

Testimony of Ablechild.org: Joint Children & Health & Human Services:

DCF Investigative Hearing

Thursday, December 18, 2008

Good Morning. My name is Sheila Matthews, Cofounder of Ablechild, a non-profit that focuses on full informed consent and the right to refuse psychiatric treatments. Ablechild petitioned Connecticut and had two psychotropic drugs, Effexor and Paxil, removed from the DCF psychotropic drug formula due to their link to suicide ideation in children. Ablechild also participated in Connecticut's \$13 million dollar mental health transformation grant. There, we met strong resistance upon requesting oversight to avoid conflicts of interest with the State's vendors and secondly, when we promoted drug free alternatives for mental health.

On February 21, 2007, I personally provided Attorney General Blumenthal documents that demonstrated a drug company was covering up adverse events, which linked their drug to suicide and hostility in adolescents. Further, we identified two DCF cases in which children were forced onto multiple psychiatric drugs and held by the State with no legal standing. We also reported these two cases to the Child Advocate's office.

In response, on April 12, 2007, rather than holding the State vendors responsible, the Attorney General simply put out a joint press release with the Child Advocate, Jean Milstein, stating: If you have had a problem accessing a psychiatrist for care, please call 1-800 etc.

We requested the procedures a family would follow in reporting a psychiatric abuse case with DCF from Rudy Brooks of Prevention and External Affairs who is slated to oversee the Ombudsman's office. He could only reply, " We acknowledge that this is not an exact science". It appears as though there is a clear policy to administer drugs but none when it comes to dealing with adverse side effects.

In closing we would like to point out that the SSRI dosing guidelines the State of Connecticut is relying on are the same SSRI dosing guidelines of the Texas Algorithm Program, which have been deemed unscientific and are under legal challenge in court. Therefore, we urge this committee to abandon this model immediately.

I have attached to my testimony five recommendations for the State to incorporate into any DCF reorganization plan to achieve meaningful reforms. I have also attached documents that substantiate the problems associated with dosing guidelines.

Thank you.



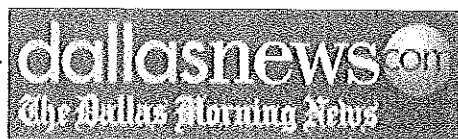
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As such, Ablechild has the following recommendations:

- 1) In any DCF reorganization the Ombudsman's office, as the investigator of complaints, must be established outside of the control of the behavioral health vendors, the Attorney General, the child advocate, and the Governor's office. This office must have complete financial and political independence and most importantly full transparency.
- 2) The State fully fund and implement Public Act Number 04-238 to track how many children in State care are on psychiatric drugs.
- 3) Establish an electronic record for each child in State Custody to include science based, non-psychiatric services to address behavior concerns including educational strategies, nutritional and allergy testing, vision and hearing tests and a complete medical check up
- 4) Promote and establish a clear understanding of the Federal Medwatch Program and file reports for all adverse events.
- 5) Open the State funding for a state family to select their choice of mental health evaluations outside of those contracted by DCF. This shall include an educational evaluation.





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Conflict of interest fears halt children's mental health project

06:30 AM CDT on Monday, August 18, 2008

By **EMILY RAMSHAW** / The Dallas Morning News
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AUSTIN – A state mental health plan naming the preferred psychiatric drugs for children has been quietly put on hold over fears drug companies may have given researchers consulting contracts, speakers fees or other perks to help get their products on the list.

The Children's Medication Algorithm Project, or CMAP, was supposed to determine which psychiatric drugs were most effective for children and in what order they should be tried at state-funded mental health centers. In April, high-ranking state health officials gave researchers the go-ahead to roll out the guidelines.

A month later, the officials delayed the protocol, after Texas Attorney General Greg Abbott's office objected to it.

At most, the suspension indicates that state investigators fear fraud has occurred. At the least, it reflects nationwide unease with potential conflicts of interest between leading medical researchers and the pharmaceutical firms that fund much of their work.

Publicly, officials say it's because the state is suing a pharmaceutical company alleged to have used false advertising and improper influence to get its drugs on Texas' now-mandatory adult protocol, the Texas Medication Algorithm Project.

Privately, individuals with knowledge of the case – who spoke only on condition of anonymity because of the pending litigation – say the attorney general's investigation of possible fraud in the adult protocol has spread to the children's version.

There's no way to know exactly what authorities are investigating. But their probe into the adult protocol turned up allegations of drug companies paying researchers who worked on the adult protocol speaking fees, and footing the bill for trips to market the Texas program.

The researchers who designed the children's protocol, who are not parties to the lawsuit over the adult drug program, insist they are motivated only by children's health. No evidence has emerged to disprove that; many have dedicated their careers to advancing child psychiatry.

And grants and consulting fees from drug companies are legal and increasingly common, despite fears that they may influence doctors' prescription habits. In the last quarter-century, drug makers have replaced the federal government as the nation's main source of research funding, even though some studies suggest this money affects the outcome of clinical trials.

At least four of CMAP's key developers – all affiliated with the University of Texas system, and all of them published child psychiatry experts – have received research funding from drug companies, or have been consultants and speakers for several different pharmaceutical firms, according to their own published papers and financial disclosure forms filed with the university. Drugs made by some of these manufacturers appear in the children's drug protocol.

The doctors say there's no room for improper influence when their reputations are at stake. If the drugs weren't effective, they wouldn't endorse them – and the research they conducted to craft CMAP wouldn't have been published in prestigious medical journals.

"When you really look at the investigators involved and the procedures they followed, they were all within what has been defined as appropriate in every medical field," said Dr. Steven Shon, who led the effort to create the adult drug list, and was forced to resign in 2006 over allegations he was improperly influenced by a drug company, according to previously published reports. "To block access to this protocol is really hurting the people who need it most."

Dr. Graham Emslie, a UT-Southwestern psychiatry expert, said he never once witnessed improper influence from drug companies while he helped conduct CMAP research. "There's much more influence relative to day-to-day prescribing" of drugs than there is doing university research or designing a protocol, he said.

At stake is the psychiatric care of tens of thousands of children treated at state and community mental health centers across Texas – many of whom are covered by Medicaid and don't have access to private health care. Without the protocol, experts say, these children will continue to be treated by individual doctors who have their own personal influences.

"This attack is causing us to go back to the system we had before, with individual doctors who may have individual influence, instead of using a standardized protocol," said Aaryce Hayes, a mental health policy specialist with Advocacy, Inc.

The News' investigation into the doctors prescribing psychiatric drugs to children in state foster care has found that many doctors received money from pharmaceutical companies, for tasks such as running clinical trials and consulting.

Most states don't require doctors to report such financial arrangements with drug companies. The few that do have found some evidence their work was affected, including doctors with drug company connections writing more prescriptions for children.

About the protocols

Drug protocols are designed to ensure all patients with a particular diagnosis receive the most effective, proven treatment available. They're created by bringing together academics, researchers and public health experts, who run trials, compare best practices and recommend a road map, or algorithm, for which drugs should be used.

While the protocols are generally created with the best intentions, they can be controversial, particularly when drug companies have a hand in designing them.

Some lawmakers and activists say it's time the state took a close look at the financial motivations of experts making drug decisions for hundreds of thousands of Texans. The adult protocol determines treatment decisions in state mental health facilities, despite the lawsuit and studies that have played down the benefits of some of the drugs chosen for it.

"In our country, there's been a switch from taking care of people to focusing on big corporate money," said Rep. Juan Escobar, D-Kingsville, who unsuccessfully offered legislation last year that would have banned researchers or government employees funded by the pharmaceutical industry from designing state psychiatric drug protocols. "There need to be restrictions on how these things are done, because the victims are our children."

State health officials and the attorney general's office refused to comment on either the adult or child drug protocols or on the formal letter the office sent ordering that CMAP not be rolled out. *The News* found no evidence that any particular drug companies had been pulled into the Medicaid fraud investigation into CMAP.

The CMAP research wasn't funded by drug companies, but most of the country's renowned scientists have used industry money for their work. Without the private dollars, which are more readily available than government grants, many pharmaceutical advances would be drastically delayed, researchers contend.

The flip side is that the scientists conducting the research become familiar with and invested in the drugs, making them, in effect, some of the pharmaceutical firms' best salespeople.

Some universities, like UT, require that their researchers fill out extensive financial disclosure forms, and document every case where they conduct research on drugs manufactured by a company they consult for. Most of the CMAP researchers appear to have complied with these guidelines.

But many of the nation's researchers must do little more than disclose their relationships in fine print at the bottom of their published papers. There's no way to verify these disclosures are accurate; in all but a handful of states, drug companies aren't required to reveal their payments.

Last month, Sen. Charles Grassley revealed that three Harvard psychiatry experts whose research contributed to the explosion of antipsychotic use in children had failed to report a combined \$3.2 million in drug company consulting fees to the university, a violation of Harvard's rules.

Mr. Grassley, R-Iowa, has proposed legislation to force drug companies to disclose their payments to physicians. But he faces an uphill battle. In 2007, drug companies spent an industry record – \$168 million – lobbying lawmakers on Capitol Hill, according to a Center for Public Integrity study. That's up more than 30 percent from 2006.

Patricia Ohlendorf, UT-Austin's vice president for legal affairs, said several university system researchers, including the head of UT's pharmacy college, M. Lynn Crismon, have been asked to give depositions for the lawsuit over the adult protocol. They are not named in the civil suit.

Dr. Crismon, who led the effort to create the children's protocol and has received research or consulting

dollars from at least 10 different drug manufacturers, according to his published papers, said he was "not at liberty" to comment on the drug protocol or the lawsuit.

Last month, an e-mail sent to some employees at the Department of State Health Services indicated that "all CMAP activities" were to be "removed from the UT College of Pharmacy" – where Dr. Crismon and a key piece of the roll-out program were centered.

An official close to CMAP said that within the last month, investigators from the attorney general's office seized hard drives from state health offices and questioned employees. That has not happened at UT, Ms. Ohlendorf said.

The adult protocol

Texas' adult-drug protocol, spearheaded in the mid-1990s, aimed to provide better and more consistent treatment to adult patients in state mental health facilities. The plan was designed and tested by a team of university researchers, state government experts and mental health advocates, and a presidential mental health commission lauded it in 2004 as a model for the nation.

But there were criticisms from the start by clinicians who feared the protocol would override their judgment and Scientologists opposed to all use of drugs for psychiatric care. And its research funding from 11 pharmaceutical companies prompted allegations of improper influence after several cutting-edge, high-dollar drugs were chosen over traditional generics.

Most researchers involved in the protocol, many of whom also conducted research for the children's version, declined to comment for this report. But privately, they say their financial relationships with drug companies didn't cloud their judgment. While the newer drugs were costly, the researchers believe they are better and that they should be available for people in state care, not just for those with private insurance.

State lawmakers moved forward with the adult protocol, using it in state psychiatric hospitals and community mental health facilities. Texas researchers were shuttled across the nation to give drug company-hosted lectures about the protocol's merits, according to previous newspaper reports and allegations in the state lawsuit. Within years, 16 other states were using similar protocols, and Texas was designing its own for children.

But as new research about the drugs chosen for the protocol emerged, questions resurfaced. A 2005 study by the federal government's National Institute of Mental Health showed the new antipsychotic drugs, which cost roughly 10 times more than the traditional drugs, performed no better and had nearly as many side effects.

"Taken as a whole," the report notes, "the newer medications have no substantial advantage over the older medication."

A year later, a British national study mirrored those findings.

Meanwhile, a Pennsylvania official became an unlikely whistle-blower when he discovered the state's chief pharmacist – who was designing a drug plan based on Texas' protocol – was reportedly on the payroll for a drug company, according to previously published news reports.

Allen Jones' bosses in the Pennsylvania inspector general's office told him to lay off, Mr. Jones alleges, and when he didn't, he was fired. Mr. Jones traced the pharmaceutical influence all the way back to the TMAP protocol, filing a whistle-blower lawsuit in Texas that quickly caught the eye of state authorities.

Mr. Jones could not be reached for comment. His Dallas-based attorney did not return phone calls.

Not long after, Dr. Shon, then the medical director for the Department of State Health Services, was ousted over allegations the pharmaceutical company Janssen improperly influenced him to include its schizophrenia drug in the protocol, according to previous news reports and the TMAP lawsuit.

Dr. Shon was accused of accepting consulting money from the company – income he says was unrelated to his work for the state – and of taking dozens of trips underwritten by drug companies to promote the protocol.

In 2006, the Texas attorney general's office joined Mr. Jones' lawsuit, accusing Janssen of concealing the risks and exaggerating the benefits of the drug, Risperdal, and of trying to persuade researchers with "trips, perks, travel expenses, honoraria and other payments." As a result, the state says, the protocol includes high-priced drugs instead of cheaper generics, which costs Texas' Medicaid program more money.

Executives with Janssen did not return repeated phone calls. In court papers filed in Travis County, the drug company denied any wrongdoing, calling Mr. Jones an "opportunistic 'late-comer' " who had "at best, only secondhand knowledge of the alleged fraud."

Dr. Shon, who retired to Las Vegas, says for every speaking engagement where he represented the state of Texas, he gave the payment he received to the state. Over the course of 15 years, he said, he probably earned less than \$15,000 from private consulting gigs with drug companies – jobs that weren't related to his state position.

"They were done on my own time, and they followed all the guidelines," he said. "In terms of what I've been involved with, I haven't seen anybody paid by the industry to promote a product."

KEY PLAYERS: CMAP RESEARCHERS

Several of the researchers who developed the Children's Medication Algorithm Project have received income or grants from drug companies, according to their published papers and university financial disclosure forms:

DR. M. LYNN CRISMON: The CMAP project director who heads UT-Austin's College of Pharmacy has received research funding or consulting dollars from at least 10 different drug companies, according to his published studies, including Eli Lilly, Janssen, and Pfizer. He said he could not comment on CMAP or the lawsuit.

DR. GRAHAM EMSLIE: The UT-Southwestern Department of Psychiatry researcher has consulted for several different drug companies, including GlaxoSmithKline and Pfizer. He has received research grants from at least three drug companies, including Eli Lilly and Forest Laboratories. University financial disclosure forms, where these drug companies are listed, report income in broad ranges. They indicate he may have made up to \$125,000 from drug companies since 2004. He said the CMAP protocol was about evidence-based medicine, "not the [drug] the most recent representative told me about."

DR. STEVEN PLISZKA: The UT Health Science Center in San Antonio scientist has received research funding from Cephalon and AstraZeneca and has served as a consultant and speaker for McNeil and Shire. University financial disclosure forms, where these drug companies are listed, indicate he has made at least \$130,000 in drug company speakers fees and consulting contracts since 2002. Dr. Pliszka said he didn't know CMAP had been delayed until a reporter asked about it. "For any physician, the bottom line is, does their patient get better," he said.

DR. CARROLL HUGHES: The UT-Southwestern's Department of Psychiatry doctor has received research funding from GlaxoSmithKline. University financial disclosure forms also indicate he was once an ad-hoc consultant for BioBehavioral Diagnostics, which designs equipment to test for behavioral disorders, and was awarded shares of company stock. He declined to comment.

SOURCE: *Dallas Morning News* research



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Study finds new anti-psychotics no better than generics for kids

12:00 AM CDT on Friday, September 19, 2008

By **EMILY RAMSHAW** / The Dallas Morning News

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AUSTIN – Texas has spent nearly \$300 million since 2003 on expensive anti-psychotic medications for poor children – drugs that cost more, have worse side effects in kids and are no more effective than older generics, according to a new federal study.

The drugs, known as atypical anti-psychotics, are designed to treat schizophrenia but are also used for everything from autism to attention deficit disorder. Pharmaceutical firms have aggressively marketed the drugs to child psychiatrists and state health officials. And because they don't cause tremors and joint aches, as older drugs do, prescriptions for kids have increased fivefold in the last 15 years.

But the government study of Janssen's Risperdal and Eli Lilly's Zyprexa, two of the top five most commonly prescribed atypical anti-psychotics, found neither performed any better in children and adolescents than an older generic drug – and both led to unhealthy weight gain.

Drug companies have said the study didn't accurately reveal the side effects of the older drug, because patients on it were given a medication to offset them.

"When these were first coming out, let's not forget that there was a reason – the disabling side effects of the first generation drugs," said Eli Lilly spokesman Jamaison Schuler. "That's being lost in the context of this study."

Still, the findings are raising questions about years of prescription trends in Texas and the nation. In 2007 alone, Texas Medicaid records show, prescriptions for Risperdal were written to thousands of underprivileged children – including 2,500 10-year-olds, 2,000 5-year-olds and 25 1-year-olds.

"States have spent a tremendous amount of money unnecessarily for drugs that are no safer than the older drugs that are a fraction of the cost," said Allen Jones, a Pennsylvania whistleblower who investigates drug company influence. "It appears, based on what the science is telling us, that an enormous amount of money was spent for no real benefit."

The study may also bolster a state lawsuit – originally filed by Mr. Jones but joined by Texas Attorney General Greg Abbott – against Janssen over allegations the company improperly influenced state officials to add Risperdal to a list of preferred drugs. Officials from Janssen did not return phone calls, but they have previously denied any such action.

The federal study, published by the *American Journal of Psychiatry*, compared the two atypical anti-psychotics with an older drug, molindone.

While all three drugs reduced hallucinations, children on Zyprexa gained so much weight so fast – as much as 15 pounds in eight weeks – that a safety panel took them off the drug. Risperdal also caused substantial weight gain, while children on molindone gained less than a pound on average.

Both groups of children on the new drugs experienced metabolic changes that heightened their risk for diabetes. Researchers considered those side effects worse than the tremors and joint aches, which can be treated with other medications. The study's authors said that while both classes of anti-psychotics have some adverse effects, those associated with the new drugs are more likely to have persistent, "long-term effects on physical health."

Texas has spent a combined \$150 million on Zyprexa and Risperdal for poor children in the last five years, state records show. More than \$7 million was for foster children.

Between 2002 and 2007, Texas foster children were written more than 25,000 prescriptions for Risperdal, at an average cost of \$253 per prescription. They were written 3,400 prescriptions for Zyprexa at a cost of \$469 per prescription, state records show. The older drugs generally cost a tenth of what the newer drugs do.

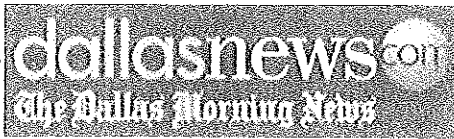
This spring, a state mental health plan naming the preferred psychiatric drugs for children was put on hold, over fears drug companies may have improperly influenced researchers to put their drugs on the list. That drug plan recommended treating attention deficit disorder patients who are aggressive with atypical anti-psychotics.

Meanwhile, the state lawsuit accuses Janssen of using false advertising and trips and other perks to get Risperdal listed on the Texas Medication Algorithm Project, which mandates the use of certain drugs for adults whose medications the state pays for. Individuals with knowledge of the case say it has spread to the children's drug protocol.

The latest study isn't the first to call the atypical anti-psychotics into question. A 2005 federal study by the National Institute of Mental Health showed the new anti-psychotic drugs performed no better than and had nearly as many side effects as the older ones.

A year later, a British national study mirrored those findings.

"We've got to look into this, particularly with this high cost," said state Sen. Bob Deuell, R-Greenville, a family physician who has patients who have been prescribed atypical anti-psychotics in state facilities. "If they're really helping these kids, we need to use them. But if these kids develop diabetes from them, and they don't work any better, it will only cost the state more money."



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State medication protocol researchers sought money from drug firms

12:00 AM CDT on Sunday, October 26, 2008

By **EMILY RAMSHAW** / The Dallas Morning News
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AUSTIN – Pharmaceutical company money, initially rejected as being ethically questionable, was eventually sought and used by researchers developing a list of preferred psychiatric drugs for children in state care, according to documents reviewed by *The Dallas Morning News*.

A spot on the since-suspended children's drug plan could have meant millions to pharmaceutical firms. The documents released to *The News* were collected by the Texas attorney general's office, which is suing a pharmaceutical company accused of trying to influence researchers on a similar adult drug plan.

Citing the pending lawsuit over the adult plan, officials in two state health agencies declined to comment on the Children's Medication Algorithm Project, or CMAP – which was put on indefinite hold in May. The researchers have insisted that pharmaceutical companies never influenced their work.

The CMAP records obtained by *The News* don't refute this. Nor were the researchers banned from soliciting funding from drug companies.

However, the records reflect a common pattern in state and university medical programs. Unable to get ample government funding, researchers are increasingly forced to rely on drug company money – even when it's their last resort.

When CMAP was started in the late 1990s, researchers were loath to accept pharmaceutical grant funding. At an April 1998 meeting, "it was concluded that we should try to avoid this if possible," according to minutes of a meeting between CMAP researchers.

By June 1999, researchers needed more grant money and had changed their minds. CMAP's director, M. Lynn Crismon, head of the University of Texas College of Pharmacy, wrote to at least 10 drug companies, asking for donations.

"Although we have received grant funding in support of this effort," he wrote, "these amounts fall short of the funds required to complete this important outcomes project."

By late that year, CMAP budgets included pledges for \$10,000 a year from Wyeth and Pfizer, an \$80,000

one-time grant from Forest Laboratories, and \$70,000 from Eli Lilly. While a few of the line items seem to limit the grant to CMAP's "patient and family education" program, others are listed as unrestricted CMAP "research gifts."

When, in 2006, questions surfaced about drug company connections to the adult drug plan, however, CMAP researchers were again cautious about drug company money.

And as recently as this spring, Dr. Crismon assured top state health officials there was no pharmaceutical link to CMAP, saying that any drug company money was used for a patient and family education study unrelated to CMAP.

"No pharma funding has ever been received for CMAP to the best of my knowledge," he wrote. The Eli Lilly and Forest money "was not for CMAP."

Eli Lilly officials, however, confirmed that the company donated \$70,000 to the state for a CMAP education program.

These mixed messages seem to have made their way to the top. In a 2007 e-mail, Department of State Health Services Commissioner David Lakey asked Bill Race, then the agency's medical director for behavioral health, for a meeting to discuss an outside review.

"I will give you more background when we meet, but we will need to put together a group to review it and make sure the algorithms truly represent best practice as of 2007," he said. "No pharmaceutical company funding should be a part of this."

Speaking through a UT attorney, Dr. Crismon told *The News* that he believes CMAP was funded entirely by the state, but that he didn't have the records available to check.

Staff writer John Jordan contributed to this report.