Kevin Reynolds official testimony submitted to the U.S. Senate Finance Committee

I, Kevin Reynolds stand before this committee on behalf of my mother Lillian Kaulbach and patients across the country who have been harmed by physician owned distributors (PODs). My testimony today describes my family's involvement with PODs, specifically a POD called Apex Medical Technologies LLC that was owned partly by Dr. Aria Sabit.

Based on my mother's experience with a POD, I believe that PODs are a serious threat to patient health and must be stopped immediately.

PODs pose a conflict of interest with the oath that doctors take, which states that they must "do no harm." Beyond that oath, there is an unspoken trust and belief in our healthcare system that doctors make decisions based on the patient's best interest. When doctors recommend surgery, patients put trust in their judgement.

My mother's medical problems started in 2002, when she called to tell me that she was having a hard time taking care of her paralyzed mother and her brother who recently had half of his skull removed after an accident. I dropped everything to go help my mom.

With my help, my mother continued to take care of her mother and brother for several years. During that time, she had several major surgeries due to conditions brought on by the physical and mental stress of taking care of her family.

After seven surgeries, my mother still suffered from severe and persistent back pain. She turned to Dr. Sabit for help in the fall of 2010.

I went with my mother when she met with Dr. Sabit in his office. Our meeting with him was very brief. It lasted no more than three to five minutes, and Dr. Sabit did not perform any physical examination of my mother. Nonetheless, at the end of the meeting, Dr. Sabit recommended that she have spinal fusion surgery.

My mother and I trusted Dr. Sabit's judgement and decided that she should have the spinal fusion surgery. At the time when we met with Dr. Sabit, we had no indication that he had an ownership interest in any of the products that might be used in the surgery.

Dr. Sabit performed surgery on my mother in October 2010. My mother and I signed consent forms that authorized Level 1 spinal fusion. However, Dr. Sabit performed Level 4 surgery on his own without asking the family or my mother for consent.

After surgery, my mother developed 5 or 6 different infections. The hospital staff told me that they could do no more. They asked me to pull the plug not once, but twice. I said no.

Miraculously, my mother showed some improvement. But she was never able to walk again. Instead, she became bedridden and was sent to a nursing home to battle these infections, taking up to 25 pills a day.

On May 31, 2011, my mother passed away from complications related to Dr. Sabit's spinal fusion surgery. She was 68 years old.

It was only after my mother died that I learned about Dr. Sabit's involvement with Apex Medical Technologies LLC, a company that manufactures screws and rods that were used in my mother's surgery. A single screw used in this type of surgery costs around \$100 to make and sells for \$1,000.

It has been reported that Dr. Sabit had a 20 percent stake in Apex. It has also been reported that from May 2010 to August 2012, Dr. Sabit's share of profit in Apex was \$330,000.

Simply put, I believe that Dr. Sabit had a clear financial incentive to use more screws and rods in my mother's back surgery. And I believe that this financial incentive played a role in his decision to perform more complex surgery on her that was not medically necessary.

Some people have asked if I would do anything differently if I had known that Dr. Sabit had an ownership interest in the products he planned to use in my mother's surgery. Looking back, I believe that the answer is "yes." Knowing that information, and understanding the conflict of interest, we would have sought a second opinion before authorizing any surgery.

Of course, we weren't given that opportunity because we didn't know that Dr. Sabit was involved with a POD.

Since my mother's death, I have tried to tell her story. I've spoken with local and national news organizations, have testified in Dr. Sabit's criminal proceedings, and it's my privilege to appear before the Senate Finance Committee today.

But I know that even if Dr. Sabit goes to prison, patients will not be protected from the same dangers that claimed my mother's life. There are still other doctors who participate in PODs and have the same financial incentives that Dr. Sabit had to perform unnecessary and dangerous surgery.

On behalf of myself and my mother, Lillian Kaulbach, I ask the Committee to do everything in its power to stop these doctors. Please do whatever is necessary to ensure that doctors make decisions based on what is best for the patient, not the doctor's wallet.

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U.S.

Surgeons Eyed Over Deals With Medical-Device Makers

Justice Department Investigation Shines Light on Federal Authorities' Broader Scrutiny of Physician-Owned Distributorships

By JOHN CARREYROU

July 25, 2013 11:01 p.m. ET

pro badge

Ten months after an Afghan-born surgeon named Aria Sabit arrived in Ventura, Calif., local hospital staffers noticed he suddenly developed a preference for an obscure brand of spinal implants for many of his surgeries. Soon his volume of operations increased, with sometimes-tragic results.

By the time he moved on less than a year later in late 2010, he had become embroiled in investigations by the California medical board and the Food and Drug Administration and more than two dozen medical malpractice lawsuits, including 12 involving surgeries he did with the new implants.

Now, the Department of Justice is investigating Dr. Sabit because it has emerged that he had an ownership interest in the company that distributed, and profited from, the surgical devices he switched to, people familiar with the matter say.

Federal prosecutors' scrutiny of Dr. Sabit is part of a broader civil investigation into a network of physician-owned spinal-implant distributorships operated by two former medical-device company employees, the people with knowledge of the matter say. This



Dr. Aria Sabit, a spinal surgeon, testifying in a deposition last year. GLICKMAN & GLICKMAN

network, which was run out of Utah and comprised at least 11 physician-owned distributorships in six states, generated tens of millions of dollars in profits for its investors over six years.

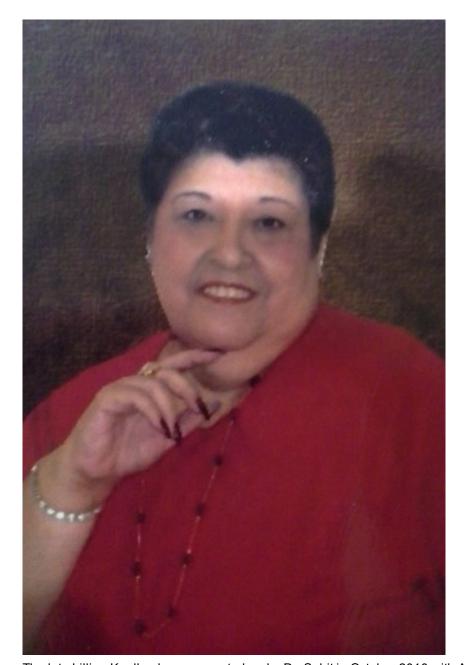
Physician-owned distributorships, or PODs, have

proliferated in medicine. Distributorships, whether owned by physicians or not, act as intermediaries between medical-device makers and hospitals: In exchange for marketing and stocking devices, the distributors get a cut of each sale. When surgeons own the distributorship, that commission goes into their pockets. And since surgeons often dictate to their hospitals which devices to buy, they can effectively steer business to themselves.

Depending on how they are set up, such entities can be legal. But in March, the Department of Health and Human Services' Office of Inspector General issued a special fraud alert about PODs, warning that they "pose dangers to patient safety" by inducing surgeons to do more procedures than necessary and to favor devices they profit from over more "clinically appropriate" ones.

In Dr. Sabit's case, the Justice Department has been looking into whether his financial interest in the implants caused him to over-operate or contributed to a spate of alleged patient complications. Twenty-eight former patients or their families have sued Dr. Sabit in Ventura Superior Court, alleging negligent acts ranging from misplacing implants in their spines to performing surgeries that were unnecessarily extensive. Dr. Sabit has settled 11 of the suits, one has been dismissed and 16 are still pending against him.

Through his attorneys, Dr. Sabit, who is now practicing medicine in Michigan, declined to comment, citing the malpractice lawsuits and California's medical privacy laws. He has denied the suits' allegations in court filings and, in a deposition, blamed a surgeon who recruited him to Ventura for encouraging patients to sue him. Dr. Sabit has sued



that surgeon and the Ventura hospital for

The late Lillian Kaulback was operated on by Dr. Sabit in October 2010 with Apex implants. KEVIN REYNOLDS

wrongful termination.

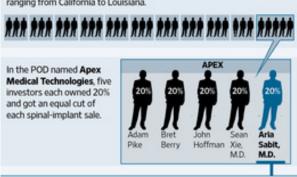
In his malpractice depositions, Dr. Sabit has alternately denied receiving any monetary benefit from the implants he used in his surgeries or said he didn't know whether he did.

However, a person with knowledge of the matter says Dr. Sabit owned one-fifth of a spinal-implant distributor called Apex Medical Technologies LLC from May 2010 to August 2012. Over that period, which includes eight months of his tenure in Ventura, he received profit distributions from Apex that averaged about \$12,000 per month, this person says.

Dr. Sabit, 39, was born in Kabul, Afghanistan, but his family fled the country in 1979

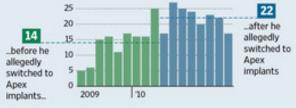
In the Network Physician-owned distributorships, or PODs, enable surgeons to profit from their use of medical devices. Typically, the identities of the physician owners aren't disclosed to the public. The Reliance network comprised a parent company that manufactured devices and 11 sister PODs that sold them. Parent company Reliance Medical Systems was formed by Adam Pike and Bret Berry. It made spinal implants.

Pike and Berry also formed 11 PODs, each with a different group of surgeon investors. The surgeons were spread out across six states, ranging from California to Louisiana.



Two of these investors were surgeons, including **Dr. Aria Sabit.**Since Dr. Sabit dictated to his hospital in Ventura which implants to buy for his use, he was allegedly steering business to himself.

Average number of spine procedures Dr. Sabit performed at Community Memorial Hospital in Ventura, Calif. per month...



Notes: Dr. Sabit left CMH in December 2010, so that month is not included in the per-month count. Xie and Hoffman didn't respond to attempts to reach them. In a deposition, Sabit alternately denied a financial tie to Appar or said he didn't know whether he had one.

Source: Community Memorial Hospital The Wall Street Journal

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during the Soviet invasion. In a deposition, he said they lived in a tent in Pakistan for four years until they emigrated to the U.S.

The family settled in Arlington, Va. Dr. Sabit's father, Abdul Jabbar Sabit, got a job as a reporter for Voice of America. He returned to Afghanistan after the fall of the Taliban and served as Afghanistan's attorney general from 2006 to 2008.

Dr. Sabit attended college and medical school at Virginia Commonwealth University and did his neurosurgery residency at the University of Medicine and Dentistry of New Jersey. He was recruited to Ventura by Moustapha Abou-Samra, a Syrian-born neurosurgeon who had practiced in the middle-class community north of Los Angeles for more than three decades.

Dr. Sabit raised eyebrows at Ventura's Community Memorial Hospital soon after he arrived in June 2009. An avid weight lifter, he said in one of his malpractice depositions that he used supplements such as creatine to build muscle mass. People who worked with him say he was physically intimidating. In the operating

room, he played loud heavy-metal music, several hospital nurses have testified.

At first, Dr. Abou-Samra portrayed his recruit as a young star on the cutting edge of neurosurgery who could perform sophisticated spinal procedures CMH had previously been forced to refer out to academic medical centers, several Ventura doctors say. Dr. Abou-Samra didn't return

calls for comment. A spokesman for CMH declined to comment for this article.

Though he was fresh from his residency, Dr. Sabit said in a deposition that he quickly became one of the hospital's busiest surgeons and was billing four times as much as Dr. Abou-Samra within a year. He said this created tensions with Dr. Abou-Samra. During 18 months at CMH, Dr. Sabit performed 371 procedures, including 306 spine operations, according to a list of his cases the hospital provided in the malpractice litigation.

Dr. Sabit prided himself on working fast, according to Joan Kruse, a CMH nurse deposed in the malpractice litigation. "He would grab instruments. He'd shove them into the wound," she testified. "I've never seen any neurosurgeon be that rough and brutal with" tissue "that close to the spinal cord," she said.

In one of his depositions, Dr. Sabit said he found Ms. Kruse to be "very disagreeable" and had asked that she be barred from his surgeries.

Dr. Sabit used a variety of spinal-implant brands during his first 10 months in Ventura, but he switched to Apex in April 2010, according to Marilyn Harris, CMH's director of surgical services. In her deposition in the malpractice litigation, Ms. Harris said the switch prompted speculation at the hospital that Dr. Sabit had joined a POD and was profiting from his use of Apex implants.

Dr. Sabit denied to Ms. Harris that this was the case, and later testified he couldn't recall when he began using Apex products. Ms. Harris testified that he showed up in her office unannounced and told her: "I don't even know what a POD is. I'm not part of a POD." Ms. Harris said "he was in a heightened state of anxiety" and "very emphatic."

However, a person with knowledge of the matter says that Apex was in fact a POD and that Dr. Sabit purchased a one-fifth stake in it in May 2010, after a short trial period.

Apex was created by two men, Adam Pike and Bret Berry. Following a model they replicated at least 11 times across six states, Messrs. Pike and Berry recruited Dr. Sabit and a neurosurgeon in Los Angeles to become partners with them in Apex. Each surgeon bought a 20% interest in the company, with the remaining 60% going to Messrs. Pike and Berry and one of their business associates.

The two men are veterans of the medical-device industry who partnered up to create their own spinal-implant company, Reliance Medical Systems. From offices in Bountiful, Utah, Reliance contracts with machine shops to manufacture replicas of bigger companies' products that it sells under its own brand. The practice is legal under a streamlined FDA approval process for medical devices deemed "substantially equivalent" to ones already on the market.

To get their products adopted, Messrs. Pike and Berry created a series of distributorships similar to Apex and sold ownership stakes to groups of surgeons across the country, according to a person familiar with the operation. Each surgeon received a monthly profit distribution, this person said. The more Reliance implants the surgeons put in patients' backs, the more business their distributorship did and the more they earned.

Under California's anti-kickback statute, it is illegal to pay doctors to induce patient referrals, or for doctors to accept such payments. The practice is also illegal under federal law if the patients are insured by health programs such as Medicare. According to the people familiar with its civil probe, the Justice Department is examining whether the distributorships Messrs. Pike and Berry created were effectively kickback mechanisms to induce surgeons to use Reliance implants.

The answer to that question hinges in part on whether the amount Dr. Sabit and the other surgeons paid for their distributorship stakes is too small to be considered a real investment, given the size of their returns, which in some cases reached \$50,000 a month.

Federal prosecutors are looking into whether Dr. Sabit's financial interest in Apex made him more prone to operate or to do bigger and riskier surgeries than necessary, the people familiar with the matter say.

The printout of Dr. Sabit's surgeries at CMH shows that, before allegedly switching to Apex, he averaged 14 spine procedures a month and spine surgeries accounted for 76% of his operations. After he allegedly switched to Apex, he averaged 22 spine procedures a month and their share of his case load rose to 87%.

In a court filing, Dr. Sabit has pointed to deposition testimony from CMH Chief Executive Officer Gary Wilde, in which Mr. Wilde stated, "we believed that the vast majority of cases Dr. Sabit did were appropriate."

It is unclear how many patients Dr. Sabit used Apex implants on. Of the 28 patients who sued, he implanted Apex hardware in 12 of them, according to the malpractice depositions and people familiar with the matter. None of those suits allege that the Apex implants were defective.

A spokesperson for Reliance says the fact that Dr. Sabit didn't use Apex on more than half of the plaintiffs shows that there is no causal relationship between his use of Apex and the suits. "It is wholly inaccurate to assume that these claims are a result of the use

of Apex products. To the best of our knowledge, there have never been any allegations by patients or doctors about faulty Apex products," the spokesperson said.

One of the patients Dr. Sabit operated on using Apex was Guanda Dusette, a 72-year-old retired nurse. Jack Padour, Ms. Dusette's primary-care doctor, says he referred her to Dr. Sabit after she complained of persistent back pain. Dr. Sabit proposed removing part of two disks in her spine, a relatively routine procedure designed to take pressure off the nerve root, Dr. Padour says.

Dr. Sabit operated on Ms. Dusette on July 8, 2010. However, the surgery he performed turned out to be much more extensive: Using Apex implants, he fused together eight vertebral levels in her spine, Dr. Padour says.

After the surgery, Ms. Dusette was "in agonizing pain," according to Dr. Padour. The metal screws and rods Dr. Sabit had drilled into her spine began coming loose, and the rods pressed against the skin of her back from the inside, according to Dr. Padour and Ms. Dusette's attorney.

Ms. Dusette was re-operated on at Cedars-Sinai Medical Center in Los Angeles, where all the hardware Dr. Sabit implanted was taken out, Dr. Padour says. She subsequently sued both Dr. Sabit and CMH. She recently reached a confidential settlement with the hospital, but her case against Dr. Sabit is still pending. Dr. Sabit has denied her suit's allegations.

Outside the hospital, Dr. Sabit's surgical outcomes caught the attention of Gary Proffett, the medical director of a physician association called SeaView that coordinates patients' care on behalf of health plans. Of 75 SeaView patients operated on by Dr. Sabit over his 18-month tenure in Ventura, 28 developed major complications, including two who died, Dr. Proffett said in an interview. Dr. Proffett reported the SeaView complications and deaths to the California Medical Board.

Many of Dr. Sabit's post-surgical complications involved infections, according to depositions by several nurses and Cary Savitch, an infectious diseases doctor at CMH.

Dr. Sabit has disputed this. In a court filing, he said CMH's infections control nurse "performed an exhaustive review of my infection rate" and concluded that it "was normal and acceptable."

One alleged victim of infection was Lillian Kaulback, an overweight woman in her late 60s with a number of health issues, ranging from diabetes to a history of ankle, shoulder

and knee surgeries. Dr. Sabit operated on her on Oct. 7, 2010, using Apex implants to fuse three vertebral levels in her spine, according to several people familiar with her case.

A person close to Ms. Kaulback says she was mobile and active before her surgery, playing bingo, attending family functions and going to a local club to watch couples dance. After the surgery, she never walked again and was in and out of the intensive care unit, this person says.

Dr. Savitch, who treated Ms. Kaulback after her surgery, recalled in his deposition that she had a big wound on her back that "was open" and "dripping pus" and had "six different bugs growing from" it.

To his astonishment, Dr. Sabit closed the infected wound and didn't document it in Ms. Kaulback's medical chart, Dr. Savitch testified. "Whenever you have an infected wound, you need it to drain...The last thing you do is close it," he said.

The wound opened back up the following day, according to Dr. Savitch's deposition. The person close to Ms. Kaulback says she was eventually transferred to a nursing home, where she spent six months in acute pain. She died there on May 31, 2011.

Ms. Kaulback's son has filed a wrongful-death suit against Dr. Sabit and CMH. The case is pending. Dr. Sabit and CMH have denied the suit's allegations.

In their depositions, Ms. Kruse and other nurses testified that Dr. Sabit was cavalier about keeping the operating field sterile and would sometimes contaminate it by not scrubbing in properly or by letting his hair dangle over an open wound.

The Reliance spokesperson said, "There is absolutely no connection between allegations of infection and Reliance's products or its sterilization procedures."

When CMH confronted him about alleged post-surgical infections among his patients, Dr. Sabit blamed one of the hospital's two operating rooms, which he argued in a letter wasn't kept sufficiently clean and sterile.

On Dec. 3, 2010, CMH suspended Dr. Sabit. Mr. Wilde, the CEO, handed him a letter stating that the hospital had decided "immediate action must be taken to protect the life or well-being of patients." The letter said the suspension was based in part on Dr. Sabit's alleged negligent treatment of two unidentified patients. In a subsequent court filing, a senior CMH staffer said one of those two patients died.

Dr. Sabit filed his own statement with the court in which he denied being negligent and said "there was no medical basis at all for the summary suspension." Instead, Dr. Sabit wrote, Dr. Abou-Samra and the hospital had conspired to suspend him so Dr. Abou-Samra could fire him and "avoid paying me the huge bonuses he would otherwise have to pay."

After Dr. Sabit threatened to sue the hospital, CMH reinstated him on Dec. 7, 2010. But Dr. Abou-Samra refused to let him rejoin his practice, so Dr. Sabit voluntarily resigned his hospital privileges on Dec. 21, 2010.

Following Dr. Sabit's departure, the California medical board launched an investigation, according to several CMH doctors and nurses interviewed by the board. A spokeswoman for the medical board declined to comment. The FDA also sent investigators to Ventura and audited Reliance's operations in Utah in May 2011. The results of the audit weren't made public. The Reliance spokesperson said: "Our products, which are certified by a third-party, meet the strict sterilization procedures and protocols established by the FDA."

Reliance discontinued its relationship with Dr. Sabit in August 2012 and stopped operating Apex as a POD, according to a person with knowledge of the company's operations. It has since bought out the ownership interests of surgeons in its other PODs but continues to pay many of them consulting fees, this person says.

Write to John Carreyrou at john.carreyrou@wsj.com

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Spinal fusion surgery spawns lawsuits, controversy

BY: Tom Kisken

POSTED: 4:49 PM, Feb 15, 2012 **UPDATED:** 6:04 PM, Feb 15, 2012

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Spinal fusion procedures that triggered many of the 17 lawsuits lodged against a former Ventura neurosurgeon regularly spawn litigation and are sometimes used on patients who have little chance of benefiting, according to surgeon specialists at USC and UCLA.

In fusions, metal rods and screws are used to anchor the spine in place while grafted bone or other material is employed to generate bone growth that fuses the vertebrae. The procedures are used to treat fractures, excessive curvature or other injuries, usually in the lower back.

The operations play a pivotal role in allegations facing Dr. Aria Sabit, a 36-year-old neurosurgeon who started operating at Community Memorial Hospital in Ventura in summer 2009, fresh out of a seven-year residency in New Jersey.

In the flood of lawsuits, patients allege he performed fusions in which the anchoring hardware was misplaced and screws pulled out of bone. They said they suffered from postoperative infections, that some of the surgeries were unnecessary or too much hardware was used.

Sabit was fired by Ventura County Neurosurgical Associates Medical Group after 17 months, in December 2010, according to a lawsuit filed by the physician against the group and then withdrawn. All of the lawsuits filed individually by patients against Sabit came after he stopped practicing in Ventura.

Now practicing in eastern Michigan, Sabit has refuted the allegations. Regulatory agencies reported no findings against him in Michigan, California or New Jersey. In his former lawsuit against the medical group, he disputed that his rates of complications and surgeries were high, blaming the group for generating untrue criticism against him.

Community Memorial officials said they initiated an investigation of Sabit by the California Medical Board. The hospital and a leader of the medical group — both targeted in some of the patient lawsuits — said they can't discuss the case but have defended themselves against accusations that they waited too long to take action against Sabit.

Tell Dr. Jeff Wang, a UCLA orthopedic surgeon who performs spinal fusion surgeries every week, about the 17 lawsuits and he offers an exclamation; the number surprises him. But fusion surgery is "very" litigious, and most doctors will face at least one lawsuit in their careers, he said.

"I think people have certain expectations," he said of patients with long histories of lower back pain. "The results can be mixed, and it's not necessarily the fault of the surgeon or the fault of the patients. We just don't have all the answers when it comes to nerves in the spine."

In the procedures, as many as a dozen vertebrae are fused together by bone. Pedicle screws, plates, small titanium or carbon fiber cages and other hardware are used to stabilize the spine in place until the graft takes hold.

The procedures are often used for fractured vertebrae or damage caused by scoliosis or tumors. But sometimes the procedures are used for patients with symptoms that show they are not likely to benefit from fusion, said Dr. Patrick Hsieh, a neurosurgeon at USC.

Elderly people who suffer from advanced conditions like heart problems, diabetes or some bone diseases like osteoporosis often are not the best candidates, Hsieh said.

Dr. Richard Deyo is an Oregon Health and Science University internist and researcher who studies back pain. He cited four studies from Europe that suggest patients who suffer from lower back pain because of worn-out disks in their spine but have no underlying spinal problems often see no more benefit from fusion than from nonsurgical care.

"And yet this is the fastest-growing reason for doing spinal fusions," he said, suggesting the procedures also push up the cost of care by generating more treatment that patients or insurers must cover.

"The U.S. does five times more spine surgery than the United Kingdom," he said. "We do twice as much spine surgery as other developing countries. There's no evidence that we're having better outcomes."

Hsieh said patients who suffer bone softening may not be good candidates for fusion.

Wang said the condition increases risk but said fusion may, in certain situations, still be appropriate.

"There are gray areas where you think it may be helpful or not helpful," said Dr. John Regan, a spine surgeon in Beverly Hills. "There are some physicians who overreach."

Sabit faces lawsuits filled with allegations that still must be proved in court. But if the cases reach trial, with one case set for an April start, spinal fusion could play a key role. His former patients allege he performed too many surgeries, relied on hardware that included rods, screws and interbody cages, and sometimes misused that equipment.

"He didn't know what he was doing," said Woodland Hills lawyer Steven Goldberg. He represents an Oxnard woman who underwent fusion surgery, only to have the screws pull away from her bone. "When I met her, she was totally bent over like a paper clip."

Sabit's lawyer, Louis "Duke" DeHaas, branded the allegations of inappropriate procedures and faulty technique as common in malpractice litigation.

"That's what they allege in these lawsuits," he said. "It doesn't mean it's meritorious. You can allege anything you want. That's why we have trials."

Sabit has denied all the allegations. Once a refugee of Afghanistan whose father returned to the country and served two years as its attorney general, Sabit attended Virginia Commonwealth University. He went through seven years of neurosurgery residency at the University of Medicine and Dentistry of New Jersey, in Newark, training at The University Hospital. In his final year, he served as chief resident.

"He successfully completed the residency," said Dr. Charles Prestigiacomo, who leads the neurosurgery residency program. "He did a fine job."

After finishing his residency in July 2009, he began operating at Community Memorial in Ventura, partnering with a highly regarded neurosurgeon, Dr. Moustapha Abou-Samra. In court papers, Sabit said he started to do some of the most difficult operations at the hospital, earning a reputation as a "go-to physician."

"He was introduced as the next generation of neurosurgery," said Dr. Jack Padour, a Ventura internist who has two patients who filed lawsuits against Sabit. "We thought, 'Great, we need a guy like that.' "

Complaints against the doctor involve infections after surgery, screws or rods that were improperly placed on patients and procedures that resulted in extreme pain and had to be redone.

Olivia Sawyer, 53, of Santa Paula said a doctor at USC took out everything Sabit put into her because the rods used for her spine were crooked. She tried to file a lawsuit but was told the one-year statute of limitations had passed.

Charles Shinn, 46, of Ventura complained in court documents that Sabit told him he was going to do a minimally invasive procedure and then, without informing him, chose a much more involved procedure that included an interbody cage placed on his spine.

Guanda Dusette, 71, of Oxnard said she paid an online service \$15 to research Sabit before choosing him for a spinal fusion. She alleged the screws pulled away from the bone after surgery, contributing to nonstop pain and leading to corrective surgery at Cedars Sinai Medical Center.

"What happened to me shouldn't happen to people," Dusette said.

But sometimes doctors can't prevent screws from loosening in the bone, said Wang of UCLA, adding that the problems can be caused by poor bone quality or a graft that failed to fully fuse the vertebrae."Whenever you're putting the hardware in, there's always a certain risk," he said. "Even in the most skilled hands, the anatomy can cause the screws to be misplaced."

Surgeons fresh out of residency face a learning curve, said Hsieh, but a seven-year residency for neurosurgery means they should be ready to handle most fusions.

"Experience matters even if you're well trained," said Deyo, the researcher. "It's always true that the more you do, the more expert you become."

Hsieh said fusion surgery problems usually stem from the planning — choosing the right patients and figuring what strategy will bring the best result.

"As surgeons, we are experts, but who we operate on and who we make better is not based on just how good we are. It's also based on if we pick an appropriate patient," he said.

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Surgeon salesmen? Doctors profit from devices they put in patients

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(CBS News) By the summer of 2010, 68-year-old Lillian Kaulback had developed severe back pain. She was referred to Dr. Aria Sabit, a spine surgeon in Ventura, Calif.

Her son Kevin Reynolds, who was at the appointment with her, says a few things struck him as strange from the start. There was no secretary or medical assistant there to greet them -- just Sabit. There was no physical exam, and Reynolds says Sabit told his mother she needed surgery within three to five minutes of meeting her.

Patients like Kaulback have a higher risk of complications -- she was 68, overweight, and diabetic. Still, Sabit performed a three-level spine fusion, screwing together four of her vertebrae. Reynolds says within days, she developed a life-threatening infection. "The independent team asked me not once, but twice to pull the plug on her," he told "CBS This Morning." "I said 'no'."

Lillian Kaulback never walked again. Seven months after the surgery, in May of 2011, she passed away.

Reynolds is now suing Sabit for wrongful death. One of his biggest questions centers on the screws and rods used to fuse the spine, which came from a company called Apex Medical Technologies LLC. Apex had no public phone number, website, or listing of its owners. "CBS This Morning" has learned one of its owners was Sabit himself, with a 20 percent stake. From May of 2010 to August of 2012, his share of the profit was about \$330,000.

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Reynolds claims the financial incentive caused Sabit to do a riskier procedure than necessary, so he could put in more hardware. A single screw used in spine fusion surgery can cost \$100 to make, and can sell for \$1,000. "I don't think he would've worked on as many levels or possibly did that type of invasive surgery," Reynolds told "CBS This Morning." He says Sabit never mentioned his ownership stake in Apex.

Court records show Kaulback's case is one of 28 brought against Sabit for just 17 months of work at Ventura's Community Memorial Hospital. At least 10 of the suits involve Apex implants. Legal filings show in the seven months before Sabit became an owner of the company, he did 115 spine surgeries. In the seven months after, he did 154, a 34 percent increase. (Seven full months was the length of time from when Sabit began using the implants to when he left the hospital in December of 2010.)

Sabit chose not to give "CBS This Morning" an interview for this story, citing pending litigation. But in a deposition, he claimed he simply had more cases as he became more established. "As time went on I got more and more referrals," he said. "By June of 2010, the wait time to have surgery done by me was probably around two-and-a-half to three months."

Physician-owned companies, also known as physician-owned distributorships or P.O.D.s, have been around for a little over a decade, but already supply an estimated one-sixth of spinal implants nationwide. Most simply serve as middlemen, buying implants wholesale and selling them to hospitals, but some also design and manufacture their own products. In addition to spinal implants, they currently supply hip, knee, cardiac, and other devices.

Doctors are not required to disclose their ownership in these companies, so it's very difficult to get information about them. Often patients -- and even hospitals -- don't know their physicians are involved. But today, the Inspector General of the Department of Health and Human Services released a long awaited study on them.

The report found that in fiscal year 2012, hospitals served by physician-owned companies averaged 28 percent more spine surgeries. Their rate of spine fusions jumped 21 percent after they began purchasing from these companies (that compares to a 9 percent increase for hospitals overall, during the same period). The report also found that surgeries involving physician-owned companies used 13 percent fewer devices.

Drs. Scott Lederhaus and Charles Rosen are on the board of the Association for Medical Ethics. Both spine surgeons, they say they've seen many patients harmed by physician-owned companies, due to the strong financial incentive to perform unnecessary procedures. "The guys that are being egregious could make, just from putting in the implants ... perhaps in excess of a half a million dollars each, per year," Lederhaus told "CBS This Morning."

"Doctors are not supposed to be salesmen," Rosen added.

Lederhaus and Rosen say physician-owned companies should be banned entirely. But Dr. John Steinmann says that would be a big mistake. His company is one of the few that discloses who its owners are. He says by cutting out the middle man and buying in bulk, he saves his hospital \$1 million a year. "I can perform exactly the same effective surgeries at a 40 percent lower rate," he told "CBS This Morning."

Steinmann says these arrangements can greatly lower healthcare costs, they just need to be regulated, to weed out the "bad apples." To help do so, he founded the American Association of Surgeon Distributors, which certifies what it believes are legal and ethical physician-owned companies. It requires doctors to disclose their ownership stakes and show cost savings, and it monitors the number of surgeries they are performing.



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But at least for now, it appears Steinmann is the exception rather than the rule. His association has fully certified just 14 of the more than 200 physician-owned companies operating across the country, according to the most recent estimates from the Centers for Medicare and Medicaid Services. And the inspector general report found that on average, physician-owned companies are charging no less than traditional suppliers. (You can read the association's response to the report here.)

The Justice Department is now investigating whether Sabit's ownership of Apex led him to do unnecessary procedures, according to the Office of Sen. Orrin Hatch, R-Utah, and the Finance Committee. No one from Apex would give "CBS This Morning" an interview, but a spokesman claimed none of the suits involving the company's implants allege unnecessary procedures. In fact, at least eight of the 10 plaintiffs we identified said they plan to argue just that, though no one has claimed the implants were defective.

In depositions, Sabit has denied the allegations. He charges that his former medical group, Ventura County Neurosurgical Associates, encouraged patients to sue, so it could fire him and avoid paying his bonuses. He claims he is owed millions and has sued for wrongful termination.

Sabit also blamed a non-sterile operating room for patient infections, and in a deposition, the chief executive officer of the hospital -- which is also being sued -defended him, saying "the vast majority of cases that Dr. Sabit did were appropriate." Sabit has settled at least nine of the 28 cases, and at least one has been dismissed. He is no longer a part-owner of Apex.

Last month, the California Medical Board accused Sabit of committing dishonest, corrupt, and negligent acts in his care of five patients. It charged that he performed unnecessary procedures on three of them, and repeatedly documented procedures that he did not perform. The board will decide whether to revoke his state license after a hearing. For the time being he is still practicing, in Lapeer, Mich.

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Podcast Feature



Image created by RRY Publications, LLC / Source: Kabul Airport/Wikipedia.org

"FROM KABUL WITH LOVE" — DR. SABIT'S **MISADVENTURES**

Walter Eisner • Tue, March 3rd, 2015

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Spine surgeon Aria Sabit, M.D., is sitting in a Michigan jail awaiting trial on federal healthcare fraud charges and trying to procure U.S. citizenship in an unlawful manner. He's sitting in jail because prosecutors convinced a federal magistrate that Sabit would flee the country in a scheme worthy of an Ian Fleming novel.

The federal government says Aria surrendered his medical license in California, effective in 2014, and moved to Michigan, where he was licensed to practice medicine in March 2011. There he opened the Southfield-based Michigan Brain & Spine Physicians Group and began performing spine surgeries.

Or so he claimed. According to a federal indictment, Sabit performed lumbar fusion surgery on a number of patients, but didn't actually install any hardware. Then he allegedly committed the worst sin—billing Medicare for work that wasn't done.



Aria Sabit, M.D. / Source: youtube.com

The U.S. Department of Justice (DOJ) charged him with false claims. After a detention hearing on December 4, 2014, the magistrate ordered Sabit held in jail. Prosecutors told the judge they fear he is a flight risk and would try to return to his native Afghanistan to start a hospital and drill for oil. They said he is a member of a politically prominent family.

After his detention, a federal grand jury indicted him on 18 counts of fraud and 1 count of "unlawful procurement of naturalization" in a 20-page indictment. That happened on December 9, 2014.

Beginning in approximately 2011, and continuing through November 2014, Sabit, according to the indictment, convinced patients to undergo spinal fusion surgeries, "which were either medically unnecessary or never rendered and then billed public and private insurance programs for the fraudulent services."

According to the government's case against him, Sabit allegedly dictated surgical notes that he had performed various spine surgeries, which included laminectomies, discectomies or other procedures, with instrumentation but which he never actually conducted.

The government is claiming that Sabit's operative reports and treatment records allegedly contained false statements about the diagnosis for the patient, the procedure performed, and the instrumentation used in the procedure. Sabit would also order spinal injections and simultaneously schedule the patient for surgery, "thus not waiting a sufficient amount of time to lapse to ascertain if the non-invasive treatment was successful."

Sabit claimed he used Zimmer Holdings, Inc.'s Transfacet Screw System. But post-operative X-ray and MRI examinations by other spine surgeons revealed that no medical device had been placed in or around the patient's spine.

"Subsequently, after continuing pain, all patients received second opinions from other doctors stating that no such spinal fusion had been performed and there was no evidence of any screw, or any medical device in the spinal column of the patient," Special Agent Peter Hayes of the FBI wrote in a court filing.

In all, Sabit billed almost \$33 million and was paid more than \$1.8 million, according to the criminal complaint. He performed surgery on almost everyone who walked through his office, an unnamed employee told an FBI agent.

"He had swagger off the charts," said Tonocca Scott, one of his former patients said of the 40-year-old Sabit in a published interview. "His hair was pulled back. He could have been a guy in a James Bond movie. Why would I go to anybody else?"

Sabit in California—PODS, Lawsuits and Kickback Charges

This isn't the first time the Justice Department had dealings with Sabit or the first time *OTW* has reported on his activities.

Between 2009 and 2010, Sabit was the subject of more than two dozen medical malpractice lawsuits in California. Special Agent Hayes testified at Sabit's detention hearing in Michigan that Sabit performed over 200 spinal fusion surgeries in California from June 2009 to December 2010 and that the DOJ had filed a Civil Complaint against him in September 2014.

Hayes also said that DOJ presently has an ongoing criminal investigation of Sabit in California.

Anti-POD Poster Child

During Sabit's detention hearing prosecutors also told the judge that the DOJ's California investigation of Sabit was focused on his participation in a physician-owned-distributorship (POD), which owned a particular device—an Apex pedicle screw made by Reliance Medical.

After buying into the POD, Hayes said Sabit began to use the Apex in 90% of his surgeries, and earned over \$400,000. He added that Sabit had been subject to civil kickback charges in September 2014 based on California kickback allegations and that Federal California criminal kickback charges are likely coming.

A Flight Risk: From Dubai to Kabul to London

Accusations of unnecessary surgeries and false claims are not uncommon. But here is where Sabit is different and the story turns into an international thriller.

The government labeled Sabit a flight risk, noting that he was questioned in September in Atlanta while trying to fly to Dubai. There he allegedly told a customs officer that he owned a company involved in mining in Afghanistan. In his luggage, officers found a ruby and a 3.6-carat emerald, according to the complaint.

Dubai Informant

Special Agent Hayes testified that the FBI had information from an informant who was employed in Dubai, but had first met Sabit in Michigan in late 2013. The informant told the FBI that Sabit had asked him to help obtain a medical license in Dubai because he was considering practicing medicine there or in the United Arab Emirates.

The informant also told Hayes that Sabit went to Afghanistan in December 2013 to set up a hospital in Kabul. When the FBI searched Sabit's house they found plans dated October 2014, for Aria International Community Hospital in Kabul. They also found emails dated around the same time indicating he had invested \$300,000 to \$400,000 into the hospital with a profit hope of \$30 million.

London's Newcastle Upon Tyne

Hayes testified that Sabit traveled to London in November 2013, and based upon papers seized in the home

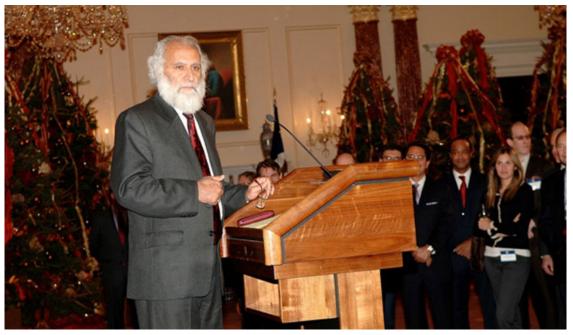
search, was in the process of applying for a position at a London area hospital: "Newcastle Upon Tyne", application dated November 11, 2013.

The application stated that Sabit was applying for the position of consultant spinal surgeon; "I am moving to the U.K., as most of my family resides in the U.K." Hayes testified, and Sabit's wife's subsequent testimony confirmed, that none of Sabit's family resides in the U.K.

Afghan Blue Bloods and Oil

The informant, according to Hayes, traveled to Afghanistan to meet Sabit and his relatives, and government officials—Sabit's father, who was the former Attorney General of Afghanistan; his uncle, the Speaker of the House, the Minister of Mines; Abdullah Abdullah, an individual then running for President of Afghanistan, who lost the final election, but who is now the Chief Executive Officer of Afghanistan.

The informant had an axe to grind. He claims that he had been "stiffed" out of money on a deal by Sabit.



Abdul Jabar Sabit / Source: Wikipedia.org

Sabit, according to Hayes, incorporated the American Mineral and Oil Company in August 2014, to extract natural resources in Afghanistan. Emails from Sabit to his business partner regarding their proposed venture, said that Sabit had secured the rights to survey and extract the 2 billion barrels of oil available for drilling in northern Afghanistan.

A Sabit August 4, 2014 email states:

"Through connections and talks with the Government, including the President and incoming Prime Minister, I am able to secure these and any other mineral rights for our companies, and ideally partner with an American company."

"The rights to the grounds and all mineral content are secured. I met with the Minister of Mining and Petroleum, as well as the President of the country. My first cousin is the Minister of Finance. My other cousin is the head of the Central Bank. My uncle is the Speaker of the Lower House. My father is a very influential politician. My point is that we have very significant pull in the Government."

Sabit's Defense

Sabit's wife, an RN, testified that she was willing to surrender her and her daughters' passports and offer the house as security. She also said that Sabit and his father are now estranged.

Dr. Khusraw Sabit is Sabit's younger brother, who lives in Montreal, Canada. He testified on December 8, 2014 that Afghanistan is not safe for Sabit because their father, who has not been speaking to Sabit, also has made many enemies and was kidnaped and released for ransom in 2011-2012.

The Money Flow

Hayes showed the court a flow chart showing some of Sabit's money movement of over \$2 million from Michigan Brain and Spine into a joint account that he had with his wife at PNC Bank, and then over \$1.7 million was transferred out to six accounts: two held by his wife, and two each held in the name of each of his then-two children, 8 and 6 years-old, respectively.

A home search of Sabit's house revealed a proposed complaint for divorce, seeking sole custody of the children. The home search also showed that Sabit had been living in the basement.

Hayes further testified that the informant said that Sabit had explained that the only reason he was still in the U.S. was because he had young children here, but that if he did leave, the U.S. "would never get him back."

Sabit's "Suspect" Character

After listening to the evidence, the detention hearing judge found that Sabit's character is "suspect given his past conduct of leaving his medical license behind in California and not including that history in his curriculum vita in applying for future medical positions, and his transfer of a significant amount of funds to his wife and children as the investigations unfolded."

The judge noted that prosecutors offered proof that Sabit "has transferred significant sums of money to two of his young children (allegedly around \$1,000,000 each), that he claimed to have spent \$300,000 on the Kabul hospital project already, that the government has already frozen \$750,000 in one of his bank accounts, and that it has not been able to identify accounts into which other transfers may have been made."

The judge ruled that Sabit would remain imprisoned until his trial.

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Supplemental Statement for the Record, Submitted by Kevin Reynolds in Sentencing Proceedings for Dr. Aria Sabit in the U.S. District Court for the Eastern District of Michigan

To the Honorable Judge Paul D. Borman 8/17/15

I (Kevin Reynolds) am the son of victim in 2011 Lillian Kaulback. I'm writing to you about the Aria Sabit case.

The butcher Sabit operated on my mother in California she died of so many complications from surgery and the unbearable grief of never walking again at the hands of Sabit. She had to take 25-30 pills a day because of his Greed and infections.

I am one of the few that have had him admit and settle a case of a wrongful death lawsuit against the evil Aria Sabit. I've spoken out against him in the local Ventura County Star, The Wall Street Journal, The CBS morning news broadcast and also the California Medical Board. In the last month I've spoken to Federal prosecutors representing California and Michigan.

Please, please, on behalf of all the victims in California and Michigan. We beg you to hand down the maximum sentence against this MONSTER.

There are hundreds of people mutilated, scarred and or DEAD because of Aria Sabit. Please make sure he receives the maximum prison sentence "YOU" can hand down and that he never leaves!

On behalf of my mother and the tortured souls.

Thank you for the Justice and your time.

Kevin Reynolds