Borison- Diamond: Systemic Failure, No Checks & Balances_WSJ/ CBS/ Psych Times

Monday, 18 August 1997

Two American Academics Are Accused Of Endangering Patients And Stealing $10 Million

http://www.cbsnews.com/stories/2000/07/31/48hours/main220233.shtml
Drug Money---- CBS-48 Hours AUGUSTA, Georgia, July 31, 2000 (CBS) Excited bargain hunters packed the hall in Augusta, Ga., in December 1998 for one of the weirdest auctions of all time. On the block were items from antiques and paintings to suits of armor worth a fortune. They all belonged to the town's infamous Richard Borison and Bruce Diamond. They no longer need this old stuff; it doesn't work with their new décor. Pharmacologist Diamond, now in prison, was convicted on 53 counts, including practicing medicine without a license and prescription fraud. 48 Hours Correspondent Susan Spencer reports. "I liked the money," Diamond explained. "It was almost like an addiction to see how much you can make. It was like a game." Over eight years, he and his partner, psychiatrist Dr. Borison, raked in more than $11 million, turning human drug trials into their personal money machine. They pretended to be doing the trials for the Medical College of Georgia, where they both were on staff, but they kept payments meant for the college for themselves. In the process, they deceived some of the top drug companies in the country, to say nothing of the patients they put at risk. Drug companies pay enormous amounts to get doctors to do drug trials, sometimes as much as $20,000 per patient in a study. It's a system that invites corruption. "I know there are an awful lot of doctors getting into it," Diamond said. "Probably ones that aren't even competent in doing research." Bill Hatcher said he had to come to the auction to see how they spent it all. Marion, Hatcher's wife of 52 years who had Alzheimer's disease, was in one of the trials. She has since died. "When you discover that your wife, or your spouse, or your loved one has this disease, then you become very, very desperate," Bill Hatcher said. He saw an ad seeking Alzheimer's patients to participate in a test of an experimental drug designed to slow the disease. It was their understanding from the very begining that this study was being supervised by the Medical College of Georgia. "No if, ands or buts. I mean it was plainly in the paper," said Bill Hatcher. The lie was even caught on tape in a video the clinic shot to record Marion Hatcher's progress. Though these trials involved powerful drugs, no doctor oversaw Marion Hatcher's care and she was getting worse, Bill Hatcher said. So where was Dr. Borison? "I met Dr. Borison the day I withdrew my wife from the program, which was one and a half years later," Bill Hatcher said. Janice Huckeba never saw Dr. Borison either. Her husband Lewis also was in the Alzheimer's study. One day he became violent and psychotic. Panicked, she called the clinic. Dr. Diamond was there, but he's not a medical doctor. "Dr. Diamond wrote a prescription for my husband and signed it," she said. She did not know at the time that Diamond had a doctorate but was not a medical doctor. And Bruce Diamond wasn't correcting anyone's impression. After all, of the staffers who saw patients, he did have the best credentials. Angela Touhey was just two years out of college but she was the research coordinator - in charge of depressed and schizophrenic patients. "I determined whether they needed to go up a dose," she said. "Who did I think I was that I could do that kind of thing?" She tried explaining her concerns to the doctors. She recalled Dr. Diamond saying, "We don't care how these patients are doing. We want to know how many patients you recruited in the past week." Dr. Diamond said he remembered no such thing, but he didn't deny that volume was key to keeping the money rolling in. It came in so fast that Dr. Borison had trouble dealing with it all, according to prosecutor David Mcloughlin, who noted he would deposit six or seven multithousand dollar checks every day at a drive-through bank. "Banks love checking accounts that are this big," McLoughlin said. It took a hefty chunk of money to buy all the antiques, art and armor but the doctor had big plans. Dr. Borison clearly felt a man's home should be his castle. An architect's model depicts the 11,000-square-foot castle he planned to build just outside Augusta. "This is Borison's pride and joy," said McLoughlin. This castle was slated to have medieval pennants hanging from it, chandeliers hanging from turrets and a moat. And it might have been built but for Angela Touhey, who was desperately worried that the patients were at risk. She blew the whistle. If she hadn't they probably would have gotten away with it. But how did they get away with it as long as they did? Who is watching doctors to make sure drug trials are run properly and to guarantee that patients are safe? The short answer is, no one. Does the system give the patients any safeguards? "If the doctor's not acting in good faith, I'd say the patient's at risk," says George Grob, deputy inspector general for the U.S. Department of Health and Human Services. The supposed watchdog in the system is what's called the Institutional Review Board, an independent organization set up to approve and oversee drug trials. But it often oversees only on paper. It's probably one of the crucial weaknessess of the the current system, according to Grob. There's no requirement for any hands-on inspection. Diamond estimated that he was probably visited once in 10 years. "They monitor us quarterly by paperwork," he said. About the only thing to discourage a doctor bent on fraud may be what happens if you get caught. Dr. Borison, the mastermind, is serving 15 years in a maxiumum security prison. He refused to speak to 48 Hours. Diamond, who is serving five years, apparently found it changed him. "I'd like to say at this point (o) who's ever watching and whoever I hurt in this process, I'm sorry," Diamond said. After 14 months in prison, he's repenting, he said. "I know what I did was wrong and I'm really sorry." ~~~~~~~~~~~~~~~~~~~~

The Wall Street Journal Europe

Test Case: Drug Makers Relied On Two Researchers Who Now Await Trial
The Americans Are Accused Of Endangering Patients And Stealing $10 Million
`Checks and Balances' Failed
By Steve Stecklow and Laura Johannes
August 18, 1997
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EXHIBIT NO. 29
AM 5/29/08

AUGUSTA, Georgia -- For most of this decade, many pharmaceutical companies relied heavily on two distinguished clinical researchers, Richard L. Borison and Bruce I. Diamond, to test new mental-health drugs. Now, the two men are awaiting trial in Richmond County, Georgia, after pleading not guilty to 172 criminal charges.
Georgia state investigators accuse the two men of running a secret, renegade drug- testing operation, recklessly endangering patients and stealing from Georgia's only state medical school more than $10 million in drug-company payments. They contend that Dr. Borison, a 47-year-old medical doctor, was rarely around the test sites and left unqualified employees to treat patients and that Dr. Diamond, 52, a pharmacologist, routinely forged Dr. Borison's signature on patient and test records. Former employees of the pair say they were pressured to enroll large numbers of patients, whether eligible to participate or not. The doctors deny all the charges.

Prosecutors and medical-college officials are incredulous that none of the drug companies appeared to notice anything wrong. The companies, which are required to monitor clinical trials to ensure integrity of the data and patient safety, overlooked or ignored obvious signs that the two professors at the Medical College of Georgia here didn't follow proper procedures, investigators say.
"The checks and balances that are in place didn't work," says Georgia Assistant Attorney General David McLaughlin. The two men "were doing this for years and didn't get caught."
The companies say they trusted Drs. Borison and Diamond to follow proper procedures and medical-college rules. They say they hired the two because they were prominent in their field and could sign up test subjects quickly -- an important consideration because of the companies' growing need for human test subjects to satisfy regulatory requirements. In addition, pharmaceutical companies testing similar drugs often compete fiercely for the same limited pool of patients.

The two researchers "had been active in the development of many successful drugs, and they were good recruiters," says William Kennedy, vice president of Zeneca Inc., of Wilmington, Delaware, which hired them in 1990 to test Seroquel, a schizophrenia drug.

Among other companies, Johnson & Johnson hired the men to test Risperdal, its new schizophrenia medicine, and SmithKline Beecham PLC had them evaluate Paxil, a now-popular antidepressant. Their dozens of other clients also included Bristol-Myers Squibb Co., Eli Lilly Co. and Glaxo Wellcome PLC.
Some drug companies acknowledge they complied with Dr. Borison's requests to send payments to companies he controlled or even to his house, instead of the medical college. The companies also didn't question the researchers' practice of obtaining approval from outside human-test review boards, including one 4,000 kilometers away, instead of the one across the street that the college says they were supposed to use. "That should raise a red flag to anybody," says Manuel Casanova, an Alzheimer's researcher at the school.
And when one inspector from a test-monitoring company hired by Sandoz AG aggressively questioned the authenticity of Dr. Borison's signatures on patient records, the inspector was abruptly taken off the case after Dr. Diamond complained to the man's superiors, three former employees say.

Drs. Borison and Diamond decline to be interviewed. Their attorneys say they didn't commit any crime and term the entire matter a contractual dispute with the school. "Whether Borison or Diamond owe the Medical College of Georgia money is a matter of contractual interpretation, not criminal law," says Michael C. Garrett, who represents Dr. Borison. The attorneys also say the drug studies were performed appropriately and dispute any former employees' claims to the contrary. "Some persons may feel there were shortcuts taken," says Donald F. Samuel, Dr. Diamond's attorney. "That's maybe because they don't have the knowledge to properly evaluate what was going on."
Drs. Borison and Diamond made the lucrative switch from scholarship to entrepreneurship after collaborating for years, first at the University of Health Sciences/The Chicago Medical School (an independent institution now called Finch University of Health Sciences/The Chicago Medical School), where both earned doctorates in pharmacology. Dr. Borison also went to medical school at the University of Illinois in Chicago.

By the time Dr. Borison finished his residency in 1981, he had published 85 articles in scholarly journals. Beginning in the mid-1970s, he and Dr. Diamond, who isn't a physician, had collaborated on more than 50 research projects. They got job offers in Augusta, where Dr. Borison went to work for a Veterans Affairs hospital and Dr. Diamond at the college. Both chose to specialize in research on how chemicals affect the brain just as scientific breakthroughs were expanding pharmaceutical treatments for the mind.
Some of Dr. Borison's research was criticized by regulators. In a paper delivered in May 1985 before the American Psychiatric Association, he reported that the generic version of Thorazine, a SmithKline schizophrenia drug, wasn't as effective as the brand-name medicine. Patients on Thorazine at the VA hospital in May 1984 became agitated and hostile, he said, when they were switched to generics the following month.

But when the U.S. Food and Drug Administration examined Dr. Borison's claims, it found that the VA hospital hadn't stocked Thorazine in May 1984 and had been using a generic equivalent exclusively for months. In addition, three of the 11 patients supposedly taking Thorazine that month weren't in the hospital then, the FDA said. In response, Dr. Borison said he had altered the time periods to protect patient confidentiality. But the FDA said a review of all possible time periods also failed to corroborate his data. It publicly rebuked him.
In a speech before pharmaceuticals manufacturers in June 1986, James C. Morrison, then deputy director of the FDA's office of drug standards, said of Dr. Borison's claims, "We conclude it is shameful that serious allegations about the

performance of generic drugs have been made and widely repeated based on such faulty data." But the FDA had no disciplinary power because the incident didn't involve data submitted to it.

Dr. Borison, defending himself to the VA, complained that the FDA criticism had prompted companies to withdraw research work. But any setback was brief. In 1988, he was promoted to a full professorship at the medical college and later became chairman of its psychiatry department. Between 1988 and 1996, companies including Abbott Laboratories Inc., Hoechst AG, Warner-Lambert Co., Pfizer Inc. and Sandoz showered him and Dr. Diamond with contracts for more than 160 studies.
Drug companies either say they didn't know about the FDA's harsh criticism of Dr. Borison or discounted it because no formal action was taken. "I have never heard of it," says Ravi Anand, who was in charge of the clinical trials performed by Dr. Borison for Sandoz (now part of Novartis AG). Dr. Anand, who joined Sandoz in 1989, says that if he or his predecessors had known, "we would drop that person like a hot potato."

With business booming in early 1994, Drs. Borison and Diamond opened a new drug- testing site across the street from the medical college, in the BioTech Park office complex. Its entrance was only marked Suite 7. "I kept asking when are we going to get a sign out," says Debra Brown, drug-study coordinator who worked there until June 1996 and left of her own volition. "They just skirted the issue."

Former employees and patients say they believed the test site, which used medical-college employees, supplies and appointment cards, was connected to the school. But the college says it didn't know about the operation. Like most medical schools, Medical College of Georgia requires faculty members to get its approval for all research and is supposed to collect all research money, using some for overhead. But in many Borison-Diamond trials, it says, it got no funds. It also concedes it did a poor job of tracking the studies.
The FDA requires that clinical research be approved by institutional review boards -- self-regulatory oversight entities -- and academics typically go through review boards on campus. But in at least 44 trials, Drs. Borison and Diamond went outside the college to find a review board, including one in Olympia, Washington.

Some Borison-Diamond staffers had no medical training before arriving at the clinic, but were asked to do sophisticated tasks, the FDA and former employees say. Two of their study coordinators had been hired after working as Girl Scout administrators; another had recently been a Delta Airlines flight attendant. At Suite 7, the office secretary became the staff pharmacist, keeping track of experimental drugs; she had no professional training.

Christy Hernandez, who began working at BioTech Park as a study coordinator in December 1994, also had no medical training, yet was put to work interpreting electrocardiograms and blood tests -- tasks normally done by physicians. She says she was deciding whether Alzheimer's patients could safely continue taking an experimental Sandoz drug. "There are many intricacies in reading medical data, and I didn't know how to do it," she says. Answering the telephone, she adds, is "all I should have been doing."
Dr. Borison, meanwhile, was rarely in, several former employees say. "He was never at BioTech Park other than for, like, a birthday," says Angela Touey, another former study coordinator.

The FDA, which launched its own investigation of the test operation last year, says Dr. Diamond performed medical tasks and "routinely" forged Dr. Borison's signature on patient charts and other documents. Prosecutors and former employees say the nonphysician even forged prescriptions -- a violation of state law. Ms. Touey says that prior to scheduled visits from drug-company inspectors, employees would place yellow stickers on documents that required Dr. Borison's signature and give them to Dr. Diamond. "We would tote these books to Bruce's office, and he would just sign away," she testified to a VA investigative board last year. Attorneys for the two men decline to comment on these accounts.

Rigorous FDA standards require that new drugs be tested on large numbers of human patients. But because many people are reluctant to participate, drug companies, anxious to beat competitors to market with new products, prize researchers who excel at recruiting. Drs. Borison and Diamond were masters, able to round up dozens of willing patients within weeks.
An August 1994 letter from Abbott complimented Dr. Borison on his "impressive" enrollment for trials of the schizophrenia drug Sertindole, adding: "For your efforts, we will purchase a fax machine for the high-enroller award for the month of May." When sign-ups reached 20, the letter promised "an enrollment bonus of $3,000, with which you may purchase a computer." Abbott terms the compensation "appropriate."

Ms. Hernandez and other former employees say that Dr. Diamond pressured them to recruit large numbers of test subjects quickly, including some who may not have qualified, and that their pay depended on it. The employees' low pay was supplemented by frequent bonuses -- of $500 or more -- that were partly based on the number of patients they recruited.

Ms. Brown says Dr. Diamond once wrote on a cocktail napkin that "he would double my salary that year" if she recruited 30 new patients for a Sandoz Alzheimer's study. Ms. Brown says she barely missed the quota. A contract shows the drug company had offered to pay $19,380 per subject -- one of the highest amounts ever offered in an Alzheimer's trial. "It became like a game to Bruce Diamond," Ms. Brown says. "He was just crazy about enrolling all of these patients, and it

became more and more obvious that this isn't right." Dr. Diamond's attorney acknowledges that employees were paid recruiting bonuses, but says, "If the incident with the cocktail napkin occurred, it was obviously a joke."
Paige Horan, who coordinated Borison-Diamond drug trials at the VA hospital, says Dr. Diamond pushed her so hard to recruit and retain subjects for a Sandoz study of a schizophrenia drug that she misled patients -- claiming the experimental medicine may be the "next wonder" drug. The recruiters "were promising them things that we knew were wrong," she says in an interview. "I was very wrong for doing it."

Ms. Hernandez says Dr. Diamond "just wanted us to recruit as many people as possible, and whether we thought they would be eligible or not." Dr. Diamond's attorney says some unqualified patients may have been enrolled but denies his client knew at the time that anybody was ineligible.

Eligibility requirements for drug studies are designed to make sure that drugs are tested on patients they are most likely to help. The studies' rules usually specify the type and stage of disease the test subjects must have, and they exclude people with other health or substance-abuse problems. The results could be skewed if researchers enroll ineligible patients, and patients could suffer because they pass up opportunities to try other therapies that might be more helpful.

When Nancy Sisk brought her husband, Leroy, to BioTech Park in June 1995, intrigued by an experimental Sandoz drug for Alzheimer's, the retired minister couldn't even remember what state he lived in. At Dr. Borison's clinic, Mrs. Sisk says a staff member, whom she can't identify, took her husband into a back room and administered a mental-acuity test with a scale from zero to 30. "She came and told us, `He made an eight, but we'll give him a 12,' " Mrs. Sisk says. A score of 10 was needed to enroll in the study, which was aimed at people who still retained much of their cognitive ability.
Three months into the study, Mrs. Sisk, concerned that her husband wasn't improving, took him to Edward Zamrini at the VA hospital. Dr. Zamrini gave him the same acuity test. Mr. Sisk's score was two. "There was no way he could have legitimately been admitted or enrolled in the Sandoz study," Dr. Zamrini later testified to the VA investigative board. Because Mrs. Sisk had said her husband hadn't deteriorated significantly since the first test, Dr. Zamrini added, "In my opinion, their initial score of 12 is suspect." Mr. Sisk ultimately quit the study. Dr. Diamond, his attorney says, didn't perform the test on Mr. Sisk or order any employee to put him in the study.

As activity at Suite 7 picked up, rumors began circulating around the college that Drs. Borison and Diamond were making a killing by running drug studies on the side. Dr. Borison amassed a collection of antiques, including suits of armor, and made plans to build a full-scale castle outside Augusta. Dr. Diamond bought a Mercedes. Dr. Borison, who earned $154,000 at the college, reported gross income of $1.2 million on his 1995 federal tax return. Dr. Diamond, who earned $65,000 at the school, reported $1.1 million. (The tax returns were attached to the indictments.) In both cases, most of the money came from PharmEd Inc., their research company.

The drug companies complied when Dr. Borison asked that money be sent directly to PharmEd or his home rather than to the college. A Warner-Lambert spokesman says one company unit sent a $10,000 check to PharmEd at Dr. Borison's request because it trusted him and the request came on medical-college stationery. The U.S. unit of Japan's Otsuka Pharmaceutical Co. also sent payments this way. "We were relying on his representations as a prestigious person," Scott Willoughby, Otsuka's U.S. general counsel, explains. The company has adopted controls to prevent a recurrence, he says.

In January 1996, Drs. Borison and Diamond opened a new research site to prospect for subjects in Charlotte, North Carolina. John Stokes, an inspector from Quintiles Transnational Corp., visited it a few months later. Sandoz had hired Quintiles, a medical-research contractor in Research Triangle Park, North Carolina, to help oversee its Alzheimer's studies, and Mr. Stokes questioned how Dr. Borison could sign records for patients seen in Charlotte on a day when he was nearly 320 kilometers away in Augusta. "The more questions he asked, the more nervous Dr. Diamond got," says a former study coordinator.

A person familiar with the matter says Dr. Diamond complained to Mr. Stokes's superiors at Quintiles. The next business day, Mr. Stokes was off the case. "Poor guy, he got in trouble," says Sharad Mogul, who managed the Charlotte office for Drs. Borison and Diamond at the time and had formerly worked at Quintiles. The drug- testing inspection system, he says, "is a joke, and what happened to John Stokes is a classic example." He says drug companies treat researchers like "kings" and are reluctant to antagonize them because they supply the study data. Mr. Stokes and Quintiles decline to comment.

Things began to unravel for the two researchers when Ms. Touey left her job in Suite 7 to go to graduate school. A few months later, in the autumn of 1995, she took a part-time job with David Hess, a neurologist and researcher at the VA hospital. Dr. Hess told the VA investigative board that Ms. Touey asked him, on her first day on the job, how she should obtain a patient's consent to participate in a stroke study. He testified that when he explained that as the principal investigator, only he was supposed to obtain consent, she said it didn't work that way at her previous job.
Alarmed by this and other accounts from Ms. Touey, Dr. Hess spoke to other former employees and alerted officials at the medical college and the VA hospital, he testified. Days later, in June 1996, Drs. Borison and Diamond resigned their medical-school positions and are no longer testing any drugs; drug companies either stopped the trials or transferred them to other researchers. In February, the two men were indicted on state criminal charges. No trial date has been set.

Meanwhile, a court-appointed receiver is overseeing assets of the testing operations -- including equipment, files, money and bank accounts -- which, if the two are convicted, are subject to state forfeiture.

George Schuster, chairman of the medical school's institutional review board, says he is still disturbed by the drug companies' response to the scandal. He notified about two dozen companies in June 1996 that Drs. Borison and Diamond had resigned their positions after allegations of research misconduct and wrote that the school was "very concerned" about patients' welfare. But many of the companies "didn't seem particularly concerned" about patients, Dr. Schuster says, adding that most were interested only in whether data had been faked. Told there was no immediate evidence of that, "most of them seemed to lose interest," he says.

Ms. Brown recalls a time when Sandoz did show some concern. Two years ago, it sent a representative to Augusta after discovering that she was dispensing medication at a time of day before most doctors' offices had opened -- suggesting that Dr. Borison wasn't around. Sandoz says its representative told the clinic to stop dispensing medication without a physician present. But employees say the practice continued anyway. Ms. Brown says the Sandoz representative never asked her any questions and left Augusta saying that if she "had a mother with Alzheimer's disease, [she] would want her to come to our clinic."

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Reprinted on Eli Lilly Drugs by Karl Loren http://www.oralchelation.net/data/Lilly/data6.htm#p9

http://www.mhsource.com/pt/p970401b.html
Ex-Profs Charged in Psych Department Research Scam
by Michael Jonathan Grinfeld
Psychiatric Times April 1997 Vol. XIV Issue 4

A scandal-rocked Medical College of Georgia (MCG) has announced tightened compliance controls for clinical studies in the wake of a 172-count indictment that charged two former professors with diverting more than $10 million in research funds. Richard L. Borison, M.D., the former chair of MCG's department of psychiatry and health behavior, and Bruce I. Diamond, Ph.D., once a professor in the department, were jailed in February pending the posting of a $1 million bond each. Borison posted bond on March 5 after spending 10 days behind bars; Diamond remained incarcerated at the time this article was filed.

The charges stem from claims that the pair spent the last eight years conducting over 100 research projects for more than 20 pharmaceutical companies using MCG resources, but then pocketing the proceeds. The alleged scheme began to unravel during the last week of May 1996, according to MCG officials, after a whistleblower complained about irregularities in the medical management of research subjects. The study coordinator who raised the red flag, however, didn't even know they were working for research enterprises that weren't a part of MCG.

Within three days after MCG officials began asking questions about Borison and Diamond's operations, both researchers resigned their positions and refused to cooperate with an internal investigation, according to Malcolm Kling, Ph.D., a pharmacologist and MCG's interim vice-president of research. The Augusta-based medical school, one of the oldest in the country, then notified the attorney general's office, the U.S. Food and Drug Administration, other federal regulators and the pharmaceutical companies about the irregularities.

In a prepared statement, school officials said that they were initially "appalled by the conduct of these two former faculty members." But as the internal investigation proceeded "the initial reaction changed to frank anger as the extent of the allegations of misconduct became more apparent."

The 3-inch thick indictment chronicles a history of alleged misconduct dating back to 1988. The grand jurors charged that Borison and Diamond "developed and executed a scheme through which they systematically stole in excess of $10 million from the Medical College of Georgia," and that they "routinely lied to conceal their crimes and endangered the safety of the patients and study participants they were employed to serve, protect and heal."

Borison and Diamond conducted research into a broad spectrum of mental illnesses including Alzheimer's disease, schizophrenia, anxiety and depression, and they contracted with pharmaceutical companies throughout the United States and abroad. Their research included clinical trials for drugs such as olanzapine, Eli Lilly's new schizophrenia treatment, and Janssen Pharmaceutica's risperidone. A Medline search revealed that Borison and Diamond published more than 20 articles since 1988.

But the indictment, coming after months of painstaking investigation, charges that Borison and Diamond's national reputations were built upon a foundation of theft, false statements and representations, prescription forgeries, violations
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of controlled substances laws, income tax evasion, reckless conduct in the providing of medical care, bribery and racketeering. In addition to the criminal indictment, the Georgia attorney general has also brought a civil forfeiture suit against Borison and Diamond, claiming that millions of dollars in assets located in three states and London, England, are in actuality the fruits of their alleged illegal activities. A receiver appointed in the case has taken control of assets that include bank accounts, real estate, antiques and art work.

Michael Hobbs, counsel to Attorney General Michael Bowers, told Psychiatric Times that it could be a year before the criminal trial begins. Although he declined to comment on the merits of the case, other than to refer to allegations in the indictment, Hobbs said that the state will seek to prove that this is not just a case about financial misfeasance, but also one that involves patient safety.

"There are a number of allegations in the indictment concerning the use of untrained, undertrained, inadequately trained, or improperly trained clerical personnel to perform some of the procedures that were necessary in conducting the studies, such as drawing blood," Hobbs said. "There is some indication in the indictment of inattentiveness on the part of Dr. Borison and Dr. Diamond to subjects in the studies who had suffered from a serious, adverse event and were not seen or followed up with by Borison or Diamond."

A bribery count in the indictment alleges that Borison and Diamond paid an undisclosed sum to an MCG employee in exchange for her not filing a complaint regarding a patient suicide that occurred during a clinical study of olanzapine. A spokesperson for Eli Lilly and Co., the drug's manufacturer, said that despite the allegations of financial misfeasance against Borison and Diamond, they are confident that none of the data provided was compromised in any way. Following the pair's resignation from MCG, Lilly arranged for new principal investigators to take over ongoing trials.

According to Hobbs, he has no evidence, "one way or the other," that data provided to any of the pharmaceutical firms was falsified, fabricated or plagiarized, although an FDA investigation is underway. A spokesperson for the agency refused to comment on the status of their inquiry while it is pending.

Meanwhile, Jay Sawilowsky, an Augusta attorney representing Borison and Diamond in connection with the civil forfeiture suit and the FDA audit, and who is consulting with respect to their criminal defense, denies that his clients were involved in any improper conduct. Rather he says the case is a dispute over money and who is entitled to the wealth generated by Borison and Diamond's research. He lashed out at MCG's leadership, calling it "maladministration," and charged that school officials will have some explaining of their own to do when the business arrangements involving the research are "finally hashed out in court."

"They are not accused of any plagiarism; they're not accused of faking data...," Sawilowsky said. "When you get down to what is the dispute between them, the doctors and the medical college, it is about a dispute over money, money, money. That's what it's about."

Sawilowsky accused the attorney general's office of turning the situation into a media circus, and filed a motion in the civil suit to prevent further disclosures of the identities of psychiatric patients involved in research programs. The indictment named the psychiatric patients in conjunction with forged prescription allegations, individuals who were then deluged by media requests for interviews after the charges became public. The motion to restrain further disclosures was denied, though Sawilowsky claimed that the attorney general's office promised the judge there would be no further disclosures unless absolutely necessary.

"The torment to these psychiatric patients who have been publicly exposed is terrible," Sawilowsky said. "I accuse the staff of the attorney general's office of being completely indifferent to the welfare of the patients. Of being completely unconcerned about harm to the patients."

Jill P. Hauenstein, M.D., president of the Georgia Psychiatric Physicians Association (GPPA), and an associate clinical professor at MCG, agreed that the disclosure of confidential patient identities by the attorney general's office was inappropriate and could have been handled more sensitively. "Confidentiality is the cornerstone of the psychiatric doctor-patient relationship, and to violate that is [to violate] one of the most basic trusts that a patient has. This was not done by Dr. Borison or Dr. Diamond or their attorneys, it was done by the attorney general's office."

Efforts by the GPPA's legislative consultant to sensitize the attorney general's office to confidentiality issues has thus far not resulted in any assurances that any changes will take place. In a letter from Attorney General Michael Bowers, the GPPA was told that while he is concerned about confidentiality, the disclosures were necessary in order to ensure the indictment passed legal muster.

Meanwhile, MCG's Kling said that the school is instituting changes to assure better controls over research contracts and the investigators who enter into them. "We will be doing things after the barn door was left open and the horse is long gone, but we'll keep the next horse from getting out," he said.

Already, a new Office of Clinical Trials Compliance will monitor all research contracts, and manage their compliance with

"federal, state and local regulations and policies to protect the research subjects and the interests of the university," according to an MCG announcement.

In addition Kling said that audit controls would be tightened so that issues like the ones that arose in connection with Borison and Diamond's research project would be discovered sooner. For instance, no one noticed when research projects by the two former faculty members dropped off precipitously. Some of the research was performed literally across the street from MCG's campus using the medical school's employees, but no one caught on for years, Kling said.

"The way we manage our studies and we manage the flow of money and we manage contracts, they're handled through different offices," Kling said. "...We didn't know where they were working. Why didn't we know where they were working? We're going to take a look at that process. Why didn't someone hold up some red flags, and say 'look at this?'"

Finding answers to these questions will occupy the medical school for some time, Kling added. Thus far, there are no indications that irregularities in the management of research contracts will surface in other departments, though efforts are underway to ascertain whether problems exist elsewhere in the medical school.

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