First Draft: "Antipsychotic treatment has also been linked to hyperprolactinemia. A survey of prolactin levels at baseline and after 6 weeks of treatment in children and adolescents (mean age=14.1 years) showed elevations with both atypical and typical antipsychotics (Wudarsky, 1999). Prolactin increase was significantly higher with haloperidol (mean=47.8 ng/ml) compared with olanzapine (mean=23.7 ng/ml) or clozapine (mean=11.2 ng/ml; P<0.001). Prolactin levels with treatment exceeded the upper limit of normal for 90% of the patients treated with haloperidol, 70% treated with olanzapine, and none of those treated with clozapine. A post-hoc analysis of 592 children with DBD participating in long-term risperidone treatment showed elevation in serum prolactin within the first 4-8 weeks of treatment, followed by the steady decline to values within the normal range by 3-5 months (Findling, 2003). In addition, prolactin-mediated AEs occurred in 4.7% (most commonly gynecomastia, seen in 3.4%). Interestingly, prolactin elevation did not correlate with these AEs." (J-TXCID1204326-7)

Page 115 Published Article: "Antipsychotic treatment has also been linked hyperprolactinaemia. A survey of prolactin levels at baseline and after 6 weeks of treatment in children and adolescents (mean age 14.1 years) showed elevations with both atypical and typical antipsychotics. (Wudarksy,1999) Prolactin increase was significantly higher with haloperidol (mean: 47.8 ng/ml) compared with olanzapine (23.7 ng/ml) or clozapine (mean: 11.2 ng/ml; P< 0.001). Prolactin levels with treatment exceeded the upper limit of normal in 90% of the patients treated with haloperidol, 70% treated with olanzapine, and in none treated with clozapine. .... Post-hoc analysis from five large prospective clinical trials including a total of 592 children with DBD and subaverage intelligence demonstrated that, despite hyperprolactinaemia associated with the first 4-8 weeks of risperidone treatment, prolactin levels tended to normalize by 1 year of treatment. (Findling, 2003) Adverse events potentially related to prolactin were reported in 4.9 %(most commonly gynaecomastia in males, seen in 3.7%)."

First Draft: "Cognitive AEs occur infrequently with atypical antipsychotics. In addition, although treatment of cognitive deficits is not improved by neuroleptics in adult schizophrenics, they are improved with atypical antipsychotics (Meltzer, 1999). Verbal learning and continuous performance tasks showed improvements with risperidone in two large, open-label studies of children with DBD (Findling 2004, Croonenberghs INT-70). Additional

studies measuring cognitive changes and academic performance in pediatric patients are needed." (J-TXCID1204327)

Page 116 Published Article: "Cognitive adverse events were infrequently reported with atypical antipsychotics. Although cognitive deficits do not improve in adult patients with schizophrenia receiving conventional antipsychotics, it has been reported that they can improve with atypical antipsychotics (Meltzer, 1999). Verbal learning and continuous performance tasks showed improvements with risperidone in two large open-label studies of children with DBD (Croonenberghs 2005, Findling 2004). Additional studies measuring cognitive changes and academic performance in paediatric patients are needed."

First Draft: "Atypical antipsychotics are recommended for children requiring antipsychotic medication, due to consistently documented efficacy and superior tolerability to neuroleptics. Numerous open-label and double-blind studies have demonstrated both rapid efficacy and good short-and long-term tolerability of atypical antipsychotics for treating a broad spectrum of psychiatric disorders in children and adolescence. Symptoms of DBD, PDD, schizophrenia, and mania are often reduced during the first 1-3 weeks of typical antipsychotic therapy." (J-TXCID1204327)

Page 116 Published Article: "Atypical antipsychotics might be considered because of their documented efficacy in both double-blind and open-label studies and low incidence of EPS. As noted above, a number of double-blind and open label studies have demonstrated rapid efficacy in combination with favourable short-and long-term tolerability of atypical antipsychotics for treating a broad spectrum of psychiatric disorders in children and adolescents."

First Draft: "In addition to measuring cognition development, future studies using atypical antipsychotics in pediatric patients should also measure long-term academic and social development in treated children. Longer-term studies may also help establish how long medication treatment of pediatric psychiatric symptoms needs to be continued to maintain symptom control. Pharmacoeconomic studies, measuring both treatment and societal costs from pediatric psychiatric diseases, should also be conducted." (J-TXCID120328-9)

Page 117 Published Article: "In addition to measuring cognitive development, future studies using atypical antipsychotics in paediatric patients should also measure long-term academic and social development in treated children, as well as the need for long-term maintenance therapy. Pharmacoeconomic studies, measuring both treatment and societal costs from paediatric psychiatric diseases, should also be conducted."

First Draft: "In summary, significant psychiatric illness occurs in about 20% of children. These psychiatric disorders lead to impaired academic and social development, as well as increased societal costs. Atypical antipsychotics offer effective management of a broad spectrum of common pediatric disorders, including DBD, PDD, schizophrenia, and mania." (J-TXCID1204329)

Page 117 Published Article: Conclusion "Significant psychiatric illness occurs in about 20% of children. These psychiatric disorders lead to impaired academic and social development, as well as increased societal costs. In patients with DBDs and PDD and moderate-to-severe symptoms who have not adequately responded to behavioural interventions or primary disease therapies, it is apparent that atypical antipsychotics can effectively reduce disabling behaviours across a broad spectrum of common paediatric psychiatric disorders, with a growing literature suggesting tolerability."

Jensen was a prominent J&J KOL. He was a member of its CNS Child and Adolescent Advisory Board between 2002 and 2004. Over these years, J&J paid him honoraria and expenses in excess of $80,148.50. (Hunt, 1628)

10. RIS-USA-97

Findling RL, Aman MG, Eerdekens M, Derivan A, Lyons B, "Long-Term Open-Label Study of Risperidone in Children with Severe Disruptive Behaviors and Below-Average IQ," American Journal of Psychiatry 2004; 161: 677-684.

Message:

"Long-term risperidone appears to be generally safe, well tolerated, and effective for treating severely disruptive behaviors in children with subaverage intelligence." (Abstract, 677)

"This 48-week follow-up study suggests that risperidone is generally well tolerated at doses up to 0.06mg/kg/day and may have long-term effectiveness in children with severe disruptive behavior disorders and subaverage intelligence. Given these findings and the chronic nature of these conditions, further study is warranted to assess the safety and efficacy of risperidone in pediatric patients treated for more than 1 year." (Conclusion, 683)

This article provides an example of EM's and J&J's extensive involvement in manuscript developing and editing, an involvement that could not be known from a review of the eventual publication. The following detailed calendar makes the case.

On December 5, 2001 EM was writing the manuscript. (J-TX4696052) On March 29, 2002, EM sent the first draft to J&J. On June 26, 2002, EM sent the final copy to authors and J&J. On August 7, 2002, Robert Findling, an external author, submitted the manuscript for publication. On November 14, 2003, EM reported to J&J that the American Journal of Psychiatry had sent a revise and resubmit decision to Findling, the external author, and asked him to address the reviewers' comments. On December 3, 2003, EM addressed the reviewers' comments with assistance from one of the J&J authors, De Smedt. On January 28, 20003, EM sent the revised manuscript to the authors and to J&J. On February 27, 2003, EM sent the revised manuscript to M. Eerdekens, a J&J employee. She sent EM an email telling it to remove De Smedt as author and to substitute her. In his deposition, Gahan Pandina confirmed that De Smedt was removed from the author list, but he states that he did not know why she had been removed. (Pandina deposition, 546-547) Although he maintained that J&J had "authorship criteria" (548), both EM reports and Pandina's own statements demonstrate the fluid and self-serving nature of authorship on J&J sponsored publications.

On April 15, 2003, EM received Eerdekens' comments on the revised manuscript and incorporated the changes. On April 18, 2003, EM sent the revised manuscript to all the authors. On April 22, 2003, EM received the authors' responses and incorporated the changes. On April 23, 2003 EM sent the revised manuscript to Findling, Aman, and B. Lyons. On May 8, 2003, EM received additional data from Lyons. On May 12-14, 2003 EM incorporated the data and then reviewed and prepared the resubmission package. On May 20, 2003, EM sent the final manuscript to all the authors.

It then revised the cover letter per Findling's request, and on June 12, 2003 sent the package to Findling for submission. (J-TXCIDrev212721)

J&J conducted a separate review of the manuscript and made changes that would put Risperdal in a better light. (Pandina Exhibit 1248) Pandina reviewed the manuscript and made "comments both in the paper and in the summary form." (J-TXCID1051211) In the abstract, for example, Pandina changed "no negative effects" to "positive effects." (J-TXCID1051262), and in his deposition acknowledged making this change. (Pandina Deposition, 536) Only after J&J signed off was the external author allowed to resubmit the article to the journal. On June 26, 2002, Karen Zimmerman wrote to the J&J team: "Attached For your approval is the **final version** of the RIS-USA-97 manuscript.... After you've reviewed the manuscript, please send your approval to me at the address below. The manuscript has been sent simultaneously to the authors for their approval." She went on to note that this version of the paper had been reviewed by "all Janssen and external authors and reflects our efforts to incorporate multiple and sometimes conflicting reviewer comments...Once we have received approval from all authors, we will prepare and send to Dr. Findling a journal submission package." (J-TXCID1051613)

RIS-USA-97 appeared in the American Journal of Psychiatry in April, 2004. The authors were Robert Findling, Michael Aman, Marielle Eerdekens, Albert Derivan, and Ben Lyons. The first two authors were external authors; the other three were J&J employees. The paper acknowledged J&J Pharmaceutical Research and Development for support and for providing the study medications. However, there was no conflict of interest statement for the authors and no acknowledgement of the work of EM or its writers. Editors, reviewers, and readers could not know the extent of the roles that J&J and the communications company played.

The external author, Robert Findling, was a member of one of J&J's Speakers' Bureau Program, a member of its Risperdal Child and Adolescent National Advisory Board, an attendee at its CNS Summit meetings and a speaker at an American Academy of Child and Adolescent Psychiatry Symposium. From 2000 to 2004, Findling received at least $28,260.48 for his participation in these Risperdal promotional activities. (Hunt 1628) Findling was also a member of J&J's KOL media program. J&J trained him on how to work with the media on how to effectively deliver the J&J messages that promoted the safety and efficacy of Risperdal. (J-TXCID1261521)

Michael Aman, the second external author, was a member of at least two J&J advisory boards, the Mental Retardation and Developmental Disabilities Board (MRDD) and the Risperdal Child and Adolescent National Advisory Board. During the years 2001 to 2004, Aman received at least $16,337.68 for his participation in these Risperdal promoting activities. (Hunt 1628)

Records of J&J sales representatives submitted to the company indicate that they used the article to market Risperdal. For example, a sales representative visiting a physician in San Antonio, Texas on June 8, 2004 reported: "talked prolactin and findling (sic) he did not know infor (sic) and was curious about it, showd (sic) safety info and how risp (sic) is safe." (J-TX3024570) The same sales representative visiting another physician in San Antonio a few days later reported that the physician was concerned about the safety of prolactin and fertility. The rep told the physician "about prolactin article from findling (sic) and studies up to 3 yrs. (sic) have not shown any problems int(sic) this area." (J-TX3026249)

11. RIS-INT-41

Croonenberghs J, Fegert JM, Findling RL, De Smedt G, Van Dongen S, "Risperidone in children with Disruptive Behavior Disorders and Subaverage Intelligence: A 1-year, Open-label Study of 504 Patients," Journal of the American Academy of Child and Adolescent Psychiatry 2005; 44: 64-72.

Message:

"Risperidone was well tolerated and effective in the long-term treatment of disruptive behavior disorders in children with subaverage intelligence." (Abstract, 64)

"Our data demonstrate that long-term treatment with risperidone is generally well tolerated and that children and adolescents receiving long-term treatment with risperidone appear to have a stable response under study conditions in which there were frequent reevaluations." (Conclusion, 71)

Wells Healthcare was another medical communication company that developed manuscripts for J&J, its "client." The production schedule that Wells Healthcare prepared for J&J made clear that it assumed primary

responsibility for drafting, writing, and revising articles. The external author was to approve the product and make minor (if any) comments. Thus, on May 27, 2002 Wells HealthCare sent J&J a Production Schedule for RIS-INT-41.

> "Wells Healthcare Communications will manage the production and journal submission of this paper. Production of the paper includes: a paper outline; 3 draft reviews (where the 3rd draft is approved for submission to agreed journal); liaison with authors; production of up to 3 professionally drawn black and white figures. The paper should be no longer than 4500 words (including references). Following submission to journal, Wells Healthcare will make minor revisions based on referee's comments. Major re-writes or re-submissions will be subject to additional charge." (J-TXCID 1480794)

After outlining its tasks and schedule, the document listed five authors: J. Croonenberghs, J. Fegert, R. Findling, B. Lyons, G. De Smedt, three external, two internal. (J-TXCID1480795) When the study appeared, one internal author was removed and another substituted. The production schedule assigns them no tasks and does not even provide for their review.

The document also included a draft of the conclusions, giving a message that J&J would want to transmit:

"Risperdal is well tolerated during a year long study. Risperdal is associated with significant improvements in behavior. Risperdal is the only antipsychotic with long-term safety and efficacy data in this population. Risperdal dose can be tailored to the individual needs of the patient." (J-TXCID1480798) When the paper appeared in the Journal of the American Academy of Child and Adolescent Psychiatry in 2005, the conclusions mirrored the earlier message.

J&J and Wells Healthcare considered RIS-INT-41 a secondary publication whose goal was to educate the target audience about its product and reinforce the messages in primary publications. By the Wells Healthcare definition, secondary publications constituted "the recycling of data already presented in primary publications." (J-TXCIDrev1492301) "These will reinforce the clinical messages in the primary publications and add the marketing messages not covered in the primaries." (J-TXCIDrev149302) In all: "The secondary publications need to fulfill the following objectives: Educate the target audience about the disease area; Prepare the target

audience for the primary publications; Reinforce the messages in the primary publications; Fill the 'message gaps' left by the primary publications; *Ensure continued positive noise about the product and the disease area.* " (Italics added, J-TXCIDrev1492319)

Thus, secondary publications were marketing activities presented in the guise of scientific publications rather than outright advertisements. It was necessary to have "authors," titles and affiliations. In this sense, ghostwriting was an essential element in the marketing campaign. J&J arranged for "ghosts" so as to give promotional materials credibility, in the process subverting scientific integrity and misleading payors.

11. RIS-AUS 5

Brodaty, H, Ames D, Snowdon, J, Woodward M Kirwan J, Charnette R, Lee, E, Lyons B, Grossman F, " Randomized Placebo-Controlled Trial of Risperidone for the Treatment of Aggression, Agitation, and Psychosis of Dementia," Journal of Clinical Psychiatry 2003; 64: 1708-1714.

Conclusions: "Treatment with low dose (mean=0.95)mg/day) risperidone resulted in significant improvement in aggression agitation and psychosis associated with dementia." (134)

"The reduction in aggression was not secondary to sedation or to the antipsychotic properties of risperidone, indicating a direct effect of risperidone on this behavior." (140)

This article reveals how ghostwriting by a J&J team was incorporated into a manuscript to minimize unfavorable data on serious adverse events experienced by participants taking risperidone. J&J repeatedly intervened to edit the text so as to best serve its marketing goals.

RIS-AUS-5 was an investigator-initiated placebo controlled trial of risperidone funded by J&J. The authors had submitted the manuscript to the Journal of Clinical Psychiatry and apparently received a "revise and resubmit" response from the journal. J&J wanted changes made to the manuscript. It was concerned about the presentation of some findings in the Results Section, particularly those reporting Serious Adverse Events. J&J wanted two sentences deleted. (Vergis Exhibit, 1990) The first: "No serious cerebrovascular events occurred in the placebo group." The second: "Two of

the 5 patients in the risperidone group who had a stroke died." (J-TX4221449)

The email chains of Vincent Nye of J&J-Belgium, key marketing/scientific personnel in J&J U.S., and Dominic Barnes, medical director of J&J-Cilag Australia, (who was to discuss the changes with Henry Brodaty, the principal investigator), demonstrates how J&J intervened in a scientific publication. On April 19, 2002 Nye informed his colleagues that the changes made in the manuscript which included deleting the two sentences in the Serious Adverse Effects section, had been approved by four key J&J staff members and that he was ready, to send them to Henry Brodaty, the principal author. (Vergis Exhibit, 1990) "Should you have any additional comments please let me know by Monday April 22. We will submit to Henry Brodaty on Tuesday April 23. The idea is that Henry addresses the changes to the Journal and they come back with questions/comments and this is expected to happen in the near future." (J-TX4221447) On April 26, 2002, Nye again wrote to colleagues that since he had not heard from them, "I presume the proposed attached changes to the RIS-AUS-5 manuscript are accepted by the group. The next step is to discuss with Henry Brodaty via Dominic Barnes.... Probably Henry will seek input from the other investigators and we can expect comments from them." (Vergis Exhibit, 1990 J-TX4221447)

On June 11 2002, Dominic Barnes sent J&J both Brodaty's response and his comments embedded in "BLOCKS". (Vergis Exhibit, 1993) "FIRST, I think we should resist watering down the reporting of AEs. Stroke is a much more appropriate term than cva. SECOND I'm comfortable with the rewordings, but not with the dropping of information/interpretation. THIRD I am not in favour of the use of the term CVA instead of stroke. Stroke is an accepted clinical term whereas the term CVA dates from the 1950s when nobody knew what the pathology was. CVA is not really acceptable terminology." (J-TX3183837) Brodaty also indicated that he would resist some changes: "This is an efficacy paper, so not too much focus on SE. CAN DE-EMPHASISE BUT NOT TOO MUCH –EFFICACY PAPERS GENERALLY DO PROVIDE DATA ON SEs. (J-TX4183838)

J&J turned to Excerpta Medica International, assigning it the task of communicating with the authors to see if they could insert language that would be more favorable to its product. On October 9, 2002 Hester Kulpers, the Plan Manager, Strategic Publication Planning of Excerpta Medica

International, wrote J&J that the authors were insistent: "Please find attached for your review the response prepared by the authors to accompany the revised RIS-AUS-5 manuscript (together with the original comments from the reviewers). In short, based on the authors' request, in the results section we changed CVA to stroke in the following sentence: 'Regarding cerebrovascular disorder, in the risperidone group, 5 patients suffered a stroke and 1 had a transient ischemic attack (TIA).'" Knowing the desire to minimize the Serious Adverse Events associated with Risperdal in comparison to the placebo, Hester met with one of the J&J authors, Fred Grossman, and made additional changes that would be favorable to Risperdal. "In liason (sic) with Fred and Grant, the following was included in the discussion. Cerebrovascular disorders were reported in 18 (sic) patients, (5 patients in the risperidone and 3 in the placebo group) Patients suffering a CVA had significant predisposing medical risk factor (sic) across treatment and placebo groups." (Vergis Exhibit-1992: J -TX4210554)

J&J still remained concerned and involved. On October 14, 2002, Janet Vergis communicated her concerns. "I have concerns about the additional comments added to the discussion. They appear to simply be restating more results as opposed to discussing the implications and really only add to the amount/percentage of text spent on CVA." (Vergis Exhibit, 1992; J-TX4210553) Instead, Vergis proposed: "Changing the first sentence in the discussion section to delete the number of patients and simply state 'Cerebrovascular disorders were reported in more patients treated with risperidone than with placebo.'" (Vergis Exhibit, 1992; J-TX4210552) On October 16, Hester responded with new language: "Cerebrovascular disorders were reported in more patients treated with risperidone than with placebo. Patients suffering a cerebrovascular event had significant predisposing medical risk factors. This study, however, was not designed to stratify by risk factors? across treatment and placebo groups." (Vergis Exhibit 1992; J-TX4210551)

To further obscure negative findings about Risperdal, J&J decided to ghostwrite a commentary to accompany RIS-AUS-5. (Vergis Exhibit, 1992) On October 18, 2002, Mahmoud informed his colleagues about his communications with John Shelton, the publisher of the JCP: "I have spoken with John Shelton several times, and he has been in touch with the editor (Alan). They accept the idea of an accompanying commentary to be published with the AUS-5 manuscript. We would need to have it authored by someone recognized in the field.... We will now need to contact the

outside author with a sense of real urgency to make this happen Are we 100% clear on what we want discussed in such a commentary? I feel it should not be focused on stroke (!), but we need to balance how much we use the vehicle to communicate on the stroke issue (how much of the text should be on stroke?)" Mahmoud also noted that the journal planned to publish the article in the December of January issue. (J-TX4210550)

That same day Ronald Kalmeijer, the Director of Marketing CNS, responded to Mahmoud: "Ramy, Outstanding news!!! Could you take the lead in gost (sic) writing the letter to the editor. Within such a tight time frame I don't think it will be feasible to get high quality, accurateness and business needs." (Vergis Exhibit 1992; J-TX4210549) Marketing was also in favor of a commentary. On October 21, 2002, Bridget Ross, the Director of the Business Unit of CNS, Dementia-Neurology & Eldercare wrote: "This is great news – congrats! I will be speaking with the team here about this and could probably suggest an individual or two for the commentary—if this would be of value." (Vergis Exhibit 1992; J-TX 4210549)

Although J&J produced a draft of the commentary, they decided not to pursue it. On December 31, 2002, Mahmoud informed his colleagues "This editorial is canceled." (J-TX479531)

The article as published reflected some, albeit not all, of J&J's ghostwriting. It did not contain the sentence: "No serious cerebrovascular events occurred in the placebo group." The fact that 2 of the 5 patients in the risperidone group who had a stroke died became a phrase in a sentence that discussed the most frequent causes of death. "The most frequent causes of death were pneumonia (3 in the risperidone and 1 in the placebo group) and stroke (2 in the risperidone group)." (140) Finally, Vergis' effort to eliminate the numbers of patients suffering adverse events did not succeed. In the published article the sentence regarding cerebrovascular events read: "Regarding cerebrovascular adverse events, in the risperidone group, 5 patients suffered a stroke and 1 had a transient ischemic attack (TIA). (140) In any event, J&J's deep involvement in the process of writing and publication worked to the detriment of scientific integrity.

J&J sales reps' call notes indicate that physicians in Texas were concerned about giving patients a product that might cause cerebrovascular adverse events (CAE). J&J explained to its sales reps in its CAE Package Insert Revision Backgrounder April 1, 2003: "CAEs include not only

stroke, but also temporary events like a transient ischemic attack (TIA)." (J-TX2166952) For example, a sales rep referred to a physician in Pearland Texas as "CAE shy," and indicated that the rep would provide the Brodaty article information on the next call. (J-TX2820810) In another instance, a sales rep visiting a physician in Houston Texas reported that he addressed the physician's "concerns w/CAE using brodaty." (sic) (J-TX2907501)

13. RIS-OUT—66

RIS-OUT-66 provides an example of how J&J subverted the integrity of scientific research by not publishing data that was unfavorable to Risperdal. In November 1998, J&J entered into a Research Agreement with Covance Health Economics and Outline Services Inc. to "Examine the association between use of antipsychotic agents and clinical events related to drug-induced hyperprolactinemia such as amenorrhea." (Grogg Exhibit 1583) (J-TX2767095) J&J agreed to pay Covance $194,520.00 in five installments based upon completion of study milestones and a final report. (J-TX2767102) Covance, in turn, agreed that all information developed from the study was J&J's property as was the decision to publish the data. "Covance will prepare a final report to Janssen ....If the decision is made to publish then the principal investigator from Covance will lead the development of the manuscript. Other employees from Covance or Janssen...could be coauthors." (J-TX2767101)

J&J's internal documents reveal that its goals were more commercial than scientific, seeking to demonstrate Risperdal's superiority to competitor's drugs. In its Quarterly U. S. Outcomes Research Status Report 1Q 1999, J&J looked to RIS-OUT-66 " to demonstrate that the incidence of prolactin-related side effects is low with Risperdal, is not elevated relative to conventionals, and possible that it is lower." (Grogg Exhibit 1584) In April 2000, an internal report on RIS-OUT-66 observed, "Initial results do not support Risperdal advantage. Further Analysis planned." (Grogg 1585) In a report on October 4, 2000, the decision was made to forego publication. "Results do not support Risperdal advantage. Internal report distributed for review—no follow-up planned." (Grogg Exhibit 1586)

9) Did defendants disguise promotion of Risperdal through the use of advocacy and third party organizations?

Yes. Advocacy organizations are powerful stakeholders in the formation of policies on access to health care resources. As J&J noted in 2003: "Advocacy groups greatly influence patient acceptance and awareness of new medications as well as reimbursement support for the treatment." (JTXCID0043568) In light of this power and the public trust they enjoy, advocacy organizations should be open and transparent in their relationships with their contributors, including the pharmaceutical companies. They should disclose the sources of their funding, the purposes of the funding, and the exact sums.

In light of their special standing, J&J should have placed a firewall between their marketing departments and advocacy organizations. In disregard of these obligations, J&J exercised undue influence, in particular with the Texas chapter of the National Alliance on Mental Illness (NAMI). J&J financially supported organizations that represented advocates and patient voices. J&J's goal was to have these organizations promote public policies that were in J&J's best marketing interests, including open formularies and a preeminence in purchasing for Risperdal. Both on the part of J&J and on the part of NAMI, there was a notable absence of transparency. Neither Texas decision makers, Medicaid payors nor policy makers could know that NAMI was receiving funding from J&J; were they aware of the facts, the groups would have been equipped to make more informed decisions. One telling incident reveals J&J's strong preference for acting outside of the public eye. In 2004, one of the leaders of Texas NAMI, Joe Lovelace, responded via email to queries from a New York Times reporter and openly copied J&J employees on it. J&J was distressed by his action, apparently not wanting it known that Lovelace kept the company informed. "We need to contact Mr. Lovelace to request that he remove all J&J names from any future communications to NYT reporter." It should be taken care of "ASAP." (J-TXCID1102836)

NAMI figured very prominently in J&J's marketing strategies. Already in 1995, J&J was using Texas NAMI, through its then president, Joe Lovelace, to advocate for expanding the use of Risperdal. (Vaughan Exhibit, 712) In its 1996 "Risperdal Business Plan," J&J set forth its plans to use NAMI to help "Build Anti-Psychotic Market." The plan declared: "In order to increase the size of the anti-psychotic market, our efforts need to be focused on public education." It went on to explain: "This ties in very well to the 1996 NAMI Anti-Discrimination Campaign that Janssen is committed to and will play a very important role.... This is a great opportunity to

leverage both NAMI and Janssen interests through the 'Treatment Works' program, the Public Service Announcement (PS) developed by Janssen, early intervention, and schools/military programs." (J-TXCID0022943)

In 1999, as J&J explained in its Reimbursement Management Business Review (J-TXCID 0070906): "Partnering efforts with Advocacy continue to grow. Advocacy is a strong force in opening closed markets and maintaining access in existing open markets." This was particularly important because of the need to: "Leverage their [advocates] influence to minimize any negative impact on atypical dollars due to budget shortfall." (J-TXCID 0070903, 06).

J&J's June 6, 2000 Business Plan outlined many of the components of this approach: "Continue pivotal partnerships with national, state and local advocacy organizations (e.g. NAMI, NMHA)." The "Deliverables" include visits to national offices of NAMI, giving "appropriate and guided funding at national and local levels," supplying "key Risperdal information for publication in journals, newsletters, etc." And: "Positioning key speakers at regional meetings." J&J also trained patient advocacy group lecturers on the "intricacies of public speaking" (with press, legislators etc.) The goal is "to target key advocacy leaders and ready them for tough battles regarding access to services and medications." J&J wanted to be known as a prime "consumer advocate" so as to "Ensure Risperdal atypical drug access is clearly highlighted as an important mental health issue." There was a quid pro quo in these arrangements: "NMHA commitment to return their support (advocacy) in kind to issues important to Janssen and Risperdal access." (CID09-0017994-5; Roman Exhibit, 129; J-TXCID 1395178)

The very same formulation appeared in the Public Health Systems & Reimbursement 2001 Texas Business Plan. As its "Mission Statement" declared: "Support CNS Sales by working proactively with Public Mental Health Care Systems to identify, maximize and protect Risperdal sales opportunities." With particular regard to "Advocacy NAMI Texas," the J&J "Goal" was to "Continue to develop relationship /partnership to enhance Risperdal access." Its "Tactics" included: "Monthly calls on Administrators…. Advisory Board participation…Conference support and participation…." (J-TXCID 1395178)

To these same ends, in 2002, when Joseph Lin of CNS Marketing was setting forth his Media Management Plan, he proposed both to support

family/patient advocacy groups and to "Identify and further develop relationships with key advocacy groups." NAMI was prominent among them. Lin also proposed a Children's Mental Health Summit, with NAMI to be included, whose "output" included publishing position papers for media, government, and academia. (Lin Exhibit, 1071; J-TXCID1261302)

To insure that NAMI would promote its marketing interests, J&J wanted to increase its presence at NAMI annual meetings and to "influence speaker selection." (J-TXCID 0069351) It was also prepared to fund a variety of NAMI activities. Already in July 1995, Paulo Costa, President of J&J Research Foundation, informed Laurie Flynn, Executive Director NAMI, that J&J would serve as a founding sponsor for NAMI's National Campaign to End Discrimination against People with Severe Mental Illness." (J-TXCID 0064040) In 1995, J&J would provide $300,000; in 1996, $500,000; and in 1997, $500,000. In addition to financial contributions, Costa told Flynn, J&J "will also provide programs that have received import and support of NAMI, which are designed to support the national campaign." J&J explained its commitment: "Recognizing NAMI's effectiveness as a public advocate we feel strongly that funding should be 'front-loaded' in earlier years and directly targeted to the general public and key influentials." Costa listed nine other NAMI programs that J&J was considering funding and should J&J do so, NAMI would receive on average $1 million per year for the next three years. To supplement this funding, "Janssen employees are willing to devote their time and effort in supporting your anti-discrimination efforts. We can also offer you the in-house marketing expertise to assist you in your drives for membership." J&J accepted NAMI's offer to participate on the national campaign's steering committee. Bruce Given, Group Vice President, would participate and "be in attendance at this year's NAMI Annual Meeting."

NAMI was so central to J&J's marketing strategy that the company spared no effort to buttress NAMI's capacity. Two slides that were part of the Public Sector & Institutional Business: Public Health Systems and Reimbursement presentation of J&J employee Roman, reveal the company tactics. (J-TXCID 1391272)

Slide 1: 2000 Goals and Key Accomplishments: ADVOCACY

Consumer Media Training: With the tremendous response to the 1999 program, conduct at least one more during 2000. The CMT

teaches the intricacies of public speaking (e.g. public hearings, meetings with state officials) TV and written press. The overall goal is to target key advocacy leaders and ready them for tough battles regarding access to services and medications.

State/Local Programs: Continue pivotal partnerships with national, state and local advocacy organizations (e.g., NAMI, NMHA) mental health coalitions and state health trade associations. *Ensure these same groups clearly understand our concerns with access, understand the cost/dose comparative profile among the atypicals and ready to advocate on behalf of RISPERDAL and the atypicals as warranted.* (Italics added)

SLIDE 2: 2002 Goals & Objectives: ADVOCACY:

Advocacy Advisory Board

NAMI/NMHA annual meetings: Influence speaker selections and increase PHS& R representation at national meetings (Public Health Systems & Reimbursement)

Develop/Feature Joe Lovelace (NAMITX)

Empower advocacy to publicly support and work toward increasing state funding, as well as supporting cost-weighing factors among atypicals

To these same ends, in 2002, in response to negative media publicity about psychopharmacology, J&J established an Advocacy Advisory Panel. The first meeting took place in Miami, March 19-20. The panel was composed of 19 members, 9 of whom were from NAMI. (Ten were from a kindred advocacy organization, Mental Health America.) All attendees were presidents or executive directors of state programs. A second meeting was to be held in 2003. (Josephson 23541-47) (Lin Exhibit 1071, J-TXCID1261313)

The objectives spelled out J&J's interests:

Impact of treatment guidelines on quality of care
Access to atypical antipsychotics and legislative actions

Clinical understanding of antipsychotics
Impact of non-adherence to all medications
Coalition building with alternative associations

J&J was also prepared to give NAMI $12,500, in the form of an unrestricted educational grant "in support of NAMI's distribution of the J&J video: 'The Science of Schizophrenia: Milestones to the Millennium,' the A&E Investigative Report: 'The Worst Disease,' and the PBS program, 'The Visionaries.' We are excited about the opportunity to assist NAMI as you disseminate resources to your affiliates and other key mental health community representatives. We look forward to continuing to partner with NAMI." To have a so-called patient advocacy group with standing in the community distribute company products was a victory for J&J's marketing. (October 19, 2000, Nadia Dac Project Director CNS, to Charles Harman, NAMI-JAN 0220; see also Payson Exhibits, 1522, 1529)

J&J's interests in having NAMI as well as other advocacy groups fulfill its marketing aims continued to be powerful. In 2005, for example, J&J representatives worked with advocacy groups to increase the Texas use of Risperdal in its community mental health centers. As one rep described the process: "I went into the NAMI. I said listen, I'm working as an advocate to try to get open access." (Daniels Deposition 185) What was not said was J&J's financial stake in access. The appearance was of doing well by mentally ill patients, not doing well by J&J's sales charts. (Daniels Deposition, 175-180)

NAMI, for its part, sought J&J support, although it did not disclose the extent of the funding. It regularly reported to J&J to demonstrate the ways by which the organization's efforts furthered the company's interests.

A report to J&J (Sid Frank) from NAMI (1997) described the progress made by its Campaign to End Discrimination in the Care and Treatment of the Mentally Ill: (J-TXCID 0064020)

1. Federal Parity for mental health care:
   Flooded White House with Calls and Letters:

2. Media Outreach:

NAMI placed ad in Washington Post under the headline: "Stand Tall, Mr. President."

NAMI partnered with the Rand Institute to promote a study in JAMA on the cost of parity for the care and treatment of mental illness.

3. Membership Marketing

NAMI also mailed 2000 letters asking state legislators to join NAMI, assisted by NAMI board member Garnet Coleman, the Texas representative who sponsored and helped pass the state's parity act. NAMI included in the mailing copies of THE DECADE OF THE BRAIN which featured information on the latest anti-psychotic medications. (J-TXCID 0064020)

Relations between NAMI and J&J officials were very close. In October 1998, for example, NAMI's Laurie Flynn thanked Sid Frank for providing $500,000 for the Campaign to End Discrimination. She noted that NAMI had 185,000 members and over 1,140 affiliate organizations. She addresses him as Sid, signs it Laurie, and writes in the margin: "I deeply appreciate your support and look forward to working with you." (J-TXCID 0064109)

It is not surprising, therefore, to read an internal NAMI email of December 11, 2000, from Charles Harman to colleagues, with the "*Subject: Jan$$en*" Harman wrote that J&J would continue to fund NAMI in 2001 "equal to the previous years. First check which is a portion of next year's grant" was $350,000. (NAMI-Jan-0217)

To make certain that J&J support continued, Harman kept J&J officers fully informed about the NAMI activities that would please the company. "Attached are two letters to key Senators from Dr. Richard Birkel [NAMI 's executive director] regarding proposed legislation that we believe would restrict access to medications used to treat people with mental illness. NAMI continues to fight to protect access to treatment through strong advocacy on the state and federal levels. Please let me know if you have any questions about this issue." (Charles Harman to Alex Gorsky July 25, 2002)

So too, he told Laurie Snyder that NAMI programs aimed:

To drive the local, state and national debate on mental illness system reform
To improve treatment outcomes by advancing evidence-based and emerging science-based practice
To reach out to under-severed and priority populations
To rebuild the NAMI grassroots by strengthening the network of state and affiliate organizations (J-TXCID0111410)

"In addition to the Campaign, we continue to have an interest in collaborating on a national, region and state basis with Janssen." (December 6, 2002, ...410)

The exercise of improper influence by J&J and NAMI's readiness to further J&J's interests is particularly evident in the activities undertaken by Joe Lovelace, the preeminent figure in Texas NAMI.

Lovelace received funding from J&J not only for the organization but personally, noting in his deposition that he deposited the monies in his wife's law firm account because "she needed the money...there was a loss there." (Lovelace Deposition, 86) He also "expressed a desire," as J&J's Coard informed colleagues, "to partner with Janssen as a consultant," which several of them considered "a tremendous asset to Janssen in current and future initiatives." (J-TXCID 1559353) Lovelace advocated for J&J's interests, and trained other community and NAMI members to do so as well. He was a frequent speaker for J&J between 2000 and 2003. (Deposition Exhibits, 1753, 1755, 1766, 1767; J-TXCID 0079268) He worked hand in hand with J&J to get Risperdal Consta favorably positioned in Texas Medicaid. When asked whether he "worked with people at Janssen to try to get Texas Medicaid to cover Risperdal Consta," he replied yes. (Lovelace Deposition, pp. 174-175, 191; J-TXCID 0142701) He arranged to have NAMI host meetings with "key members of the legislature and the executive branch" of the Texas government, thereby giving J&J access to them. (Lovelace Deposition, 178-179) Lovelace kept J&J well informed of his activities with Texas medical benefit personnel on behalf of Risperdal Consta, and the J&J employees carefully evaluated and reviewed his efforts. As one internal J&J email noted: "Joe Lovelace's email outlining what he plans to do with his meeting with the Tx Medical benefit Medical Director was discussed. Everyone on the call was satisfied with the objectives, agenda, and level of responsibility." (J-TX4460370) (See also Lovelace

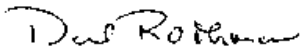
Exhibit, 1770, 1786, J-TXCID 1130103 for documents demonstrating how J&J used Lovelace to ensure coverage for Risperdal Consta.)

Many of the activities that Lovelace carried out in conjunction with J&J violated principles of transparency. When asked if he let state officials know that he was copying the emails with them to J&J, he replied no. (Lovelace Deposition, pp. 193-194) When asked "did you ever let on to the Texas Medicaid folks that you were reporting at each stage and at each step to Janssen your interactions with people at Texas Medicaid?" he responded: "The answer to each step is no" (Lovelace Deposition, 216-217) Thus, when he wrote to Texas representative John Davis to promote Risperdal Consta, his email openly copied other Texas officials but did not openly copy J&J employees—although he sent it to them as well. (J-TXCID rev0086242) He also received travel payments and honoraria from J&J, including to Europe and Hawaii. (Lovelace Deposition 143, 149-150; see also Lovelace Exhibits, 1741, 1743, 1745, 1747, 1751, 1753, 1755-57, 1759, 1761, 1764-69) Lovelace was so indifferent to obvious conflict of interest considerations that he tried to get J&J to bring him onto its staff as a consultant. (Lovelace Deposition, 156, 160; J-TX4057588) J&J itself took no steps to remedy the situation.

The value of Lovelace to J&J went beyond his own work for them to include his training of community and NAMI members to advocacy. When asked if he would have NAMI members "come up to testify and relate their personal stories," he responded by noting that when he had a chairman of a legislative insurance committee from Amarillo, he "made sure that a person in his church sat down in front of him." (Lovelace Deposition, 72) "You can't imagine how good advocates this folks are just in the raw state. And when you bring them in and talk to them and give them talking points and they sit and observe the process, they do pretty effectively." And if Lovelace himself did not inform legislators of his J&J links, these advocates surely did not do so either. (Lovelace Deposition, 74) When asked whether there was a session between 1995 and 2005 when NAMI was not using grass roots advocacy, Lovelace replied "we were there." When asked: "Every Time? he answered, "Yes."(Lovelace Deposition, 70)

In sum, the J&J-NAMI collaboration allowed the company to use a health advocacy organization to disguise its marketing interests. That NAMI was a willing partner does not make J&J any less culpable. It was the company funds that fueled the operation. To use an

organization that presents itself as the public voice of the mentally ill in order to enhance marketing strategies is an egregious example of the exercise of undue influence.



David J. Rothman

October 15, 2010