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BUSINESS

THE SELLING OF SCIENTIFIC PROMISES PROBLEMS ARISE AS LINE IS BLURRED BETWEEN BUSINESS, BIOMEDICINE

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They make strange business partners:

- Frank J. O'Donnell Jr. is protege to a leading figure in American medicine. He was one of the nation's youngest medical school department chairmen and, by most accounts, is one of its best eye surgeons.

- Jonnie R. Williams is a former car salesman with a string of bad debts. He is so good, an ex-employee said, he "could sell a snowball to an Eskimo."

A Massachusetts drug company the two organized is as unusual as the men. Investigators are trying to determine whether the scientist who devised the company's principal product distorted or delayed releasing results of research showing the drug is largely ineffective.

The company, Spectra Pharmaceutical Services Inc., has prompted internal investigations at both Harvard and Johns Hopkins universities, where most of the research was done. As a congressional subcommittee prepares for a hearing on whether the universities adequately supervised the work, the question being asked is: Were scientific standards trampled in a search for profits?

But Spectra is not O'Donnell and Williams' only business venture. Since the early 1980s, the two men have started a series of companies. The first is bankrupt. The second, Spectra, is target of a half dozen investigations. The latest also has attracted investigators who question the evidence its product works. Not one has made a sustained profit.

That has not deterred the partners. They have raised almost $20 million for the companies by arranging for sale of stock to the public. In the process, they have made themselves rich. Other investors have not fared as well.

Defenders of the two men say their efforts help speed new medical ideas into marketable products. And they say investors are warned of the risks before putting their money in. No one has accused either man of breaking the law.

But O'Donnell and Williams are a new breed of entrepreneur who operate at the borderline between American business and biomedical science. And the way they straddle that line is causing trouble for people on both sides.

Unlike traditional businessmen, they are not selling proven products. In some cases, it turns out they are not selling discoveries near ready to turn into products. More than anything else, what they are selling is scientific promises.

The problem for investors is that the two men seem to have found a way to sell promises that virtually assures they make money no matter what happens. The problem for the public is that those best equipped to appraise the promises -- the scientists whose research they commercialize -- are part of their ventures.

O'Donnell, 38, did not return phone calls in recent weeks. In an interview in New York recently, Williams, 33, defended his business practices and his partner's. "We invest in start-up situations," he said. "There's nothing special in that."

Records and interviews suggest otherwise. Today, the stocks of almost all the companies the two men have been involved in are under investigation by the federal Securities and Exchange Commission and several state securities divisions.

Investigators with the Massachusetts and Florida divisions raided a Florida brokerage house Wednesday that handled stock sales for the two men's most recent ventures. They reportedly were looking for evidence that laws requiring disclosure and registration have been violated.

When St. Louis University hired O'Donnell in the early 1980s, the committee that chose him thought they had found the best man for the job.

"The feeling was that O'Donnell was a brilliant young scientist who held promise for an outstanding career in academic medicine if he'd stayed," said medical school Dean William Stoneman.

But neither O'Donnell nor Williams has stayed anywhere long. And almost everywhere they have gone, trouble has followed.

LIVING ON THE BORDERLINE

O'Donnell and Williams met at Johns Hopkins University in Baltimore in the late 1970s.

Already, according to people who knew them, they were operating at the borderline between business and medicine, even when university policies and state regulations prohibited it.

O'Donnell was a medical resident under A. Edward Maumenee, who headed Johns Hopkins' Wilmer Eye Institute, is still an eminent eye specialist and later would be an O'Donnell business partner. The young doctor is described as tanned, handsome, equipped with a photographic memory and brilliant. He charmed his academic elder.

Williams was a short-lived graduate student at Hopkins' School of Advanced International Studies. His earnest good looks already had brought him considerable success. In the words of a local newspaper story, he was "one of the best salesmen ever to hit" his hometown of Fredericksburg, Va.

Williams had earned that reputation by selling more cars for the local Ford dealership and more homes for a local real estate office than any salesman before him.

By 22, he was running his own business, an optical shop called Colonial Opticians, and driving a gold Mercedes 450 SEL. A local court fined him for fitting contact lenses without a license.

Colonial Opticians seems to have been where O'Donnell and Williams first did business.

People who knew O'Donnell at the time said he regularly traveled to Fredericksburg to examine patients at the shop, in apparent violation of a Johns Hopkins policy against residents moonlighting. In his interview, Williams denied O'Donnell worked out of the shop, but acknowledged O'Donnell saw patients in Fredericksburg and referred some to Williams for glasses.

Whatever the arrangement between the two, it abruptly ended shortly before Christmas in 1980 when Williams disappeared, leaving behind tens of thousands of dollars of debts and countless unclaimed eyeglasses.

The Small Business Administration auctioned off the shop to collect on its $45,000 loan. James Anderson, an SBA official in Richmond, Va., said last week the auction did not cover the loan, which has yet to be paid.

A Colonial employee attending the auction reflected on his former boss. "Jonnie Williams could sell a snowball to an Eskimo," he is quoted as saying in a news story about the event. "But when it comes to backing up what he was selling, now that was another story."

In his interview, Williams refused to talk about what happened in Fredericksburg.

TURNING ACADEMIC CONTACTS INTO CASH

O'Donnell and Williams went in opposite directions after Johns Hopkins and the collapse of the optical shop. But within a few years they would join forces again in a business that tapped their university connections to turn ideas into money.

Williams came to the Boston area, where for a time he sold cars for Prestige Motors in Norwell. "He's probably the best salesman we ever had," said Prestige owner Helmut J. Schmidt.

With Maumenee's help, O'Donnell returned to his hometown of St. Louis as the medical equivalent of a conquering hero.

Among the accomplishments of which Maumenee is said to be proudest is having trained more university ophthalmology chairmen than anybody else in the nation. He used his considerable academic influence to help land the job at St. Louis University for O'Donnell.

O'Donnell quickly hired several top-notch professors and pushed through construction of a $10 million eye institute at the university-affiliate d Bethesda General Hospital.

Almost as quickly, he came up with a plan for making money by producing training videos for ophthalmologists and later other medical specialists.

When he first floated the video idea in 1982, he told colleagues the venture would operate out of the university and put the school on the map as a center for educational innovation. But that idea did not last long.

Virtually all medical specialists are required to keep up with advances in their fields by taking continuing medical education courses, but the requirement is widely viewed as a burden. O'Donnell's idea was to ease the burden by providing physicians with videotaped courses.

O'Donnell convinced some of the biggest names in medicine -- including a substantial contingent from Boston -- to give on-camera lectures. Early on, contributors worked for only small honorariums.

"This was a very good idea we thought," said Alexander S. Nadas, a Harvard Medical School emeritus professor who made a series of films on pediatrics. "I thought it would be a little like being Alistair Cooke," the host of PBS's "Masterpiece Theater," Nadas said.

O'Donnell depended on his contributors for more than lectures. They provided him with access to their schools' power to grant academic credit for watching his taped courses, and they helped convince their institutions to let him use their video studios. Among those that provided studio time were Johns Hopkins and Harvard-affiliated Beth Israel Hospital.

At its height, O'Donnell's video empire was churning out series in more than a dozen medical specialties and, according to people who participated, most were first-rate.

Things began to change in 1983. Apparently, O'Donnell had second thoughts about the venture's nonprofit status, and he hooked up with Williams again. By the middle of that year, he and Williams had organized their first company, CME-SAT Inc., and sold $2.2 million worth of stock in it to the public.

In documents the company filed with the SEC to sell the stock, O'Donnell is listed as its chairman, medical director and eye series editor at an annual salary of $112,000. Williams is listed as its president and treasurer at $50,000.

The documents do not mention Colonial Opticians.

BUSINESS PROFITS, ACADEMIC PROBLEMS

CME-SAT was the two men's first attempt to convert an academic idea into a profit-making venture. It showed them how much money could be made by combining business and medicine. It also demonstrated the problems the combination can generate.

Many investors were attracted by the company's impressive university ties. In fact, many investors were the very university faculty members who were appearing in company films.

Their repeated stock purchases kept the company afloat despite almost continuous losses. Those purchases also paid O'Donnell and Williams' substantial salaries for the few years they remained with the firm.

But CME-SAT's creation set off a nasty fight at St. Louis University, and was shortly producing problems at other schools as well.

O'Donnell's relations with the medical school and hospital administrations already were strained by the time he started the company, and some who witnessed the struggle say administrators used the firm's existence as a convenient reason for forcing him out.

O'Donnell's decision to take a salary from the company violated university rules against full-time faculty holding paid outside positions, and he was told to choose one job or the other. Less than three years after arriving at the university, he quit as department chairman and medical director of the Bethesda Eye Institute, which he had helped create. He retained only a part-time professorship and has had almost nothing to do with the school since.

St. Louis University officials were not alone in complaining.

Professors who had given early on-camera lectures complained that if they had known their work would be used for profit, they would have charged. Negotiations with Harvard to grant doctors credit for watching programs went nowhere. And angry Johns Hopkins officials said O'Donnell had convinced them to buy expensive video equipment in return for the promise of work that never came through.

"The business thing just totally collapsed," said Nadas, the retired Harvard professor. "It was a shoddy operation."

Shoddy or not, records show that O'Donnell and Williams continued drawing their salaries and bonuses: more than $150,000 in the last half of 1983, almost $275,000 in 1984 and another $180,000 in the first half of 1985.

Each man drove a company car, in O'Donnell's case, a 1983 Mercedes. Williams traveled widely on the company tab, accounting for a sizable portion of $150,000 in travel expenses during one 10-month period.

Starting in early 1985, the pair and close associates sold off all of their CME-SAT stock for at least $1.2 million, according to SEC documents. And by that summer they had quit.

The two men's departure spelled the beginning of the end for CME-SAT. In short order, the firm went through several managers, who added further debts, and landed in bankruptcy.

Among creditors listed with the federal bankruptcy court in Tampa are more than a dozen doctors and professors, many of whom say they were never paid for films they made, and universities and teaching hospitals across the country, including Beth Israel Hospital in Boston and Johns Hopkins, which claims it is owed $103,000.

SPECTRA

As O'Donnell, Williams and associates began selling off their CME-SAT stock in early 1985, the partners got involved in a new company, Spectra.

In many ways, Spectra has been the model for their subsequent ventures. Together with O'Donnell's medical mentor, Maumenee, they assembled another firm with strong university ties. But this time, instead of medical lectures, they had original medical research to sell.

Some of Spectra's problems also have cropped up in subsequent ventures.

One was the gap that opened between the promise of the initial research around which the company was largely organized and subsequent prospects for turning it into a marketable product.

Another was that the person best able to assess the gap's size was the man who had done the research, in this case another Maumenee protege, Scheffer C.G. Tseng. But by the time it appeared, Tseng was financially tied to the company, a fact that is now the focus of investigators.

The impetus for Spectra did not come from O'Donnell and Williams; instead they were invited to join by Maumenee, who became chairman and the largest stockholder.

The invitation was not surprising if only because O'Donnell is widely described as having been one of Maumenee's favorites. But the student also had something to teach his teacher.

Maumenee had had one of the most illustrious careers in academic medicine by the time he retired as chairman of ophthalmology at Johns Hopkins and head of the Wilmer Institute in the late 1970s. The university would shortly name a building after him. But he was not nearly as well off as his much younger colleague.

By 1985, O'Donnell was growing increasingly wealthy both from his businesses and from an eye surgery practice so large he has a private bus service to pick up patients and take them home.

By now, those enterprises provide him with a fleet of luxury cars and a stable of horses in the countryside surrounding St. Louis. The businesses alone supply Williams with a pink waterfront mansion in Sarasota, Fla. Together, Williams says, the two men recently purchased a Lear jet.

Whatever the motives, documents show that Maumenee, O'Donnell, Williams and a group of associates were involved in organizing Spectra by the spring of 1985. Most of their plans centered on Tseng's discovery that a vitamin A ointment seemed to cure a whole family of eye diseases.

Maumenee said in an interview earlier this fall that Tseng's discovery was the culmination of years of research by other scientists. But the scientific work around which Spectra was largely organized appeared in a paper that Tseng, Maumenee and others published in the academic journal Ophthalmology. It described the authors' success in testing the ointment on only 22 patients.

The financial arrangements built on those tests gave a small group the lion's share of Spectra stock. For an investment of only a few cents a share, Maumenee was alotted more than 20 percent of the company's stock, O'Donnell and Williams together about 10 percent, Tseng a little less than 10 percent and other company insiders 35 percent. In addition Tseng was paid more than $300,000 for rights to his discovery and more than $100,000 more as a consultant to Spectra.

When the remaining shares went on public sale at the end of 1985, they were sold out instantly for $3 million and the stock's price quickly climbed from an initial $2 a share to almost $8, making paper millionaires of most company insiders.

The only problem was that further tests of the vitamin A ointment, which Tseng conducted at the Harvard-affiliated Massachusetts Eye and Ear Infirmary, did not go well.

Officials of Spectra, Harvard and Mass. Eye and Ear all say the public was notified when it became apparent the ointment was not working as expected. Spectra issued a press release on March 16 of last year saying the ointment "had not produced encouraging results based on preliminary indications."

Although the release sent Spectra's stock price tumbling when it was issued, the shares had recovered much of their value by the time O'Donnell, Williams and their associates sold out most their shares in the summer of 1987 for more than $1 million. They had also recovered by the time Tseng and his family started selling for at least another three-quarters of a million dollars.

Although Harvard and Spectra officials say the drug's problems were publicized as soon as they were known, records show that the company had evidence as early as the previous fall that the drug did not work as claimed in the majority of cases. And Tseng had data dating as far back as 1985 that, according to people who have reviewed it, show much the same. He has never published anything on the results of his tests at Harvard.

Spectra issued its press release at least in part to comply with federal securities laws that require companies to give potential investors up-to-date information about their firms. But the release did not prevent Williams from arranging for the company to sell another $1 million of stock last spring, nor from marketing it with many of same claims that had been used to market its original shares, especially ones about new medical advances and close ties to universities.

Williams paid Florida financial newsletter publisher Robert E. Baker at least $5,000 to produce a glowing report about Spectra, which was then mailed to thousands of doctors by a company owned by O'Donnell and Williams.

Among other things, the report claims that a new market had been discovered for Spectra's eye drug: as a substitute for a popular skin cream. And it touts the company's university connections, especially through Maumenee.

"Other drug companies have research arms," it declares "Dr. Maumenee has friends and former students in key positions in almost every university ophthalmic research institute in the world."

A Milton man recently filed a class action lawsuit in US District Court in Boston charging that Spectra officials defrauded him and others by selling stock without adequately disclosing all the problems with the vitamin A ointment.

AROUND AGAIN

Much as they had done in the past, when O'Donnell and Williams began selling off their Spectra shares during summer of last year, they had a new company in the wings.

The company is C.A. Blockers Inc., a Louisville, Ky., firm that is developing an additive to cut the activity of a cancer-causing element of cigarette smoke. It is the partners' latest venture and has at least some hallmarks of the previous ones.

It has university connections, including a husband-wife research team at the University of Louisville School of Medicine, who discovered the additive, and a retired medical school dean who has convinced his former institution to let him begin human testing of an additive-treated cigarette.

It also seems to be having some trouble turning the discovery into a product, although it is hard to pin down exactly what the problems are because its top executive and one of the researchers have given a series of contradictory statements in interviews during recent days.

O'Donnell and Williams were invited to get involved in Blockers sometime in the spring of last year by its chief executive, L. Douglas Keeney. Keeney said in an interview that his company needed money and the pair convinced him to raise it by selling stock.

The financial arrangements built on those tests gave a small group the lion's share of Spectra stock. For an investment of only a few cents a share, Maumenee was alotted more than 20 percent of the company's stock, O'Donnell and Williams together about 10 percent, Tseng a little less than 10 percent and other company insiders 35 percent. In addition, Tseng was paid more than $300,000 for rights to his discovery and about $100,000 more as a consultant to Spectra.

When the remaining shares went on sale in October of last year, they fetched about $3 million.

Also similar is the reaction of both congressional and securities regulators, who are now examining the stock sale to see, among other things, whether the organizers fully explained how far the scientific discovery is from being turned into a product that can be sold.

In Blockers' case, the discovery was made by William J. Waddell, chairman of the University of Louisville medical school's pharmacology and toxicology department, and his wife, Carolyn Marlowe.

The couple showed that certain substances block a carcinogen found in cigarette smoke from accumulating in the lungs and other organs of mice. In 1983, they published a paper about their findings in the prestigious magazine Science. And in 1986, they sold rights to their finding to Keeney, who has been trying ever since to produce a cigarette with the additive.

One problem he has faced is that Waddell and Marlowe's blocker is alcohol, and at least the types and doses described in their Science paper would make human beings sick or worse.

In addition, independent researchers say that Waddell and Marlowe have not yet shown whether blocking the cancer-causing substance from collecting in the lungs reduces cancer or simply shunts it elsewhere. And they have not shown that the blocker works in humans.

Keeney acknowledged in an interview that his company is still a long way from producing a cigarette that reduces the cancer risk of smoking, but said it is making great strides.

He said, for example, that it has won permission from the University of Louisville medical school to begin human testing of the blocker-treated cigarettes. He said the tests will be overseen by his father, Arthur, who was until recently the company's chairman and still heads its science advisory board. The elder Keeney is also the retired dean of the medical school.

The blocker that will be used in the tests will not be any of those discussed in the 1983 Science paper, but something that Waddell and Marlowe have discovered since and that, they say, is much more potent even in small doses.

In an interview, Waddell would not name the new blocker because he has not yet published a scientific paper about its discovery. It is unclear whether either he or the Keeneys have yet tested it on mice at doses that the company says would be acceptable for human use.

In a series of interviews in recent days, Douglas Keeney first said that it had been tested at acceptable levels, then said it had not, and finally Wednesday said that it had, although he is not sure at what levels.

He also said tests are under way at Arthur D. Little Inc. in Cambridge, where an official reported preliminary results will be available shortly. In the meantime, a Blocker licensee has begun selling the blocker-treated cigarettes in Israel under the brand name "Spectra."

WHERE TO GO FROM HERE

As Spectra Pharmaceutical's fortunes sagged this year because of growing problems with its vitamin A ointment, Maumenee shifted his attention to other products, especially a solution called I-Scrub.

In a series of letters on Johns Hopkins University stationary, Maumenee began singing the praises of the substance, saying it not only helps relieve a particular eye condition, but also cleans contact lens, removes makeup, is good for brushing teeth and can kill AIDS virus.

Jonnie Williams, meanwhile, is off on a new deal, this time a laser technology company. And Frank O'Donnell told an interviewer for a St. Louis weekly that his life is in medicine.

As for business: "It's just a hobby," he said, "a fun and lucrative hobby."

SIDEBAR THE O'DONNELL-WILLIAMS CONNECTION: A CHRONOLOGY

Late 1970s - early 1980s. Partners meet in Baltimore while Frank J. O'Donnell Jr. is a resident under A. Edward Maumenee at Johns Hopkins University School of Medicine and Jonnie R. Williams is a graduate student at the university's School of Advanced International Relations. Williams owns and runs an optical shop, Colonial Opticians, in Fredericksburg, Va. O'Donnell sees eye patients in Fredericksburg in apparent violation of university rules against residents moonlighting and refers some to Williams' shop.

December 1980. Williams disappears from Fredericksburg, leaving tens of thousands of dollars in unpaid bills, scores of unclaimed eyeglasses and a Small Business Administration loan.

January 1981. O'Donnell becomes one of the nation's youngest medical school department chairman as head of ophthalmology at St. Louis University in Missouri and medical director of its affiliated Bethesda Eye Institute.

July 1983. The partners' first company, CME-SAT Inc., goes public by selling $2.2 million worth of stock. O'Donnell is chairman and Williams is president. Between them, they own more than 40 percent of stock. O'Donnell is forced to resign most of his academic jobs at St. Louis University because of his involvement in the company.

Early 1985. Partners and their associates begin selling off their CME-SAT stock. With Maumenee and others, they organize Spectra Pharmaceutical Services Inc. of Hanover, Mass. With Robert J. Fitzsimmons and others, they organize Eye Technology Inc. of St. Paul.

Summer 1985. O'Donnell and Williams resign from CME-SAT.

December 1985. Spectra goes public by selling $3 million worth of stock. Its principal product, a Vitamin A ointment for eyes developed by former Maumenee student Scheffer C.G. Tseng, is being tested at Harvard-affiliated Massachusetts Eye and Ear Infirmary. O'Donnell and Williams own about 10 percent of the stock.

February 1986. Eye Technology goes public by selling about $3 million worth of stock. CME-SAT executives accuse O'Donnell and Williams of using CME-SAT money to help pay start-up costs of new company. Williams and Fitzsimmons deny charge. O'Donnell and Williams own about 5 percent of the stock.

July 1986. Mass. Eye and Ear begins investigating Tseng's tests of Spectra's eye drug.

Late 1986. Partners try to start Morgan Laboratories Inc. of Sarasota, Fla., with Maumenee and others. Plans call for the company to sell $3 million worth of stock, for O'Donnell and Williams to own 20 percent and for Maumenee to sit on its advisory board, but organizers withdraw the deal.

Early 1987. Williams begins working out of a Sarasota brokerage house, Kashner-Davidson Securities Corp. Although he denies links to the firm, documents show he and an associate maintained offices, lent the company money and had expenses covered.

January 1987. Partners help organize stock sale for Psychemedics Corp. of Los Angeles, which goes public by selling $3 million worth of shares. Kashner Davidson handles the stock offering. O'Donnell and Williams own 15 percent.

June 1987. Harvard Medical School begins investigating Tseng's tests of Spectra's eye drug.

October 1987. Partners help organize stock sale for C.A. Blockers Inc. of Louisville, Ky., which goes public by selling $3 million worth of shares. Kashner-Davidson handles offering. Williams lends brokerage house $375,000 so it can meet regulatory requirements to handle the offering.

May 1988. Harvard concludes the Tseng's tests of Spectra's drug involved violations of rules governing patient testing, conflicts of interest, research quality and supervision.

Summer/fall 1988. State and federal regulators begin investigating most of the stock offerings in which O'Donnell and Williams have been involved.

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Caption: PHOTO

1. DR. FRANK J. O'DONNELL Jr.

Series of business ventures

2. JONNIE R. WILLIAMS

Prodigious salesman

3. St. Louis Business Journal photo / Frank J. O'Donnell Jr. is one of a new breed of entrepreneurs who operates at the border between business and biomedical science.

4. Fredericksburg Free-Lance Star photo / Jonnie R. Williams, who "could sell a snowball to an Eskimo," now uses his skills to sell scientific promises.

5. Globe photo/Suzy Mast / Dr. A. Edward Maumenee (left) had had one of the most illustrious careers in academic medicine by the time he retired as chairman of ophthalmology at Johns Hopkins and head of the Wilmer Eye Institute in the late 1970s. The university shortly named a building after him (above), and his portrait hangs in the lobby (above right).

6. Baltimore Sun photo/George Cook

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