The Risperdal trial in Texas, cont'd: Establishing not just facts, but the yardstick by which facts are to be measured, and other matters

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I. Marketing = Education

The first evidence brought before the jury on the afternoon of January 10 was the deposition of a former Janssen product manager, Thomas Anderson, who was one of two marketing managers responsible for launching Risperdal in 1993. The exhibit placed before the jury was a document from the early planning days, entitled "Building a Consensus." The slide, presumably Anderson's handiwork, exhorted the marketing team to "assemble an expert task force and body of knowledge":

- Key experts.
- Thought leaders.
- Rank and file.

The key experts, we learn, consisted of a troika of psychiatrists: Dr. Allen Frances, Chairman of the Dept. of Psychiatry, Duke University; Dr. John P. Docherty, Professor and Vice Chairman of Psychiatry, Cornell University; and David A Kahn, Associate Clinical Professor of Psychiatry, Columbia University.

These men accepted a total of $942,669, mostly in the form of "unrestricted educational grants" through their newly formed company, Expert Knowledge Systems (EKS), to prepare practice guidelines for the treatment of schizophrenia. The guidelines, which formed the basis for the Texas Medication Algorithm Project (TMAP, pronounced T-Map), endorsed the use of Risperdal as a first line treatment, dislodging the first generation of antipsychotic medicines (FGAs) from that position.

The attorney for the State, Tommy Jacks, asked Anderson: "Did it ever occur to you that by authorizing payment to EKS, their objectivity might be compromised?"

"No," Anderson replied. "They were involved in education."

Jacks: “When EKS said they would help you achieve your strategic objectives, influence state government, build brand loyalty with key providers around the country, [perform] pharmaco-economic studies, and be in touch with NAMI [National Alliance for the Mentally Ill] to develop educational materials for rapid implementation of guidelines… When they said ‘We want to make sure Janssen succeeds [in promoting] risperidone throughout the country’… Let me ask you, Mr. Anderson, are you able to distinguish between marketing and education?”

“Yes,” the witness replied. “EKS was independent. That was the presumption.”

II. Experts = Key Opinion Leaders, Key Opinion Leaders = Experts, and Unrestricted Educational Grants ? Payola.

On the morning of January 11th, after Judge John K. Dietz cried “Saddle up!” and the jury sauntered into the courtroom, the first deposition reviewed (on the four giant monitors) was that of Dr. Alexander L. Miller. Miller, professor of psychiatry at University of Texas Health Center at San Antonio was, according to his current bio at the UT website, Director of the Schizophrenia Module of TMAP. Miller confirmed that Janssen provided some of the funding for TMAP, but took umbrage at the suggestion that the $70,000-plus he accepted from Janssen (and which he deposited in his “home fund”) might have affected his objectivity when he offered recommendations regarding the guidelines, which ultimately designated Risperdal as a first-line treatment for schizophrenia. (As we will see, the defense claims that TMAP was planned and done before Janssen paid anyone, so officials like Miller could not have been acting in promotion of Risperdal.)

If the prosecutor was impugning Miller’s integrity and objectivity, these hardly seemed in question when in the cross examination the defense attorneys reviewed in painstaking detail Miller’s gold-plated credentials: Yale, Washington University, NIMH (National Institute of Mental Health), MGH (Massachusetts General Hospital), Harvard, Distinguished Life Fellow at the APA (American Psychiatric Association), twenty years of service to the Great State of Texas, and finally a full professorship at UT.

“What’s the difference between an associate and a full professor?” the defense asked. Miller smiled diffidently and explained it to the jury.

My initial thought was that the extended review of Miller’s CV was to substantiate his credibility before the jury so that they wouldn’t think his judgment was corruptible by pharma money. When Miller came around to

listing among his accomplishments that he was on the advisory board and a Texas co-researcher for CATIE (Clinical Antipsychotic Trials of Intervention Effectiveness)—the selfsame NIMH-sponsored trial which the plaintiff is using to establish that the second generation antipsychotics (SGAs) are *not* superior to the FGAs—I had a different thought.

The defense wasn't seeking mainly to exculpate Miller of any possible wrongdoing, as important as that might be for their case, or even to vindicate Janssen's practice of cultivating "strategic alliances" with key experts by lavishing them with grants and honoraria. Rather, the listing of Miller's positions and accomplishments was performed in the service of establishing a unit of measure for trustworthiness in a sphere of professional activity regarding which the jury is being asked to pass verdict. In this province, common sense about conflicts of interest seems not to apply. If everyone is on the take, is there "a take"? (Correspondingly we might ask, if a ghostwritten scientific paper passes muster in the peer-review process, can we still presume that the results are biased? The ethical inference is contingent upon what we specify as our endpoints.)

As Tom Anderson, the product manager for Risperdal, had said in self-defense when the prosecutor interrogated him about giving money to key opinion leaders (KOLs), funding speaker bureaus, unrestricted grants and the like, "This is the way it's done all over the industry."

If Miller and his Texas colleagues yet to take the stand were in fact distrusted among their peers because they (allegedly) took money from drug companies while serving on the guideline committee, they would not have been able to keep their reputations and retain their positions as professors and medical directors. On the contrary, it is difficult these days for someone to rise to prominence in academic medicine without participating in the give and take relationship with pharmaceutical companies. Not just academic status but the very science and policy of psychiatric medicine are co-constituted by drug companies and leading psychiatrists. In this sense, like a Shakespearian villain who feels completely justified in his actions—and the audience is sympathetic because Shakespeare is an excellent advocate for his characters—Miller was correct to respond to the defense attorney's question about how this attack on his reputation made him feel, "I feel like a pawn in someone else's game."

Miller shared the docket with Dr. Steven Shon. Shon, former Medical Director for Texas Mental Health and Mental Retardation (a Texas thing?), took plenty of money from Janssen. He preferred his checks made out and fedexed directly to him. Over the course of the deposition, the prosecution painstakingly sought to expose Shon as having grossly violated his

contract to the State of Texas. They brought as witness Margaret Hunt, a fraud investigator for the state's civil Medicaid division. Hunt submitted a report showing, among other things, that Shon did marketing work for Janssen during work hours, and he took moneys that were offered to him only because of his position at MHMR, which was illegal. Like the troika of psychiatrists mentioned earlier, Shon was apparently an avid marketer for Janssen, helping them strategize to make Risperdal a best seller across the country.

(A description of how Shon allegedly peddled TMAP in Pennsylvania can be found in whistleblower Allen Jones' statement, found here: http://psychrights.org/Drugs/AllenJonesTMAPJanuary20.pdf. The lawsuit against Johnson&Johnson/Janssen was originally filed by Jones in 2004. See also http://motherjones.com/politics/2005/05/medicating-aliah)

"Would it be wrong or improper as medical director [for the State of Texas] for you to advise Janssen on product marketing strategy?" the prosecutor asked Shon. To Shon's refrain of "I don't recall," the prosecution offered numerous memory aids in the form of documentary exhibits.The fraud investigator had traced as much detail of Shon's activities as would make an innocent man blush. The prosecution also exhibited internal Janssen emails referring to Shon's value to the marketing efforts of the firm. The prosecution asked Shon a question that is coming to be the leitmotif of the trial: Did you know that Janssen was using you?

Other individuals, such as Drs. John Rush, Lynn Crismon, and John Chiles were named for receiving like sums of money from Janssen while serving on the TMAP panel. NAMI Texas director Joe Lovelace also took money from Janssen, some of which was deposited in an account under the name of his wife's law firm.

III. The truth about TMAP = the truth about the state of psychiatry

For a researcher like myself interested in the rationality (and irrationality) of medication prescription practices in psychiatry, the first point brought out in the cross examination of Steven Shon struck a chord. Shon said that the reason TMAP came about was because prescription practices across the state were erratic. He said, and I paraphrase, that if the same person visited six psychiatrists, he might receive the same diagnosis from all six psychiatrists but he could still be prescribed six different medications.

We know that the DSM-III was constructed, among other reasons, to standardize diagnostic criteria—to create inter-rater reliability. Why

shouldn't another acronym, such as TMAP, be devised to standardize treatment programs? The failure of this logic lies in the non-specificity of the drugs and the variability of patient response, beneficial or adverse, to different drugs. The effort to establish a fairly strict algorithm (the 'A' in TMAP) for treatment in psychiatry is to impose pharmacological progress where it has not yet been achieved.

For Janssen and the other atypical (second generation, SGA) antipsychotics manufacturers, the key implicit messages they wanted to convey throughout the heavy marketing period including during TMAP, were (a) that this progress had in fact been achieved and psychiatrists should espouse treatment standardization, and (b) that one size fits all patients. Many honest psychiatric researchers (perhaps including some of the individuals mentioned above) may have, in naive optimism, embraced the promise of progress that the drug companies were touting with the SGAs. It was not just clinical researchers and not just psychiatrists who swallowed this pill.

If we examine (a) and (b) as commercial propositions we see an old pattern. Standardization and mass-market appeal everywhere underwrite capitalist firm expansion. TMAP may or may not have been corrupted by the bias of several of its panel members who received payments from the drug company—we must let the jury decide. Less in doubt is that Janssen did aim to influence the committee, despite the disingenuous claims of company personnel who have taken the stand. As medical science liaison for Janssen Gary Leach said in his deposition, he cultivated the relationship with Steven Shon only because of his position as MHMR Director; the disposition of TMAP had great consequence for the sales of Risperdal, Leach added.

Contemporary psychiatry itself seems lodged on the horns of this ambiguity between the motive behind the pharmaceutical industry give and the ethics behind the medical doctor's take.

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