

## The banality of corporate corruption: Janssen's reimbursement department takes the stand. (Risperdal on trial, cont'd.)

2012-01-15 05:47:14

By Kalman Applbaum

When I first began interviewing pharmaceutical company executives on site, I was baffled by the size of their "government affairs" or similarly named departments. I understood that regulatory matters were complex and important to the process of drug licensing, but did management of that task require entire departments of full-time employees? The reason for this remained unclear to me until I realized that government affairs was a subdivision of marketing, as indeed every other function has come to be in the modern pharmaceutical company (Applbaum 2011).

The first witness whose deposition was projected on the courtroom's screens on January 12<sup>th</sup> was Ms. Nancy Burke Smith, whose job it was to manage the relationship between Janssen and the Department of Mental Health and Mental Retardation (MHMR) for the state of Texas.

The attorney for the State began playing the tape at the point in the interview with Burke Smith when Janssen documents were quoted as saying, "You put Steve Shon on the map." Steven Shon was the director of MHMR during the TMAP (Texas Medication Algorithm Project) years. Burke responded: "It was many companies, probably."

What this meant of course was that Shon was probably receiving money and gaining notoriety through his relationship with more SGA (second generation antipsychotics) manufacturers than just Janssen. What struck me was Burke's easy acquiescence to this depiction of Janssen's role. It implied an extensive relationship between Janssen and Shon, which it might sensibly be in the interest of a Janssen employee deposing for a billion dollar fraud case not to accede to without a fight.

Burke Smith was a member of the curiously named "reimbursement" department. Because so much of the discussion surrounded the origin and dollar amounts of checks written to Drs. Steven Shon, John Rush and others on the TMAP advisory board, I took reimbursement department to mean the place where such accounting functions were handled. Slowly it dawned on me that reimbursement referred to Medicaid, and Nancy Burke

Smith's job was to figure out how to divert as many Medicaid reimbursement dollars as she could into Janssen's coffers. The checks written to Shon and the other TMAP advisors were moneys Janssen was laying out in exchange for "deliverables" the current trial is designed to uncover.

The process of uncovering the truth about TMAP began in earnest with Burke Smith, whose inability to recall just about anything wasn't much help to her because the lawyer for the plaintiff had in his possession many suggestively incriminating emails detailing how, in exchange for its monies to Shon and Rush, Janssen sought "a high position for Risperdal" and subsequently Risperdal Consta, the long-acting injectable version of the drug, in the TMAP algorithm (on the lackluster merits of Consta, see Rosenheck et al 2011).

Internal emails bearing Burke Smith's name or authorship also attested to the fact that Janssen was not the only drug company vying for Steve Shon's affections.

One email cc-ed to Burke Smith contained the words, "Lilly is sending their corporate jet to get [Shon]. You didn't sell our benefits to Shon."

*Burke Smith: No, that wouldn't make sense.*

*Lawyer: Here's a reply email, also cc-ing you, saying "[we] should sell our benefits to him."*

*Burke Smith: I wouldn't agree with that!*

*Lawyer: So when you replied, "Fantastic! Let's do it!!" is that your way of disagreeing?*

*Burke Smith: [Tartly] I don't remember.*

Cross examination by the defense sought to affirm Burke Smith's claim that Janssen was not "selling" to Shon but were involved only in an "exchange of information." Burke Smith also had the chance to declare that Janssen didn't approach John Rush, but the reverse. (To my ears this claim is beginning to sound plausible; I may soon change the title of my posts from Risperdal on Trial to Psychiatry on Trial.)

*Defense: Why don't you believe that [Janssen] influenced Shon's work?*

*Burke Smith: Because they told us they'd be making their own decisions.*

The next witness deposed and put up on the screen was Bill Stryk, whose

phlegmatic testimony inspired the title to this blogpost. Stryk was the Regional Director for State Affairs for Janssen for seven years. At the time of the deposition he was still working for J&J.

*The State's Lawyer: You worked for Reimbursement in 1996-1997.*

*BS: Yes.*

*Lawyer: Was it called the reimbursement group?*

*BS: Yes.*

*Lawyer: You were on the ground floor of the reimbursement team. What was your product?*

*BS: Risperdal was our primary focus.*

*Lawyer: [Takes out a company document] Among the credits listed as your accomplishments includes "Influenced guidelines."*

The guidelines in question were the so-called Tri-University Schizophrenia Practice Guidelines, compiled by psychiatry professors Frances, Docherty, and Kahn (ID-ed in an earlier Risperdal Trial post as the EKS troika, after the name of the company they founded to administer the nearly million dollars of Janssen unrestricted grants). A description of the inception of the Tri-University Guidelines is available here:

<http://www.ahrp.org/cms/content/view/822/9/>.

Stryk preferred to use the word "education" to describe the original Tri-University symposium in 1996 as well as other activities involving Steven Shon and other psychiatrists. The State's attorney asked Stryk if his department's activities were directed towards increasing sales of Risperdal with the aid of the guidelines. Impatient with the questioning, Stryk twice said, in a tone of jaded irony, "Let's put it this way. If it increased sales we were not disappointed."

*Lawyer: One of your strategies [as stated in a company document] was to "promote algorithms favoring Risperdal and that Texas was the test site for this." Did I read that correctly?*

*BS: Yes.*

The cross examination by the defense allowed Stryk to rephrase his team's purpose: Our group's mission was to remove hurdles. Our job was to educate on mental health and to make sure drugs were available to those who needed it.

The next witness to take the stand was the whistleblower, Allen Jones, whose investigations in the Pennsylvania Office of Inspector General (OIG) and subsequent activities in respect to TMAP sparked this entire trial. I will return to his testimony in the next post. Jones was called in at this point because after TMAP took root in Texas the next strategic step for Janssen was to export it to other states. I recount the deposed testimonies of two more reimbursement group personnel reviewed on January 12, since I've made the bewildering banality of their bribery the subject of this entry.

The first was Laurie Snyder, a reimbursement manager for J&J/Janssen who was involved in something called PennMAP, which was the program intended to export TMAP to Pennsylvania, where, according to a company document, 85% of the potential sales for Risperdal were linked to "public sector payers."

*State's Lawyer: Did Janssen support TMAP?*

*LS: There were unrestricted grants given.*

*Lawyer: In an email you wrote [didn't catch date, sometime in the 1990s] it says that you persuaded KOLs [Key Opinion Leaders] in Pennsylvania to adopt TMAP. Was that your goal?*

*LS: Yes.*

*Lawyer: It was your work.*

*LS: It was not just my work, but I like to think I played a pivotal role.*

*Lawyer: It says you [took advantage of] Shon's [position] on TMAP...*

*LS: Yes. It was hard to do. He was a busy guy.*

The plaintiff concluded its presentation of Snyder's deposition by reading excerpts from several emails she had written. These went more or less like this:

Wow! The Pennsylvania public sector meeting was a success... Every goal re schizophrenia and TMAP [was] achieved... Key influencers in Pennsylvania are now seeking to own TMAP... [We are] beating the competition...who are missing the train.

The team representing the defendant offered no cross-examination of Laurie Snyder.

The next deposed witness was a psychiatrist (also trained as a lawyer), Dr. Susan Stone, who was Associate Medical Director under Steven Shon at MHMR from 1994-1997, during the time TMAP was adopted. She believed that Janssen influenced the process greatly, that “there were pharma execs around [Shon’s office] a lot,” and that Shon “drove the process” of TMAP’s development. TMAP was not originally Shon’s own idea, Stone testified, but Dr. John Rush’s.

(Rush was among those psychiatrists investigated by the office of Senator Charles Grassley:

<http://www.grassley.senate.gov/about/Disclosure-of-Drug-Company-Payments-to-Doctors.cfm>; see my recent post on Grassley here: <http://somatosphere.net/2012/01/clean-pharma-crusader-senator-chuck-grassleys-enigmatic-campaign-to-combat-rising-health-care-costs.html>. Rush has until now been more famous for his involvement in the suspect STAR\*D clinical trial for second generation antidepressants; see <http://alison-bass.blogspot.com/2011/04/serious-flaws-and-conflicts-skewed.html>.)

Stone also said that the expectation for TMAP was that it would be a “relative mandate...that doctors would follow the algorithm.” The defense attorney sought to establish that because Stone had been assigned only to the Bipolar Disorder section of TMAP (there were three: Depression, Bipolar Disorder, and Schizophrenia), she was not in a position to know the details of what went on in the Schizophrenia section, which is what is mainly under consideration in this trial. Also, because she was not in attendance for many meetings, her views were merely speculation.

Still pursuing the subject of funding for TMAP, the plaintiff next called the deposition of the former head of the Robert Wood Johnson Foundation (RWJF), Dr. Steven Schroeder. The Robert Wood Johnson foundation is, along with the Bill and Melinda Gates Foundation, one of the two largest health and health care philanthropies in the US. RWJF contributed the largest single amount in financial support of the development of TMAP.

Schroeder said he did not believe that TMAP was a “marketing effort” and he was never contacted by J&J. “I don’t think they knew about it.”

The State attorney’s excerpts of Schroeder’s deposition began with the lawyer on the tape pointing out that Johnson & Johnson is the single largest financial stakeholder in RWJF. Three of the Foundation’s current (at the time of the 2009 deposition) Board of Trustees members are J&J executives.

*State Lawyer: [I understand that] TMAP was an unusual [project for RWJF]. How was TMAP unusual?*

SS: *We don't usually support treatments.*

Lawyer: *Why'd you do it?*

SS: *We thought the upside was substantial.*

Lawyer: *Did RWJF do due diligence into the motives of the TMAP people?*

SS: *We didn't look into their hearts.*

Lawyer: *How about whether they [were taking] money from pharma.*

SS: *No... Most academics probably take money from pharma.*

The final witness for the day, also brought to us via projector from a deposition recorded in 2009 or 2010, was Percy Coard II. Coard started working as a drug rep for Janssen and Risperdal in 1998, served as district manager from 1999-2002, and was then promoted to the reimbursement department (which is still funny-sounding to me, like saying he was promoted to work in the mailroom).

*The State's Lawyer: [reading from Coard's CV, I think] "Seek out individuals and find their importance to the system." Is that part of your job?*

*PC II: Yes.*

"The system" referred to several entities, including hospitals, the prison system, and MHMR, where Coard had contact with Steven Shon "on a regular basis." Coard described Drs. Shon, Miller, and Crismin as KOLs.

The State's attorney reviewed a 2002 business plan at J&J/Janssen. It specified \$42.7 million income from Medicaid—an increase over the previous year. A "threat" to continued growth in this area was identified: Texas Medicaid, which was 3<sup>rd</sup> in the country on Medicaid spending, was looking to implement cost containment measures. One measure identified in the document was "prior authorization," which (for those of you who don't live in the US) means that before a "consumer" can see a specialist or before s/he can receive a specific service or treatment, the request has to pass through a layer of approval involving the payer, such as an insurance company. Medicaid is public insurance.

Under the heading "TMAP Ownership!!! – (ongoing)" the business plan suggested that TMAP and strong advocacy support would lessen the threat of prior authorization.

*Lawyer: You thought that TMAP would make prior authorization for Risperdal prescription difficult?*

*PC II: Yes.*

*Lawyer: Why?*

*PC II: I felt that if you had these guidelines implemented within MHMR...it would be difficult for Texas Medicaid to go in a different direction than the guidelines.*

The discussion turned to the company's effort to place Consta, J&J's long-acting injectable version of Risperdal, "in a favorable position in TMAP." There was a moment of confusion when Coard made, of all things, a Freudian slip. He accidentally used the word TMAP when he meant Consta. Once back on track he explained how helpful Steve Shon was to him in strategizing the best way to get Consta to succeed on the market. "Steve Shon felt [that] a key to successfully launching Consta in Texas was to focus on [hospital] inpatients [because it is] rare for stable patients to be switched [i.e., away from Consta] once they are discharged from the hospital."

*Lawyer: You understood that TMAP had influence beyond Texas?*

*PC II: Yes.*

(An internal company document stated: "TMAP currently impacts mental health care in 17 states.")

The plaintiff lawyer screened and read aloud from an internal email: Yolanda Roman says "Shon, Miller, and Crismin have spent much time with us influencing, implementing, monitoring, and managing TMAP/TIMA-like initiatives." Another company document indicated that Shon hoped to export TMAP to Korea, and to disseminate it among Korean American psychiatrists. At a special meeting, Shon presented his ideas to several of the most senior executives at Janssen.

The defendant attorney's brief cross examination sought to establish that Coard didn't discuss the safety or efficacy of Risperdal with anyone ("It was not my job") and that he didn't discuss these matters with respect to TMAP ("My job was to collect data on reimbursement, that's all").

A good defense lawyer advises his client how not to incriminate herself in a deposition. But he cannot warp his client's professional good sense or worldview even if its manifestation in the interview might lead directly back to the crime (see A. Applbaum 2000 for philosophical analyses of the

sometime conflict between professional and general ethics). It's like the *Onion* headline: Milosevic Confesses to Crimes Against Subhumanity.

In March 2009, when documents from the federal lawsuit against AstraZeneca's SGA (Seroquel) were released (that case was settled for \$520 million: <http://www.nytimes.com/2010/04/27/business/27drug.html>) I wrote on this blog (<http://somatosphere.net/2009/03/cases-for-overhauling-pharmaceutical.html>):

While the scale of the organization of deceit revealed in the Seroquel documents astonishes, what should strike us the most in the depiction of the implemented marketing plans is how routine they appear to be. The spectacle of the court trial is in this sense a distraction, since it focuses our attention on violation, on breach. But while the actions under investigation may be legal contraventions, they are not managerial ones. On the contrary, the marketing practices conform to business and organizational norms that are positively embraced as sound managerial principles.

Because of this, the most florid violations lie on a simple continuum with all pharmaceutical marketing practices. The prosecuted cases are distinguished, if at all, by degree and not kind with other examples. If for no other reason than that competitive pressures drive companies to behave in similar ways, one can guarantee that the marketing strategies and tactics for drugs of a single class will resemble each other. When Vioxx blew, industry watchers knew that the other Cox-2 inhibitors (Celebrex and Bextra) were potentially not far behind. When Zyprexa [Lilly's SGA] was called to account, informed observers knew that the other manufacturers of atypical antipsychotics (of which Seroquel is one) were guilty of similar crimes, which would become visible if the opportunity arose for opening up their marketing records.

Cited:

Applbaum, Arthur. 2000. *Ethics for Adversaries: The Morality of Roles in Public and Professional Life*. Princeton University Press.

Applbaum, Kalman. 2011. "Broadening the marketing concept: Service to humanity, or privatization of the public good?" In Zwick and Cayla (eds.) *Inside Marketing: Practices, Ideologies, Devices*. Oxford University Press, pp. 269-298.

Rosenheck, Robert, et al. 2011. "Long-acting risperidone and oral

antipsychotics in unstable schizophrenia." *New England Journal of Medicine* 364:842-851.

(<http://www.nejm.org/doi/full/10.1056/NEJMoa1005987>)

#### **AMA citation**

Applbaum K. The banality of corporate corruption: Janssen's reimbursement department takes the stand. (Risperdal on trial, cont'd.). *Somatosphere*. . Available at: . Accessed January 16, 2012.

#### **APA citation**

Applbaum, Kalman. (). *The banality of corporate corruption: Janssen's reimbursement department takes the stand. (Risperdal on trial, cont'd.)*. Retrieved January 16, 2012, from Somatosphere Web site:

#### **Chicago citation**

Applbaum, Kalman. . The banality of corporate corruption: Janssen's reimbursement department takes the stand. (Risperdal on trial, cont'd.). *Somatosphere*. (accessed January 16, 2012).

#### **Harvard citation**

Applbaum, K , *The banality of corporate corruption: Janssen's reimbursement department takes the stand. (Risperdal on trial, cont'd.)*, *Somatosphere*. Retrieved January 16, 2012, from <>

#### **MLA citation**

Applbaum, Kalman. "The banality of corporate corruption: Janssen's reimbursement department takes the stand. (Risperdal on trial, cont'd.)." . *Somatosphere*. Accessed 16 Jan. 2012.<>