will use them. ... I will also include him in all advisory functions that we hold in the southwest part of the country." Dr. Rush: "It will be important to maintain a relationship with Dr. Rush as the TMAP project moves toward Phase III...."

In this same vein, J&J employees regularly performed what they called a SWOT (Strength, Weakness, Opportunities, Threats) analysis on the physicians whose status, marketing power, and influence over colleagues, interested them:

Dr. Crismon: track all his advisory board activities; his speaking development; information exchange; partnering activities. Strength: "nationally known; good podium skills;" Weakness: none; Opportunities: develop as a speaker for a new J&J drug; Threats: "Lynn is data driven, and as new information becomes available from other companies, Janssen products could move from favorable positions." (J-TXCIDrev 1449315-16)

Of particular importance to J&J was Dr. Steven Shon, the medical director of the Texas Department of Mental Health and Mental Retardation. J&J, for example, wanted Texas-based Magellan Health Care to give preference to Risperdal. The chief medical director of Magellan, however, wanted assurances that the state would agree. J&J's Evelyn Grasso-Sirface, in an internal email, noted that "Dr Shon has already given this his blessing." (Kraner Exhibit, 1161) Her email went on to suggest how to use Shon's assurances to open the market for Risperdal still further. She proposed a meeting for "national advocates with Magellan and J&J to address 'why Risperdal should be preferred (of course we will call it something like 'stretching the available financial resources for maximum patient care.')"

Shon was also considered a pivotal figure by another J&J employee, Percy Coard. (Frank Exhibit, 224) After thanking his colleagues for attending a Shon presentation, he listed all the reasons why J&J wanted a "strategic alliance" with him. As Coard explained, Shon was a KOL, influential in the public sector, where "85 Percent of all anti-psychotic dollars come from;" he has influenced and supported the use of new drugs in TMAP, and a proactive approach to him "to support/partner with his current and future projects in the public sector arena will continue to position Janssen as a true partner in public mental health initiatives." (Gorsky Exhibit, 952)

Apart from TMAP, J&J also funded Visiting Faculty positions to recruit national and local speakers so as to win their allegiance. "Programs for our speakers will be directed toward solidifying their message" so as to "Own schizophrenia/OL [opinion leader] endorsement." (J-TXCID 1277436) "Tactics directed at the opinion leaders are aimed at enhancing our relationship, but more importantly ensuring their endorsement for RISPERDAL." (...439) Part of this strategy was carried out through Annual CNS summits as discussed below.

J&J made gifts of food and drink part of their business strategy to win over Texas providers and increase market share. Thus: "See Dr. Katz every Monday until end of quarter. Bring in Starbucks coffee once a week.... Take out to lunch once a month. Get Risperdal Consta available in clinic by March 15." (J-TX2551850)

The importance of TMAP to J&J was so great that it made extraordinary efforts to co-opt Drs. Crismon, Chiles, Miller, and Shon. Not only were their positions in Texas vital to J&J marketing efforts in Texas, but to its marketing efforts in other states. Its strategy took several forms.

First, the four were to be invited to attend regional meetings and gatherings, with accompanying honorariums. This approach was regularly adopted and successfully implemented. The number of meetings that the four attended is almost too many to count. (Hunt Exhibit, 1623, 1624, 1626, 1629) Crismon and Miller, for example, along with Chiles, were at the J&J Dallas Regional Advisory meeting October, 1997; then a few months later, they were in Palm Springs, Ca. for another J&J advisory meeting. (Miller Exhibits, 647, 648) Beginning in 1999, these TMAP principles were invited to J&J CNS summits which they almost always attended through 2003. (Hunt Exhibit, 1624)

Second, from the very start of the TMAP project, J&J used Crismon and Shon to advise other states on how to make use of similar guidelines. J&J sent the director of pharmacy services at Harrisburg (Pennsylvania) State Hospital a memorandum on TMAP, adding that Shon, Rush, and Crismon "are available for any questions you might have." (Snyder Exhibit, 93) They invoked the four again and in the same terms in writing to Stephan Karp, Medical Director of Pennsylvania's Office of Mental Health. (Snyder Exhibit, 94) So too, J&J told the Tennessee Care Pharmacy Director that if

he and some colleagues wanted to learn more about TMAP, it would arrange for them to go to a program in Texas. "Janssen will cover the cost of the program and your travel to and from Texas. We can also bring Dr. Chiles or Miller to Tennessee to speak about the program to a defined group." (TXJAN 0061917)

Third, J&J sent the four leaders of TMAP around the country to promote TMAP, and, in the process, Risperdal. (Hunt Exhibit, 1623) The exercise of undue influence both on the leaders themselves and their audiences is apparent. In preparation for the June 2002 meeting conducted by J&J at the Mansion at Turtle Creek, Yolanda Roman of J&J wrote her colleagues to tell them that "Key states dependent on TMAP" included Pennsylvania, Ohio, Virginia, Connecticut, Washington, and four others as well. "I'm wondering if most Janssen attendees understand how wide the net is relative to the impact of TMAP?" She also noted: "These 'state' visits have been in the form of influencing, implementing, monitoring and managing TMAP or TMAP-like initiatives. Shon and Miller are also on the CME Public Sector series faculty (2000, 2001, and 2002 series) specific to TMAP initiatives. We have a great opportunity to position this subject matter again in 2003." (Roman Exhibit, 145)

When J&J brought out Consta, a longer acting form of injectable Risperdal, it carefully coordinated its efforts to position the product favorably on the TMAP algorithm. "Alec Miller and Lynn Crismon will be the primary drivers on this decision," noted one J&J employee, Rob Kraner. Observing that Miller would soon be meeting with J&J, he also wanted a meeting arranged for Crismon. "I don't mean to underestimate Steve's [Shon] importance on this decision, it's just that Alec and Lynn play a more active role relating to algorithm modifications." (TXJAN 0057124) (Miller Exhibit, 656,) This approach was duplicated by another J&J employee (Sid Frank): "We should be actively communicating with our TMAP KOLs to lay the groundwork for adding Consta as a first line agent along with Risperdal oral." (Leech Exhibit, 828) When it was suggested that Consta would not be placed in "equal status with the other atypicals," J&J felt "it would be best to wait until the appropriate data is available before RC [Consta] is added specifically to the algorithm." (Scott Exhibit, 2212)

The J&J strategy won sustained cooperation from Shon, Crismon, and Miller. Although it certainly was a breach of responsibility on their part, they devoted an exceptional amount of attention to meeting J&J's needs. As

J&J's Roman informed her colleagues in an email of May 29, 2002: "During the last few months, Steve Shon, Miller and Crismon have spend (sic) a considerable amount of field time with most of the PHS&R Managers." (Roman Exhibit, 145) That the three devoted so much time to J&J, that although they were members of TMAP they allowed themselves to monitor and manage TMAP issues for J&J, and that they were involved with CME presentations despite their own biases and involvements, points to the improper influence exerted by J&J as well as to the failure of the three to manage their own conflicts of interest and maintain professional integrity. (J-TXCID1103181)

When J&J learned in 2001 that competitors "are NOT happy with Dr. Shon's influence over prescribing behaviors that favor RISPERDAL," and were mounting "a full court press" to move him away from J&J, the company responded with alacrity. It noted: "Dr. Shon can and is influencing not only the $50m atypical dollars in Texas, but likewise in many other states." The bottom line: "WE WILL NOT LET LILLY OR PFIZER PREVAIL WITH OUR MOST IMPORTANT PUBLIC SECTOR THOUGHT LEADER." (Bursch-Smith Exhibit, 1801, 1800) When Yolanda Roman heard about competitors' efforts, she noted: "Steve I suppose is enjoying the vast attention and response he can command from Industry." Lilly was apparently flying him by corporate jet to a site visit. "Obviously Steve has the right to be served by all Industry, let's hope he remains fair balanced and remembers who PLACED HIM ON THE 'MAP' MAP." Bursch-Smith Exhibit, 1799) (Materials below address the special activities and relationships of these individuals in greater detail.)

3) Were appropriate safeguards in place to prevent opportunities for undue influence in other marketing efforts for Risperdal?

No. J&J utilized multiple channels to exert undue influence in marketing Risperdal, including: 1) meetings like the CNS Summit, Advisory Board, and other meetings; 2) research projects that were veiled attempts to promote marketing; 3) Continuing Medical Education events (CMEs) that violated ACCME guidelines; and 4) special pet projects that were funded for promotional reasons.

The undue influence exerted by J&J is manifested in its convening of annual CNS Summit meetings in order to win favor with Key Opinion Leaders (KOLs). Texas mental health leaders were frequently included,

both as a reward to them and as an opportunity to spread the TMAP approach to other states. J&J used the occasions to pay honoraria to KOLs (typical payments were $3000), gifting them to win their favor. (Shon Exhibit, 317, 319-321, 673) The meetings were also the opportunity for J&J, in both formal and informal ways, to promote and market Risperdal. This is evidenced by the very heading on J&J's internal report on the 2nd Annual CNS Summit meeting in Tempe Arizona: "MARKETING." The report notes at the outset: "The objective of the meeting was attained in that we were able to further enhance our relationship and increase endorsement of RISPERDAL with our KOLs. The meeting was very well attended with over 150 of the top US KOLs and 40 international KOLs." (TXJAN 0048992) As one J&J sales representative explained, part of a sales rep's responsibility was to identify KOLs and arrange for them to be J&J speakers. As a Field Conference report declared: "Key Opinion Leaders have been utilized to influence other customers to positively impact their prescribing decisions." (Moake Exhibit 1957) One KOL, for example, citing the Expert Consensus Guidelines that made Risperdal the first choice in switching patients to a new drug, prompted four other physicians to agree this information was "beneficial." The Conference report concluded: "Great job utilizing a KOL to influence other physicians." (Moake Deposition, 93-97)

J&J expended large sums of money to influence the attitudes and prescribing behavior of KOLs. To cite one example, a CNS Summit in Phoenix Arizona brought together KOLs at a cost of nearly one million dollars. Among the attendees were several of the key decision makers in the TMAP project: Dr. Steven Shon (who received a check for $3,000 made out to him, not his employer, the Texas Department of Mental Health) (Shon Exhibit, 317); Dr. Lynn Crismon ($3000) (Crismon Exhibit, 516); and Dr. Alexander Miller ($3000). The total cost of the honoraria distributed to physicians at the meeting $564,500; hotel costs were $187,701; and travel, $135,527. Added to this was a cost of another $47,547, to cover expenses incurred by J&J employees. (RIS 00052620)

J&J gave out invitations to these meetings so as to influence TMAP decision making. As one internal J&J memo noted, it wanted to schedule a get-together with TMAP leaders to discuss where on the TMAP algorithm Risperdal Consta would be placed. Not by accident did a J&J employee suggest that the meeting be held at an upcoming CNS Summit. "All the principles (sic) involved with TMAP are on the invitation list." (Miller

Exhibit, 656) When asked why he invited Dr. Shon to a CNS meeting, a J&J employee responded: "He was the medical director in the largest state in my geography." (Leech Deposition, 199) This statement is important because it indicates a clear violation of the Texas Penal Code Section 36.07. The Texas Ethics Commission states that a public servant may not accept an honorarium if their "official status" was a deciding factor. (Hunt Exhibit 1636) In his deposition, Dr. Shon acknowledged that he was aware of the penal code section. (Shon Deposition, 287)

J&J knew the value of using KOLs for marketing. When an article unfavorable to Risperdal appeared in a Florida newspaper, J&J brought in media experts to train KOLs to refute the story. KOLs were trained to be more effective communicators, through the use of videotaping and mock interviews. (Lin Deposition, 56-57) For example, at a meeting of KOLs held in New York in December 2002, Robert Findling, director of child and adolescent psychiatry at University Hospitals of Cleveland, spent an hour with a media expert "to work on specific on-camera interview and message techniques." (Lin Exhibit, 1072, J-TXCID1261521)

J&J also exerted undue influence in convening Advisory Board meetings to enhance its marketing activities, again paying out consulting fees to prescribers and presenting them with J&J data so as to win their prescribing allegiance. At one these meetings, for example, J&J presented findings on the research that it had conducted, organizing a round table "to discuss side effects of antipsychotics with particular emphasis on weight gain." (TXJAN 0048992) This format was designed to emphasize findings that J&J believed would give it an advantage of competitors' products. The goal was not a presentation of balanced and objective findings but an exercise in marketing.

At another advisory board meeting J&J assembled Medicaid officials to advance its marketing capacity. The purposes were laid out by Parexel, a medical marketing firm that organized the meeting. (Josephson Exhibit, 64, 65) It noted that with 50 percent of revenues for Risperdal coming from Medicaid payments, this market was of crucial importance to J&J. Bringing a select group of Medicaid officials together would give J&J knowledge of the barriers that limit access to its drug, and give it the opportunity to counter the threat of "restrictive utilization control mechanisms, such as prior authorization." The meetings would also enable Johnson and Johnson to "facilitate ownership" among Medicaid officials in "addressing barriers to

... atypical antipsychotic drug therapy." (Josephson Exhibit, 64, p, 2) Paraxel would identify those officials likely to "champion the idea of facilitating access to...psychotropic medications," and "solidify Janssen's profile among Medicaid officials." (Josephson Exhibit, 65, p. 7)

Importantly, J&J targeted Texas Medicaid decision-makers by sponsoring the Medicaid Mental Health Pharmacy Advisory Board which met April 14-16, 2000 in La Mansion del Rio in San Antonio. (JTXCID 0079013; Josephson Exhibit, 66) In attendance as a member of the Board was Martha McNeill, Director of Prescriber and Product Management in the Texas Department of Health; she was a key decision maker in the Texas Vendor Drug Program which administered reimbursement for drugs listed on the Texas Medicaid drug formulary. (J&J also brought her to the 2000 Advisory Board meeting in New Orleans.) The messages McNeill heard included Shon declaring that although physicians should use cost-effective drugs, "the problem," the J&J minutes report him saying, "is using a stage 4 drug [typicals] for stage 1 treatment [atypicals like Risperdal]" He added that Risperdal had now caught up to Zyprexa in sales—the two were "dead even." She also heard Joe Lovelace of NAMI speak to the theme of: "Cost of Medication: Being Penny Wise can Result in Pound Foolish." McNeill wrote J&J to say how grateful she was for being a member of the advisory group. (McNeill Exhibit, 1233) Her successor, Leslie Harper, attended the 2001 meeting, held at the Marriott in Miami Florida. (Vaughan Exhibit, 722)

So too, J&J convened a June 4, 2002 meeting at the luxurious, five star, Mansion at Turtle Creek for the Antipsychotic Algorithm Advisory Forum (at a cost of no less than $114,000). (Hunt Exhibit, 1625, 001904; Chiles Exhibit, 1299; Roman Exhibit, 135, 136, 138, 145; Crismon Exhibit, 565; Trivedi Exhibit, 1333). At this Forum, speakers included J&J employees (Mahmoud), and TMAP member Miller (delivering an "Overview and Update on TMAP and Clinical Opportunities for Risperdal Consta"). (J-TX2243219) Shon was also in attendance as were Crismon, Chiles, Rush, Trivedi, and Suppes). The J&J goal, as an internal memo explained, was to: "Identify hurdles to [Consta] adoption;" to "Develop next steps to overcome hurdles;" and to "Develop next steps for roll out beyond Texas." (J-TXCID1476201) (For additional discussion of this meeting, see below.)

J&J also organized a series of meetings which were the occasion to have KOLs speak on behalf of J&J at a variety of settings, both spreading

the J&J message and giving the company the opportunity to reward them financially. Thus, J&J organized a Mental Health in the Millennium series on schizophrenia and used Texas TMAP personnel frequently: Shon spoke in Sacramento (travel paid and $2000 honorarium), and in Chicago ($2000); Miller in Tampa ($2000), and in Nashville ($2000); Crismon in Tampa ($2000), in Buffalo ($2000), in Madison ($2000), in Nashville ($2000), and in Richmond ($2000). (TXJAN 0083033-11).

The choice of speakers at these events was carefully calculated to increase sales for Risperdal. As a September 21, 2002, J&J, internal memorandum stated: "It is critical that we support and maintain a strategic alliance with Dr. Shon…." (Frank Exhibit, 224) The J&J reasoning was that Shon was a KOL who was a prominent figure in the public sector, and the public sector represented the largest percentage of spending on anti-psychotic drugs.

In another example of the exercise of undue influence, **J&J coordinated its research projects to promote its business interests, merging sales and research to the detriment of scientific integrity.** As the CNS Monthly Status Report of July/August 2001 declared: "This trial *should* demonstrate correction of olanzapinic-induced glucose dysregulation by risperidone and will provide data to advise on how to switch patients from olanzapine to risperidone." (Italics added: RIS-USA-250 Rescue Study, TXJAN 0038617).

Yet another example can be found in J&J material on RIS-OUT-090: The purpose of the research was "To document Risperdal's advantages in reduced hospitalization, weight gain, and employment/vocational training." (TXJAN 0068294) Each column listing the research project is headed by "Business Strategy." The goal was not to analyze whether Risperdone has such an effect but to document it. So too, the goal of RIS-OUT-097 was: "To Document Risperdal's cost advantages over Zyprexa in the setting of the VA." (TXJAN 0068300) Again, the conclusion is presented before the research is performed. Indeed, the funding given to Joseph Biederman, discussed below, is part of this same tactic of elevating market goals over scientific integrity.

The J&J exercise of undue influence is also found in medical education and its violations of ACCME guidelines. These guidelines, and J&J's own policies, prohibit company influence over educational programs.

Nevertheless, the company was deeply involved in the selection of CME speakers and in the content of their presentations. J&J conceived of CME as part of its marketing strategies. In an internal report of October 1996, under the heading: "Aggressive Direct Promotion," it listed, along with national symposia and speaker training, "CME half day symposia." (J-TXCID1378228)

As an example of undue influence, J&J organized a CME Symposium Project, "The Emerging Public Sector Dilemma," along with Excerpta Medica, a commercial organization that organized both CME presentations and oversaw the production of journal articles. (J-TXCID1132222) J&J made the objective of the Project for 2000 to "define therapeutic options," analyze pharmoeconomics, and identify guidelines to get newer treatments to patients. The Project audience was to include mental health administrators and mental health clinicians along with legislative staff and advocates. Ten meetings were set up by J&J to export TMAP to states across the country: Shon was scheduled to speak at 5 of them, Crismon at 3 of them, Csernansky (author of a key NEJM article on Risperdal) at 3 of them, and Chiles, another TMAP leader, at 2 of them. Materials specifically note "CME Accredited for Physicians" (…31). The final page declared: "Measuring Success." 1- Target Audience Attendance; 2- Feedback from Target Audience; 3. *"Risperdal preference as a result of meeting."* (…2253, italics added) The document closed with FAQs: "How did you select faculty? Answer: "Based on recommendations from Janssen, our CME provider Excerpta Medica, selected faculty for the series." This company influence over the choice of speakers was a flagrant violation of ACCME guidelines.

Undue influence on CME was integral to J&J's 1999 Tactical Plan for Risperdal. It looked to establish "CME Case Study Programs" with the "Objective: Increase Risperdal share among HVP" (high volume prescribers). To this end, it looked to schedule an "Interactive CME discussion" in a small group setting in 8 cities, from Boston to Los Angeles. (J-TXCID 1277434)

Other examples of undue influence and violations of CME rules include:

An Arizona organization (Community Partnerships) asked J&J support for an educational grant whose stipulations included: "Specific

program content was not selected or controlled by Janssen." Companies were not to have influence over the selection of speakers. Nevertheless, the organization asked J&J for a grant specifically to bring Miller and Crismon to talk on TMAP. The $2500, the organization notes, was to be applied to the honoraria for the two speakers. (J-TXCID 0079275)

Still another example is found in a memo by J&J employee, Laurie Snyder, referencing an upcoming schizophrenia guideline program: "What's in it for CNS sales?" "This program, funded by Reimbursement, will have two speakers that present favorably on Risperdal." One of the two presenters was Shon. "Physicians will hear a favorable Risperdal message and learn about guidelines that could possibly affect Risperdal share in the long run." A week after the meeting was held, Snyder was congratulated by J&J employee Sid Frank. "Great program Laurie!! Your 'next steps' are on target and should result in business growth.-Keep up the job!" (Snyder Exhibits, 97, 98)

J&J disregarded the **fundamental conflict of interest that these practices engendered.** It is no coincidence that in 1998, TDMHMR together with Texas Medicaid represented $34.6 million in Risperdal sales, or 72% of the Texas total. (J-TXCID 0070899) From J&J's perspective the ends were clear and trumped the means: "It is incredibly important that we are the market leaders in schizophrenia and bipolar disorder." (....27) The goal is to be met through providers, influencers, and payers." (...27)

Finally, J&J's readiness to exercise undue influence and ignore principles of conflict of interest was standard company practice, not unique to Texas, and not the result of idiosyncratic relationships between J&J employees and TMAP officials. One of the most glaring examples was the funding that Johnson & Johnson gave Dr. Joseph Biederman of Harvard University and the Massachusetts General Hospital. The overt purpose of the agreement with Biederman was to give J&J access to a team which would carry out research on bipolar diseases in children and adolescents. The latent purpose, as set down in email strings and annual reports, was to have the Center's research promote the use of Risperdal for children and adolescents. J&J calculated that the fact that the research on the drug was conducted by a leading child psychiatry researcher at a very prestigious academic medical center would give the findings more authority.

The idea of a J&J Center for Pediatric Psychopathology originated with Dr. Biederman. On February 5, 2002, George Gharabawi, a J&J employee, informed his colleagues that Biederman had "approached Janssen multiple times to propose the creation of a Janssen-MGH center for C[hildren] &A[dolescent] Bipolar Disorders." Gharabawi described Biederman as "a pioneer in the area of C&A Bipolar Disorders." The purpose of the Center, Gharabawi explained, would be "to generate and disseminate data supporting the use of risperidone in this patient population." Biederman agreed that J&J support would lead to a focus on two topics, Diagnostics, and "Therapeutics including short and long-term outcomes on the management of C&A BPD with risperidone including the long-term prophylactic effect on drug abuse." (J-TX4695121)

J&J would commit $500,000 a year to support the Center, the costs shared by several J&J companies: "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." Biederman concurred. In response to J&J's request for deliverables, his team produced "A Risperdal Reanalysis, Reach and Publication grid." (J-TX4695121)

Biederman and his team consulted regularly with the company and were invited for a Home Office Visit. To give one example: "This meeting," noted Gharabawi, "will involve, in addition to Dr Biederman's research team, the Risperdal, Concerta, and Topamax team with the objective of elaborating a full research plan for the years 2002-2007." As Gharabawi saw it, the Center would position "Janssen as a major partner in the area of C&A psychopharmacology." (J-TX4695121-2) Biederman also received J&J funds for travel to conferences and funds to organize publications. (J-TX4693092) (J-TX4692727) (J-TX4691916)

For J&J, the MGH center was an opportunity to join together marketing and clinical research. Indeed, the funds that went to Biederman came from a J&J marketing division. (Lin Deposition, 77-78) In a slide set entitled, "New Initiative! J& J Pediatric Research Center at Mass General Hospital," developed by Gahan Pandina for the marketing team, the synergy that J&J so desired for research and marketing is spelled out. Biederman

was a "global expert" with a "large research team with multiple collaborations at MGH McClean (sic) Hospital, & Harvard University." The research at the center was to involve "specific extramural research with risperidone," and to review "specific scientific questions related to key business areas." The center would allow J&J to "Support a broader range of scientific activities than would be possible from JPI alone... Reinforce J&J image as a CNS company with a strong scientific commitment; Provide a model for J&J sister-company partnerships with key opinion leaders." (Pandina Exhibit, 1130)

The 2002 Annual Report of the J &J Center at MGH included references to its value for company marketing efforts. "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."* (Italics added) So too, the Center's research agenda included work on J&J products, with no attention paid to the obvious conflict of interest. "The Center is poised to test the effectiveness and safety of RISPERDAL, CONCERTA, REMINYL, TOPAMAX and new products as they emerge from the pipeline." (Pandina Exhibit, 1129)

The J&J funding appeared to impact the *choice* of studies at the center. It was primarily examining the efficacy and safety of J&J products. Thus one report noted that the Center was "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." Had objective parties been armed with full disclosure of J&J's relationship with the center, they would have viewed an outcome so favorable to J&J with great caution, if not dismissing it entirely. (Pandina Exhibit,1129)

In sum, neither J&J nor Biederman ever raised the self-evident issues of conflict of interest inherent in the collaboration or the threats it posed to scientific integrity. The Center was investigating J&J products with J&J money; that support from a pharmaceutical company to a Center to study its own products created both the appearance and reality of bias did not deter J&J or the recipients of its funding.

4) Did Dr. Shon have any relationships with any defendants that created conflicts of interest in his role as medical director of TDMHMR? If so, was disclosure sufficient to resolve the problem?

Dr. Steven Shon did not adhere to appropriate professional standards on conflict of interest in responding to or soliciting personal and institutional support from J&J. Dr. Shon's conflicts of interest were acute, undermining the scientific integrity of his medical publications, lectures, and educational activities, and his responsibilities as a state official. (A more detailed discussion of the relationships between Dr. Shon and J&J are documented in Hunt Exhibit, 1619.) Disclosure is not sufficient to resolve such profound conflicts of interest. Rather J&J and Shon himself should have refrained from such activity.

Dr. Shon cultivated financial relationships with J&J, accepting checks made out to him of at least $30,000 in fees and honoraria as well as soliciting research grants from the company. (Hunt Exhibit, 1623) Shon agreed to serve as a consultant to J&J to promote use of Risperdal. (Shon Exhibit, 315) Although these arrangements created very serious conflicts of interest, he neither curtailed nor eliminated them. Instead, Dr. Shon continued to solicit and accept favors from J&J, despite the fact that he was Medical Director of the Texas Department of Mental Health and Mental Retardation and had a significant role in the administration of TMAP. (Killion Exhibit, 1137)

Although he had significant influence over Texas drug purchases, formulary decisions, and the design as well as implementation of TMAP (and a subsequent children's medication algorithm project (CMAP), Dr. Shon often counseled J&J on how to best promote its products in Texas and many other states. (Exhibits 98, 834, 1345) His failure to consistently disclose, acknowledge or manage his conflicts of interest not only undercut his educational presentations, but also biased his official decision making capacity in the state and as a member of TMAP. Moreover, Dr. Shon accepted travel fees and honoraria from J&J so as to persuade other states to adopt TMAP-like structures. (Hunt Exhibit, 1623) He does not appear to have informed his many audiences in other states of his close financial ties to J&J. He also failed to disclose this relationship to journal readers when he served as an author. (Crismon Exhibit, 519)

The record indicates that Dr. Shon was a frequent speaker and consultant for J&J, accepting honoraria for these activities. (Hunt Exhibit, 1623) On several occasions, the payments were directed to him, not to the state of Texas, in violation of Texas law. (Hunt Exhibit, 1633) On at least one occasion he was "upset because the check was not made out to him" but rather to the Texas Department of Mental Health and Mental Retardation. J&J's medical communication firm then mailed him another check, made out to him. (Roman Exhibit, 160) Although Dr. Shon testified otherwise, he did not with any frequency consult with Department attorneys as to the propriety of his activities. (Shon Deposition, p.479) Counsel for the Department remembers having only one conversation with him, and notes "he infrequently asked me for my legal advice." (Campbell Deposition, p.138)

J&J did not move expeditiously or effectively to enforce their requirement that state employees submit an official letter from the government agency approving the arrangement. (Thompson Deposition, pp. 272-278) Not until June 10, 2003, several years after Shon had been consulting and speaking for the company, did J&J ask "for a letter from your Governmental Agency's supervisor or authorized representative, acknowledging the approval for you to speak at future programs.... This written approval must be attached to the enclosed signed agreement." (Shon Exhibit, 314; Roman Exhibit, 156, 159) When J&J official Gary Leech was asked whether in arranging payment for Shon in connection with earlier CNS Summits he had ever sought approval "from Dr. Shon's supervisor for him to receive any kind of honoraria or other monies," he replied no. (Leech Deposition, p. 199-200) Nevertheless, J&J did not report this failure despite its awareness of the relevant OIG requirements to do so. (Federal Register, vol. 68, May 5, 2003, p. 23734)

Several observations are in order. First, it took an inordinate amount of time for J&J to take note of the compliance failure. Second, even after it did take note, Shon failed to deliver such an authorization and J&J did not follow up on the failure by requiring such a submission or discontinuing using him. By admission from Defendant's counsel, no letter from state officials granting him permission to pursue these activities exists. (Newton Exhibit, 442, Defendants' response to State of Texas's first set of requests for admission No. 1) Third, even had authorization been forthcoming, it would not eliminate the clear conflict of interest.

The record is clear that despite his official position, Dr. Shon inappropriately and frequently served as a consultant to J&J. (Hunt Exhibit, 1623) The terms of the Consulting Agreement of September 10, 2002 highlight the extent of the conflict of interest created by this situation. (Shon Exhibit, 315) Notwithstanding Shon's state office, the Agreement declares: "Consultant represents that he/she is under no obligation, contractual or otherwise, to any other person, institution or entity that would interfere with the rendering of services called for in this agreement...." As consultant, Shon's 2002 duties included making two presentations to J&J senior management on TMAP "and its influence on public sector psychiatry." (Frank, Exhibit 224) That J&J had a direct interest in marketing to Texas and Dr. Shon was in the direct position to influence the use of J&J's product is a clear example of a conflict of interest, and one that a responsible public official was obliged to avoid. (See also Shon Exhibits, 295, 308, 309, 314, 322, J-TXCID 0068387, for other examples.)

Although Shon later denied participating in J&J Speaker Bureau activities, the record reveals otherwise. On July 11, 2001, Dr. Shon signed an agreement with J&J to participate as a speaker for a fee of $1500. (Shon Exhibit, 308) As the company wrote: "We appreciate your interest in participating as a speaker on behalf of Janssen regarding Risperdal and Treatment Guidelines for Schizophrenia." (Shon Exhibit, 308) The contract stipulates that Dr. Shon disclose the relationship but even if he did so, for a medical director to promote a drug, when his office influences the purchasing of that drug, created an unacceptable conflict of interest. The medical director of the state's mental health agency should not be serving as an official spokesperson for a pharmaceutical company whose product state agencies are purchasing. (See discussion above and Texas Government Code Section 572.001(a).)

Another example of an acute conflict of interest involved Dr. Shon advising J&J regarding positioning of a form of Risperdal, Consta, in the TMAP algorithm. (Bursch-Smith Exhibit, 1802) As one J&J employee informed her colleagues after her meeting with Shon: "Steve suggested that we take the TMAP algorithm, change it to how we see Consta fitting in, and then asking the TMAP folks to respond." He advised J&J to focus its marketing efforts on state mental hospitals because these institutions had greater leeway with their budgets. (Stanislav Exhibit, 599) (Roman Exhibit, 153) It should be noted, too, that accompanying the advice was a request from Shon that J&J fund him so that he could go to Korea to present on

TMAP and fund a medical resident to accompany him. (Roman Exhibit, 153) Such a quid pro quo represents a gross violation of conflict of interest standards and professional integrity. Since Shon was at the same time serving as consultant and speaker for J&J, an untenable conflict of interest existed in which state interest gave way to personal advantage.

As noted above, J&J was advised by consultant firms to emphasize the comparative cost advantage of Risperdal as compared to competitors. Dr. Shon played an active role in implementing this strategy. (Shon Exhibit, 293) He emphasized cost comparisons frequently. However, Dr. Shon made his cost comparisons among atypical antipsychotic drugs, not against first generation typicals, which were considerably less expensive than Risperdal. TDMHMR sent a memorandum to state hospital and community clinic officials, with an exhibit showing that Risperdal was less expensive than another two atypicals (Olanzapine and Quetiapine). (Shon Exhibit, 293) It did give clinic officials room for choice among drugs, allowing that cost was only one consideration. Cost, the memorandum noted, should not "override clinical rationales." However, the memorandum immediately added: "If the clinical decision does not dictate the choice of a specific medication, then cost data should be a considered factor." To make certain that the point was not lost, the closing paragraph of the memorandum observed that "resources are extremely precious," and referred to a legislative directive to the Department to "employ strategies to limit medication costs." It is again highly relevant that none of this official advice mentioned first generation anti-psychotics which were far less expensive. If costs were so important, surely Shon should have discussed the possibility that for some patients, the first generation drugs would have been effective.

This same message on cost was delivered by Shon in a memo of July 27, 2000. (Shon Exhibit 294) When drugs in one stage of a drug algorithm had been found to be equivalent, he wrote, "it is reasonable to consider medication acquisition cost in medication selection within a stage." The memo goes to say that TDMHMR is "requiring" this approach. The memo did discuss the use of generics, but only in the case of Clozaril, and even there introduced a series of qualifications that undercut its use.

J&J was well aware that Shon followed its marketing line and very pleased with its positive impact. Sid Frank, a J&J employee, noted in an internal email, that Lilly had "strong objections" to the policy. Confident that J&J was winning the battle, he was comfortable declaring: "May the

butt kicking begin!!!" (Frank Exhibit, 229; Roman Exhibit, 140; J-TXCID1121994) So too, another employee, Laurie Snyder, wrote her J&J colleagues on November 30, 2000, referring to a lecture program in Pennsylvania that her division was funding, "Steve Shon, MD will present the Texas Medication Algorithm. Currently in Texas there is a memo that mandates that physicians use the most cost effective medication within a stage. *Physicians will hear a favorable Risperdal message and learn about guidelines that could possibly affect Risperdal share in the long run."* (Italics added)

The gravity of Dr. Shon's conflict of interest is apparent in the "Summary of the Medicaid Mental Health Pharmacy Advisory Board Meeting," April 14-16, 2000, a meeting at which Martha McNeill, Director of Prescriber and Product Management in the Texas Department of Health, was in attendance. (Josephson Exhibit, 67) In the Q&A section, Shon is quoted making several comments that promote atypical antipsychotics in general and Risperdal in particular. He said: "The private sector is afraid of algorithms because they designate the new drugs as first-line therapy." He noted that he had negotiated with a managed care company, Northstar, to use "the most effective first-line option.... Shon said Janssen's Risperdal is preferred first-line treatment." He also opposed a not uncommon practice of patients dividing their pills in half, a cost-saving measure that drug companies typically resist. Finally, asked about Lilly's Zyprexa versus Risperdal, "Dr. Shon said that in Texas Zyprexa was once used 2:1 over Risperdal, but since cost became an issue, the two are dead even." To make all these statements in light of his financial involvement with J&J is a striking example of how Dr. Shon ignored conflicts of interest. There is no record of disclosure by Dr. Shon at this meeting of his relationship with J&J.

Dr. Shon, despite his official position, freely advised J&J on TMAP deliberations, assisting the company to position Risperdal favorably and increase its sales. For example, a J&J employee wrote her colleagues to report on a meeting with Shon, in which Shon counseled J&J to become more aggressive in its marketing efforts for Consta. (Stanislav Exhibit, 599) "Steve suggested that we take the TMAP algorithm, change it to how we see Consta fitting in, and then asking TMAP folks to respond." To these same ends, Shon "Suggests we hit the state hospitals and county hospitals hard." That a medical director is dispensing this type of advice to a drug company and receiving payment for it is altogether inappropriate for a state official and a medical professional.

Dr. Shon's consulting sessions with J&J were frequent. Shon was brought to the J&J home office in order to debrief them on TMAP. (J-TXCID 01898962) So too, Shon frequently attended advisory meetings for J&J. A partial list includes: February 1999; Tempe, Arizona, February 2000; Scottsdale, February 2001; Scottsdale, March 2002; Amelia Island; September 2002; private meeting with J&J, February 2003, CNS Summit, Scottsdale. (Hunt Exhibit 1624, 1626) In effect, the ties between Shon and J&J were extensive, creating conflicts of interest that were left unmanaged and clearly violated professional standards.

Several of Shon's colleagues noted his frequent absence from the office. As one of them observed: "I found Steve to be somewhat loose with his job as medical director.... He was rarely there.... I think Steve liked to travel." (Rago Deposition, 45; see also, Vesowate Deposition, 541-555; Muse Deposition, 71; Killion Deposition, 81-87) He traveled around the country to promote TMAP, typically at J&J's expense and with personal remuneration. Examples include promoting TMAP on several occasions in Pennsylvania, California, Virginia, Missouri, Florida, Georgia, Michigan, Nevada, Louisiana, Illinois, Oregon, Washington D.C., and Washington State. (Snyder Exhibit, 96; Roman Exhibit, 147; Hunt Exhibit, 1626) J&J was pleased with this arrangement, eager to use his services, as well as those of one of his TMAP colleagues, John Chiles. In its Texas Business Plan, June 21, 2000, J&J noted regarding TMAP: "Goal: favorable positioning of Risperdal in treatment guidelines. Status: John Chiles and Steve Shon used extensively throughout Texas and nation as experts in guideline development and implementation." (Vaughan Exhibit, 718)

5) Did Dr. Crismon have any relationships with any defendants that created conflict of interest in his role as a leading member of TMAP? If so, was disclosure sufficient to resolve the problem?

Dr. Lynn Crismon was a key decision maker in TMAP as well as the director of CMAP, and was, therefore, in a position to influence Texas drug purchases, reimbursements, and prescriptions. He was under contract with MHMR Office of Medical Director, at 80 percent of his working time. (Crismon Exhibit, 543; Crismon Deposition 424-425) He was also a professor at UT College of Pharmacy. (Crismon Exhibit, 544) Thus, he was in positions to exert a powerful influence in favor of Risperdal. Nevertheless, Crismon cultivated a financial relationship

with J&J, accepting substantial fees and honoraria and soliciting research grants from the company. He agreed to serve as a member of the J&J Speakers' Bureau so as to promote the use of Risperdal. Although these arrangements created serious conflicts of interest, he did not curtail or eliminate them. Instead, he continued to solicit and accept favors from J&J. As a result, Dr. Crismon subverted the scientific integrity of his research and educational presentations, and biased his decision making capacity as a member of TMAP and CMAP. Disclosure is not sufficient to resolve such profound conflicts of interest. Rather, J&J and Crismon himself should have refrained from such activity. (For a detailed discussion of the relationships between Dr. Crismon and J&J see Hunt Exhibit,1619.)

Dr. Crismon sought grants from J&J by suggesting that his research would benefit the use of its drug. (Crismon Exhibit, 549) Crismon courted J&J by telling the company that he was seeking to form a relationship with them and, therefore, he would accept a company grant that did not cover all the costs of the research project he was proposing. (Crismon Exhibit 550) Dr. Crismon sought grants from J&J with little regard for conflicts of interest or the company's stake in the outcome of the research. (Crismon Exhibit, 549) Thus, he submitted a grant to analyze medications for use in mental retardation, with the project specifically addressing "which drugs to prescribe, and at what doses." (page 2 of grant application, 5/12/99)

Although Dr. Crismon's decisions clearly had an important impact on Texas's use of Risperdal, he agreed to join the company's Speakers' Bureau. (Crismon Deposition, pp. 557-559) This activity is essentially a marketing activity, wherein speakers are trained carefully to promote a company product. The record reveals how close the link was between Crismon and J&J. He served on the J&J Speakers' Bureau, for example, in April 2001, June 2001, and May 2005. To be a member of a company speakers' bureau without recusing yourself from decision making about company products violates professional standards for managing conflicts of interest. Despite this activity, Crismon did not recuse himself from TMAP and CMAP deliberations.

Further, Dr. Crismon made visits to company headquarters in order to advise on "strategic decision making," again ignoring conflicts of interest. (Crismon Exhibit, 494) He attended the CNS advisory meeting in Amelia Island, Florida, receiving a check for $3000 for his participation. (Crismon

Exhibit, 536) On June 20, 2002, he advised J&J on "clinical and marketing-related issues" in regard to Consta. (Crismon Exhibit, 494) Although TMAP evaluated where to place Consta on its algorithm, Crismon, as per his contract with J&J, was prepared to help "guide strategic-decision making." (Crismon Exhibit, 536) For consulting and assistance, Crismon earned at least $60,000 from J&J. (Hunt Exhibit, 1623)

These conflicts notwithstanding, Crismon lectured frequently on issues related to Risperdal, including at CME presentations. The practice was to have the guest institution pay Crismon's honorarium, but the funds, as Crismon knew well, came from J&J. (See Sensabaugh, a J&J employee, writing to Crismon, March 23, 2003, to the effect that "Janssen will be providing a grant to Case Western Reserve to cover your expenses and honorarium. They will reimburse you directly." (J-TXCID 1136783) By the same token, Crismon was comfortable asking J&J for lecture slides on the cost and effectiveness of new antipsychotic drugs, treating company materials as though they were unbiased source. (Crismon Deposition, p. 273) Crismon also worked with Excerpta Medica (EM), a company that arranged meetings, lectures, and publications for J&J. Through EM he delivered lectures in Oregon, November 27 and 30, 2000, and received payment of $4500. (Crismon Exhibit 529)

Crismon was prepared to accept a smaller research grant from J&J "in order to develop a pharmacoeconomics research relationship with Janssen." We would like to develop a long term relationship with your company." (Crismon Exhibit, 550) Not only was the research subject, as we have seen, directly relevant to J&J's marketing approach but Crismon was prepared to foster a relationship even when he would be evaluating the company's products. This insensitivity to conflicts of interest considerations clearly violated the professional standards outlined above.

This same disregard of standards is found in Crismon's grant request to J&J to study clinical and economic effects of anti-psychotics in prison populations. (Crismon Exhibit, 554) He told J&J that he had been persuaded that "atypicals may have even more potential benefiting this population than they do in schizophrenia." He would be certain to look at cognition "which may be the most beneficial effect of atypical agents as compared with traditional agents." To promote a grant application by suggesting to the company that its product's use would be enhanced goes against the core

principles of research integrity, as noted by the IOM. Not surprisingly, Crismon received the grant from J&J for $20,000 (Crismon Exhibit, 518).

Dr. Crismon was so closely linked to J&J that the company tendered him a job offer. After consideration, he turned it down, on the grounds that it would require him to move from Texas to New Jersey. This negotiation itself was not only grounds for disclosure and recusal by Crismon from all decision making that affected a J&J product, but also for resignation from a decision making body that was central to J&J's commercial interests. (Crismon Exhibit 539)

In his early work as a member of TMAP, Dr. Crismon recognized the need to distance TMAP deliberations from industry funding. (Crismon Deposition, p. 97) Nevertheless, he and others (including Dr. Shon) almost immediately disregarded the principle. Rather than have TMAP remain independent of drug company funding, they proceeded to violate standards for managing conflicts of interest. Indeed, by failing to observe professional standards, they may well have encouraged J&J to dispense additional payments which personally benefited them.

6) Did Dr. Miller have any relationships with any defendants that created conflict of interest in his role as a leading member of TMAP? If so, was disclosure sufficient to resolve the problem?

Dr. Alexander Miller, professor at UT Health Science Center, cultivated financial relationships with J&J, accepting substantial fees and honoraria and soliciting research grants from the company. He also agreed to serve as a member of the J&J Speakers' Bureau. Although these arrangements created serious conflicts of interest, he neither managed nor eliminated them. Instead, he continued to solicit and accept favors from J&J, despite the fact that he was a key decision maker in TMAP and was in a position to influence Texas drug purchases. As a result, Dr. Miller subverted the scientific integrity of his research and educational presentations and biased his decision making as a member of TMAP. (A more detailed discussion of the relationships between Dr. Miller and J&J are documented in Hunt Exhibit, 1619.) Disclosure is not sufficient to resolve such profound conflicts of interest. Rather, J&J and Miller himself should have refrained from such activity.

Dr. Miller was a frequent speaker for J&J, receiving in excess of $70,000 over the period of time with which he was involved with TMAP. (Hunt Exhibit, 1623) He joined J&J's Speakers' Bureau, undertaking activities which were directly involved in promoting company products. (Miller Deposition, p. 93) He was so closely connected to the company and so inattentive to considerations of conflict of interest that he engaged in multiple back-and-forth discussions with the company about where it wished to place one of its products (Consta) on the TMAP algorithm. (Miller Exhibit 665 and Miller Deposition, p.505) At no point did Dr. Miller recuse himself from participation in TMAP decision making because of his close ties to the company.

Dr. Miller agreed to join J&J's "Making Choices" program, not uncomfortable with J&J's active engagement. (Miller Exhibit, 655) "I will have our medical editor contact him and conduct a one-on-one training," one J&J employee wrote. (Miller Exhibit, 655). His services were in great demand by J&J, who put him at its highest honoraria level and regularly invited him to regional and national advisory boards. (Miller Exhibit, 651) Miller accepted these offers, not managing the ensuing conflicts of interest affecting his research, lecturing, and decision-making responsibilities.

Miller also cooperated with J&J to the point where he became a "guest author" for the company. (See below for a full discussion of ghostwriting and violations of professional integrity.) Miller was "nominated" by J&J to be a first author on an outcome study. (Miller Exhibit, 665) On June 9, 2006, Susan Serpico sent him on behalf of J&J an "Invitation to coauthor START study Manuscript." "The attached manuscript draft is based on the SCH-404-START study and the APA 2005 poster presentation of the results, and on feedback received from coauthors during the poster presentation development process....Please confirm your participation as a coauthor at your earliest convenience and provide any comments or suggestions from your review of the manuscript." Miller responded (June 12): "Yes, I am happy to be included as a co-author. I made a few minor edits and comments in the manuscript." That he was willing to serve as a co-author after making admittedly only minor edits and comments demonstrates Miller's readiness to serve J&J's interests rather than uphold professional standards. His claims that none of his activities with J&J biased him cannot substitute for active management or elimination of conflict of