Conflict of interest fears halt children's mental health project

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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