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Re HB 2163 study 2-9-10

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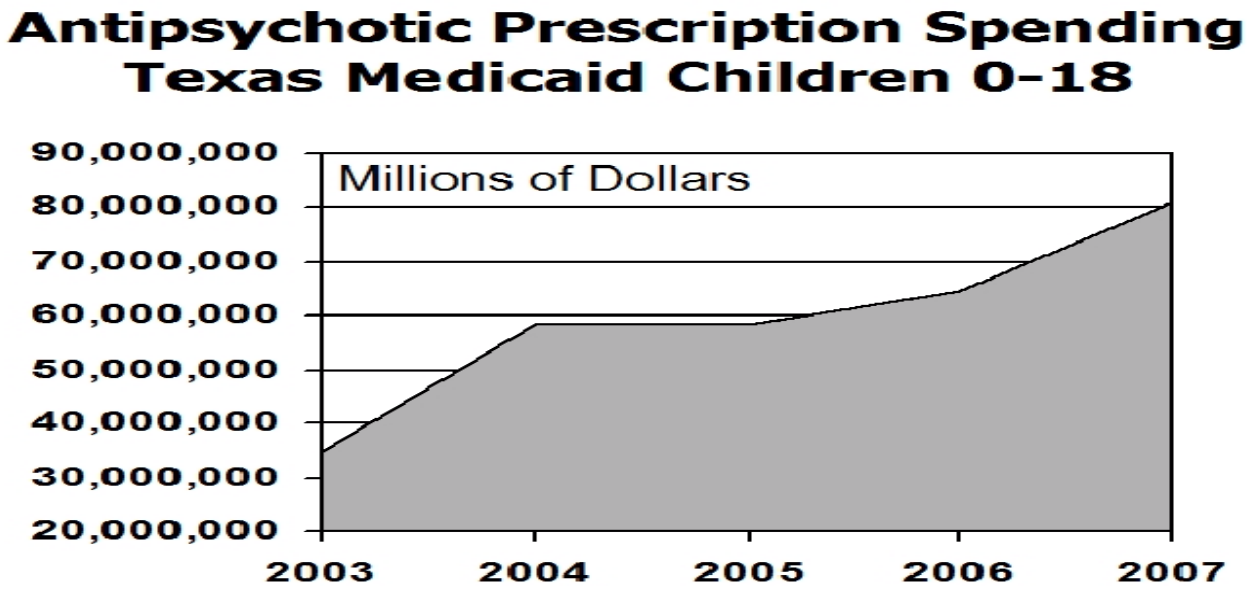
Dear Mr. Hancock and all people at HHSC,

I am writing in response to the request for information pertinent to the HB 2163 mandated study on the use of antipsychotic drugs with Medicaid children under age 16. I am an Austin psychologist and founding director of a citizens group called Texans For Safe Education. I testified on House Bill 2163 when it was being debated in the Texas legislature last session as a strong supporter of the original intention to put serious controls on the use of antipsychotic drugs for young children in the Texas Medicaid system. I did so because the drugs are extremely damaging to children and they are not truly helpful to children in any way. I prefer a ban.

The Exponential Trend

As all involved in this affair are well aware, Sylvester Turner's proposed legislation was in response to a perfect storm for Medicaid children in Texas. This chart shows the dramatic increase in Texas from 2003-2007.



The trend with Texas children is reflective of nationwide practice with all Americans.

The Motive

This is simple. As Evelyn Pringle (2009) reports, it is only necessary to follow the money:

> In 2008, the atypical antipsychotics took over the slot as the top revenue earners in the US, and include Seroquel by AstraZeneca; Risperdal and Invega marketed by Janssen, a division of J&J; Geodon by Pfizer; Abilify from Bristol-Myers Squibb; Novartis' Clozaril and Eli Lilly's Zyprexa. The average price on these drugs for 100 pills at DrugStore.com is about $1,000. Lilly also sells Symbyax, a drug with Zyprexa and Prozac combined, at a cost $1,564 for 90 capsules at DrugStore.com in May 2009.
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> The briefing material submitted to an FDA advisory panel in April 2009 reported that an estimated 25.9 million patients worldwide had been exposed to Seroquel since its launch in 1997 through July 31, 2007, in the US, and the second quarter of 2007 for countries outside the US. Of that number, an estimated nearly 15.9 million took Seroquel in the US, compared to only ten million patients in the rest of the world. In 2008, the US accounted for roughly $3 billion of Seroquel's $4.5 billion in worldwide sales.
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> For the full-year of 2008, Eli Lilly reported worldwide Zyprexa sales of about $4.7 billion, with US sales of $2.2 billion and only $2.5 billion for the rest of the world.

In Texas lies an epicenter of cause for this trend of more and more antipsychotic drugs for our nation's citizens---the Texas Medication Algorithm Project, known as TMAP. As Austin investigative reporter Nanci Wilson exposed in her award winning KEYE TV series in 2004-5 on the subject, there was (and is) a strong connection between drug company contributions to the state and the placement of their most profitable drug products in the resultant formulary mandated for state use. TDMHMR medical director Steven Shon was forced to resign his position due to his own conflicts of interests in this project. Several other prominent doctors in the University of Texas system—John Rush, Lynn Crismon, Graham Emslie and Karen Wagner to name just a few—have been shown to have severe financial conflicts of interest from monies received via Big Pharma. The state attorney general is continuing to investigate, and has a pending lawsuit against Johnson & Johnson, the makers of Risperdal. There are literally dozens of such lawsuits going on around the country.

Here is just one of numerous instances of findings against the makers of antipsychotic drugs. On January 15, 2009, Eli Lilly pled guilty to charges that it had *illegally marketed its blockbuster drug Zyprexa for unapproved uses to children* and the elderly, two populations especially vulnerable to its dangerous side effect. Lilly plead guilty to a misdemeanor charge and agreed to pay $1.42 billion, which included $615 million to end the criminal investigation and approximately $800 million to settle the civil case. The investigations of U.S. Senator Charles Grassley have revealed some of the sordid details of unethical conflicts of interest of psychiatric researchers and spokespersons in taking drug company money. Many prominent researchers and industry spokespersons are now fighting for their professional lives as the hidden monies they received from Big Pharma are revealed. Psychiatry department chairs Charles Nemeroff ($1 million from GlaxoSmithKline alone) of Emory University, Martin Keller of Brown University (associated with a severely compromised drug trial), and Alan Shatzberg of Stanford (who was

principal investigator on a drug developed by a company in which he owned $6 million of stock) have all recently resigned their positions as a result of Grassley's investigation. Joseph Biederman of Harvard (largely responsible for the explosive 4000% increase in the number of children diagnosed and treated as "bipolar," usually with the most damaging of all psychiatric drugs, the antipsychotics) received at least $1.6 million from Big Pharma in the first several years of this 21st century.

Federal prosecutors have subpoenaed Biederman and two of his Harvard colleagues. His work is particularly relevant as the 4000% increase in the diagnosis of childhood bipolar between 1994 and 2003 is largely attributable to his influence in defining and publicizing the notion of childhood bipolar disorder and recommended treatment of antipsychotic drugs (Moreno, C., et al. (2007).

This “treatment” generally happens as a matter of course: Moreno and colleagues found that 90.6% were receiving psychiatric medications, including 60.3% on mood stabilizers like Depakote and 47.7% on antipsychotics like Risperdal and Zyprexa, with most on combinations. Tragically, the study found that more children were being given the most toxic psychiatric drugs, the so-called antipsychotic drugs, than a similar group of adults labeled bipolar—even though the drugs are not approved for these purposes in children.

Another important trend we have noticed, one that should be addressed in your study, is that many of the children who are labeled bipolar and/or psychotic and given antipsychotic drugs were originally prescribed stimulants for so-called ADHD—the symptoms called Bipolar are actually iatrogenic effects of the drugs already prescribed. A quick perusal of the effects profile for drugs like Ritalin and Adderall reveals that virtually all the diagnostic symptoms of Bipolar are also listed as drug effects of stimulants—irritation, restlessness, insomnia, mania, and psychosis on the one hand; listlessness and depression on the other. Tragically, a deranged state is induced by the drugs, then attributed to another “mental illness,” leading to more powerful and dangerous drugs.

The Lack of Science on Childhood “Mental Illness”

My comments here can be very brief. Simply put, there is absolutely no scientific evidence of specific physical or chemical abnormalities that connote a biologically based mental illness in children. As astounding as it may seem to some, it is an incontrovertible fact that no problem routinely seen by child psychiatrists has been scientifically demonstrated to be of biological or genetic origin. The so-called “chemical imbalance” theory that justifies the use of psychotropic drugs with children is just that—a theory. There is no objective test or indicator for any of the child psychiatric diagnoses, from ADHD to Bipolar to Schizophrenia. What Joanna Moncrief and David Cohen present in their 2006 article about drug treatment of depression is equally true for other diagnoses that are said to warrant the use of antipsychotics.

I will cite here just one more thorough review of the literature with adults that shows a dearth of scientific evidence that antipsychotics can even beat placebo in the short-term. In the long-term, the evidence is damning. First, when a drug is effective in temporarily curbing a symptom, it very often actually exacerbates the symptom in the long-run! Furthermore, it is often the case

that the higher the dose, the greater the probability of relapse. And in general, exposure to antipsychotic drugs increases probability of relapse (Whitaker, 2007). This is with adults. What it means for children is that the state of Texas, rather than promoting our children's well-being, is contributing to their becoming lifelong chronic mental patients and disabled dependents on the state.

These are some of the reasons why I and Texans For Safe Education are so saddened and angry that Texas is giving our children these drugs. The biggest factor is that they are incredibly toxic and damaging.

The Damage Caused by Antipsychotic Drugs

The dangers of antipsychotic drugs have been documented since their advent around 1950; in fact, as Peter Breggin points out in his book *Toxic Psychiatry*, the neuroleptic drugs are responsible for the largest epidemic of neurological disease in the history of the world. Literally millions of people are suffering from permanent neurological damage as a result of various expressions of Tardive Dyskinesia cause by antipsychotic drugs. It is estimated that people become permanently damaged at the rate of about 5% per year. The effect is cumulative and giving these poisonous substances to our children is a disgrace. As psychiatrist George Ayana (1999) stated, standard antipsychotics "have adverse side effect profiles that can affect every physiological system."

Lest one attempt to justify drugging our children with so-called atypical antipsychotics like Risperdal and Zyprexa, a brief look at the compromised, biased drug trials behind these drugs shows there is no strong evidence they are more effective or better tolerated (Geddes et al, 2000).

Even if there were slightly fewer permanent Tardive Dyskinesia cases resulting from the atypicals, this is more than compensated by the fact that drugs like Zyprexa, Risperdal and Seroquel have proven to be pure poison to the endocrine system. Class action lawsuits abound with very large payouts to individuals now suffering from permanent metabolic damage, Diabetes, as a result of taking atypical antipsychotics.

Leonard Roy Frank (2005) summarized some of the extant data on Zyprexa:

> FDA reviewers found there was an average weight gain of almost one pound a week during the six-week trial period and 26 pounds over a year-long period for the Zyprexa subjects who remained for the extension trial. Other drug effects included shaking, spasms, sedation, diabetic complications, rapid heartbeat, restlessness, constipation, seizures, liver problems, white blood cell disorders, and decreased blood pressure.
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> In addition, there were 20 deaths, including 12 suicides, in the Zyprexa group. Shockingly, these deaths went unreported in the scientific literature. The death cover-ups also took place in reporting trial results of several other atypicals during the 1990s.
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> Information concerning these deaths was obtained from FDA documents through the Freedom of Information Act by science writer Robert Whitaker, who wrote that one in

> every 145 subjects who entered the trials for Zyprexa, Risperdal, Seroquel, and Serdolect had died. [See *Mad in America: Bad Science, Bad Medicine, and the Enduring Mistreatment of the Mentally Ill*, by Robert Whitaker.]

Here is just a small sampling of other studies on the atypical antipsychotics.

A government sponsored study (Sikich et al, 2008) comparing an old and two most prescribed new antipsychotics in children aged 8 to 19, confirms that widely promoted second generation neuroleptic drugs--Zyprexa and Risperdal--pose even higher risks of harm for children's health than the old neuroleptic (Molindone).

The authors report in the *American Journal of Psychiatry*:
"Risperidone and olanzapine did not demonstrate superior efficacy over molindone for treating early-onset schizophrenia and schizoaffective disorder. Olanzapine and Risperidone were associated with significantly greater weight gain. Olanzapine showed the greatest risk of weight gain and significant increases in fasting cholesterol, low density lipoprotein, insulin, and liver transaminase levels. Molindone led to more self-reports of akathisia."

Ten lawsuits in the Philadelphia court are charging that Risperdal causes breast enlargement in young males who take it. This from the Risperdal website confirms: “RISPERDAL ® and similar medications can raise the blood levels of a hormone known as prolactin, causing a condition known as hyperprolactinemia. Blood levels of prolactin remain elevated with continued use. Some side effects seen with these medications include the absence of a menstrual period; breasts producing milk; the development of breasts by males; and the inability to achieve an erection. The connection between prolactin levels and side effects is unknown.” (http://www.risperdal.com/)

A study in the *New England Journal of Medicine*, comparing the intelligence quotient (IQ) levels of children whose epileptic mothers were prescribed one of several antiepileptic drugs during pregnancy, confirms that Depakote (valproate) significantly lowers children's IQ, regardless of the mother's intelligent quotient (Meador et al, 2009).

The list could go on and on. The bottom line is permanent neurological and/or metabolic damage for a very large percentage of individuals who take antipsychotic drugs, as well as host of other severely damaging effects. These facts are sadly related to the data that Marilyn Elias reported in 2007; American adults in the United States public mental health system die on average 25 years younger than the general population.

A Trauma Sensitive Perspective

The reality of our state’s way of responding to Medicaid children, largely in foster care, is that a high percentage of the children who enter come out in worse shape than when they entered. They come out with more labels and more drugs in their system. We are hurting the children. Many are already traumatized, and they are all traumatized further by separation from family. Why does a trauma-sensitive perspective not guide us? Why instead do we label the children

themselves as defective and drug them? There is no evidence of disease. There is vast evidence of trauma.

The good news is we know how to help with trauma. We know what children really need to heal from trauma and be well. It is not a great mystery. I could help with this, and so could many others. That help will be limited severely, however, until we agree to stop poisoning them.

A Solution

I have one solution:

1) Ban all antipsychotic drugs for children in state care. It is tragically harmful to unnecessarily damage the developing bodies and minds of our young children.

Palliative Recommendations

1) Institute a tracking and reporting system to be very clear and specific about which children are placed on what drugs. Look for patterns of variability by area and section, and by physician. Most definitely include a mechanism for reporting and red flagging any activity of so-called polypharmacy as it is especially grievous and dangerous to be placing our precious children on multiple psychotropic drugs. At the very least, any incidence of a child being placed on 3 or more psychotropic drugs should be red flagged, reported to the medical examining board, and investigated.

2) Follow children right from the start. Look closely at diagnoses and prescriptions. Look very closely at the effects caused by the drugs themselves. The pattern of iatrogenic worsening needs to recognized, interrupted and stopped.

3) Hire a knowledgeable doctor to systematically be available and help to facilitate dose reduction and withdrawal for children on antipsychotic drugs. It is dangerous to abruptly stop when one has been taking the drugs for more than a couple of weeks. It is also vital to recognize and interrupt the tendency to misinterpret drug withdrawal reactions as evidence on “mental illness.”

4) Institute an external monitoring and enforcement system. Those who have created this tragedy and who continue to defend and resist reform are not capable of ensuring these changes will happen. External monitoring and auditing is vital to success, in large part due to conflicts of interest and perverse financial incentives to label and drug our children.

5) Institute training on at least two items: a) the facts about psychiatric diagnoses and drugs, and b) the nature of psychological trauma and recovery, especially emphasizing issues of separation, and the nature of and necessary conditions for psychological healing.

A Legal Warning and Final Recommendation

One final warning for HHSC in its study on antipsychotic drug use with Texas Medicaid children is to take a good hard look at the legal ramifications of using poisonous drugs with well-known extremely severe damaging effects on children. And look hard at the fact that the vast preponderance of such drug use is "off-label," unapproved in the medical compendia for such use with children. It is the opinion of many lawyers that this is illegal and grounds for litigation.

The following was provided by attorney James Gottstein, is from paragraph 22 of his Law Project for Psychiatric Rights Complaint in *PsychRights v. Alaska*

> 22. It is unlawful to for the State to use Medicaid to pay for outpatient drug prescriptions except when medically necessary and for indications approved by the Food and Drug Administration (FDA) or included in the following compendia:
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> > (a) American Hospital Formulary Service Drug Information,(b) United States Pharmacopeia-Drug Information (or its successor publications), or (c) DRUGDEX Information System.[1]
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> _____
> [1] Ex Rel Franklin v Parke Davis, 147 F.Supp.2d 39 (DMass2001).

The relevant recommendation, of course, is to stop using antipsychotic drugs with children in the care of the state of Texas.

I am happy to respond to any questions. Thank you.

Respectfully Yours,

/s/

John Breeding, PhD

Cc Representative Sylvester Turner
Representative Lois Kolkhorst

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