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DELICATE OPERATION

# How a Famed Hospital Invests In Device It Uses and Promotes

## *Cleveland Clinic Set Up Fund That Has Stock in Maker Of Heart-Surgery System*

By DAVID ARMSTRONG Staff Reporter of THE WALL STREET JOURNAL

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CLEVELAND -- Since 2001, more than 1,200 patients at the prestigious Cleveland Clinic have had an operation aimed at correcting atrial fibrillation, a form of heart fluttering.

Doctors commonly call it the "AtriCure procedure," after the maker of the equipment used in the surgery, a company called AtriCure Inc. In medical journals and at conferences, the Cleveland Clinic and its doctors have been leading advocates of the AtriCure procedure.

The Clinic's relationship with AtriCure, however, goes deeper. A venture-capital partnership that the Clinic helped found and invested in owns about 4.1% of AtriCure's stock, valued at about \$7 million. The Clinic's chief executive, heart surgeon Delos "Toby" Cosgrove, sat on AtriCure's board of directors until March. He also invested personally in the fund and was one of the general partners managing it until, according to a Clinic spokeswoman, he cut his ties to the fund at the end of October.

In addition, Dr. Cosgrove will be entitled to royalties for a medical device he developed that AtriCure plans to begin selling next year. Marc Gillinov, another Clinic surgeon who performs the AtriCure procedure, is a paid consultant to the company, as is another doctor who recently left the Clinic.

The Clinic didn't disclose these ties to AtriCure to the patients on whom it performed the AtriCure procedure. The venture fund the Clinic helped found has also invested in two other medical companies conducting clinical trials at the Clinic.

All this last spring came to the attention of the hospital's conflict-of-interests committee, where famed cardiologist Eric Topol and blood specialist Alan Lichtin were among those who questioned the ties to AtriCure, according to people familiar with the situation. Dr. Cosgrove last week told Dr. Topol he was losing his top post at the Clinic's medical school, a change that will take Dr. Topol off the conflict-of-interests committee and the Clinic board of governors. Dr. Topol also is an outspoken critic of Vioxx, the withdrawn Merck & Co. drug, and testified at a trial against Merck.

The Clinic ascribed Dr. Topol's loss of his medical-school position -- as provost and chief academic officer -- to an administrative reorganization. Asked whether it was related to his criticism of Vioxx or of the

Clinic's ties to AtriCure, the Clinic spokeswoman said no. Dr. Topol had a conflicts issue of his own last year when an investment fund to which he was a paid adviser bet against Merck's stock. He resigned that post.

The Cleveland Clinic's board of trustees, meeting Monday, is expected to discuss the change in Dr. Topol's status, which needs its approval. Meanwhile, at the behest of the conflicts committee, the Clinic this spring redid a consent form for atrial-fibrillation patients taking part in clinical trials, and it imposed a limit on the consulting fees doctors could earn.

The Cleveland Clinic is a huge and prominent establishment with 30,000 employees and \$3.8 billion in revenue last year. Besides its main 155-acre complex, it owns eight other hospitals in the area, two more in Florida and three hotels. Its cardiac center, routinely ranked No. 1 by U.S. News and World Report magazine, is building a new \$400 million complex in the city.

In an interview, Dr. Cosgrove said the Clinic favors the AtriCure procedure because it works and is safe, not because of any financial considerations. Clinic doctors and others have reported that nearly 90% of patients have normal heart rhythms six months after the procedure. Long-term data are sketchy.

The Food and Drug Administration has three times rejected AtriCure's application to have its system approved for cardiac use, most recently earlier this year. Doctors may legally do the procedure anyway because the equipment is approved for "soft tissue" surgery. Though that category doesn't include the heart, they may use it on the heart in what's known as "off-label" usage. AtriCure says that all current use of its equipment is off-label.

Four patients are known to have died shortly after having the AtriCure procedure, at hospitals other than Cleveland Clinic. AtriCure didn't notify the FDA -- which requires companies to tell it of any "adverse consequences" related to their products -- because it says it didn't believe its equipment was to blame. Dr. Cosgrove said he wasn't aware of the patient deaths.

As for the three FDA rejections of AtriCure applications for heart use, Dr. Cosgrove said much of the medicine practiced in the U.S. is off-label. "It's the nature of what we do and how we learn," he said. "The important thing is the candor by which you discuss results and failures."

A research ethicist, Adil Shamoo of the University of Maryland, says the Clinic shouldn't perform any research related to companies in which it invests. "The whole process of institutions having large-scale holdings in equities is corrupting the process," said Dr. Shamoo, a biochemist who edits a journal called *Accountability in Research*. "It sends the wrong message and could lead to serious harm to human subjects because it clouds your judgment." The U.S. Health and Human Services Department requires hospitals to consider the impact of financial ties on human research work and develop plans to manage, reduce or eliminate the conflicts. How they do so is left largely to them.

The Cleveland Clinic began looking for new ways to make money several years ago amid financial stress caused by managed-care programs, by cuts in Medicare reimbursements and later by stock-market losses in its endowment. Around the country, many doctors have reacted to pressures such as these by looking for business opportunities. Some have started specialty hospitals that target profitable patients. Others get extra compensation from labs and scanning centers for sending them patients, despite laws against fees for referral. It is so common for leading doctors to be compensated by industry that medical-journal editors say it can be hard to find disinterested parties to do peer reviews.

The Clinic first explored the idea of a venture-capital fund in 1998, "seeking to leverage its intellectual capital to generate returns for the institution," according to a recent memorandum seeking investors for a second venture fund. Dr. Cosgrove, then chairman of thoracic and cardiovascular surgery, was tapped to lead the effort.

He turned to Harry Rein, a friend who managed Canaan Partners, a Connecticut venture-capital fund in which Dr. Cosgrove was, and remains, an investor. The Clinic's full name is the Cleveland Clinic Foundation, and the fund took a name based on that: Foundation Medical Partners, or FMP. Dr. Cosgrove said in an interview that trustees approved his role at FMP, which is confirmed by the board chairman, Malachi Mixon. Dr. Cosgrove didn't become the Cleveland Clinic's CEO until last year.

At the fund's launch in 2001, the Clinic was its largest investor, supplying \$25 million of the \$61 million raised from investors, known as limited partners. The Clinic is entitled to 38% of its profits. Dr. Cosgrove also invested in the fund personally. He became one of a handful of general partners managing the fund.

FMP uses its clinic tie to suggest to prospective investors that it has an edge in spotting promising young companies. A document for a second FMP fund now being organized notes that the Clinic's "prominence, prestige, and sheer scale...prompt" many health-care entrepreneurs to seek to develop a relationship with the institution.

In 2002, FMP invested \$3 million in AtriCure, then a private Cincinnati start-up that was one of several companies, including Guidant Corp. and Medtronic Inc., making surgical devices to treat atrial fibrillation.

An estimated 2.2 million Americans have this condition, which was once thought relatively benign but which the American Heart Association now blames for about 15% of strokes. Atrial fibrillation causes no symptoms in many people, but others get dizzy spells, nausea, chest pains and shortness of breath. Doctors usually start patients on drugs to control heart rhythm and on blood thinners to reduce the risk of stroke, though these drugs don't work for many patients.

AtriCure's system uses radiofrequency energy to destroy heart tissue near pulmonary veins that are believed to carry electrical impulses causing the irregular heart beat. The aim is to create scar tissue at the site that will block the impulses.

AtriCure makes a special clamp that doctors apply to heart tissue in the operation. It is wired to an AtriCure generator, which delivers the radio energy to create scar tissue. Then the clamp is removed. AtriCure says it has some 50% of the market for surgery to treat atrial fibrillation.

AtriCure has won frequent endorsements from the Cleveland Clinic and its surgeons. For instance, at an American Association for Thoracic Surgery meeting last year, Dr. Cosgrove took the pro side in a debate about whether atrial-fibrillation surgery should be done on patients having a heart-valve replacement. He mentioned only one company by name, AtriCure.

Not mentioned during the debate or in the disclosure section of the program guide was his seat on AtriCure's board or his investment ties to the company. A Clinic spokeswoman said his secretary mistakenly checked a box on a disclosure form indicating he had no conflict.

The Clinic's Drs. Cosgrove and Gillinov were among authors of a study published in the Journal of Thoracic and Cardiovascular Surgery of 513 AtriCure surgery patients at the Clinic in June. It found that 87% were free of atrial fibrillation after six months, declining to 72% after one year. The journal disclosed Dr. Gillinov's tie to AtriCure -- he's a paid consultant to it -- but not Dr. Cosgrove's. Dr. Cosgrove said it

was "an oversight on my part."

Dr. Gillinov and another surgeon then at the clinic, Patrick McCarthy, co-wrote a favorable review of AtriCure's technology in the *Annals of Thoracic Surgery* in 2002. The journal mentioned they'd been asked to become AtriCure consultants, which they later did. AtriCure granted each doctor options to buy 25,000 shares of its stock, it said in a June filing with the Securities and Exchange Commission.

Dr. Gillinov, through a clinic spokeswoman, said he declined the options offer. An attorney for AtriCure said Dr. Gillinov doesn't own AtriCure options now, but "if it was in the prospectus, it was true then." Dr. Gillinov is paid \$10,000 a year as an AtriCure consultant, said Eileen Sheil, the spokeswoman for the Clinic. She said he had been paid more, but the Clinic forced him this spring to reduce it to conform to its guidelines.

Dr. McCarthy, who confirmed his options grant, said he was a paid AtriCure consultant while at the Clinic and currently gets \$2,000 a month from the company. He said he continues to perform the atrial-fibrillation surgery with the AtriCure procedure, as well as with other companies' systems, in his current position as chief of cardiothoracic surgery at Northwestern Memorial Hospital in Chicago. He said he didn't need any convincing because he believes in the procedure.

### *Conflicts Committee*

Last winter the Cleveland Clinic's conflict-of-interest committee learned that the FMP venture fund was an investor in companies doing research at the Clinic, said committee chairman Guy Chisholm. He said the committee was informed by the hospital's Institutional Review Board, headed by Dr. Lichtin. It had been told of the investment by a doctor who ran across the ties to AtriCure while researching the AtriCure procedure.

The conflicts committee and review board also learned that the FMP fund had invested in two other companies conducting trials at the Clinic: Immunicon Corp. and CardioMems Inc. FMP has invested \$5 million in Immunicon, a Pennsylvania developer of cancer-screening products, and \$3 million in CardioMems, an Atlanta maker of heart devices. The Clinic also has a direct investment of \$2.75 million in Immunicon.

Some committee members worried that the Clinic's ties to AtriCure could color what patients were told when weighing treatment options. They also worried that their CEO's roles at AtriCure and the venture fund that invested in the company created a conflict, said someone familiar with the panel's discussions. At a minimum, the committee concluded, patients should be told of the Clinic's and doctors' financial ties, according to Dr. Chisholm, a Ph.D. researcher at the Clinic. He said many Clinic doctors and nurses conducting the research were unaware of the links.

Mr. Rein, Dr. Cosgrove's investing partner said there is a natural tension at the Clinic between those who believe "all of this is a bunch of people trying to take advantage of patients" and those who believe the entrepreneurial efforts are part of a "virtuous cycle" where the clinic and patients both benefit from medical advances.

The Institutional Review Board in February directed Clinic researchers conducting clinical trials of the three companies' products to put a "voluntary" hold on their work, said Ms. Sheil, the Clinic spokeswoman. The hold was lifted in May after the Clinic reworded consent forms. The new forms say the Clinic and some of its doctors have financial ties to AtriCure and the other companies and "the Clinic would probably benefit financially if the research results are favorable." The forms don't name the doctors or give any dollar amounts.

None of the patients undergoing the AtriCure surgery outside of clinical trials will see these disclosures, Ms. Sheil said. So far, 1,247 patients have had the AtriCure procedure at the Clinic, including 16 who are enrolled in current clinical trials, and Ms. Sheil said Clinic staff members have performed the procedure on 100 more patients in other hospitals. None of these patients saw the new consent form with added disclosure.

### *Fund's Profits*

The conflicts committee began to look into the role of Dr. Cosgrove at FMP and AtriCure, and some members wrote a detailed list of questions to submit to him, say people familiar with the matter. Not long afterward, Dr. Cosgrove stepped down from AtriCure's board and said he would give up his position as a general partner at FMP. Dr. Cosgrove said he wasn't prompted to vacate the posts by conflicts-committee pressure but by his wish to avoid the perception of a conflict. He said he had already been thinking about the issue and what he should do about it before the committee raised it.

Among the questions the panel posed was how much he earned as a general partner at FMP and how much he got of fund profits. According to internal Clinic documents, the fund's general partners were entitled to share an annual management fee of 2.75% of the money raised from investors, fees that total about \$1.7 million a year. There were three general partners.

The fund distributes 80% of its profits to limited partners. Of the other 20%, a 6-percentage-point slice goes to the Clinic and a 14-point chunk is divided among the general partners.

The fund's profits are known as "the carry." Mr. Rein said in an interview that Dr. Cosgrove was "compensated with carry," but didn't receive any of the management fees. Mr. Rein said the fund has made one distribution of profits and Dr. Cosgrove would have received a payment from that distribution. Later, however, Mr. Rein said that general partners hadn't received any of the profits distributed by the fund so far, that only limited partners had.

Dr. Cosgrove said he was required to invest in the fund by virtue of his role as a general partner. Mr. Rein said the three general partners at the time the fund was created, including Dr. Cosgrove, put in a total of 1% of the total raised, or about \$600,000. He said the fund lent them the money to invest.

Clinic spokeswoman Ms. Sheil initially said that Dr. Cosgrove told her, "I have not received one penny from FMP." Later, when told of Mr. Rein's description of the distribution, she said, "He hasn't received anything yet..., but when and if it gets to him, he will donate it to the Clinic." Ms. Sheil said that Dr. Cosgrove ceased having any role at FMP at the end of October.

Dr. Cosgrove said he never received any fund distributions and any future payments "will go the Clinic." He said he has no more financial interest in FMP -- "I gave it all up." He declined to say what had become of the money he personally invested.

### *Canaan Partners*

The second FMP venture fund that's now raising money says in a "private-placement" document that "with Dr. Cosgrove's decision to change his role" at FMP, the Clinic's chief of staff, Joseph Hahn, "was selected to join the firm as a partner." The document says he will spend one day a week on fund business. Mr. Rein said Dr. Hahn said won't be paid by the fund. The Clinic has committed to put \$20 million in this second fund, which is just beginning to invest.

Dr. Cosgrove confirmed he also has a financial interest in companies doing research at the Clinic through his personal investment in Canaan Partners, the venture fund Mr. Rein founded and ran for many years. Mr. Rein left Canaan in 2002 to work for FMP, later investing in it and becoming one of its general partners. Mr. Rein is also Cleveland Clinic trustee.

Canaan and FMP share a street address in Rowayton, Conn., and have invested in many of the same companies. Canaan owns 9% of Immunicon, according to that company's latest SEC filing, and also has invested in other companies with which the Clinic has done or is doing clinical trials. These investments aren't a concern, said Dr. Chisholm, the conflicts-committee chairman, because Dr. Cosgrove doesn't influence Canaan's investments.

Dr. Cosgrove also has developed a device for AtriCure, related to its procedure, which the company says it plans to begin marketing in the second half of next year. Dr. Cosgrove would receive royalties for this device, known as the Cosgrove Clip. Dr. Chisholm said he'd be surprised if the conflicts committee would want to intervene in that matter if it was in place before Dr. Cosgrove became the Clinic's CEO.

Prominent doctors and hospitals can be helpful to start-up medical companies in a number of ways. At AtriCure, these have included assistance in advancing a minimally invasive version of the atrial-fibrillation surgery, involving just two small chest incisions.

This procedure brings AtriCure more money than the more common method of using its device, open-heart surgery. Average Medicare reimbursement for the less-invasive procedure is around \$25,700, and AtriCure says it gets about \$7,000 of that from sales of disposable equipment. With open-heart surgery, it gets about \$2,500 in sales.

At a conference at the Cleveland Clinic last year, AtriCure Chief Executive David Drachman thanked the hospital and its doctors for helping persuade Medicare to approve the reimbursement rate for the minimally invasive version. In an interview later, he said the Clinic didn't directly lobby Medicare overseers, but helped boost the reimbursement argument by being "instrumental in advancing the whole field of surgical atrial-fibrillation treatment." He said surgical societies that include Clinic doctors among their leadership are directly involved with fighting for reimbursement.

### *Four Deaths*

In June, when AtriCure filed with the SEC to go public, its prospectus listed among risk factors that "serious complications, including death...have been encountered in connection" with its minimally invasive procedure. Mr. Drachman said there have been four deaths. One occurred at Sarasota Memorial Hospital last year and prompted a "temporary moratorium" on the procedure that's still in place on the procedure, said an official of the Florida hospital.

Another death was in Dallas. The doctor who did that operation was Michael Mack. He said the patient died three days afterward when a clot developed in his leg. Dr. Mack said the death wasn't due to any defect in the AtriCure equipment, but "I have to say it is related to the procedure. The point of fact is the guy had the procedure and three days later he had a complication from it."

While the death was "very disconcerting," Dr. Mack said, he believes the minimally invasive surgery is safe and has done it 40 times. He said he is taking part in a AtriCure-sponsored clinical trial and has no financial tie to the company. The Cleveland Clinic's relationship with AtriCure, Dr. Mack said, "is a funny position for the Clinic to be in: As much as you would like to stay unbiased or conflicted, if you do have a financial stake, you want the procedure to do well."

AtriCure's Mr. Drachman said the company heard about Sarasota and Dallas deaths months after they occurred, contacted the surgeons and determined the deaths were unrelated to any problem with its equipment. While not disclosing any deaths to the FDA, he noted that AtriCure did disclose two to the SEC. They were cases where the company had conversations with the surgeons "during the time the patients were dying." AtriCure didn't tell the SEC of the Sarasota or Dallas deaths because they were never "officially reported to the company," he said.

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