the company whose product was being studied, and federal rules required such conflicts to be managed.

Mr. Grassley said these discrepancies demonstrated profound flaws in the oversight of researchers' financial conflicts and the need for a national registry. But the disclosures may also cloud the work of one of the most prominent group of child psychiatrists in the world.

In the past decade, Dr. Biederman and his colleagues have promoted the aggressive diagnosis and drug treatment of childhood bipolar disorder, a mood problem once thought confined to adults. They have maintained that the disorder was underdiagnosed in children and could be treated with antipsychotic drugs, medications invented to treat schizophrenia.

Other researchers have made similar assertions. As a result, pediatric bipolar diagnoses and antipsychotic drug use in children have soared. Some 500,000 children and teenagers were given at least one prescription for an antipsychotic in 2007, including 20,500 under 6 years of age, according to Medco Health Solutions, a pharmacy benefit manager.

Few psychiatrists today doubt that bipolar disorder can strike in the early teenage years, or that many of the children being given the diagnosis are deeply distressed.

"I consider Dr. Biederman a true visionary in recognizing this illness in children," said Susan Resko, director of the Child and Adolescent Bipolar Foundation, "and he's not only saved many lives but restored hope to thousands of families across the country."

Longtime critics of the group see its influence differently. "They have given the Harvard imprimatur to this commercial experimentation on children," said Vera Sharav, president and founder of the Alliance for Human Research Protection, a patient advocacy group.

Many researchers strongly disagree over what bipolar looks like in youngsters, and some now fear the definition has been expanded unnecessarily, due in part to the Harvard group.

The group published the results of a string of drug trials from 2001 to 2006, but the studies were so small and loosely designed that they were largely inconclusive, experts say. In some studies testing antipsychotic drugs, the group defined improvement as a decline of 30 percent or more on a scale called the Young Mania Rating Scale — well below the 50 percent change that most researchers now use as the standard.

Controlling for bias is especially important in such work, given that the scale is subjective, and raters often depend on reports from parents and children, several top psychiatrists said.

More broadly, they said, revelations of undisclosed payments from drug makers to leading researchers are especially damaging for psychiatry.

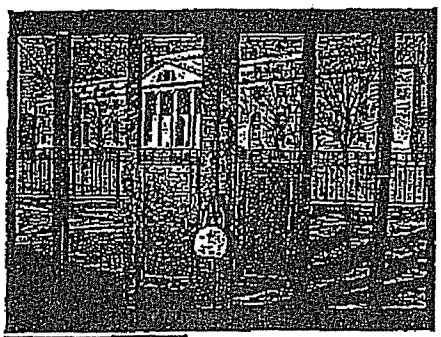
"The price we pay for these kinds of revelations is credibility, and we just can't afford to lose any more of that in this field," said Dr. E. Fuller Torrey, executive director of the Stanley Medical Research Institute, which finances psychiatric studies. "In the area of child psychiatry in particular, we know much less than we should, and we desperately need research that is not influenced by industry money."

Exhibit E attached to
Exhibit B

Bloomberg.com

Harvard Doctors Failed to Disclose Fees, Senator Says (Update2)

By Rob Waters



Enlarge/Detail

June 8 (Bloomberg) -- Harvard Medical School doctors who helped pioneer the use of psychiatric drugs in children violated U.S. government and school rules by failing to properly disclose at least $3.2 million from drugmakers led by **Johnson & Johnson** and Eli Lilly & Co., a U.S. senator said.

Joseph Biederman, Timothy Wilens and Thomas Spencer conducted studies on how kids are affected by drugs such as Lilly's attention deficit treatment Strattera. They filed yearly disclosure forms with the Boston school showing they got a total of $120,000 from several drugmakers, Senator **Charles Grassley** said in the Congressional Record. When Grassley sought added documentation in March, they admitted getting more, he said.

Grassley, an Iowa Republican, said the ethics violations put the medical school and the affiliated Massachusetts General Hospital, where the three work, in jeopardy of losing federal funds. The **hospital** and school said they will investigate the researchers and review current ethics policies.

``Obviously, if a researcher is taking money from a drug company while also receiving federal dollars to research that company's product, then there is a conflict of interest,'' Grassley said in a statement. He sent letters to the medical school and the U.S. National Institutes of Health last week.

Biederman directs, and Wilens and Spencer are affiliated with, a research center at Mass General that studies psychiatric medications in children. Biederman is the leading proponent of the idea that bipolar disorder, once viewed as an adult disease, can begin early in childhood and be treated with drugs.

Bipolar Disorder

Biederman's research helped convince many psychiatrists and pediatricians to look for and diagnose bipolar disorder in children, said **Larry Diller**, a behavioral pediatrician in Walnut Creek, California, who has written two books on the overuse of psychiatric drugs by children.

``He single-handedly put pediatric bipolar disorder on the map,'' Diller said in a telephone interview yesterday.

The number of kids diagnosed as bipolar increased 40-fold between 1994 and 2003, according to a recent study. Sales of drugs used to treat the condition doubled from 2003 to 2006.

Grassley, a member of the Senate Finance Committee, has proposed legislation that would require disclosure of the fees physicians receive for speaking, consulting and research.

Repeated attempts yesterday to reach the three doctors by telephone and e-mail were unsuccessful. Grassley, 74, also wasn't immediately available for comment.

`Examining Policies'

Arch MacInnes, a spokesman from Mass General, said in an e- mail that the hospital is investigating the doctors' disclosure and conflict of interest forms in coordination with Harvard Medical School.

The hospital and its corporate parent, Partners HealthCare, have also convened a commission to ``re-examine its policies to ensure that they appropriately address all issues in the relationships between Partners institutions and its physicians and industry,'' MacInnes said.

Harvard Medical School's office of the dean has referred the case to the Standing Committee on Conflicts of Interest and Commitments, **Robert Neal**, a spokesman for the school, said yesterday in an e-mailed statement.

The university and hospital ban researchers from working on a company's product if they receive more than $20,000 a year from the company, Neal said. The limit was $10,000 before 2004.

`[illegible]'

Tara Ryker, a spokeswoman for Indianapolis-based Lilly, said in a phone interview yesterday that she had no information about payments to the doctors, and that the company supports Grassley's legislation.

``The bill is a really important step in trying to build public trust and confidence in the relationship between the pharmaceutical industry and physicians,'' she said.

A telephone message for **Srikant Ramaswami**, a Johnson & Johnson spokesman, was not immediately returned.

The **National Institutes of Health**, which oversees $24 billion in federal health funding, requires researchers to disclose to their institutions relationships of least $10,000 with companies whose products are involved in studies.

Biederman is currently recruiting 4- to 6-year-olds with bipolar disorder to test London-based AstraZeneca Plc's Seroquel, and 6- to 12-year-olds with the condition to test Equetro, developed by U.K.-based Shire Ltd., according to a U.S.-run registry of clinical trials.

Limited Disclosure?

According to Grassley, the three researchers initially disclosed receiving less than $80,000 from Lilly, the maker of Zyprexa, an antipsychotic, and Strattera, a drug used to treat attention deficit disorder. On further review, in March, they said they had received $172,198 while the company told Grassley it had paid the three a total of $259,756.

Biederman initially said he had gotten less than $10,000 from Johnson & Johnson, the maker of the antipsychotic Risperdal. In March, he said the amount was $5,500. The company told Grassley it paid Biederman $64,378.

All three researchers have received support from the NIH, including funding to study Lilly's Strattera, Grassley said. In his letter to NIH, Grassley said he had become ``increasingly concerned about the lack of oversight'' in its grant process.

``Every year, the NIH hands out almost $24 billion in grants,'' he said. ``But nobody is watching.''

John Burklow, a spokesman for the NIH, said in an e-mail that if the agency finds its **policies** were violated ``we will take the appropriate action and consider the full range of options'' including terminating grants or withholding the award of money committed for future projects.

To contact the reporter on this story: **Rob Waters** in San Francisco at **rwaters5@bloomberg.net.**

Last Updated: June 8, 2008 15:43 EDT

Exhibit F attached to
Exhibit B

tampabay.com Know it now.

Medicine research corrupted

Published Monday, June 9, 2008 6:52 PM

The pharmaceutical industry's corrupting influence on medical research has reached a new low with a case that has stained the reputations of Harvard University and three of its top researchers in child psychiatry. It took a congressional investigation to uncover a conflict of interest that could violate federal and university rules. As a result, the credibility of a supposed breakthrough in treating childhood bipolar disease is now in doubt.

Dr. Joseph Biederman and two colleagues — who have promoted the use of antipsychotic drugs to treat bipolar children — withheld information about payments they were getting from drugmakers. While the Harvard faculty members were doing their research, some of it paid for by taxpayers, they were quietly taking millions of dollars from drug companies such as Johnson & Johnson, Eli Lilly and others that profited from the findings, the *New York Times* reported.

The researchers were supposed to report earnings in excess of $10,000 as consultants for drug companies, but they failed to do so. Even after Senate investigators forced Biederman to disclose his income, he reported receiving less than the drug companies say they gave him. In all, the three researchers accepted drug company payments of at least $2.6-million over the past seven years.

Did such hefty inducements affect the outcome of their research? It's a question that so far is unanswered. The doctors' findings have been influential but controversial, with 500,000 bipolar children being prescribed antipsychotic drugs. Some doctors say the medication saves young lives, though the side effects can be serious. Others say it is an experimental treatment that hasn't been proved effective over time.

There is no doubt what effect the scandal has had on the medical research field, which relies on a voluntary honor system. "The price we pay for these kinds of revelations is credibility, and we just can't afford to lose any more of that in this field," said Dr. E. Fuller Torrey of the Stanley Medical Research Institute.

Neither the pharmaceutical industry nor the medical researchers they try to influence can be trusted under the current system. Sen. Charles Grassley, R-Iowa, wants to create a national registry of drug research to keep track of such payments. Maybe a new bureaucracy isn't the answer, but something has to be done before people are injured and the public loses all trust in medical research.

Exhibit G attached to
Exhibit B

CONCURRENT RESOLUTION ON THE BUDGET FOR FISCAL YEAR 2008—S. CON. RES. 21, FURTHER REVISIONS TO THE CONFERENCE AGREEMENT PURSUANT TO SECTION 308(a) DEFICIT-NEUTRAL RESERVE FUND FOR ENERGY LEGISLATION

[In millions of dollars]

Current Allocation to Senate Environment and Public Works Committee:	
FY 2007 Budget Authority	42,426
FY 2007 Outlays	1,667
FY 2008 Budget Authority	43,535
FY 2008 Outlays	1,753
FY 2008–2012 Budget Authority	183,497
FY 2008–2012 Outlays	9,658
Adjustments:	
FY 2007 Budget Authority	0
FY 2007 Outlays	0
FY 2008 Budget Authority	0
FY 2008 Outlays	0
FY 2008–2012 Budget Authority	134,696
FY 2008–2012 Outlays	114,402
Revised Allocation to Senate Environment and Public Works Committee:	
FY 2007 Budget Authority	42,426
FY 2007 Outlays	1,667
FY 2008 Budget Authority	43,535
FY 2008 Outlays	1,753
FY 2008–2012 Budget Authority	318,193
FY 2008–2012 Outlays	124,070

REMEMBERING JOHN W. KEYS, III

Mr. BINGAMAN. Mr. President, I rise today on a sad note—to inform the Senate of the recent death of a model public servant who served our country well. John W. Keys, III, was the 16th Commissioner of the Bureau of Reclamation. He served in that capacity from July 17, 2001, to April 15, 2006, and worked closely with the Committee on Energy and Natural Resources which I have the privilege of chairing. Commissioner Keys retired 2 years ago to return to Utah and pursue his favorite pastimes which included flying. Tragically, he was killed on May 30, 2008, when the airplane he was piloting crashed in Canyonlands National Park, UT, with one passenger aboard.

Commissioner Keys' appointment by President Bush to lead the Bureau of Reclamation was actually his second stint with the agency. He returned to Federal service after previously retiring from a 34-year career with reclamation. During that time, he worked as a civil and hydraulic engineer in various positions throughout the western United States. Ultimately, he served as reclamation's Pacific Northwest regional director for 12 years before his initial retirement in 1998.

Commissioner Keys was a dedicated public servant whose knowledge, experience, and demeanor were key factors in his successful leadership of the Bureau of Reclamation. Those same skills, combined with his willingness to work with Congress on a bipartisan basis, were instrumental in addressing a wide range of water resource issues across the West. He will be sorely missed, but left a legacy of accomplishments that will ensure that he is long-remembered. I offer my condolences to his wife, Dell, and their daughters, Cathy and Robyn.

Mr. SMITH. Mr. President, I rise today to honor the memory of John W. Keys, III, who died tragically in a plane crash on Friday, May 30, 2008. John was a long-time Federal official, and a kind and thoughtful man.

John Keys was born in Sheffield, AL. He earned a bachelor's degree in civil engineering from the Georgia Institute of Technology and a master's degree from Brigham Young University. John was dedicated to his community, and spent much of his spare time serving as a search-and-rescue pilot for Utah County and as a college and high school football referee.

The majority of John Keys' life, however, was centered on his marriage to his wife Dell and his professional career at the Bureau of Reclamation, an agency of the Department of the Interior. John spent nearly 40 years working with Reclamation. From 1964 to 1979, he worked as a civil and hydraulic engineer in the Great Basin, Missouri River Basin, Colorado River Basin, and Columbia River Basin. I first met John when he served as Reclamation's Pacific Northwest regional director. In 1995, he was awarded Interior's highest honor—the Distinguished Service Award—for maintaining open lines of communication and keeping interest groups focused on solutions. After 12 years as Northwest regional director, John retired in 1998.

In 2001, John emerged from retirement to take a position as the 16th Commissioner of the Bureau of Reclamation. As Commissioner, John oversaw a venerable agency charged with the operation and maintenance of water storage, water distribution, and electric power generation facilities in 17 Western States. John placed great emphasis on operating and maintaining Reclamation projects to ensure continued delivery of water and power benefits to the public, consistent with environmental and other requirements. He was committed to honoring State water rights, interstate compacts, and contracts with Reclamation's users. This commitment helped the agency develop creative solutions to address the water resource challenges of the West.

John had retired as Commissioner in 2006. He was a highly respected and dedicated public servant. I stand today to express my appreciation for his service to the Northwest and to our country. I want to offer my sincere condolences to his wife, his daughters, and those he leaves behind.

PAYMENTS TO PHYSICIANS

Mr. GRASSLEY. Mr. President, starting last year, I started looking at the financial relationships between physicians and drug companies. I first began this inquiry by examining payments from Astra Zeneca to Dr. Melissa DelBello, a professor of psychiatry at the University of Cincinnati.

In 2002, Dr. DelBello published a study that found that Seroquel worked for kids with bipolar disorder. The study was paid for by Astra Zeneca, and the following year that company paid Dr. DelBello around $100,000 for speaking fees and honoraria. In 2004, Astra Zeneca paid Dr. DelBello over $80,000.

Today, I would like to talk about three physicians at Harvard Medical School—Drs. Joseph Biederman, Thomas Spencer, and Timothy Wilens. They are some of the top psychiatrists in the country, and their research is some of the most important in the field. They have also taken millions of dollars from the drug companies.

Out of concern about the relationship between this money and their research, I asked Harvard and Mass General Hospital last October to send me the conflict of interest forms that these doctors had submitted to their institutions. Universities often require faculty to fill these forms out so that we can know if the doctors have a conflict of interest.

The forms I received were from the year 2000 to the present. Basically, these forms were a mess. My staff had a hard time figuring out which companies the doctors were consulting for and how much money they were making. But by looking at them, anyone would be led to believe that these doctors were not taking much money. Over the last 7 years, it looked like they had taken a couple hundred thousand dollars.

But last March, Harvard and Mass General asked these doctors to take a second look at the money they had received from the drug companies. And this is when things got interesting. Dr. Biederman suddenly admitted to over $1.6 million dollars from the drug companies. And Dr. Spencer also admitted to over $1 million. Meanwhile, Dr. Wilens also reported over $1.6 million in payments from the drug companies.

The question you might ask is: Why weren't Harvard and Mass General watching over these doctors? The answer is simple: They trusted these physicians to honestly report this money.

Based on reports from just a handful of drug companies, we know that even these millions do not account for all of the money. In a few cases, the doctors disclosed more money than the drug companies reported. But in most cases, the doctors reported less money.

For instance, Eli Lilly has reported to me that they paid tens of thousands of dollars to Dr. Biederman that he still has not accounted for. And the same goes for Drs. Spencer and Wilens.

What makes all of this even more interesting is that Drs. Biederman and Wilens were awarded grants from the National Institutes of Health to study the drug Strattera.

Obviously, if a researcher is taking money from a drug company while also receiving Federal dollars to research that company's product, then there is a conflict of interest. That is why I am asking the National Institutes of Health to take a closer look at the grants they give to researchers. Every year, the NIH hands out almost $24 billion in grants. But nobody is watching

to ensure that the conflicts of interest are being monitored.

That is why Senator KOHL and I introduced the Physician Payments Sunshine Act. This bill will require companies to report payments that they make to doctors. As it stands right now, universities have to trust their faculty to report this money. And we can see that this trust is causing the universities to run afoul of NIH regulations. This is one reason why industry groups such as PhRMA and Advamed, as well as the American Association of Medical Colleges, have all endorsed my bill. Creating one national reporting system, rather than relying on a hodge-podge of state systems and some voluntary reporting systems, is the right thing to do.

Before closing, I would like to say that Harvard and Mass General have been extremely cooperative in this investigation, as have Eli Lilly, Astra Zeneca and other companies. I ask unanimous consent that my letters to Harvard, Mass General, and the NIH be printed the RECORD.

There being no objection, the material was ordered to be printed in the RECORD, as follows:

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC, June 4, 2008.

ELIAS A. ZERHOUNI, M.D.
Director, National Institutes of Health,
Bethesda, Maryland.

DEAR DIRECTOR ZERHOUNI: As a senior member of the United States Senate and the Ranking Member of the Committee on Finance (Committee), I have a duty under the Constitution to conduct oversight into the actions of executive branch agencies, including the activities of the National Institutes of Health (NIH/Agency). In this capacity, I must ensure that NIH properly fulfills its mission to advance the public's welfare and makes responsible use of the public funding provided for medical studies. This research often forms the basis for action taken by the Medicare and Medicaid programs.

Over the past number of years, I have become increasingly concerned about the lack of oversight regarding conflicts of interest relating to the almost $28 billion in annual extramural funds that are distributed by the NIH. In that regard, I would like to take this opportunity to notify you about five problems that have come to my attention on this matter.

First, it appears that three researchers failed to report in a timely, complete and accurate manner their outside income to Harvard University (Harvard) and Massachusetts General Hospital (MGH). By not reporting this income, it seems that they are placing Harvard and MGH in jeopardy of violating NIH regulations on conflicts of interest. I am attaching that letter for your review and consideration.

Second, I am requesting an update about a letter I sent you last October on problems with conflicts of interest and NIH extramural funding regarding Dr. Melissa DelBello at the University of Cincinnati (University). In that letter, I notified you that Dr. DelBello receives grants from the NIH, however, she was failing to report her outside income to her University.

Third, the Inspector General for the Department of Health and Human Services Office (HHS OIG) released a disturbing report last January which found that NIH provided almost no oversight of its extramural funds. But your staff seemed to show little interest in this report. In fact, Norka Ruiz Bravo, the NIH deputy director of extramural programs was quoted in The New York Times saying, "For us to try to manage directly the conflict-of-interest of an NIH investigator would be not only inappropriate but pretty much impossible."

Fourth, I am dismayed to have read of funding provided to several researchers from the Foundation for Lung Cancer: Early Detection, Prevention & Treatment (Foundation). Dr. Claudia Henschke and Dr. David Yankelevitz are two of the Foundation's board members. As reported by The New York Times, the Foundation was funded almost entirely with monies from tobacco companies, and this funding was never fully disclosed. Monies from the Foundation were then used to support a study that appeared in The New England Journal of Medicine (NEJM) back in 2006 regarding the use of computer tomography screening to detect lung cancer. The NEJM disclosure states that the study was supported also by NIH grants held by Drs. Henschke and Yankelevitz.

Regarding the lack of transparency by Dr. Henschke and Dr. Yankelevitz, National Cancer Institute Director John Niederhuber told the Cancer Letter, "[W]e must always be transparent regarding any and all matters, real or perceived, which might call our scientific work into question."

The NEJM later published a clarification regarding its earlier article and a correction revealing that Dr. Henschke also received royalties for methods to assess tumors with imaging technology. There is no evidence that the Foundation's tobacco money or Dr. Henschke's royalties influenced her research. But I am concerned that the funding source and royalties may have not been disclosed when the NIH decided to fund Dr. Henschke.

Fifth, I sent you a letter on April 15, outlining my concerns about a report on the National Institute of Environmental Health Sciences (NIEHS). That report found 45 cases at the NIEHS where extramural grants had not receiving sufficient peer review scores but were still funded. This finding is yet another example that the NIH provides little oversight for its extramural program.

Dr. Zerhouni, you faced similar scandals back in 2003 when it came to light that many NIH intramural researchers enjoyed lucrative arrangements with pharmaceutical companies. It took you some time, but you eventually brought some transparency, reform and integrity back to NIH. As you told Congress during one hearing, "I have reached the conclusion that drastic changes are needed as a result of an intensive review by NIH of our ethics program, which included internal fact-finding as well as an external review by the Blue Ribbon Panel."

NIH oversight of the extramural program is lax and leaves people with nothing more than questions—$24 billion worth of questions, to be exact. I am interested in understanding how you will address this issue. American taxpayers deserve nothing less.

In the interim, I ask you to respond to the following requests for information and documents. In responding to each request, first repeat the enumerated question followed by the appropriate response. Your responses should encompass the period of January 1, 2000 to April 1, 2008. I would appreciate receiving responses to the following questions by no later than June 18, 2008:

1. Please explain what actions the NIH has or will initiate to provide better oversight and transparency for its extramural funding program.

2. Please explain how often the NIH has investigated and/or taken action regarding a physician's failure to report a "significant financial interest," as defined by NIH regulation. For each investigation, please provide the following information:

a. Name of the Doctor(s) involved;

b. Date investigation began and the date ended;

c. Specific allegations which triggered investigation;

d. Findings of the investigation; and

e. Actions taken by the NIH, if any.

3. Since receiving notice that the University of Cincinnati was provided incomplete information from Dr. DelBello regarding her outside income, what steps has/will NIH take to address this issue? Please be specific.

4. Please provide a list of all NIH grants received by Dr. DelBello. For each grant, please provide the following:

a. Name of grant;

b. Topic of grant; and

c. Amount of funding for grant.

5. Please provide a list of any other interactions that Dr. DelBello has had with the NIH to include membership on advisory boards, peer review on grants, or the like.

6. Since reports appeared in the press regarding the undisclosed funding of the Foundation for Lung Cancer: Early Detection, Prevention & Treatment, what steps has/will NIH take to address this issue? Please provide all external and internal communications regarding this issue.

7. Please provide a list off all NIH grants received by Dr. Claudia Henschke. For each grant, please provide the following:

a. Name of grant;

b. Topic of grant; and

c. Amount of funding for grant.

8. Please provide a list of any other interactions that Dr. Henschke has had with the NIH to include membership on advisory boards, peer review on grants, or the like.

9. Please provide a list off all NIH grants received by Dr. David Yankelevitz. For each grant, please provide the following:

a. Name of grant;

b. Topic of grant; and

c. Amount of funding for grant.

10. Please provide a list of any other interactions that Dr. Yankelevitz has had with the NIH to include membership on advisory boards, peer review on grants, or the like.

11. Please provide a list off all NIH grants received by Dr. Joseph Biederman. For each grant, please provide the following:

a. Name of grant;

b. Topic of grant; and

c. Amount of funding for grant.

12. Please provide a list of any other interactions that Dr. Biederman has had with the NIH to include membership on advisory boards, peer review on grants, or the like.

13. Please provide a list off all NIH grants received by Dr. Timothy Wilens. For each grant, please provide the following:

a. Name of grant;

b. Topic of grant; and

c. Amount of funding for grant.

14. Please provide a list of any other interactions that Dr. Wilens has had with the NIH to include membership on advisory boards, peer review on grants, or the like.

I request your prompt attention to this matter and your continued cooperation. I also request that the response to this letter contain your personal signature. If you have any questions please contact my Committee staff, Paul Thacker at (202) 224-4515. Any formal correspondence should be sent electronically in PDF searchable format to brian_downey@finance-rep.senate.gov.

Sincerely,

CHARLES E. GRASSLEY,
Ranking Member.

U.S. SENATE,
COMMITTEE ON FINANCE,
Washington, DC, June 4, 2008.

Dr. DREW GILPIN FAUST,
President, Harvard University,
Massachusetts Hall, Cambridge, MA.
Dr. PETER L. SLAVIN,
President, Massachusetts General Hospital (Partners Healthcare), Boston, MA.

DEAR DRS. FAUST AND SLAVIN: The United States Senate Committee on Finance (Committee) has jurisdiction over the Medicare and Medicaid programs and, accordingly, a responsibility to the more than 80 million Americans who receive health care coverage under these programs. As Ranking Member of the Committee, I have a duty to protect the health of Medicare and Medicaid beneficiaries and safeguard taxpayer dollars appropriated for these programs. The actions taken by thought leaders, like those at Harvard Medical School who are discussed throughout this letter, often have a profound impact upon the decisions made by taxpayer funded programs like Medicare and Medicaid and the way that patients are treated and funds expended.

Moreover, and as has been detailed in several studies and news reports, funding by pharmaceutical companies can influence scientific studies, continuing medical education, and the prescribing patterns of doctors. Because I am concerned that there has been little transparency on this matter, I have sent letters to almost two dozen research universities across the United States. In these letters, I asked questions about the conflict of interest disclosure forms signed by some of their faculty. Universities require doctors to report their related outside income, but I am concerned that these requirements are disregarded sometimes.

I have also been taking a keen interest in the almost $28 billion annually appropriated to the National Institutes of Health to fund grants at various institutions such as yours. As you know, institutions are required to manage a grantee's conflicts of interest. But I am learning that this task is made difficult because physicians do not consistently report all the payments received from drug companies.

To bring some greater transparency to this issue, Senator Kohl and I introduced the Physician Payments Sunshine Act (Act). This Act will require drug companies to report publicly any payments that they make to doctors, within certain parameters.

I am writing to try and assess the implementation of financial disclosure policies of Harvard University (Harvard) and Massachusetts General Hospital (MGH/Partners), (the Institutions). In response to my letters of June 29, October 26, and October 26, 2007, your Institutions provided me with the financial disclosure reports that Drs. Joseph Biederman, Thomas Spencer, and Timothy Wilens (Physicians) filed during the period of January 2000 through June 2007.

My staff investigators carefully reviewed each of the Physicians' disclosure forms and detailed the payments disclosed. I then asked that your Institutions confirm the accuracy of the information. In March 2008, your Institutions then requested additional information from the Physicians pursuant to my inquiry. That information was subsequently provided to me.

In their second disclosures to your Institutions, the Physicians revealed different information than they had disclosed initially to your respective Institutions. On April 29, 2008, I received notification from Harvard Medical School's Dean for Faculty and Research Integrity that he has referred the cases of these Physicians to the Standing Committee on Conflicts of Interest and Commitment ("Standing Committee"). The Chief Academic Officer (CAO), Partners HealthCare System, also wrote me that Partners will look to the Standing Committee to conduct the initial factual review of potential non-compliance that are contained in both the Harvard Medical School Policy and the Partners Policy. In addition, the CAO stated that, in addition to the Standing Committee's review process, Partners will conduct its own independent review of conflicts of interest disclosures these Physicians submitted separately to Partners in connection with publicly funded research and other aspects of Partners Policy. I look forward to being updated on these reviews in the near future.

In addition, I contacted executives at several major pharmaceutical companies and asked them to list the payments that they made to Drs. Biederman, Spencer, and Wilens during the years 2000 through 2007. These companies voluntarily and cooperatively reported additional payments that the Physicians do not appear to have disclosed to your Institutions.

Because these disclosures do not match, I am attaching a chart intended to provide a few examples of the data that have been reported me. This chart contains three columns: payments disclosed in the forms the physicians filed at your Institutions, payments revealed in March 2008, and amounts reported by some drug companies.

I would appreciate further information to see if the problems I have found with these three Physicians are systemic within your Institutions.

INSTITUTIONAL AND NIH POLICIES

Both Harvard and MGH/Partners have established an income de minimus limit. This policy forbids researchers working at your Institutions from conducting clinical trials with a drug or technology if they receive payments over $20,000 from the company that manufactures that drug or technology. Prior to 2004, the income de minimus limit established by your institutions was $10,000.

Further, federal regulations place several requirements on a university/hospital when its researchers apply for NIH grants. These regulations are intended to ensure a level of objectivity in publicly funded research, and state in pertinent part that NIH investigators must disclose to their institution any "significant financial interest" that may appear to affect the results of a study. NIH interprets "significant financial interest" to mean at least $10,000 in value or 5 percent ownership in a single entity.

Based upon information available to me, it appears that each of the Physicians identified above received grants to conduct studies involving atomoxetine, a drug that sells under the brand name Strattera. For example:

In 2000, the NIH awarded Dr. Biederman a grant to study atomoxetine in children. At that time, Dr. Biederman disclosed that he received less than $10,000 in payments from Eli Lilly & Company (Eli Lilly). But Eli Lilly reported that it paid Dr. Biederman more than $14,000 for advisory services that year—a difference of at least $4,000.

In 2004, the NIH awarded Dr. Wilens a 5-year grant to study atomoxetine. In his second disclosure to your Institutions, Dr. Wilens revealed that he received $7,500 from Eli Lilly in 2004. But Eli Lilly reported to me that it paid Dr. Wilens $27,500 for advisory services and speaking fees in 2004—a difference of about $20,000.

It is my understanding that Dr. Wilens' NIH-funded study of atomoxetine is still ongoing. According to Eli Lilly, it paid Dr. Wilens almost $65,000 during the period January 2004 through June 2007. However, as of March 2008, and based upon the documents provided to us to date, Dr. Wilens disclosed payments of about half of the amount reported by Eli Lilly for this period. Dr. Wilens also did three other studies of atomoxetine in 2005 and 2007.

I have also found several instances where these Physicians apparently received income above your institutions' income de minimus limit. For instance, in 2003, Dr. Spencer conducted a study of atomoxetine in adolescents. At the time, he disclosed no significant financial interests related to this study. But Eli Lilly reported paying Dr. Spencer over $25,000 that year.

In 2001, Dr. Biederman disclosed plans to begin a study sponsored by Cephalon, Inc. At the time; Dr. Biederman disclosed that he had no financial relationship with the sponsor of this study. Yet, on his conflict of interest disclosure, he acknowledged receiving research support and speaking fees from Cephalon, Inc., but did not provide any information on the amounts paid. In March 2008, Dr. Biederman revealed that Cephalon, Inc. paid him $13,000 in 2001.

In 2005, Dr. Biederman began another clinical trial sponsored by Cephalon, Inc., which was scheduled to start in September 2005 and end in September 2006. Initially, Dr. Biederman disclosed that he had no financial relationship with the sponsor of this study. But in March 2008, Dr. Biederman revealed that Cephalon, Inc. paid him $11,000 for honoraria in 2005 and an additional $24,750 in 2006.

In light of the information set forth above, I ask your continued cooperation in examining conflicts of interest. In my opinion, institutions across the United States must be able to rely on the representations of its faculty to ensure the integrity of medicine, academia, and the grant-making process. At the same time, should the Physician Payments Sunshine Act become law, institutions like yours will be able to access a database that will set forth the payments made to all doctors, including your faculty members. Indeed at this time there are several pharmaceutical and device companies that are looking favorably upon the Physician Payments Sunshine Bill and for that I am gratified.

Accordingly, I request that your respective institutions respond to the following questions and requests for information. For each response, please repeat the enumerated request and follow with the appropriate answer.

1. For each of the NIH grants received by the Physicians, please confirm that the Physicians reported to Harvard and MGH/Partners' designated official "the existence of [his] conflicting interest." Please provide separate responses for each grant received for the period from January 1, 2000 to the present, and provide any supporting documentation for each grant identified.

2. For each grant identified above, please explain how Harvard and MGH/Partners ensured "that the interest has been managed, reduced, or eliminated?" Please provide an individual response for each grant that each doctor received from January 2000 to the present, and provide any documentation to support each claim.

3. Please report on the status of the Harvard Standing Committee and additional Partners reviews of the discrepancies in disclosures by Drs. Biederman, Spencer and Wilens, including what action, if any, will be considered.

4. For Drs. Biederman, Spencer, and Wilens, please report whether a determination can be made as to whether or not any doctor violated guidelines governing clinical trials and the need to report conflicts of interest to an institutional review board (IRB). Please respond by naming each clinical trial for which the doctor was the principal investigator, along with confirmation that conflicts of interest were reported, if possible.

5. Please provide a total dollar figure for all NIH monies annually received by Harvard and MGH/Partners, respectively. This request covers the period of 2000 through 2007.

6. Please provide a list of all NIH grants received by Harvard and MGH/Partners. This request covers the period of 2000 through 2007. For each grant please provide the following:

a. Primary Investigator;

b. Grant Title;

c. Grant number;

d. Brief description; and

e. Amount of Award.

Thank you again for your continued cooperation and assistance in this matter. As you know, in cooperating with the Committee's review, no documents, records, data or information related to these matters shall be destroyed, modified, removed or otherwise made inaccessible to the Committee.

I look forward to hearing from you by no later than June 18, 2008. All documents responsive to this request should be sent electronically in PDF format to Brian Downey@finance-rep.senate.gov. If you have any questions, please do not hesitate to contact Paul Thacker at (202) 224-4515.

Sincerely,

CHARLES E. GRASSLEY,
Ranking Member.

SELECTED DISCLOSURES BY DR. BIEDERMAN AND RELATED INFORMATION REPORTED BY PHARMACEUTICAL COMPANIES

Year	Company	Disclosure filed with institution	Payments revealed in March 2008	Amount company reported
2000	GlaxoSmithKline	Not reported	$2,000	$3,378
	Eli Lilly & Company	<$10,000	3,500	14,105
	Pfizer Inc.	Not reported	7,000	7,000
2001	Cephalon	No amount provided	13,000	n/a
	GlaxoSmithKline	No amount provided	3,500	4,428
	Eli Lilly & Company	No amount provided	6,000	14,339
	Johnson & Johnson	Not reported	3,500	58,105
	Medical Education Systems	Not reported	21,000	n/a
	Pfizer Inc.	No amount provided	5,625	5,625
2002	Bristol-Myers Squibb	No amount provided	2,000	2,000
	Cephalon	No amount provided	3,000	n/a
	Cotwood	Not reported	14,000	n/a
	Eli Lilly & Company	No amount provided	11,000	2,289
	Johnson & Johnson	Not reported	Not reported	706
	Pfizer Inc.	No amount provided	4,000	2,000
2003	Bristol-Myers Squibb	No amount provided	500	250
	Cephalon	<10,000	4,000	n/a
	Eli Lilly & Company	<10,000	8,250	18,347
	Johnson & Johnson	<10,000	2,000	2,889
	Medicenting	Not reported	26,500	n/a
	Pfizer Inc.	<10,000	1,000	1,000
2004	Bristol-Myers Squibb	No amount provided	6,266	6,266
	Cephalon	Not reported	4,000	n/a
	Eli Lilly & Company	No amount provided	8,000	15,636
	Johnson & Johnson	Not reported	Not reported	982
	Medicenting	Not reported	26,000	n/a
	Pfizer Inc.	Not reported	3,000	4,000
2005	Cephalon	Not reported	11,000	n/a
	Eli Lilly & Company	<20,000	12,500	7,500
	Johnson & Johnson	Not reported	Not reported	982
	Pfizer Inc.	Not reported	3,000	3,000
	Medicenting	Not reported	34,000	n/a
2006	Cephalon	Not reported	24,750	n/a
	Johnson & Johnson	Not reported	Not reported	750
	Primedia	Not reported	56,000	n/a
2007	Primedia	Not reported	30,000	n/a

Note 1: Dr. Biederman revealed in March 2008 that his outside income totaled about $1.6 million during the period January 2000 through June 2007. Information reported by the pharmaceutical companies indicate that they made additional payments that are not reflected in Dr. Biederman's disclosures.

Note 2: When a Physician named a company in a disclosure but did not provide an amount, the text reads "no amount reported." When a Physician did not list the company in the disclosure, the column reads "not reported." The Committee contacted several companies for payment information and the notation n/a (not available) reflects that a company was not contacted.

SELECTED DISCLOSURES BY DR. SPENCER AND RELATED INFORMATION REPORTED BY PHARMACEUTICAL COMPANIES

Year	Company	Disclosure filed with institution	Payments revealed in March 2008	Amount company reported
2000	GlaxoSmithKline	Not reported	$3,000	$1,500
	Eli Lilly & Company	Not reported	12,345	11,453
2001	GlaxoSmithKline	Not reported	4,000	1,000
	Eli Lilly & Company	Not reported	8,500	10,859
	Strategic Implications	Not reported	16,800	n/a
2002	GlaxoSmithKline	Not reported	3,000	3,369
	Eli Lilly & Company	Not reported	14,000	14,016
	Strategic Implications	Not reported	29,000	n/a
2003	Eli Lilly & Company	Not reported	6,000	25,500
	Johnson & Johnson	Not reported	1,250	0
	Thomson Physicians World	Not reported	46,500	n/a
2004	Eli Lilly & Company	Not reported	Not reported	23,000
	Pfizer Inc.	Not reported	3,500	3,500
2005	Eli Lilly & Company	<$20,000	6,000	7,500
	Johnson & Johnson	Not reported	1,500	227
	Medicenting	Not reported	28,250	n/a
2006	Eli Lilly & Company	No amount provided	15,688	8,188
	Johnson & Johnson	Not reported	5,500	0
	Primedia	Not reported	44,000	n/a
2007	Eli Lilly & Company	No amount provided	6,000	16,188

Note 1: Dr. Spencer revealed in March 2008 that his outside income totaled about $1 million during the period January 2000 through June 2007. Information reported by the pharmaceutical companies indicate that they made additional payments that are not reflected in Dr. Spencer's disclosures.

Note 2: When a Physician named a company in a disclosure but did not provide an amount, the text reads "no amount reported." When a Physician did not list the company in the disclosure, the column reads "not reported." The Committee contacted several companies for payment information and the notation n/a (not available) reflects that a company was not contacted.

SELECTED DISCLOSURES BY DR. WILENS AND RELATED INFORMATION REPORTED BY PHARMACEUTICAL COMPANIES

Year	Company	Disclosure filed with institution	Payments revealed in March 2008	Amount company reported
2000	GlaxoSmithKline	Not reported	$5,250	$12,009
	Eli Lilly & Company	Not reported	2,000	2,057
	Pfizer Inc.	Not reported	1,250	2,250
	TVG	Not reported	11,000	n/a
2001	GlaxoSmithKline	<$10,000	n/a	2,269
	Eli Lilly & Company	No amount provided	3,952	952
	A.R. Austin	Not reported	14,500	n/a
2002	GlaxoSmithKline	Not reported	7,500	20,764
	Eli Lilly & Company	Not reported	4,500	3,000
	Pfizer Inc.	Not reported	1,500	1,500
	Phase 5	Not reported	20,000	n/a

SELECTED DISCLOSURES BY DR. WILENS AND RELATED INFORMATION REPORTED BY PHARMACEUTICAL COMPANIES—Continued

Year	Company	Disclosure filed with institution	Payments revealed in March 2008	Amount company reported
2003	Eli Lilly & Company	Not reported	12,000	0
	Phase 5	Not reported	60,500	n/a
	TVG	Not reported	31,000	n/a
	Medlearning	Not reported	24,000	n/a
2004	Eli Lilly & Company	Not reported	7,500	77,500
	Phase 5	Not reported	84,250	n/a
	Medlearning	Not reported	46,000	n/a
2005	Eli Lilly & Company	<20,000	9,500	9,500
	Promedix	Not reported	70,000	n/a
	Advanced Health Media	Not reported	37,750	n/a
2006	Eli Lilly and Physician World (Lilly)	No amount provided	5,963	12,798
	Advanced Health Media	Not reported	56,000	n/a
	Primedia	Not reported	32,000	n/a
2007	Eli Lilly & Company	Not reported	9,000	14,589
	Veritas	Not reported	25,388	n/a

Note 1: Dr. Wilens reveiled in March 2008 that his outside income totaled about $1.6 million during the period January 2000 through June 2007. Information reported by the pharmaceutical companies indicate that they made additional payments that are not reflected in Dr. Spencer's disclosures.

Note 2: When a Physician named a company in a disclosure but did not provide an amount, the text reads "no amount reported." When a Physician did not list the company in the disclosure, the column reads "not reported." The Committee contacted several companies for payment information and the notation n/a (not available) reflects that a company was not contacted.

MINNESOTA'S 150TH BIRTHDAY

Ms. KLOBUCHAR. Mr. President, in May, I joined Governor Pawlenty, Senator COLEMAN and our Minnesota Congressional Delegation, our State legislators and thousands of Minnesotans in celebrating Minnesota's 150 years as a State.

We are proud to be a State where—in the words of our unofficial poet laureate Garrison Keillor—all the women are strong, all the men are good-looking, and all the sesquicentennials are above average.

For 150 years, our State has been built by people who knew they had to work hard, had to be bold, and had to persevere—to overcome the adversities and hardships that confronted them.

Each one of us here is a part of Minnesota's illustrious history. And each one of us has our own story about our Minnesota heritage.

Mine has its roots in the rough and tumble Iron Range, where my grandpa worked 1,500 feet underground in the mines of Ely. He and my grandma graduated from high school, but they saved money in a coffee can to send my dad to college. The little house they lived in all their lives they got when the mine closed down in Babbitt. They loaded it on the back of a flatbed truck and dynamited out a hole for the basement in Ely. The only problem was my grandpa used too much dynamite and the neighbor's wash went down a block away from all the flying rocks.

I told the story up north a while back and some old guy stood up and yelled out, "As if we don't remember!" They have long memories up on the Range.

Today is a day to remember that Minnesota is recognized and admired both for our natural beauty and our hard-working people.

We are home to the headwaters of the Mississippi River and to Lake Superior, the "greatest" of the Great Lakes.

We are home to native peoples whose history stretches far before our statehood.

We are the State that mined the iron ore for America's ships and skyscrapers.

We are the home to Fortune 500 companies that lead the way in innovation—bringing the world everything from the pacemaker to the Post-It Note.

We are home to hospitals and medical institutions that heal the sick from around the world.

And we are now a national leader in the renewable energy that will power our future.

For 150 years, we have served our country with great honor. Back in the Civil War, it was the First Minnesota that held the line during the Battle of Gettysburg, preventing a breach in the Union lines. The price this volunteer unit paid was the highest casualty rate of any military unit in American history, and today their flag flies here in the Capitol rotunda as a reminder of their bravery and sacrifice.

Now, the Minnesota National Guard's 34th Infantry Regiment—the famed Red Bulls—traces its roots to the 1st Minnesota Volunteers and they continue to honor that tradition of service to country.

On the sports field, we are home to the 1987 and 1991 World Series Champion Minnesota Twins.

It was a Minnesotan, Herb Brooks, who coached the U.S. Hockey Team to the gold medal in the 1980 Winter Olympics—the "Miracle on Ice."

Of course, after years of anguish, my dad, still an avid sports fan, continues to ask if the Vikings will ever win the Super Bowl.

We brought the world music legends from Bob Dylan to Prince to "Whoopie John," the King of Polka from New Ulm.

And speaking of culture, Darwin, MN, is home to the world's largest ball of twine built by one person (my husband made me add the "by one person!"). He saw a documentary about some other ball of twine.

Then we have our many colorful politicians, from Senator James Shields, who challenged Abraham Lincoln to a saber duel, to Senator Magnus Johnson, whose Swedish accent was so thick that his nickname going into the Senate was "Yenerally Speaking Yohnson", to Governor Rudy Perpich and his polka-mass; to Governor Ventura and his feather boa, to Paul Wellstone and his green bus, to two of America's most beloved Vice Presidents.

In fact, I read in a national magazine way back that ours is the only State where parents bounce their babies on their knees and say, "One day you could grow up to be Vice President."

But, Minnesota's celebration is not just about our history. It is also about our future. That is why the involvement of young people is so important—especially our young essay winners.

I always think of our State as a "work in progress."

We are a State whose people have always believed—despite the cold, the snow, the windswept prairies . . . Despite all that, we have always believed that anything was possible.

We are a State that is defined by the optimism of our people. We look to the future and we believe that—with hard work, education and good values—we can make tomorrow better than today.

I am reminded of an Ojibwe prayer passed down from the ages—the prayer that our leaders and our people make decisions not for their own generation but for those seven generations from now.

That is what that ragtag brigade of Minnesota citizen soldiers did in 1863 when they held the line at the Battle of Gettysburg.

That is what Sigurd Olson was thinking as he wrote about the beauty of our State and this Earth and its stewardship.

And that is what an Iron Range miner was hoping for as he saved those dollars in that coffee can, never dreaming his granddaughter would end up in the United States Senate.

After 150 years, we celebrate the courage and forethought of those who came before us and pray that we can live up to their expectations.

Happy birthday, Minnesota!

CONGRATULATING CARRIS REELS

Mr. LEAHY. Mr. President, I rise today to congratulate Carris Reels of Rutland, VT, for receiving the 2008 ESOP Association's "Company of the Year" award.

Founded in 1951 by Henry Carris, and bought by his son, Bill Carris, in 1980, Carris Reels sells a full line of manufactured reel products for a wide variety of industries. Today, Carris Reels has about 550 employee owners and

ORDER OF HON. BRYAN D. GARRUTO, J.S.C.
SUPERIOR COURT OF NEW JERSEY
MIDDLESEX COUNTY SUPERIOR COURT
LAW DIVISION: MIDDLESEX COUNTY
1 JFK SQUARE, P.O. BOX 964
NEW BRUNSWICK, NJ 08903
(732) 981-3116

FILED
MAR 23 2007
BRYAN D. GARRUTO, J.S.C.

MELISSA KAYE BROWN and
GLENN ALLEN BROWN

Plaintiffs.

vs.

JOHNSON & JOHNSON, JOHNSON & JOHNSON PHARMACEUTICAL RESEARCH & DEVELOPMENT, LLC, and ORTHO-MCNEIL PHARMACEUTICAL, INC.

Defendants.

SUPERIOR COURT OF NEW JERSEY
LAW DIVISION: MIDDLESEX COUNTY

DOCKET NO.: MID-L-5446-05 MT

CIVIL ACTION

This Order also applies to the following Docket Nos.: MID-L-6209-05 MT, MID-L-6227-05 MT, and MID-L-7291-05 MT

ORDER TO DECLASSIFY DOCUMENTS SUBJECT TO A STIPULATED PROTECTED ORDER OF CONFIDENTIALITY

THIS MATTER having been opened by Plaintiffs Melissa Kaye Brown and Glenn Allen Brown on their Motion to De-Designate Defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, LLC and Ortho-McNeil Pharmaceutical, Inc.'s "Protected" Document Designations, and for good cause shown:

ON THIS 23rd DAY OF MARCH, 2007;

IT IS ORDERED that the five within documents provided to the plaintiffs during discovery subject to either the *Lilly* Protective Order or the Multi-District Litigation ("MDL")

Order entered by the N.D. Ohio are hereby de-designated as "Protected". The following documents, which are attached to the Opinion accompanying this Order, are hereby de-designated:

1. Document page numbers POEPOE05293286-POE05293288; POE05293242-POE05293243. Attached as Exhibit 10 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations. (Attached to the Court's Opinion as "Exhibit A")

2. Document page numbers POE05286980-POE005286986, Attached as Exhibit 11 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations. (Attached to the Court's Opinion as "Exhibit B")

3. Document page numbers POE05306871-POE05306873, Attached as Exhibit 13 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations. (Attached to the Court's Opinion as "Exhibit C")

4. Document page numbers POE05307256-POE05307258, Attached as Exhibit 14 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations. (Attached to the Court's Opinion as "Exhibit D")

5. Document page numbers POE05307256-POE05307258, Attached as Exhibit 15 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations. (Attached to the Court's Opinion as "Exhibit E")

AND IT IS ORDERED that the supplemental briefs to the extent they reference the five documents are declassified within 10 (ten) days of this Order;

AND IT IS FURTHER ORDERED that a copy of this Order shall be served upon all parties within seven (7) days of the date herein.

THE HON. BRYAN D. GARRUTO, J.S.C.

SUPERIOR COURT OF NEW JERSEY

CHAMBERS OF
BRYAN D. GARRUTO
JUDGE

MIDDLESEX COUNTY COURT HOUSE
P O BOX 964
NEW BRUNSWICK, NEW JERSEY 08903 0964

MEMORANDUM OF DECISION ON MOTION

TO: **Jerrold S. Parker**
Jason Mark
Parker & Waichman, LLP
111 Great Neck Road, First Floor
Great Neck, New York, 11021-5402

W. Mark Lanier
Richard D. Meadow
The Lanier Law Firm, PLLC
126 East 56th Street, 6th Floor
New York, New York, 10022

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BRYAN D. GARRUTO, J.S.C.

RE: ***Brown v. Johnson & Johnson, et al.*, MID-L-5446-05 MT; This Opinion also applies to the following Docket Nos: MID-L-6209-05 MT, MID-L-6227-05, and MID-L-7291-5**

NATURE OF MOTION: Motion to De-Designate Defendants' "Protected" Document Designations

Having carefully reviewed the moving papers, I have made the following determination:

This case arises out of one of 309 mass tort cases centralized in the Superior Court of New Jersey, the plaintiffs alleging personal injuries caused by use of the Ortho Evra® birth control patch. The Ortho Evra® birth control patch is manufactured by, and/or developed by, and/or trademarked by defendants Johnson & Johnson, Johnson & Johnson Pharmaceutical Research & Development, LLC, and/or Ortho-McNeil Pharmaceutical, Inc. ("the defendants" or "Johnson & Johnson").

Pursuant to the Ortho Evra® birth control patch litigation, the defendants produced nearly six (6) million pages of documents, all of which were universally stamped as "Protected Document. Document Subject to Protective Order." On February 1, 2006. both plaintiffs and defendants agreed to sign and be bound by the terms of a Stipulated Protective Order of Confidentiality, which was signed by Magistrate Judge Patty Shwartz in the United States District Court for the District of New Jersey in an Ortho Evra® case captioned *Lydia M. Lilly v. Johnson & Johnson, et al.* (hereinafter the "*Lilly* Protective Order"). Subsequently thereafter, the parties entered into another Stipulated Protective Order of Confidentiality in connection with Ortho Evra® birth control patch Multi-District Litigation in the Northern District of Ohio, Western Division, which was signed by Judge David Katz on April 19, 2006 (hereinafter the "MDL Protective Order").

To date, no protective orders in this case have been entered by any judge of the Superior Court of New Jersey, although documents have been filed with this court under seal and purportedly subject to one of the two consensual protective orders. While no New Jersey Court Rule specifically provides for a stipulated protective order, Comment 3 to New Jersey Court *R.* 1:2-1 suggests that a stipulated protective order – similar to the two orders entered into by the parties in this matter – is permitted in limited instances. That comment provides: "If there is no presumption of public access of unfiled documents, then sealing can be accomplished by stipulation of the parties who, if they are able to agree, can avoid a protective-order proceedings." Pressler, *Current N.J. Court Rules*, Comment 3 on *R.* 1:2-1 (2007).

Both the *Lilly* Protective Order and the MDL Protective Order contain agreements that potentially cover the declassification of the documents in this matter. The *Lilly* Protective Order specifically states, in relevant part: "This Stipulated Protective Order of Confidentiality shall not

be construed as a waiver by any party of the right to contest the designation of documents as "PROTECTED" under this Stipulated Protective Order of Confidentiality." (*Lilly* Protective Order, at ¶2). The MDL Protective Order also provides similar language: "This Stipulated Protective Order of Confidentiality shall not be construed as a waiver by any party of the right to contest the designation of documents as 'PROTECTED' under this Stipulated Protective Order of Confidentiality." (MDL Protective Order. at ¶1). The MDL Protective Order further provides that: "[T]o the extent that a document designated as "PROTECTED" under this Order has been produced in another action and determined by a court of competent jurisdiction not to be confidential. then said document will be considered non-confidential and non-protected for purposes of this litigation." (MDL Protective Order, at ¶1).

Where there is a stipulated protective order between parties and where no "good cause" finding to protect those documents was made by the Superior Court of New Jersey, a trial judge may review the documents for "good cause" *de novo*. Comment 3 to *R.* 1:2-1 provides guidance on that issue:

> Where, ... a good-cause finding must be made, the question arises as to whether sealing can be accomplished by a consent order entered without judicial determination of the good-cause issue. Although the issue was unaddressed by [the New Jersey Supreme Court in] *Frankl*. it would seem that a consent order so entered should have no greater status than a stipulation and that on an access application by a non-party. the court would not be bound by the consent order but would, rather, be obliged to made a good-cause determination *de novo*.

Here, because both the *Lilly* Protective Order and the MDL Protective Order give the parties the right to challenge the "protected" designations, and because Comment 3 to *R.* 1:2-1 permits this court to make "good cause" determinations where none were previously made, this court will review the five contested documents *de novo*.

Litigation documents produced in connection with a case filed in the Superior Court of New Jersey[1] fall into either one of two categories: (1) "filed" or (2) "unfiled". "Filed" documents refer to those documents submitted to the court as attachments to briefs or certifications in connection with "pre-trial non-discovery motions" such as summary judgment motions or motions to dismiss. *Hammock by Hammock v. Hoffmann-LaRoche, Inc.*, 142 *N.J.* 356, 380-81 (1995). "Unfiled" documents produced during discovery that are either subject to a stipulated or judicially-determined protective order are not presumed to be public. *Id.* at 380. *See also R.* 4:10-3(g)(stating "Neither vacation nor modification of the protective order, however, establishes a public right of access to unfiled discovery materials.") Further, discovery that has not been used by the parties in court proceedings or in support of outcome-determinative motions is considered "unfiled". *Id.*

While New Jersey law recognizes a common-law "presumption of public access to documents and materials ***filed*** with a court in connection with civil litigation", that right of access is "not absolute". *Id.* at 375 (emphasis added). "The universal understanding in the legal community is that ***unfiled documents in discovery are not subject to public access.***" *Estate of Frankl v. Goodyear Tire and Rubber Co.*, 181 *N.J.* 1, 10 (2004)(referencing *Seattle Times Co. v. Rhinehart*, 467 *U.S.* 20, 33 (1984))(other citations omitted)(emphasis added). In maintaining the distinction between "unfiled" and "filed" documents, the *Hammock* Court recognized "that there must continue to be confidentiality of materials submitted in the discovery process." *Hammock, supra*, 142 *N.J.* at 379. Based on that notion, the Supreme Court maintained that "discovery delivered to a plaintiff's counsel under a protective order is not subject to public access as long

[1] In all but two states, the distinction between unfiled and filed documents dictates their accessibility to the public. *Frankl, supra*, 181 *N.J.* at 11 (stating "Only two states arguably provide for public access of unfiled discovery, and only upon a showing that public health and safety or the administration of public office are implicated. *Fla. Stat. Ann.* § 69.081; *Tex.R. Civ. P.* 76a (2)(c)").

as it remains in the private domain of plaintiff's counsel." *Id.* (referencing *Bank of America Nat. Trust and Sav. Ass'n v. Hotel Rittenhouse Associates*, 800 *F.*2d 339, 343 (3d Cir. 1986)).

Absent a stipulated agreement between parties to designate documents as "protected", a court must decide whether there exits proper grounds to enter a protective order in a particular matter. Pursuant to *R.* 4:10-3(g), a trial judge must determine whether "good cause" exists. While that rule does not define what constitutes "good cause", New Jersey law sets forth criteria a court can use to analyze documents. First, the court will determine whether the documents contain trade secrets, which will almost always be protected. If not, then the court will consider six other factors enunciated below.

In *Hammock*, the Supreme Court discussed the spectrum of evidence that may or may not be subject to a protective order suggesting a sliding scale of protected information. First, the court will almost always protect trade secrets. Quoting Comment b of the *Restatement of Torts* § 757 (1939), the Supreme Court held that it would protect a trade secret, defined as:

> any formula, pattern, device or compilation of information which is used in one's business, and which gives him an opportunity to obtain an advantage over competitors who do not know or use it. It may be a formula for a chemical compound, a process of manufacturing, treating or preserving materials, a pattern for a machine or other device, or a list of customers. *Hammock, supra*, 142 *N.J.* at 383 (referencing *Smith v. BIC Corp.*, 869 *F.*2d 194, 199 (3d Cir.1989) and (quoting *Restatement of Torts* § 757 comment b (1939)).

Conversely, the *Hammock* court found that the following information would not be protected as trade secrets: "'"information that is in the public domain or which has been 'reverse engineered.'- i.e., garnered by beginning with the finished product and determining the process used to manufacture it'" *Id.* (citing *Smith, supra*, 869 *F.*2d at 199-200).

Below the status of trade secrets is confidential and proprietary information. "Confidential information and proprietary information are not entitled to the same level of

protection from disclosure as trade secret information." *Hammock*, *supra*, 142 *N.J.* at 383 (referencing *Littlejohn v. Bic Corp.*, 851 *F.*2d 673, 685 (3d Cir. 1988)). The *Hammock* Court adopted factors enunciated by the Third Circuit in *SI Handling Systems, Inc. v. Heisley*, 753 *F.*2d 1244, 1256 (3d Cir. 1985) to consider whether "good cause" existed to maintain the protection of a protective order:

> (1) the extent to which the information is known outside of the owner's business; (2) the extent to which it is known by employees and others involved in the owner's business; (3) the extent of measures taken by the owner to guard the secrecy of the information; (4) the value of the information to the owner and to his competitors; (5) the amount of effort or money expended by the owner in developing the information; and (6) the ease or difficulty with which the information could be properly acquired or duplicated by others. *Hammock*, *supra*, 142 *N.J.* at 384. (citations omitted).

The Supreme Court in *Frankl*, also addressed a similar issue of document designation. In that case, the Supreme Court recommended the issue of unfiled discovery to the Civil Practice Committee to address whether the court should "maintain the position that unfiled discovery is insulated from forced public access or whether changes are warranted in that approach, and if so, what those changes should entail." *Frankl*, *supra*, 181 *N.J.* at 12. The Court in *Frankl* suggested the Civil Practice Committee consider the following questions:

> Whether unfiled discovery should be immune from public access, presumptively immune, or accessible on the same terms as filed discovery; if accessible, how the burden of going forward and the burden of proof should be allocated; whether some refinement of the good cause standard is in order; and whether there should be some limitation on the public's right of access after the settlement of a case. Those questions are posed by way of example and not limitation. *Frankl*, *supra*, 181 *N.J.* at 12.

The Civil Practice Committee considered the Supreme Court in *Frankl*'s concerns. Subsequently, *R.* 4:10-3 was amended to include the following paragraph:

> When a protective order has been entered pursuant to this rule, either by stipulation of the parties or after a finding of good cause, a non-party may, on a proper showing pursuant to *R.* 4:33-1 or *R.* 4:33-2, intervene for the purpose of challenging the protective order on the ground that there is no good cause for the continuation of the order or portions

thereof. Neither vacation nor modification of the protective order, however, establishes a public right of access to unfiled discovery materials.

The effect of this amendment is to permit a non-party to intervene to challenge the parties' needs for a protective order. In such cases, the intervenor bears the burden of proof to show that there exists no "good cause" to continue the protective order. This amendment nevertheless maintained a parties' right to agree to keep documents private. Thus, even if a court grants a non-party intervenor's motion to vacate the parties' protective order, the parties to the lawsuit can still agree to keep the documents produced in discovery confidential and do not have to turn over the unfiled documents to the public. This is not the issue before the court, however, as the plaintiffs are seeking declassification of documents produced pursuant to a protective order of which they were a signatory.

In the present matter, neither party has filed the five documents with the court in conjunction with a pre-trial, non-discovery motion. For that reason, the proponent of the protective order (here, the defendants) need not prove by a preponderance of the evidence that Johnson & Johnson's continued interest in confidentiality outweighs the public interest in disclosure. Unlike in *Hammock*, where the defendants filed two motions for summary judgment and attached as exhibits documents subject to a protective order, the parties in this litigation did not seek to use the protected documents in support of any pre-trial, non-discovery motion. *Hammock, supra*, 142 *N.J.* at 363. Rather, the documents filed with this court were attached as exhibits in support of plaintiff's motion to declassify certain documents subject to a protective order. For that reason, the documents – although technically filed with the court – will be considered "unfiled" for purposes of declassification and the assumptive right of public access will not govern the court's determination of their declassification.

In the present matter, Plaintiffs seek to declassify the following five documents:

1. Document page numbers POEPOE05293286-POE05293288; POE05293242-POE05293243, Attached as Exhibit 10 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations. (hereinafter "Document #1")

   A. This document reflects an email correspondence entitled "ORTHO EVRA Domain Names", which is dated Nov. 20, 2005 and Nov. 21, 2005. In this email correspondence, Asha Mahesh, of Janus, requested the email recipient conduct a search of the following domain names to see if they were already owned:

   - thePatchkills.com, -.net, -.biz
   - thePatchStinks.com, -.net, -.biz, .-org
   - Badpatch.com
   - BadEvra.com
   - BadOrthoEvra.com
   - Dontusepatch.com
   - DontuseOrthoEvra.com
   - OrthoEvrarisks.com
   - OrthoEvraLawsuit.com
   - OrthoEvrainjuries.com
   - OrthoEvrasafety.com
   - Patchsideeffects.com
   - DeathPatch.com, -.net, -.org, -.biz
   - AboutBirthControlPatch.com, -.net, -.biz, -.org
   - ThePatchTruth.org, -.com, -.net, -.biz
   - AboutOrthoEvra.com, -.net, -.biz, -.org

   The email involved the purchase of these domain names and whether Johnson & Johnson would also seek to purchase the domain names that were already owned.

   B. The second document attached as Exhibit 10 is entitled: "ORTHO EVRA Interactive programs/ Defensive actions to minimize impact of negative presence:" This document identifies nine actions for minimizing the negative presence of information about the Ortho Evra® birth control patch as it relates to the internet. The actions suggest/discuss the following:

      (1) The purchase of "top key words" related to the Ortho Evra® patch on various search engines, including Yahoo!, Google, and Overture.
      (2) Strategies for optimizing a natural search of various words related to the Ortho Evra® birth control patch.

(3) Building an unbranded website listing "key information" about Ortho Evra®, a process that was already in progress at the time of the memorandum.

(4) The development of "educational" and informational materials to be "webcasted" through the leading syndicate of health content on the web, called "Healthology".

(5) Buying "negative" URLs, namely those referenced in the emails discussed *supra*.

(6) Google's trademark policy providing that only trademark owners can use a product's trademark in the body of their advertisement.

(7) "Desk sides" with key media, such as monthly magazines, health websites, etc.

(8) The monitoring of blogs wherein representatives of Johnson & Johnson would respond to postings thereon.

(9) Updating the orthoevra.com press section to include news releases and other information that would be helpful to the press.

2. Document page numbers POE05286980-POE005286986, Attached as Exhibit 11 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations (hereinafter "Document #2").

A. This document contains an email correspondence, dated July 22, 2005, between Georgia Lehnert and Heidi Youngkin regarding the purchase of various domain names involving the Ortho Evra® birth control patch. The email discussed the purchase of various forms of the following domain names:

- Orthoevrakills.com, - .biz, -.info, -.net, -.org, -.ca
- Orthoevratruth.com, - .biz, -.info, -.net, -.org, -.ca
- Orthoevralies.com, - .biz, -.info, -.net, -.org, -.ca
- Aboutorthoevra.com, - .biz, -.info, -.net, -.org, -.ca
- Orthoevraproblems.com, - .biz, -.info, -.net, -.org, -.ca
- Orthoevradangers.com, - .biz, -.info, -.net, -.org, -.ca
- Orthoevrainfo.com, - .biz, -.info, -.net, -.org, -.ca
- Deathpatch.com, - .biz, -.info, -.net, -.org, -.ca
- Deathbypatch.com, - .biz, -.info, -.net, -.org, -.ca
- Deadlypatch.com, - .biz, -.info, -.net, -.org, -.ca
- Patchthatkills.com, - .biz, -.info, -.net, -.org, -.ca
- Patchsucks.com, - .biz, -.info, -.net, -.org, -.ca
- Patchtruth.com, - .biz, -.info, -.net, -.org, -.ca
- Patchlies.com, - .biz, -.info, -.net, -.org, -.ca
- Patchproblems.com, - .biz, -.info, -.net, -.org, -.ca

- Patchdangers.com, - .biz, -.info, -.net, -.org, -.ca
- Patchinfo.com, - .biz, -.info, -.net, -.org, -.ca

3. Document page numbers POE05306871-POE05306873, Attached as Exhibit 13 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations (hereinafter "Document #3").

   A. This document consists of an email correspondence between a domain name purchase representative [name not on email – "DNrequest" is listed in the "from" column] and Georgia Lehnert and Asha Mahesh dated Dec. 8, 2005, indicating Johnson & Johnson successfully registered the following domain names:

   - Orthoevrasucks.com, - .biz, -.info, -.net, -.org, -.ca
   - Orthoevrakills.com, - .biz, -.info, -.net, -.org, -.ca
   - Orthoevratruth.com, - .biz, -.info, -.net, -.org, -.ca
   - Orthoevralies.com, - .biz, -.info, -.net, -.org, -.ca
   - Aboutorthoevra.com, - .biz, -.info, -.net, -.org, -.ca
   - Orthoevraproblems.com, - .biz, -.info, -.net, -.org, -.ca
   - Orthoevradangers.com, - .biz, -.info, -.net, -.org, -.ca
   - Orthoevrainfo.com, - .biz, -.info, -.net, -.org, -.ca
   - Deathpatch.biz, -.info, -.net, -.org, -.ca (NOT -.com)
   - Deathbypatch.com, - .biz, -.info, -.net, -.org, -.ca
   - Deadlypatch.com, - .biz, -.info, -.net, -.org, -.ca
   - Patchthatkills.com, - .biz, -.info, -.net, -.org, -.ca
   - Patchsucks.com, - .biz, -.info, -.net, -.org, -.ca
   - Patchtruth.com, - .biz, -.info, -.net, -.org, -.ca
   - Patchlies.com, - .biz, -.info, -.net, -.org, -.ca
   - Patchproblems.com, - .biz, -.info, -.net, -.org, -.ca
   - Patchdangers.com, - .biz, -.info, -.net, -.org, -.ca
   - Patchinfo.biz, -.info, -.net, -.org, -.ca (NOT -.com)
   - ThePatchkills.com, -.net, -.biz

4. Document page numbers POE05307256-POE05307258, Attached as Exhibit 14 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations (hereinafter "Document #4").

   A. This document consists of an email correspondence between Georgia Lehnert and Cheryl Callan, dated Nov. 18, 2005-Nov. 23, 2005, indicating the need to purchase the following domain names before a person or company unrelated to Johnson & Johnson does so.

   - ThePatchkills.com, - .biz, -.info, -.net, -.org, -.ca
   - Thepatchstinks.com, - .biz, -.info, -.net, -.org, -.ca

- thePatchtruth.com, - .biz, -.info, -.net, -.org, -.ca
- Deathpatch.com, -biz, -.info, -.net, -.org, -.ca
- Orthoevrakills.com. - .biz, -.info, -.net, -.org, -.ca
- Orthoevrasucks.com, - .biz, -.info, -.net, -.org, -.ca
- Orthoevratruth.com, - .biz, -.info, -.net, -.org, -.ca
- Evratruth.com, - .biz, -.info, -.net, -.org, -.ca
- evrakills.com, - .biz, -.info, -.net, -.org, -.ca
- evrasucks.com, - .biz, -.info, -.net, -.org, -.ca
- birthcontrolpatchkills.com, - .biz, -.info, -.net, -.org, -.ca
- birthcontrolpatchsucks.com, - .biz, -.info, -.net, -.org, -.ca
- birthcontrolpatchtruth.com, - .biz, -.info, -.net, -.org, -.ca
- thebirthcontrolpatchkills.com, - .biz, -.info, -.net, -.org, -.ca
- thebirthcontrolpatchsucks.com, - .biz, -.info, -.net, -.org, -.ca
- theorthoevraptachkills.com, - .biz, -.info, -.net, -.org, -.ca
- theorthoevrapatchsucks.com, - .biz, -.info, -.net, -.org, -.ca
- orthoevrapatchkills.com, - .biz, -.info, -.net, -.org, -.ca
- orthoevrapatchsucks.com, - .biz, -.info, -.net, -.org, -.ca
- orthoevrapatchtruth.com, - .biz, -.info, -.net, -.org, -.ca
- aboutorthoevra.com, - .biz, -.info, -.net, -.org, -.ca
- aboutbirthcontrolpatch.com, - .biz, -.info, -.net, -.org, -.ca

5. Document page numbers POE05307256-POE05307258, Attached as Exhibit 15 to Plaintiff's Appendix in Support of Her Motion to De-Designate Defendants' "Protected" Document Designations (hereinafter "Document #5").

   A. This document consists of an email correspondence, dated Nov. 21, 2005, between Asha Mahest, Tracey Bogart and Georgia Lehnert discussing plans to make a PO [uncertain whether it is a "public offer", "purchase order", or something else] for the following domain names that were already owned by someone other than J&J:

      - patchinfo.com
      - orthoevra.info
      - deathpatch.com
      - patchinfo.org

After considering these five documents pursuant to the factors enunciated by the Supreme Court in *Hammock*, this court determines that those documents are not subject to protection. Documents #1, #2, #3, #4, and #5 reflect numerous email correspondences between representatives of both Johnson & Johnson and an internet domain name company. The content of those email exchanges included inquiries by Johnson & Johnson representatives to see if

various forms of domain names related to the Ortho Evra® birth control patch were available for purchase, the subsequent purchase of various domain names, as well as the bids to obtain domain names that were already owned by persons or entities unrelated to Johnson & Johnson.

In considering the *Hammock* factors to determine "good cause", the court will consider the following factors:

1. **The extent to which the documents contain trade secrets.** *Hammock, supra*, 142 *N.J.* at 384. These five email conversations do not reference trade secrets. In addition, no information in the email correspondences can be classified as 'proprietary'.

2. **"The extent to which the information is known outside of the owner's business."** *Id.* The ownership of domain names is public information and, as such, Johnson & Johnson cannot claim that its discussions to purchase domain names relating to the Ortho Evra® birth control patch are proprietary information awarded protection under the law. *Id.*

3. **"The extent to which it is known by employees and others involved in the owner's business".** *Id.* These email conversations were among several employees in Johnson & Johnson. None of the messages were marked "confidential" in either the subject headings or through the email program used to send them.

4. **"The extent of measures taken by the owner to guard the secrecy of the information".** *Id.* Because the emails were sent around as "unclassified" messages to various employees at Johnson & Johnson and because the nature of the emails relates to information that is public in nature, the court is not persuaded that Johnson & Johnson took measures to keep the information contained in the emails "secret".

5. **The "value of the information to the owner and to his competitors".** *Id.* Information about the purchase of domain names related to the Ortho Evra® birth control patch

is of little to no value to Johnson & Johnson's competitors, as Johnson & Johnson owns the exclusive rights to that trademarked name.

6. **"The amount of effort or money expended by the owner in developing the information".** *Id.* The information contained in the emails was not "developed" by researchers nor was money expended in developing the information contained in the emails.

7. **"The ease or difficulty with which the information could be properly acquired or duplicated by others".** *Id.* Information regarding who or what company owns a website is public information. A search executed by this court on the website: http://whois.domaintools.com/ of the URL "orthoevrasucks.com" shows that Johnson & Johnson owns the website. (*See* attached Exhibit F). The search also shows other websites owned by Johnson & Johnson, many of which are included in the email correspondences that are the subject of this opinion. Therefore, because such information is publicly available, it cannot be considered proprietary by this court.

For the foregoing reasons, plaintiffs' motion to declassify the five documents is **granted**. This court will declassify the five documents discussed in this opinion. The supplemental briefs to the extent they reference the five protected document are also declassified at the same time. Attached to this Opinion are the five documents that are now declassified. This Order is effective 10 days after the date hereof.

DATED: **March 23, 2007**

Bryan D. Garruto, J.S.C.

Exhibit I attached to
Exhibit B

CNNMoney.com

PR

Powered by

Report: J&J under probe over Risperdal

Texas attorney general wants company documents related to sales of the schizophrenia treatment, newspaper says.

March 15, 2006: 9:11 AM EST

NEW YORK (CNNMoney.com) - Johnson & Johnson says it remains under scrutiny from federal and state authorities over the drug manufacturer's sales of its top-selling drug Risperdal, according to a news report.

Johnson & Johnson (up $0.21 to $59.29, Research), a drug and consumer products company based in New Brunswick, N.J., said that in January the Texas attorney general issued a civil-investigative demand to the company's Janssen Pharmaceutica subsidiary, seeking documents related to the sales of the anti-psychotic treatment, according to *The Wall Street Journal*.

In addition, the company says it was subpoenaed in November 2005 by the U.S. attorney in the Eastern District of Pennsylvania about Risperdal marketing and adverse reactions to the drug, which is used to treat schizophrenia, the *Journal* reported.

The company was also subpoenaed in 2004 by the Office of the Inspector General of the Office of Personnel Management, seeking documents on Risperdal sales, marketing and clinical trials from 1997 to 2002.

Risperdal sales totaled $3.6 billion in 2005. Johnson & Johnson's 2005 sales totaled $50.5 billion.

To read more about Risperdal, click here and here. ■

Find this article at:
http://money.cnn.com/2006/03/15/news/companies/jnj

Exhibit J attached to
Exhibit B

WEITZ & LUXENBERG
A New York Professional Corporation
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Tel. (856) 755-1115
Attorneys for Plaintiff

BAILEY PERRIN BAILEY LLP *(OF COUNSEL)*
F. Kenneth Bailey, Jr.
Michael W. Perrin
K. Camp Bailey
440 Louisiana St., Suite 2100
Houston, Texas 77002
(713) 425-7100
(713) 425-7101 fax

Alma Avila, as Next Friend of Amber N. Avila, a Minor,

Plaintiffs,

v.

JOHNSON & JOHNSON COMPANY, JANSSEN PHARMACEUTICA PRODUCTS, L.P. a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc., JOHN DOE Nos. 1 through 20 and JANE DOE Nos. 1 through 20,

Defendants.

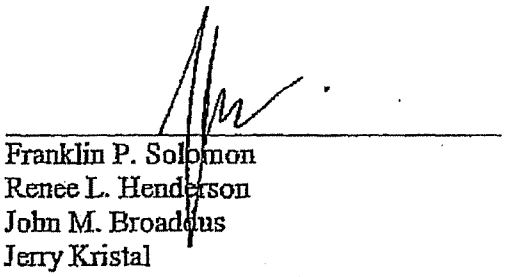
SUPERIOR COURT OF NEW JERSEY
LAW DIVISION
MIDDLESEX COUNTY

DOCKET NO.: L 6661-06

CIVIL ACTION

COMPLAINT AND
DEMAND FOR JURY TRIAL

Plaintiffs, residents of the State of Texas, by way of Complaint against the Defendants named herein, incorporate by reference each an every allegation of the Complaint annexed hereto.



Franklin P. Solomon
Renee L. Henderson
John M. Broadous
Jerry Kristal
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Tel #: (856)755-1115
Fax #: (856)755-1995

Dated: July 20, 2006

WEITZ & LUXENBERG
A New York Professional Corporation
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Tel. (856) 755-1115

SHELLER LUDWIG & SHELLER
A Pennsylvania Professional Corporation
One Greentree Centre
10000 Lincoln Drive East, Suite 201
Marlton, NJ 08053
Tel. (856) 988-5590

BAILEY PERRIN BAILEY
A Texas Limited Liability Partnership
440 Louisiana St., Suite 2100
Houston, Texas 77002
(713) 425-7100

Attorneys for Plaintiffs

Mable Adams; Rickey D. Adams; Vivian Allen; Patricia A. Arredondo; Robert J. Ausura; Alma Avila, as Next Friend of Amber N. Avila, a Minor; Michael Azevedo; Della Baker; Oscar A. Barbosa; James S. Barnes; Kenneth L. Belt; Loren B. Bennett; Jerome T. Bielak; Susan A. Blake; Bertha M. Bonner; Charles Broadus; Bion L. Brown; Edward M. Brown; Shelettie Brown; Sylvia J. Brown; Willie A. Brown, on behalf of Robin A. Brown, an Incapacitated Adult; Angela Burley, as Next Friend of Lorenzo Stephen, a Minor; Carrie Burrell; Alana A. Calabrese; Juliana Capela; Steve Capela; Rebecca Carlisle; Danny L. Carroll; Elizabeth Carroll, on behalf of Thomas D. Carroll, an Incapacitated Adult; Karen Cesal, on behalf of Gerald M. Cesal, an Incapacitated Adult; Johnny L. Clark; Wayne Clark; David Clay; Thomas Clayton; Rosie Cohen; George Cole; Senora Collins; Libbell Count; Carol Cox; Loraine M. Cox; Barbara A. Cross; Mary Crum; Rafael S. Davis; Mary L. Diamond; Cynthia C Donaldson; Rebecca Dora; Ronald J. Dracy; David Dufrene; Jeanne A. Duggan; Stafford B. Elahi, Jr.; Debra K. Elliott; Jerry R. Erickson; Anthony Evans; 57	:	SUPERIOR COURT OF NEW JERSEY LAW DIVISION MIDDLESEX COUNTY DOCKET NO.: CIVIL ACTION COMPLAINT AND DEMAND FOR JURY TRIAL

Stephen J. Farrell; Edith Fearce; Mary Fedoris; :
Megan D. Finch; Sheral D. Flowers; Janice :
Ford; Allen Foster; Robbi L. Freed; Judy K. :
Freed, as Next Friend of Amanda F. Freed, a :
Minor; Karla Fuller; Debra A. Garrison; :
Kathleen Gates, as Personal Representative of :
the Estate of Cameron R. Lyseng, Deceased; :
Claudie Grace; Reginald L. Green; Jacqueline :
Griffith; Lametta M. Guerary; Fayquita :
Haggins; Wayne A. Hall; Lyle R. Hamons; Lisa :
Hardy; Mary Harris; Diane Harvey; Patrick :
Harvey; George Hayes, Jr.; Bryan T. Hayward; :
Bonnie Heard, as Next Friend of Russell B. :
Houston, a Minor; Sondra D. Henley; Marianne :
K. Henricks; Job Henry; Paula Hernandez; :
Catherine Henderson; Laura Herring; Brinda :
Hill-West; Rita Hodges; Penelope Holliday; :
Patrick J. Hurson; Diane Hurst; Brenda D. :
Hutson; Ross L. Illsley, Jr.; Rita Issa; Hollie S. :
Jackson; Katie Jackson; Patricia Jackson; :
Robert L. Jackson, Jr.; Belinda Johnson; James :
Johnson; Latricia Johnson, as Next Friend of :
Dequita S. Johnson, a Minor; Kimberly S. :
Jones; Cheryl Joyner; Hattie Keithly; Ella :
Kelly, as Personal Representative of the Estate :
of Myrtle K. Hughes, Deceased; Mary R. :
Kender; Randall C. King; Joan C. Kyle; Larry :
Ladner; Marie P. Laird; Shon E. Laissen; Ruth :
L. Lambert; Edna Langdon; Anne Lawson; :
Kelly S. Lehto; Ronald Lenoir; Ethel G. Lott; :
Mark A. Lovich; Richard Lunn; Lorine :
Malone; Jerry N. Mangan; Mary A. Martin- :
Dover; James D. Maynard; William J. :
McAleer; Tracy McBride, as Next Friend of :
Devon McBride, a Minor; Joseph M. :
McCracken; Joshua McCreary; Mary :
McDaniel; Randy L. McDaniel; Shirley :
McDonald; Willie McGhaw; Earl McNair; :
Tonya E. Melvin; Alonzo L. Mitchell, Sr.; :
Raymond Moore; Ricky Morris; Patricia L. :
Morrison; Harvey Munn; Christy Myers; :
Elizabeth Oribamise; Diane M. Otero; Cynthia :
R. Owens; Lonnie C. Owens, Sr.; Paula :
Pafford; Brenda Parks; Robert E. Paulin; :
Tammy Pelison, as Next Friend of Dwain :
Pelison, Jr., a Minor; Barbara Pilate; Crystal Y. :
Poole; Michael W. Prebe; Ornemus Reed; :
Harry M. Rich; Melody Richardson; Glenda D. :

Ridgway-Coulter; Sheila Riggs, as Next Friend of Kara S. Riggs, a Minor; Sharon A. Roberts; Cora L. Robinson; Sheila Robinson; John Rodgers; Jack K. Rogers; Karl D. Rupp; Jack W. Salamone; Cynthia Saul, as Next Friend of Jade Saul, a Minor; John M. Schum; John Schwamlein; Mildred E. Seymour; Debbie Shaw; Robbie J. Sills; Lara A. Sims; Linda Singleton, as Personal Representative of the Estate of Bobbylee H. McWilliams, Deceased; Gary D. Skala; Carol Smith; Carolyn Smith; Shirley Smith; Daryl W. Smith, II; John R. Sowers; Percival D. Stacy; Terry G. Stalling; Maria L. Stanton; Brenda Stewart; Robert W. Stitt, Jr.; Ruthie Taylor; Rowena G. Teachey; Vanessa Thomas; Carolyn Thompson; Jennifer L. Thompson; Robert L. Tucker, Jr.; Bettie J. Tullos; Natasha Turner; Orlando M. Turner; Kelly Vermette; Robert L. Vogt; Sarah L. Watkins; Everett F. Watson, Jr.; Sylvia Wells; Dorothy White; Shirley L. White; Benjamin O. White, Jr.; Bonnie Williams; Jeanette Williams; Tommy Williams; Kent Willis; Tommy Worcester; Violet R. Wynnemer; Patricia Wysong, on behalf of Donald L. Wysong, an Incapacitated Adult; Verlin G. Yeary; David D. York; Bernard A. Young; and William W. Young,

Plaintiffs,

vs.

JOHNSON & JOHNSON COMPANY; JANSSEN PHARMACEUTICA PRODUCTS, L.P. a/k/a JANSSEN, L.P., a/k/a JANSSEN PHARMACEUTICA, L.P., a/k/a JANSSEN PHARMACEUTICA, INC.; JOHN DOE Nos. 1 through 20; and JANE DOE Nos. 1 through 20,

Defendants.

Plaintiffs, identified more specifically by way of individualized caption pages annexed hereto, for their complaint against the Defendants named herein, say:

THE PARTIES

1. Plaintiffs are individuals who currently reside in various States of the United States, who have suffered personal injuries and incurred other damages as a result of ingesting the atypical antipsychotic drug Risperdal (a trade name for risperidone) that was designed, developed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, distributed and/or sold by Defendants.

2. Defendant Johnson & Johnson is a corporation organized under the laws of the State of New Jersey with its principal place of business at One Johnson & Johnson Plaza, New Brunswick, New Jersey.

3. Defendant Johnson & Johnson does business in the State of New Jersey and throughout the United States, and at all times relevant hereto designed, developed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, distributed, and/or sold the atypical antipsychotic drug Risperdal in interstate commerce, including in New Jersey.

4. Defendant Janssen Pharmaceutica Products, L.P., a/k/a Janssen, L.P., a/k/a Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc. (hereinafter "Janssen") is a subsidiary of Johnson & Johnson, and is a business entity with its principal place of business at 1125 Trenton-Harbourton Road, Titusville, New Jersey.

5. Janssen does business in the State of New Jersey and throughout the United States, and at all times relevant hereto designed, developed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, distributed, and/or sold the atypical antipsychotic drug Risperdal in interstate commerce, including in New Jersey.

6. Defendants John Doe Nos. 1 through 20 (fictitious-name-designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto designed, developed, formulated, researched,

manufactured, labeled, packaged, promoted, marketed, distributed and/or sold the atypical antipsychotic drug Risperdal in interstate commerce, including in New Jersey.

7. Defendants Jane Doe Nos. 1 through 20 (fictitious-name designations of one or more individuals, partnerships, corporations, and/or other entities whose actual identities have yet to be determined) at all times relevant hereto labeled, packaged, promoted, marketed, distributed and/or sold the atypical antipsychotic drug Risperdal in interstate commerce, including in New Jersey.

8. At all times relevant hereto, each Defendant acted as the agent of every other Defendant, within the course and scope of that agency, regarding the acts and omissions alleged.

FACTUAL BACKGROUND

9. Risperdal is an "antipsychotic" medication belonging to a class of drugs referred to as atypical antipsychotics, and was approved for certain uses in the United States in 1994.

10. In 1997, the United States Food & Drug Administration ("FDA") approved Risperdal for use for the treatment of schizophrenia.

11. In 1999, the FDA approved Risperdal for use in the short-term treatment of acute mixed or manic episodes associated with bipolar disorder.

12. Risperdal is one of the Defendants' top-selling drugs and produced approximately $3.5 billion in sales in 2005.

13. Plaintiffs used Risperdal pursuant to Defendants' instructions and advice and in a foreseeable manner, and the drug reached Plaintiffs without substantial change in its condition since manufacture or sale.

14. Since the drug's introduction to the market, the FDA has received numerous reports of hyperglycemia, diabetes mellitus, worsening of existing diabetes, pancreatitis and other severe conditions and diseases among patients, including children, who were prescribed

Risperdal.

15. Shortly after Defendants began selling Risperdal, reports began to surface of Risperdal users who were suffering from hyperglycemia, acute weight gain, diabetes mellitus, pancreatitis, and other severe conditions and diseases. Defendants knew or reasonably should have known of these reports. Furthermore, prior to and during the time that Plaintiffs ingested Risperdal, Defendants were aware of studies and journal articles linking the use of Risperdal with these and other severe and permanent hyperglycemia-related adverse events and diseases.

16. The diabetes risk associated with Risperdal is much higher than with older "typical" antipsychotic drugs that were already available and approved for use.

17. In December 2000, the *British Medical Journal* found no clear evidence atypical antipsychotics like Risperdal were any more effective or better-tolerated than conventional antipsychotic drugs, including Haldol and Thorazine.

18. Defendants' marketing efforts were designed and implemented to create the false impression in physicians' minds that Risperdal was safe and effective for their patients, and that it was more efficacious and carried a lower risk of side effects and adverse reactions than other available treatments.

19. The marketing and promotion efforts of Defendants overstated the benefits of Risperdal while minimizing and downplaying the risks associated with the drug. These promotional efforts were made while withholding important safety information from prescribing physicians, the FDA, and the public.

20. For example, Defendants were aware of numerous reports of diabetes mellitus associated with the use of Risperdal, well beyond the background rate, and well beyond the rate associated with older antipsychotic agents.

21. In April 2002, the Japanese Health and Welfare Ministry issued Emergency Safety

Information regarding the risk of diabetes mellitus, diabetic ketoacidosis, and other diabetic conditions, for patients prescribed atypical antipsychotics, including Risperdal.

22. In September 2003, Defendants received a letter from the FDA informing them that the product packaging for Risperdal failed to convey appropriate risk information related to the drug's association with serious diabetes mellitus and related conditions.

23. Despite having this information, Defendants failed to take action to correct this obvious defect in Risperdal product labeling for several months. During this period, Defendants did not pass on to physicians information regarding the risk of diabetes mellitus, nor did they issue new labeling containing specific warnings.

24. On November 6, 2003, Defendants submitted supplemental New Drug Applications covering the addition of information to the Warnings section of the product labeling for Risperdal. The FDA approved the supplements and requested that the Defendants issue a "Dear Healthcare Provider letter" communicating the important new risk information. Additionally, the FDA asked Defendants to submit a copy of the letter to the FDA and to the MedWatch program.

25. Instead of preparing a letter that accurately communicated risk information, on November 10, 2003, Defendants sent a Dear Healthcare Professional letter that misrepresented those risks. The letter stated, in pertinent part:

> Hyperglycemia-related adverse events have infrequently been reported in patients receiving RISPERDAL. Although confirmatory research is still needed, a body of evidence from published peer-reviewed epidemiology research suggests that RISPERDAL is not associated with an increased risk of diabetes when compared to untreated patients or patients treated with conventional antipsychotics. Evidence also suggests that RISPERDAL is associated with a lower risk of diabetes than some other studied atypical antipsychotics.

By sending this letter, Defendants prevented physicians and patients from adequately

understanding the risks associated with Risperdal.

26. In response to Defendants' misleading letter of November 10, 2003, the FDA issued a Warning Letter on April 19, 2004 to Ajit Shetty, M.D., CEO of Janssen, reprimanding the company. The FDA determined that the Dear Healthcare Provider letter omitted material information, minimized risks, and claimed superior safety to other drugs in its class without "adequate substantiation." Additionally, by sending the letter, Defendants failed to comply with FDA requirements regarding post-marketing reporting. As a result, the FDA requested that Defendants immediately cease dissemination of promotional materials for Risperdal containing the same or similar claims, and warned that the FDA was continuing to evaluate all aspects of the promotional campaign for Risperdal.

27. Three months after the FDA issued its Warning Letter, Defendants mailed another Dear Health Care Provider letter on July 21, 2004, admitting that the previous letter omitted material information about Risperdal, minimized potentially fatal risks, and made misleading claims suggesting superior safety in comparison to other atypical antipsychotics without adequate substantiation, in violation of the Federal Food, Drug and Cosmetic Act.

28. By reason of the acts and omissions of Defendants, Plaintiffs have been severely and permanently injured and will require ongoing medical care and treatment.

29. Defendants knew of the hazards associated with Risperdal, but nevertheless affirmatively and actively concealed information that clearly demonstrated the dangers of the drug and misled the public and prescribing physicians with regard to the material and clear risks associated with the drug.

30. Defendants acted with the intent that physicians would continue to prescribe their atypical antipsychotic drug even though the Defendants knew that prescribing physicians would not be in a position to know the true risks of the drug, and that they would rely upon the

misleading information that Defendants promulgated.

31. Defendants, through their funding and control of certain studies concerning the effects of atypical antipsychotic drugs on human health, their control over trade publications, promoting, marketing, and/or through other agreements, understandings and joint undertakings and enterprises, conspired with, cooperated with and/or assisted in the wrongful suppression, active concealment and/or misrepresentation of the true relationship between their drugs and various diseases, all to the detriment of the public health, safety and welfare.

32. Defendants acted in concert with one another to fraudulently conceal from the public, Plaintiffs and prescribing physicians the risk of diabetes mellitus and diabetes-related conditions associated with Risperdal, resulting in significant harm to consumers of Risperdal, including Plaintiffs.

33. Defendants also acted in concert to unlawfully and improperly promote Risperdal for "off-label uses" not approved by the FDA.

34. Defendants improperly provided financial inducements to physicians to promote Risperdal for uses beyond those which the FDA approved and beyond those for which the drugs were medically accepted.

35. Defendants improperly provided financial inducements to State government officials to encourage acceptance of their atypical antipsychotic drugs for uses beyond those which the FDA approved and beyond those for which the drugs were medically accepted.

36. At all times relevant hereto, Defendants purposefully and intentionally engaged in these activities, and continue to do so, knowing full well that when the public, including Plaintiffs herein, used Risperdal in the manner that Defendants intended they would be substantially and unreasonably at risk of suffering disease, injury and sickness.

37. The statements, representations and promotional schemes made and undertaken

by the Defendants were deceptive, false, incomplete, misleading and untrue.

38. Defendants knew, or in the exercise of reasonable care should have known, that their statements, representations and advertisements regarding Risperdal were deceptive, false, incomplete, misleading and untrue at the time of making such statements.

39. Neither Plaintiffs nor the physicians who prescribed the Defendants' atypical antipsychotic drug had knowledge of the falsity or untruth of the Defendants' statements, representations and advertisements when prescriptions for the drug were written.

40. Plaintiffs and their prescribing physicians reasonably relied on the Defendants' statements, representations and advertisements and Defendants knew that Plaintiffs and their prescribing physicians would be relying upon Defendants' statements. Each of the statements, representations and advertisements were material to Plaintiffs' purchase of, or otherwise obtaining, the Defendants' atypical antipsychotic drug, in that Plaintiffs would not have purchased nor taken the drug if Plaintiffs had known that Defendants' statements, representations and advertisements were deceptive, false, incomplete, misleading and untrue.

41. Had Plaintiffs been adequately warned of the potential life-threatening side effects of Defendants' atypical antipsychotic drugs, Plaintiffs would not have purchased or taken the drugs and could have chosen to request other medications or treatments.

42. Defendants negligently, recklessly and wantonly failed to warn Plaintiffs and the general public of the risks associated with taking Defendants' atypical antipsychotic drug, and failed to do so even after various studies, including their own, showed that there were problems concerning the risks of diabetes and diabetes-related injuries associated with the drug.

43. Defendants endeavored to deceive Plaintiffs and the general public by not disclosing the findings of various studies, including their own, which revealed problems concerning the dangers of Defendants' atypical antipsychotic drugs.

44. Defendants failed to provide adequate warnings and instructions that would have put Plaintiffs and the general public on notice of the dangers and adverse effects of Defendants' atypical antipsychotic drugs.

45. Defendants designed, manufactured, distributed, sold and/or supplied their atypical antipsychotic drug and otherwise placed the drug into the stream of commerce in a defective and unreasonably dangerous condition, taking into consideration the utility of the drug and the risk to Plaintiffs and the general public.

46. Defendants' atypical antipsychotic drug as designed, manufactured, distributed, sold and/or supplied by the Defendants were defective due to inadequate warnings, instructions and/or labeling.

47. The Defendants' atypical antipsychotic drugs as designed, manufactured, distributed, sold and/or supplied by the Defendants were defective due to inadequate testing before and after the Defendants knew, or in the exercise of reasonable care should have known, of the various studies, including their own, evidencing the risks of diabetes and diabetes-related conditions, disease and injuries associated with the drug.

48. Plaintiffs ingested the Defendants' atypical antipsychotic drugs and as a result suffered emotional and personal injury and economic loss.

COUNT I
PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-2*et seq.*)

49. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

50. Defendants designed, formulated, produced, created, made, packaged, labeled and sold Risperdal and held themselves out to users of the product as the manufacturer(s) of Risperdal.

51. Defendants' Risperdal product was not reasonably fit, suitable or safe for its

intended purpose because it failed to contain adequate warnings and/or instructions.

52. Defendants failed to otherwise provide adequate warnings and instructions to consumers of Risperdal who had purchased or received the product, or to their prescribing physicians.

53. Defendants' Risperdal product was not reasonably fit, suitable or safe for its intended purpose because it was designed in a defective manner.

54. The ordinary user or consumer of Defendants' Risperdal product could not reasonably be expected to have knowledge of the product's inherent risks and dangers.

55. The dangerous and defective character of Risperdal was in fact unknown to the product's ordinary consumer or user, including Plaintiffs, and Plaintiffs' injuries were caused by an unsafe aspect of Risperdal that is an inherent characteristic of the product and that would not be recognized by the ordinary person who uses or consumes the product and for whom the product is intended.

56. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demand judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT II
PUNITIVE DAMAGES, PRODUCT LIABILITY ACT (N.J.S.A. 2A:58C-5)

57. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

58. Defendants' manufacture, marketing, promotion, distribution and sale of a defective product and their failure to provide adequate warnings and instructions concerning its hazards was willful, wanton, reckless and without regard for the public's safety and welfare. The defendants misled both the medical community and the public at large, including Plaintiffs herein, by making false representations about the safety of Risperdal. Defendants downplayed, understated and/or disregarded their knowledge of the serious and permanent side effects and risks associated with the use of Risperdal despite available information demonstrating that Risperdal was likely to cause serious and potentially fatal side effects to users.

59. At all times relevant hereto, defendants knew of the defective nature of their Risperdal product, and continued to design, manufacture, market, label, and sell Risperdal so as to maximize sales and profits at the expense of public health and safety, with wanton and willful disregard of the safety of product users, consumers, or others who foreseeably might be harmed by the product, including Plaintiffs who did suffer such harm.

60. Defendants misled regulators, the medical community and the public at large, including Plaintiffs, by making false and misleading representations about the safety of Risperdal. Defendants knowingly withheld or misrepresented information required to be submitted to the FDA under the agency's regulations, which information was material and relevant to the harm suffered by Plaintiffs.

61. As a direct and proximate result of Defendants' reckless, willful and wanton acts in disregard of the safety of the public generally and of Plaintiffs in particular, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require

medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demand judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT III
NEGLIGENCE

62. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

63. Defendants had a duty to exercise reasonable care when they designed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, and/or sold the drug ingested by Plaintiffs, including a duty to ensure that the drug did not cause users to suffer from undisclosed dangerous side effects when used alone or in foreseeable combination with other drugs.

64. Defendants were negligent when they designed, formulated, researched, manufactured, labeled, packaged, promoted, marketed, and/or sold their atypical antipsychotic drug, in that, among other things, they:

a. Failed to accompany the product with proper warnings regarding all possible adverse side effects associated with the use of their drugs;

b. Failed to conduct adequate pre-clinical and clinical testing and

post-marketing surveillance to determine the safety of their drugs;

c. Failed to provide adequate training and instruction to medical care providers for appropriate use of their drugs;

d. Failed to warn Plaintiffs while actively encouraging the sale of their drugs, either directly or indirectly (through Plaintiffs' prescribing physicians), orally or in writing, about:

1. The need for diagnostic tests to be performed on the patient prior to ingesting the Defendants' atypical antipsychotic drugs to discover and ensure against potentially fatal side effects; and/or

2. The need for comprehensive, regular medical monitoring to ensure early discovery of potentially fatal side effects;

e. Failed to warn that the risks associated with the ingestion of their drugs exceeded the risks of other alternative forms of medication;

f. Failed to effectively warn about the increased danger and potentially fatal relationship in combining the use of their drugs either together or with various other drugs for use in treatment of Plaintiffs' condition(s);

g. Negligently marketed their drug despite the fact that the risks of the drug were so high and the benefits of the drug were so low that no reasonable pharmaceutical company, exercising due care, would have done so;

h. Recklessly, falsely, and deceptively represented or knowingly omitted, suppressed, or concealed material facts regarding the safety and efficacy of

their drugs from prescribing physicians and the consuming public; had prescribing physicians and the consuming public known of such facts, Defendants' atypical antipsychotic drugs would never have been prescribed to, or used by, Plaintiffs;

i. Remained silent despite their knowledge of the growing public acceptance of misinformation and misrepresentations regarding both the safety and efficacy of ingestion of their drugs and did so because the prospect of huge profits outweighed their concern for health and safety issues, all to the significant detriment of Plaintiffs;

j. Failed to perform their post-manufacturing and continuing duty to warn which arose when they knew, or in the exercise of reasonable care should have known, that their drugs were being prescribed in a dangerous manner;

k. Unlawfully and improperly marketed and promoted their atypical antipsychotic drugs for "off label" uses beyond those uses approved by the FDA or supported by medical science;

l. Unlawfully and improperly provided financial incentives to physicians and others to prescribe the drugs and approve its use;

m. Were otherwise careless, negligent, grossly negligent, reckless, and acted with willful and wanton disregard with respect to the rights of Plaintiffs;

n. Continued to market the drugs to consumers, including Plaintiffs and their prescribing physicians, when there were safer alternative methods of treating Plaintiffs' condition(s), despite the fact that Defendants knew or should have known that the drugs caused unreasonable, dangerous side

effects; and

o. Knew or should have known that consumers such as Plaintiffs would foreseeably suffer injury as a result of the Defendants' failure to exercise ordinary care as described above.

65. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE, Plaintiffs demands judgment against the Defendants for damages for pain and suffering, loss of enjoyment of life, past and future medical expenses, past and future lost wages, and punitive damages, together with interest from the date of injury and costs.

COUNT IV
STRICT LIABILITY

66. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

67. Defendants are manufacturers and/or suppliers and/or marketers of Risperdal and are strictly liable to plaintiff for designing, creating, manufacturing, distributing, selling and placing into the stream of commerce the drug Risperdal.

68. Risperdal manufactured and/or supplied and/or marketed by Defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, it was unreasonably dangerous, it was more dangerous than an ordinary consumer would expect and more dangerous than other forms of antipsychotic treatment available.

69. Risperdal manufactured and/or supplied and/or marketed by defendants was defective in design or formulation in that, when it left the hands of the manufacturer and/or suppliers, the foreseeable risks exceeded the benefits associated with the design or formulation.

70. Risperdal manufactured and/or supplied and/or marketed by defendants was defective due to inadequate warnings or instructions because the manufacturer knew or should have known that the product created, among other things, a risk of diabetes mellitus and diabetes-related conditions when used in the manner intended and/or reasonably foreseeable by Defendants, and failed to adequately warn of said risks.

71. Risperdal manufactured and/or supplied and/or marketed by Defendants was defective due to inadequate pre-marketing testing.

72. Risperdal manufactured and/or supplied and/or marketed by Defendants was defective due to Defendants' failure to provide adequate initial warnings and post-marketing warnings or instructions after the manufacturer and/or supplier knew or should have known of the risks of adverse effects including diabetes mellitus and diabetes-related conditions from Risperdal, and continued to promote the product.

73. Risperdal manufactured and/or supplied and/or marketed by defendants was unreasonably dangerous and defective because it was not accompanied by proper warnings to prescribing physicians and the medical community regarding all possible adverse side effects associated with the use of Risperdal and the comparative severity, incidence, scope and duration of such adverse effects.

74. Such warnings and information that Defendants did provide to the medical community did not accurately reflect the symptoms, scope, severity, or frequency of the potential side effects.

75. Defendants failed to provide warnings that would have dissuaded physicians from

prescribing Risperdal and consumers from purchasing and consuming Risperdal, thus depriving physicians and consumers from weighing the true risks against the benefits of prescribing and/or purchasing and consuming Risperdal.

76. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT V
BREACH OF EXPRESS WARRANTY

77. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

78. Defendants in their manufacturing, design, distribution, marketing and promotion of Risperdal expressly warranted same to be safe and effective for Plaintiffs and members of the public generally.

79. At the time of making of these express warranties, Defendants had knowledge of the purpose for which the product was to be used and warranted same to be in all respects safe, effective, fit and proper for such purpose and use.

80. Defendants further expressly warranted that their Risperdal product was safer and

more effective than other antipsychotic drugs.

81. Risperdal does not conform to these express warranties and representations because Risperdal is not safe or effective, nor is it safer or more effective than other anti-psychotic drugs available, and it may produce serious side effects, including among other things diabetes mellitus and other diabetes-related conditions.

82. As a direct and proximate result of the breach of express warranties by Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demand judgment against each Defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VI
BREACH OF IMPLIED WARRANTY

83. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

84. Defendants marketed, manufactured, promoted, distributed and/or sold Risperdal for use by the public at large and including the Plaintiffs herein. Defendants knew the use for which their product was intended and impliedly warranted said product to be of merchantable quality, safe and fit for use.

85. Plaintiffs reasonably relied on the skill and judgment of Defendants, and as such

their implied warranty, in using Risperdal. Contrary to same, Risperdal was not of merchantable quality or safe or fit for its intended use, because said product is unreasonably dangerous and unfit for the ordinary purpose for which it was intended and used.

86. As a direct and proximate result of the breach of implied warranties by Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VII
CONSUMER FRAUD ACT (N.J.S.A. 56:8-2 *et seq.*)

87. Plaintiff incorporates by reference all other paragraphs of this Complaint as if fully set forth herein and further alleges as follows:

88. Prescription drugs such as Risperdal are "merchandise," as that term is defined by the Consumer Fraud Act, N.J.S.A. 56:8-1 et seq.

89. Defendants are persons within the meaning of the Consumer Fraud Act, N.J.S.A. 56:8-1, et seq.

90. Defendants violated the Consumer Fraud Act, N.J.S.A. 56:8-1, et seq., in the following particulars:

(a) Defendants engaged in unconscionable commercial practices, through

deception, fraud and making false promises and misrepresentations including but not limited to:

i. Failing to make complete and appropriate disclosures to the FDA in conjunction with the approval process for Risperdal;

ii. Marketing and promoting this product as safe and effective for the treatment of schizophrenia, psychosis, dementia and other conditions.

(b) Defendants used and employed deception, fraud, false pretense, false promise and misrepresentation in the following particulars:

i. Failing to disclose to the FDA and the public knowledge of the health hazards posed by the use of this product;

ii. Downplaying and understating the health hazards and risks associated with the use of this product;

iii. The methods and manner by which they undertook to create a market environment, which fostered the aggressive dispensation of this product.

(c) In connection with the sale and advertisement of Risperdal, defendants engaged in knowing concealment, suppression and omission of material facts regarding the health hazards created by the use of this product.

91. The aforesaid promotion and release of Risperdal into the stream of commerce constitutes an unconscionable commercial practice, deception, false pretense, misrepresentation, and/or the knowing concealment, suppression, or omission of material facts with the intent that others would rely upon such concealment, suppression or omission in connection with the sale or advertisement of such merchandise by defendants, in violation of the Consumer Fraud Act.,

N.J.S.A. 56:8-1 *et seq.*

92. Defendants' actions in connection with manufacture, distribution, and marketing of Risperdal as set forth herein evidence a lack of good faith, honesty in fact and observance of fair dealing so as to constitute unconscionable commercial practices, in violation of the Consumer Fraud Act., N.J.S.A. 56:8-2 *et seq.*

93. Defendants' unlawful sale and advertising practices were specifically designed to induce the public to seek out, obtain prescriptions, purchase and consume this product.

94. Defendants knew of the growing public acceptance of their misinformation and misrepresentations regarding the safety and efficacy of Risperdal but remained silent because defendants' appetites for significant future profits far outweighed their concern for the health and safety of the consuming public and Plaintiffs herein.

95. Plaintiffs' physicians prescribed and/or otherwise provided Plaintiffs with Risperdal, and Plaintiffs consumed Risperdal, primarily for personal and family reasons.

96. As a result of Defendants' violation of the Consumer Fraud Act by use or employment of the methods, acts, or practices described herein, Plaintiffs have suffered ascertainable losses, in that Plaintiffs paid money to purchase Risperdal, which was the subject of the aforementioned unlawful practices.

97. Pursuant to the New Jersey Consumer Fraud Act, plaintiff is entitled to recover treble the actual damages sustained, reasonable attorneys fees, filing fees and reasonable costs of suit.

98. Defendants are liable to Plaintiffs for all general and equitable relief to which Plaintiffs are entitled by common law and statute, including but not limited to treble damages, reasonable attorneys fees, filing fees and reasonable costs of suit.

99. As a direct and proximate result of the acts of consumer fraud set forth above,

Plaintiffs purchased an unsafe product and incurred monetary expense as well as risk to themselves, and thereby suffered an increased risk of harm as previously set forth herein.

WHEREFORE Plaintiffs demand judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT VIII
NEGLIGENT MISREPRESENTATION

100. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

101. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and/or promotion of Risperdal described herein, owed a duty to provide accurate and complete information regarding their product.

102. Defendants falsely represented that the aforesaid product was safe and effective for the treatment of conditions suffered by Plaintiffs. These representations by Defendants were in fact false and the product was not safe for said purpose and was in fact dangerous to the health of Plaintiffs. Defendants concealed, omitted, or minimized the side effects of Risperdal or provided misinformation about adverse reactions, risks and potential harms from Risperdal and succeeded in persuading consumers and Plaintiffs to purchase and ingest Risperdal despite its lack of safety and the risk of adverse effects, including diabetes mellitus and diabetes-related conditions.

103. At the time the aforesaid representations were made, Defendants concealed from Plaintiffs and health care providers information about the propensity of their product to cause great harm. Defendants negligently misrepresented claims regarding the safety and efficacy of said product despite the lack of information regarding same.

104. Defendants' misrepresentations in promoting and marketing Risperdal created and reinforced a false impression as to the safety of Risperdal, thereby placing consumers at risk of serious and potentially lethal effects.

105. The aforesaid misrepresentations were made by Defendants with the intent to induce Plaintiffs to use the product, to the detriment of Plaintiffs.

106. At the time of Defendants' misrepresentations and omissions, Plaintiffs were ignorant of the falsity of these statements and reasonably believed them to be true.

107. Defendants breached their duties to Plaintiffs by providing false, incomplete and/or misleading information regarding their product. Plaintiffs reasonably believed defendants' representations and reasonably relied on the accuracy of those representations when agreeing to treatment with Risperdal.

108. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE Plaintiffs demand judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT IX
FRAUDULENT MISREPRESENTATION

109. Plaintiffs incorporate by reference all other paragraphs of this Complaint as if fully set forth herein and further allege as follows:

110. Defendants, having undertaken the manufacturing, marketing, prescription, dispensing, distribution and promotion of Risperdal described herein, owed a duty to provide accurate and complete information regarding its product.

111. Defendants fraudulently misrepresented information regarding their product including, but not limited to, its propensity to cause serious physical harm.

112. At the time of Defendants' fraudulent misrepresentations and omissions, Plaintiffs were unaware and ignorant of the falsity of the statements and reasonably believed them to be true.

113. Defendants breached their duties to Plaintiffs by providing false, incomplete and misleading information regarding their product.

114. Defendants acted with deliberate intent to deceive and mislead Plaintiffs.

115. Plaintiffs reasonably relied upon Defendants' deceptive, inaccurate and fraudulent misrepresentations.

116. As a direct and proximate result of one or more of these wrongful acts or omissions of Defendants, or some or any one of them, Plaintiffs suffered profound injuries which are permanent and continuing in nature; required and will require medical treatment and hospitalization; have become and will become liable for medical and hospital expenses; lost and will lose financial gains; have been and will be kept from ordinary activities and duties and have and will continue to experience mental and physical pain and suffering, disability and loss of enjoyment of life, all of which damages will continue in the future.

WHEREFORE plaintiff demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT X
LOSS OF CONSORTIUM

117. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further allege as follows:

118. At all times relevant hereto, such Plaintiffs as are married have spouses who are entitled to their comfort, care, affection, companionship, services, society, advice, guidance, counsel and consortium.

119. As a direct and proximate result of one or more of those wrongful acts or omissions of the Defendants described above, Plaintiffs' spouses have been and will be deprived of Plaintiffs' comfort, care, affection, companionship, services, society, advice, guidance, counsel and consortium.

WHEREFORE plaintiff demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XI
WRONGFUL DEATH
(Applicable to Plaintiffs Gates, Kelly and Singleton)

120. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further allege as follows:

121. As a result of the acts and/or omissions of the defendants as set forth herein, which resulted in the death of Plaintiffs' decedents, decedents' survivors suffered pecuniary and other losses.

122. Plaintiffs, as personal representatives of their respective decedents' estates, are entitled to recover damages on behalf of decedents' survivors for wrongful death, pursuant to N.J.S.A. 2A:31-2.

WHEREFORE plaintiff demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

COUNT XII
SURVIVAL ACTION
(Applicable to Plaintiffs Gates, Kelly and Singleton)

123. Plaintiffs incorporate by reference all other paragraphs of this complaint as if fully set forth and further allege as follows:

124. As a result of the acts and/or omissions of the defendants as set forth herein, Plaintiffs' decedents were caused to suffer injuries both physical and mental in nature before their deaths.

125. Plaintiffs, as the personal representatives of their respective decedents' estates, are entitled to recover damages on behalf of decedents' estates pursuant to N.J.S.A. 2A:15-3.

WHEREFORE plaintiff demands judgment against each defendant individually, jointly and/or severally for all such compensatory, statutory and punitive damages available under applicable law, together with interest, costs of suit, attorneys' fees and all such other relief as the Court deems proper.

JURY TRIAL DEMANDED

Plaintifsf hereby demand a trial by jury as to all issues so triable.

Dated: July 20, 2006

WEITZ & LUXENBERG
A New York Professional Corporation
Attorneys for Plaintiffs

Franklin P. Solomon
John McN. Broaddus
Renee Henderson
Jerry Kristal
210 Lake Drive East, Suite 101
Cherry Hill, NJ 08002
Telephone: (856) 755-1115
Fax: (856) 755-1995

-and-

Jamie L. Sheller
SHELLER LUDWIG & SHELLER
A Pennsylvania Professional Corporation
One Greentree Centre
10000 Lincoln Drive East, Suite 201
Marlton, NJ 08053
Tel. (856) 988-5590

Of Counsel:

F. Kenneth Bailey, Jr.
Michael W. Perrin
K. Camp Bailey
BAILEY PERRIN BAILEY
A Texas Limited Liability Partnership
440 Louisiana St., Suite 2100
Houston, Texas 77002
(713) 425-7100

CERTIFICATION PURSUANT TO RULE 4:5-1

Plaintiff(s) upon information and belief is not aware of any pending or contemplated action. Further, upon information and belief, Plaintiff(s) is not aware of any other party who should be joined in this action.

Dated: July 20, 2006

WEITZ & LUXENBERG
A New York Professional Corporation
Attorneys for Plaintiffs

Franklin P. Solomon
John McN. Broaddus
Renee Henderson
Jerry Kristal

CERTIFICATION OF NOTICE

Pursuant to N.J.S.A. 56:8-20, Plaintiffs are mailing a copy of this Complaint and Jury Demand to the Office of Attorney General, CN-006, Trenton, New Jersey, within ten (10) days of the date of filing.

Dated: July 20, 2006

WEITZ & LUXENBERG

A New York Professional Corporation
Attorneys for Plaintiffs

Franklin P. Solomon
John McN. Broaddus
Renee Henderson
Jerry Kristal

Exhibit C

PARTNERS HEALTHCARE

October 15, 2008

An integrated health care system founded by Brigham and Women's Hospital and Massachusetts General Hospital

SENT VIA FEDEX OVERNIGHT

John J. Russell, Esq
15 Court Square
Boston, MA 02108

Re: Subpoena to Dr. Biederman

Dear Mr. Russell:

I represent Dr. Biederman in connection with the subpoena you had served on him in the matter of Avila v. Johnson & Johnson. I understand from the lawyer representing Johnson & Johnson that the subpoena is being withdrawn. Please see the enclosed confirmation letter. Accordingly, Dr. Biederman will not be responding to the subpoena or appearing for deposition on October 22, 2008. Please contact me if you have questions or if you think my understanding is incorrect in any way.

Sincerely,

Paul G. Cushing
Legal Counsel

Cc: Dr. Joseph Biederman

Office of the General Counsel

50 Staniford Street, Suite 1000, Boston, MA 02114-2521
Tel: (617) 726-8625, Fax: (617) 726-1665

Exhibit D

BAILEY PERRIN BAILEY

The Lyric Centre Building
440 Louisiana St., Suite 2100
Houston, TX 77002

Leslie LaMacchia, Attorney
Direct: (713) 425-7248
Fax: (713) 425-7101
Email: llamacchia@bpblaw.com

October 16, 2008

Via Federal Express:
Jeffrey A. Peck, Esq.
Drinker Biddle & Reath, LLP
500 Campus Drive
Florham Park, New Jersey 07932

Re: ***In Re Risperdal/Seroquel/Zyprexa litigation (Case Code 274)***
Plaintiff, Alma Avila, as Next Friend of Amber N. Avila, an Individual Case vs. Johnson & Johnson, et al., Docket No.: MID- L-6661-06

Dear Counsel:

Enclosed please find the Amended Notice to Take the Deposition of Joseph Biederman, M.D.

Please do not hesitate to contact me should you have any questions.

Respectfully,

Leslie LaMacchia

LBL:ilf
Enclosure: As stated

cc: Mr. Daniel Epstein, Esq. (Via electronic mail)
Mr. Steven J. Greenstein, Esq. (Via electronic mail)
Mr. Dennis Canty, Esq. (Via electronic mail)
Mr. Brian J. McCormick, Esq. (Via electronic mail)
Mr. Paul Pennock, Esq. (Via electronic mail)
Mr. Michael W. Perrin (Via electronic mail)

BAILEY PERRIN BAILEY
440 Louisiana Street, Suite 2100
Houston, Texas 77002
(713) 425-7100

WEITZ & LUXENBERG, P.C.
A New York Professional Corporation
210 Lake Drive East, Suite 101
Cherry Hill, New Jersey 08002
(856) 755-1115

SUPERIOR COURT OF NEW JERSEY LAW DIVISION
MIDDLESEX COUNTY

---X

In re: Risperdal/Seroquel/Zyprexa Litigation
Case Code 274

---X

Alma Avila, as Next Friend of Amber N. Avila,
an Individual Case,

Plaintiff,

DOCKET NO.: L-6661-06

CIVIL ACTION

JOHNSON & JOHNSON COMPANY, JANSSEN PHARMACEUTICA PRODUCTS, L.P. a/k/a/ Janssen, L.P. a/k/a/ Janssen Pharmaceutica, L.P., a/k/a Janssen Pharmaceutica, Inc., JOHN DOE Nos. 1 through 20 and JANE DOE Nos. 1 through 20.

AMENDED NOTICE TO TAKE THE DEPOSITION OF JOSEPH BIEDERMAN, M.D.

Defendants.

---X

TO: Joseph Biederman, M.D.
Massachusetts General Hospital
Pediatric Psychopharmacology Department
55 Fruit Street
Warren 7
Boston, Massachusetts 02114

ON NOTICE TO:

Jeffrey A. Peck
Drinker Biddle & Reath, LLP
500 Campus Drive
Florham Park, New Jersey 07932

SIRS:

PLEASE TAKE NOTICE that in accordance with the New Jersey Rules of Court, testimony shall be taken by deposition upon oral examination of JOSEPH BIEDERMAN, M.D. pursuant to R. 4:14-2(a) before a person authorized by the laws of the State of Massachusetts to administer oaths on November 19, 2008 and November 20, 2008 beginning at 9:00 a.m. at the office of Dr. Joseph Biederman located at Massachusetts General Hospital, Pediatric Psychopharmacology Dept., 55 Fruit St., Warren 7, Boston, Massachusetts 02114, with respect to all matters relevant to this litigation, at which time and place you shall please produce all documents requested on Schedule A, attached hereto.

PLEASE TAKE FURTHER NOTICE that the deposition will be stenographically recorded.

BAILEY PERRIN BAILEY
Attorneys for Plaintiff

By: Leslie LaMacchia
Leslie LaMacchia

Dated: October 16, 2008

SUBPEONA DEFINITIONS

1. "RISPERDAL" means the drug risperidone, also known by the brand name Risperdal, and any predecessor or non-final derivation of the drug that later became Risperdal. Also included in the definition of Risperdal are any chemical equivalents marketed in foreign countries.

2. "JANSSEN" refers to Johnson & Johnson Company, Janssen Pharmaceutica Products, L.P., Janssen L.P., Janssen Pharmaceutica L.P., Janssen Pharmaceutica, Inc., Ortho-McNeil-Janssen Pharmaceutical, Inc. and all of its partners, directors, officers, employees, consultants, servants, agents, attorneys, joint ventures, or other representatives, including all corporations and entities affiliated with Janssen.

3. "DOCUMENT" or "DOCUMENTS" as used herein shall be construed in the broadest possible sense and means, without limitation, any reports, memorandum, records, studies, data compilations, graphs, charts, invoices, receipts, recordings, notes, photographs, studies, analyses, projections, forecasts, plans, estimates, working papers, summaries, opinions or reports of consultants, and other types of written, graphic, printed or electronic submissions of information, and all drafts thereof.

4. "RELATED TO" and "RELATING TO" means constituting, pertaining to, in connection with, reflecting, respecting, regarding, concerning, referring to, based upon, stating, showing, evidencing, establishing, supporting, negating, contradicting, describing, recording, noting, embodying, memorializing, containing, mentioning, studying, analyzing, discussing, specifying, identifying or in any manner logically,

factually, indirectly or directly, or in any other way connecting to the matter addressed in the request, in part of whole.

5. "COMMUNICATION" or "COMMUNICATIONS" shall mean and include all discussions, conversations, interviews, negotiations, letters, cablegrams, mailgrams, telegrams, telexes, cables or other forms of written or verbal intercourse, howevr transmitted, including e-mail and postings on Internet bulletin boards, as well as reports, notes, memoranda, lists, agenda and other documents and records of communications, and when used shall require a statement of the individual who made the communications, the recipient(s) of the communication, the date it was made and the form in which it was made.

6. "MARKETING MATERIALS" includes without limitation any records or documents relating to the following:

(a) Product pricing, selling, shipping, mailing, distributing, delivering, advertising, and promoting;

(b) Market planning;

(b) Communications to consumers or doctors, including advertising, press releases, detail pieces (including e-detailing materials), promotional literature, Dear Doctor letters, Q and As, etc.;

(c) Testing, including copy testing, persuasion testing, market testing, and focus groups performed to determine or identify key messages to be sent to consumers or doctors;

(d) Tracking and message recall; and

(e) Media plans.

7. "PERSON" shall include an individual, corporation, firm, partnership, proprietorship, association and other organizational entities.

SUBPOENA INSTRUCTIONS

1. In responding to this Deposition Duces Tecum, you are required to produce all documents known or reasonably available to you, regardless of whether such documents are in your possession, custody, or control or in the possession, custody, or control of your agents, consignees, representatives or investigators, or your attorneys or their agents, employees, consultants, representatives, or investigators.

2. All documents produced in response to this request shall be either:

   (a) Produced in the order and in the manner that they are kept in the usual course of business, or

   (b) Organized and labeled to correspond with the categories in the demand.

3. All documents requested shall include all documents and information that relate in whole or in part to the relevant time period, or to events or circumstances during such relevant time period, even though dated, prepared, generated or received prior to the relevant time period. Unless otherwise indicated, the relevant time period for the information sought is 1988 to present.

4. All documents that exist in electronic form are to be produced in electronic form and in their native form or other searchable form, not in an electronic form that is merely a picture of a document such as a TIFF file, a TIF file, or a PDF file. All documents that do not exist in electronic form are to be produced in single page TIFF files with corresponding load files.

5. Notwithstanding anything else to the contracry herein, each word, term or phrase, is intended to have the boradest meaning permitted under the New Jersey Court

Rules.

6. Each request shall be construed conjunctively or disjunctively as necessary to make the request inclusive rather than exclusive. Any request propounded in the singular shall also be read as if propounded in the plural and vice versa. Any request propounded in the present tense shall be read as if propounded in the past tense and vice versa.

7. The documents responsive to this request shall be produced as they have been kept in the usual course of business or shall be organized and labeled to correspond with teh enumerated categories in this request.

8. If you object to any of the requests herein, whether in whole or in part, on the grounds that information sought therein is subject to a claim of attorney-cllient privilege, work-product immunity, or other privilege or immunity, you shall produce as much of the document concerned as to which no clai mof privilege or immunity is made. With respect to documents or portions of documents for which a cliam of privilege or immunity is made, state the following:

a. the types and nature of the document or communication;

b. the date of the document;

c. the person(s) in receipt of the document or the person(s) present during the communication;

d. the person(s) who authored or created the document or the person(s) who made the communication;

e. the person(s) to whom such documents or communcation was made;

f. the general subject matter of the document or communication in a

manner sufficient to support the privilege claimed;

g. the nature of the privilege asserted and/or the specific reason why the document is not being produced; and

h. the same information referenced in a-g above for each enclosure to each listed document if the enclosure also is withheld from production.

9. An objection or claim of privilge directed to part of a request does not constitute or excuse for failure to respond to the parts of a request for which no objection or claim of privilege is made.

10. If any document responsive to this request has been lost, destroyed, or otherwise disposed of, such document is to be identfieid as completely as possible, including, the following information: contents; author(s); recipient(s); sender(s); copied recipients (indicated or blind); date prepared or received; date of disposal; manner of disposition; person(s) currently in possession of the doucment; and person(s) disposing of the document.

11. If any document responsive to any request for production has been lost, destroyed, or otherwise disposed of, identify any and all of persons who participated in, or were invovled in, the decision to destroy or dispose of such documents, any document retention or destruction policy under which such document was destroyed or disposed of and any and all persons who participated in, or were invovled in, the formulation of any such policy, the reason for the destruction or disposition of such document, and the date (approximate, if precise date is not known) of the destruction of disposition of such document.

12. The documents produced pursuant to these requests for production shall be

deemed confidential pursuant to the Stipulated Protective Order of Confidentiality dated August 6, 2007 and Stipulated Amendment to Protective Order dated August 8, 2008.

SCHEDULE A
(DOCUMENTS REQUESTED)

Plaintiff requests that Joseph Biederman, M.D. produce and permit the inspection and copying of these documents, to the extent they are in the deponent's possession and not already produced, at or before the deposition:

1. Any and all documents pertaining to Amber N. Avila (D.O.B. 02/21/1993) ("Minor Plaintiff") including, but not limited to, calendar or diary entries, prescription receipts, medical records, billing records, and any other documents, correspondence or emails.

2. Any and all documents in your possession reflecting communications between Minor Plaintiff and any other person, including but not limited to letters, cards, electronic mail, correspondence, and notes, in which the subject of the plaintiff's health, medical condition, atypical antipsychotics or any lawsuits filed by plaintiff was discussed.

3. A copy of your current Curriculum Vitae.

4. Any and all contracts or agreements between you and Janssen relating to Risperdal.

5. Any and all communications between you and Janssen, including but not limited to any written, oral or electronic communication, relating to Risperdal.

6. Any and all communications between you and any other person relating to Risperdal.

8. Any and all documents prepared by, prepared for, or received by you relating to Risperdal.

9. Any and all marketing materials relating to Risperdal prepared by, prepared for, or received by you.

10. Any and all documents relating to your association, participation and involvement with the Robert Wood Johnson Foundation.

11. 10. Any and all documents relating to your association, participation and involvement with the Robert Wood Johnson University Hospital.

12. Any and all documents related to your association, participation and/or involvement with the Johnson & Johnson Center for Pediatric Psychology

13. Any and all documents reflecting the amount of money paid to you by Janssen relating to professional services provided by you relating to Risperdal.

CERTIFICATE OF SERVICE

I, Leslie LaMacchia, one of the attorneys for Plaintiff, do hereby certify that I served a true and correct copy of the foregoing instrument to all counsel by mailing same to:

Jeffrey A. Peck
Drinker Biddle & Reath, LLP
500 Campus Drive
Florham Park, New Jersey 07932

ATTORNEYS FOR DEFENDANT

So certified this the 16 day of October, 2008.

Leslie LaMacchia