

The Death of Subject 13

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Subject 13 was dead.

Enrolled in a clinical trial testing the effects of anti-psychotic drugs at the University of Minnesota, the schizophrenic had killed himself May 8, 2004, in a grisly suicide.

Tragic, a U official wrote in a "serious adverse event" memo to the U.S. Food and Drug Administration, but suicide was "unfortunately not uncommon in this study population."

Unfortunate, but not unpredicted. Subject 13 had a mother who thought that her son, Dan Markingson, wasn't getting better during his six months in the study. Mary Weiss sent five letters and made numerous calls to the researchers, complaining that her son, the 13th enrollee, didn't have the wherewithal to consent to the study and requesting that he be withdrawn.

The university disregarded her letters and calls. She later filed a lawsuit, accusing Markingson's psychiatrist and the study's director, Dr. Stephen Olson, of coercing him to sign up. The lawsuit claimed the university kept Markingson enrolled to preserve its research and to keep payments coming for his participation.

"Do we have to wait until he kills himself or someone else," she asked three weeks before the suicide, "before anyone does anything?"

The death prompted reviews by the state mental health ombudsman and the U.S. Food and Drug Administration about the conduct of the university and Olson, who was Markingson's only psychiatrist at the time he recruited him into the study. The reviews and the lawsuit probed whether Markingson was coerced into the study by the threat of commitment to a psychiatric hospital and whether the university provides adequate protection of mentally ill research subjects. The lawsuit also revealed the pressure to recruit research subjects.

Neither Olson nor the U has been blamed by any oversight agency for the death, or cited for research violations. The U was dismissed from the lawsuit in February, and Olson settled in April. Four years after Markingson's death, the university has moved on. Weiss has not. She endures the pain of a mother who says she couldn't get anyone to listen.

He fit the profile

Markingson was a celebrity-tour bus driver in Los Angeles in summer 2003 when his mother, from South St. Paul, arrived for a visit. Weiss found a 26-year-old who believed that aliens had burned a spot on his carpet and that a secretive world order would call on him to kill people in a "storm."

Desperate to get her only son back home, Weiss sent him e-mails pretending to be the "guardian angel" spirit of Markingson's dead grandmother and suggesting the storm would start in Minnesota.

The deception worked, but the return home didn't seem to change Markingson's mental state. He started having visions of killing his mother in the storm. Markingson was taken Nov. 12, 2003, to Regions Hospital in St. Paul, but it had no open psychiatric beds. He was then transferred to the University of Minnesota Medical Center, Fairview.

Weiss said discussions about research started right away at the hospital. Markingson was placed in Fairview's Station 12, a new unit at the time created to treat psychotic patients and screen them for research. Olson and Dr. Charles Schulz, head of the U's psychiatry department, helped launch the unit in part to enhance the hospital's startup schizophrenia program and meet the U's mandate to bring in more research dollars.

Olson first recommended on Nov. 14 that a Dakota County District Court commit Markingson to the state treatment center in Anoka because he was not fit to make decisions about his care. He wrote to the court that Markingson was convinced his delusions were real and that he wasn't mentally ill.

The doctor changed his opinion about the commitment in less than a week, telling the court Markingson had started to acknowledge the need for help.

Reversals by patients are common, Olson explained in an interview with the Pioneer Press last month. Schizophrenics often arrive for treatment with delusions and denial but change their outlook while hospitalized.

A judge agreed Nov. 20 with Olson's new recommendation, requiring Markingson to follow the doctor's treatment plan. The next day, Markingson signed a consent form to be part of a national anti-psychotic drug study, Comparison of Atypicals for First Episode, or CAFE.

Weiss didn't understand. How could her son be deemed incapable of making decisions one day and then consent to a drug study the next?

The study, funded by drugmaker AstraZeneca and spread among 26 institutions, compared the effectiveness of three commonly used anti-psychotic drugs — Seroquel, Zyprexa and Risperdal.

Olson had been searching for recruits for more than a year. The study required a very specific and elusive person — a schizophrenic experiencing his first symptoms. Markingson fit that profile.

Weiss wasn't expecting a schizophrenia diagnosis. At Regions, her son responded well to a medication for bipolar disorder. The family has a history of that disorder as well.

Question of bias

Full participation required Markingson to take one anti-psychotic drug for up to a year and to appear at the U for checkups. Markingson received AstraZeneca's Seroquel. As Subject 13, Markingson was worth \$15,000 to the U, with some of that going to Olson's salary and the psychiatry department. Switching or adding medications could have disqualified Markingson and halted payments to Olson and the department from AstraZeneca.

Overall, the study offered \$327,000 to the U and an opportunity to raise the profile of its schizophrenia program.

Weiss' lawsuit claimed that this money gave Olson a conflict of interest regarding Markingson's care.

Four experts hired by Weiss' attorneys agreed that Olson had an ethically questionable position — as the gatekeeper over Markingson's commitment, as his treating psychiatrist, and as the researcher with a financial incentive to enroll patients.

"For a physician to exercise such medical, research and legal power and control over a research subject is an extraordinary, if not unprecedented, example of unethical coercive practices," said Dr. Keith Horton, a Minneapolis psychiatrist who gave a written opinion in Weiss' suit.

The university's own Web-based guidance on research ethics advises recruiting "in a non-biased, non-power-based manner" and states that "doctor-patient relationships between the investigator and participants should be avoided, when possible, to eliminate any power-based coercion."

In a recent interview, Olson said that it is difficult for an academic physician to avoid this conflict and that in this case the conflict didn't matter. As Olson's patient, Markingson was going to receive one of the three anti-psychotic drugs being tested in the study anyway. As a study participant, Olson said, Markingson would receive more attention and monitoring.

Olson also said in his deposition that participation in the study was never linked to the commitment decision. Markingson could have selected standard treatment or backed out of the study, Olson said.

Weiss doesn't believe her son understood he could have those options. Markingson signed a consent form that said he was "not under any obligation to participate in a research project offered by your doctor." He also signed a hospital discharge plan that warned him to follow Olson's instructions, take his medication and show up for CAFE study appointments.

"Consequences for not following this plan," it stated, "could result in court commitment to the hospital."

Mother's intuition

Markingson was transferred from the hospital Dec. 8, 2003, to a West St. Paul halfway house where he was often reclusive — spending entire days in his room — but showed no delusions or psychotic episodes.

Notes from Fairview's day treatment program showed no problems either, though Markingson often tuned out group discussions and wore headphones.

Weiss said her son no longer verbalized his most outlandish delusions — about the killing storm or his "sister" Angelina Jolie. But Weiss still saw signs. Markingson believed he should return to California to resume an acting career he never had. He called himself bulletproof and said his mom would be bulletproof, too, while with him.

Weiss' letters to Olson and Schulz, who was a co-investigator in the study, urged them to consider different treatment options for her son, which would have disqualified him from the study. But the doctors were unconvinced by her pleas. Screenings as part of the U study showed that the drug had managed Markingson's delusions and disordered thoughts.

Weiss was infuriated. Why didn't anyone trust a mother's insights? She looked into a legal guardianship so she would have the power to withdraw her son.

Recruiting pressure

Recruiting patients for psychiatric research is a challenge, but CAFE presented special problems. First-episode schizophrenics aren't easy to locate. They don't go to clinics or support groups. Some don't admit to an illness until they are brought to a hospital against their will.

CAFE was an early opportunity at the U for Olson to add research experience to his academic credentials. The U had recruited him in 2001 for his expertise in schizophrenia.

It was a slow start. Olson recruited one patient in 2002, and CAFE study leaders considered dropping him altogether, according to monthly recruiting summaries. Olson and the university had been dropped from a previous study because of low recruiting numbers, the doctor later said in his court deposition.

Exchanges between local and national study officials made it clear that there was pressure for results and a "risk" that the study would be shut down if it didn't recruit enough patients.

The opening of Station 12 — which evaluated every patient for research — made a difference, Olson and Schulz said. One-third of the U's patients for CAFE came from this unit. By mid-2003, CAFE leaders were praising Olson and his recruiter, Jeannie Kenney, and asking them to share recruiting tips.

Warning signs

Trouble dotted Markingson's final weeks. Screenings at the U showed an increase in symptoms. Markingson neglected his appearance, wearing the same clothes daily. He read a headline about Easter and then told a halfway house worker he'd never heard of that word.

Two changes seemed to add stress for Markingson. His mother drove his car and belongings back from California. He was furious. Also, his county case manager, David Pettit, recommended he seek an apartment and a job.

More than ever, Weiss worried that the research study was failing her son. She didn't think he would listen to her face to face, so she wrote her concerns in a May 7 letter to him. Writing had always connected them, even when Markingson went to college in Michigan and then moved to California.

Her son would never open his mother's letter.

May 8 started normally. A worker wasn't surprised when Markingson took a midnight shower — he often did. But then an hour passed and he didn't come out.

The worker burst in to find Markingson dead in the bathtub. He killed himself in ritualistic fashion, mutilating himself with a knife. A note on his nightstand said, "I went through this experience smiling!"

Questions surfaced. An autopsy showed no medication in Markingson's bloodstream, and a coroner's photo showed a sealed bottle of his medication. Had he been taking his drugs?

Study officials could have been fooled. They only counted drugs left in pill bottles instead of testing blood levels in patients.

While others were baffled, Weiss was angry. When a sympathy plant arrived from the university, she drove it back with new words on the card:

"How dare you!"

Lack of oversight?

Olson originally recommended that Markingson be committed, but then advised a judge to stay the commitment for six months. Olson did not disclose to the court that he was

Markingson's only psychiatrist at the same time he recruited him for his drug study.

Markingson's county case manager learned of Olson's dual roles, but after Markingson had enrolled in the study.

Two weeks before Markingson's death, Olson recommended another six-month stayed commitment to prevent his patient from moving back to California. Olson's letter to the case manager stated that Markingson had "little insight" into his illness and would be at "risk" on his own of slipping back into delusional behavior.

The letter didn't mention the study, which had several months left.

The university's Institutional Review Board acted as the safety watchdog of the study, but leaders of the IRB said in court depositions that they never learned about Weiss' concerns or how Markingson was recruited until after he died.

The FDA's involvement came after the death as well. The agency inspects 1 percent of the thousands of U.S. clinical trial sites each year.

The state ombudsman raised concerns after Markingson's suicide, including the method of ensuring that patients were taking their pills and the ethics of one doctor both recruiting and treating a patient. The report also questioned whether Markingson was truly eligible for the study, because he wasn't diagnosed with schizophrenia until several weeks after he had enrolled.

Weiss' attorneys found other concerns about the study as they built their case. Olson fell behind in required training to evaluate CAFE study subjects, according to e-mails from national study leaders. Records suggested Olson had met two or three times with Markingson in his last six months, while Kenney, a social worker, conducted most of the screenings.

Olson waited several weeks before notifying participants of a new diabetes risk with anti-psychotic drugs. The U's records also showed an office visit with Markingson that would have occurred after his death.

The lawsuit ended this year after a judge ruled that the university had statutory immunity from such lawsuits and that AstraZeneca shouldn't stand trial because there was no convincing proof that its drug caused Markingson's death. Weiss settled with Olson, the only defendant left. She said she was granted \$75,000, which went entirely toward legal bills.

Final chapter

CAFE's results came out in June 2005. They showed little difference in the effectiveness of the three drugs or the amount of unhealthy weight gain by study participants.

Some observers believed AstraZeneca had backed the study to prove that its drug, Seroquel, caused less weight gain than the others. Buried in CAFE's results: There had been five attempted suicides, two completed suicides.

Researchers weren't shocked. The lifetime suicide rate among schizophrenics is as high as 10 percent. Two deaths among 400 study participants wasn't unexpected.

U leaders believe that their system to protect human research subjects is effective and that Markingson was a sad aberration.

"It is a tragedy" to lose a patient to suicide, Olson said. "We're just redoubling our efforts to understand what goes on in the mind of someone whose mind isn't working properly."

Olson is enrolling patients in studies, including another AstraZeneca drug trial called HALO, and worries that publicity of the suit will make recruiting harder.

QUESTIONING THE QUESTIONERS

Clinical research drives medical progress but presents risks to participants. Here are 10 questions to ask before signing up:

1. Why do you want to study me or people like me?
2. Who is running the study and paying for it?
3. Who from the study can I go to with ideas, questions or complaints?
4. Can I quit the study after signing the consent form? Will anything happen to me?
5. What will I get out of this study?
6. How could I be harmed in this study and how will I be protected?
7. If I am harmed, who will take care of me and who pays if I need treatment?
8. Is there a written guarantee of privacy?
9. How much of this study have you already done? Have there been any problems so far?
10. Will results be in places where the public can see them?

Source: U.S. Centers for Disease Control and Prevention

SCHIZOPHRENIA

Definition: A chronic and disabling brain disease with terrifying symptoms such as hearing internal voices or believing that people are reading your mind, controlling your thoughts or plotting harm. Schizophrenics may be fearful and withdrawn and have disorganized speech and behavior.

Diagnosis: Generally requires two classic symptoms for one month and signs of disturbance for six months. Also requires the absence of notable depressive or manic episodes that would instead suggest a mood disorder.

Demographics: 2.7 million Americans, or 1.1 percent of adult population. Onset is most common among men in their teens and early 20s, and among women in their 20s and 30s. Five percent to 10 percent of schizophrenics will die by suicide. The rate in the general population is about 4 percent.

Source: National Institute for Mental Health; American Psychiatric Association

PART TWO

Patient's suicide raises questions
By Paul Tosto and Jeremy Olson
Pioneer Press

When people enter drug studies at the University of Minnesota, they're supposed to be protected by a safety net keeping watch that the vulnerable are not coerced, that standards of conduct are met and that researchers aren't tangled in conflicts that might influence their decision-making.

That system was supposed to protect Dan Markingson.

A schizophrenic, Markingson killed himself in 2004 while enrolled in a study at the U comparing anti-psychotic drugs. Documents surfacing the past year in a lawsuit over his death have raised questions about whether the U psychiatrist running the study followed university ethical guidelines. They also raise questions about why the Institutional Review Board, the internal group charged with protecting people in university studies, didn't intervene.

University officials say their nationally accredited review board — a volunteer panel of 57 experts in medicine and other disciplines — works well and rigorously reviews studies. They would not talk specifically about the Markingson case to the Pioneer Press. A judge ruled in February that as a state agency, the university and its IRB are immune from the lawsuit.

The legal ruling didn't allow questions to be explored about who's ultimately responsible for the safety of research subjects and whether the university did everything reasonable to protect Markingson from harm.

According to the U's human subjects protection guide, the IRB's first charge is "to protect human subjects involved in research at the university from inappropriate risk."

In reality, the IRB operates largely on trust. Trust that researchers will follow the rules. Trust that people will speak up when a safety plan is violated, even if they have professional or financial pressures to stay quiet.

"It's the people who implement the plan who are responsible for protecting the subjects," said Moira Keane, the U's director of research subjects protection programs.

The IRB approves all clinical research — modifying safety rules when necessary — and samples study records every year or so to make sure its conditions are met. It also has the power to shut down projects that aren't complying with safety requirements or have caused "unexpected serious harm" to subjects.

Keane recalled four studies out of thousands at the U over the past two decades that the IRB stopped.

The lawsuit by Markingson's mother, Mary Weiss, alleged that the IRB's trust was misplaced in the so-called CAFE study, led by Dr. Stephen Olson, a U psychiatrist.

A central allegation was whether Olson had too much power over Markingson, and too many conflicts that obscured his clinical judgment. Olson recruited Markingson into the study at the same time he served as Markingson's treating doctor and advised a Dakota County judge on whether Markingson should be committed to a psychiatric hospital.

Had the IRB followed its own guidelines, it would have discouraged Olson from recruiting his own patient. The IRB Web site states that "doctor-patient relationships between the investigator and participants should be avoided, when possible, to eliminate any power-based coercion."

It's impossible to know whether Markingson would have killed himself if he hadn't enrolled in the research study. He was in a sensitive early stage of his schizophrenia diagnosis, during which the suicide risk is greatest. Even so, the study's rigid guidelines meant that Markingson received only one anti-psychotic drug to help control his delusions.

Experts hired by Weiss' attorneys said in court depositions that the IRB missed opportunities to make the study safer.

Dr. Harrison Pope from Harvard Medical School called the IRB's role an "essential link in the chain of causation that improperly admitted Mr. Markingson into the CAFE study, improperly held Mr. Markingson within the CAFE study, prohibited effective treatment of Mr. Markingson, and thus became a substantial, proximate cause of Mr. Markingson's death."

The IRB could insist researchers turn over all complaints about their studies, which might have raised concerns in this case. Weiss had complained in letters to Olson and Dr. Charles Schulz, head of the U's Department of Psychiatry, that her son wasn't getting better and was at risk for harm. She had requested that the doctors try other treatments, even if he had to be withdrawn from the study.

The U hired its own national IRB expert to refute Pope's claims. The IRB had no legal obligation to require someone other than Olson to evaluate Markingson's competency or his ability to consent to research, said Ernest Prentice, associate vice chancellor at the University of Nebraska Medical Center.

Nor is there a requirement that complaints such as Weiss' letters be forwarded to the IRB unless there is some unanticipated risk. Had the IRB received complaints, it could have investigated, he said.

Weiss said she'd never heard of an IRB.

The CAFE study was fairly prominent, involving 26 academic institutions and 400 schizophrenic patients. Financed by the pharmaceutical company AstraZeneca, it was worth up to \$327,000 to the U, with some of those funds going to Olson's salary and other study personnel.

U officials said the IRB acted ethically and within its obligations and federal regulations to protect human subjects in this study.

After the suicide, the IRB sought information from Olson on how Markingson consented to the study. But IRB officials said in depositions for the lawsuit that the review board never formally investigated Markingson's death.

The IRB investigates when there is evidence of misconduct. There was no evidence of that in the Markingson case, said Dr. Richard Bianco, a U physician who oversaw the U's research subjects program at the time Markingson participated in the study.

Bianco declined a Pioneer Press interview request. But in a court deposition, he acknowledged that the U has some 8,000 studies involving humans — research he estimated was worth about \$15 million — but that the IRB doesn't track the number of people enrolled in U research, only the number of projects approved.

Bianco agreed with Keane that the IRB system operates largely on self-disclosure by researchers.

The U's top research official says researchers and IRB reviewers "are aware and understand their ethical and moral obligations to do the right thing.

"If people write with concerns and issues, they will be reviewed," said Tim Mulcahy, the U's vice president of research. "If the IRB were to become aware of a suggestion of coercion or heavy handedness," he added, "we have an obligation to act promptly and very directly."

Olson declined to talk to the Pioneer Press about Markingson's care.

He said it would be difficult for any researcher to get away with violating research rules because they are observed by so many medical students, residents, nurses and others. However, a 2006 internal audit of the U's psychiatry department challenges the notion that those workers would speak up.

Nearly 40 percent of the psychiatry department staff responding to the auditor survey said they did not believe they would be protected from retaliation for blowing the whistle on a suspected violation in the department.

Some experts believe the nation's system of review boards is dysfunctional and in need of reform.

"We have a very haphazard way of overseeing (IRBs) and collecting data on adverse events," said Dr. Ezekiel Emanuel, bioethics chair at the Clinical Center of the National Institutes of Health and a national expert on institutional review boards.

"There's no one in America who can tell you how many people are enrolled in clinical research," he said. "No one can tell you how many people died in (ways) attributable to clinical research. No one can tell you how many people got injured, and no one can tell you over time whether the system is getting less safe."

PART THREE

Conflict of Interest?

By Jeremy Olson and Paul Tosto
Pioneer Press

Dan Markingson had delusions. His mother feared that the worst would happen. Then it did.

Drug companies have given \$88 million in gifts, grants and fees to Minnesota doctors and caregivers since 2002, according to state payment records, including \$782,000 to the two University of Minnesota psychiatrists who oversaw Dan Markingson's participation in a clinical drug trial.

A lawsuit over Markingson's suicide, which happened during the drug trial, accused Dr. Stephen Olson and Dr. S. Charles Schulz, chairman of the U's psychiatry department, of coercing the schizophrenic Markingson into the study.

The lawsuit, brought by Markingson's mother, Mary Weiss, charged that the doctors were under pressure to recruit patients such as Markingson to maximize payments from AstraZeneca and gain prestige by participating in the drug company's national study.

Both doctors said in court depositions that their roles were appropriate and that the money didn't influence their decisions over Markingson — including when his mother argued that he wasn't getting better in the study and should be withdrawn.

Schulz was dismissed from the lawsuit in February; Olson settled this spring for an amount a university official described as little more than court costs. Federal reviews of the death didn't result in any penalties against the doctors or the university.

The case nonetheless offered an inside look at the kind of financial payments to doctors that some health policy experts and congressional representatives say should be restricted or at least fully disclosed to the public.

It also scrutinized the ethics of drug company funding of research — something that has received less public attention and criticism than the free lunches, dinners and trips that drug companies have provided to doctors to promote their drugs.

Markingson, 27, killed himself May 8, 2004, in the bathroom of a West St. Paul halfway house. He had been enrolled for more than five months in the university's "CAFE" study, which compared three antipsychotic drugs.

Weiss sued the university and the psychiatrists. In an interview, she said doctors have a conflict of interest when they are financially benefiting from studies and caring for patients in those studies at the same time.

"I think they lose sight that these are people," she said, "not their own special little guinea pigs."

Minnesota is unique in requiring drug companies to report how much money they give to each doctor, but the reporting system has limitations. It doesn't always distinguish between money for a doctor's travel expenses and money for a research trial, nor does it distinguish money that was in a doctor's name but was passed directly to a research institution.

U.S. Sen. Chuck Grassley, R-Iowa, is urging a national reporting system. Grassley held a hearing last year in which two doctors said their colleagues have become trapped by the lures and pressures of drug company money.

"Physicians face a difficult choice," testified Dr. Greg Rosenthal, an Ohio eye specialist. "One path is to go along. With drug company money, you can increase your income, prestige, build your practice or fund a department, research or professorships. The middle ground is to simply look away. The hard choice is to fight back."

Olson received \$220,000 from six companies since 2002, including \$149,000 from AstraZeneca, according to the state records. Schulz received \$562,000, including \$112,000 as a researcher and consultant to AstraZeneca.

Olson said his AstraZeneca money went straight to the U but did support his salary. Markingson's full participation in the yearlong study meant up to \$15,000 for the university.

The amounts aren't unusual, according to the payment records collected by the Minnesota Board of Pharmacy. The records, which were updated this month to include 2007 figures, show 167 Minnesota doctors who have received \$100,000 or more since 2002. One in

four psychiatrists has received funding from pharmaceutical companies, averaging about \$50,000 over the six years.

Greater awareness of drug company payments has prompted tighter rules among some Minnesota health care organizations. The Mayo Clinic prohibits its doctors from being paid by drug companies to serve on their speaker's bureaus. Doctors in speaker's bureaus give lectures to other doctors about the company's medications.

The St. Mary's clinic system in Duluth recently banned pens, mugs or other freebies bearing drug company logos.

There have been fewer steps to restrict drug company funding of research, though most medical journals long ago required doctors to disclose the funding source of any research results they publish. Some health officials are now questioning the drug companies' use of "ghostwriters" to revise articles about research results to promote the drugs they sell.

Many universities view industry-sponsored research as a necessity amid tightening state and federal science budgets. Drug company funding makes up less than 7 percent of the psychiatry department budget at the University of Minnesota, but Schulz said it is needed as the U tries to move up the list of top-funded U.S. research institutions.

Since Olson was recruited in 2001 to boost the university's expertise in schizophrenia, he has led the U's efforts in three drug trials funded by AstraZeneca. He also took part in the federally funded "CATIE" trial, which suggested that older antipsychotic drugs were as effective as AstraZeneca's Seroquel and other newer drugs.

A growing body of research suggests that drug company money has an influence on study outcomes. One analysis found that industry-funded research was four to five times more likely to produce positive outcomes for a paying company's drug than federally funded research. A report last year found that drug company-funded studies of cholesterol medications were much more likely to produce results that favored their own drugs as well.

The CAFE results didn't show that AstraZeneca's Seroquel offered much benefit over two competitors — Zyprexa and Risperdal. Patients gained control over schizophrenic symptoms and tended to stop taking the medications at the same rate, regardless of which drug they took. The level of unhealthy weight gain was comparable, too, albeit slightly higher among the Zyprexa patients.

Weiss sued AstraZeneca as well, though the company also was dismissed from the lawsuit. Her attorneys argued that AstraZeneca's goal with the CAFE study was to gain a marketing edge and that the company used selective information from the study to promote Seroquel.

The attorneys cited internal documents, which have been sealed under court order, in which AstraZeneca discussed its use of ghostwriters and strategies to present CAFE results in a way that "sells" Seroquel.

AstraZeneca declined to discuss documents from the case, but brand corporate affairs manager Abigail Baron said the company's financial arrangements with doctors are necessary to improve health through drug discovery.

"That mission cannot be fulfilled," she said, "without close partnership with those on the front lines of patient care and ... research."