

August 18, 2006

Side Effects

Heart Procedure Is Off the Charts in an Ohio City

By [REED ABELSON](#)

ELYRIA, [Ohio](#) — People with blocked coronary arteries can typically choose among drugs, bypass surgery and vessel-clearing procedures like [angioplasty](#).

But in this small, aging industrial city in northeast Ohio, doctors are much more likely than those anywhere else in the country to steer patients toward angioplasty — a treatment that typically involves threading balloon catheters through arteries and sometimes placing drug-coated [stents](#) to unblock them.

No one has accused the doctors involved of any wrongdoing. But the statistics are so far off the charts — Medicare patients in Elyria receive angioplasties at a rate nearly four times the national average — that Medicare and at least one commercial insurer are starting to ask questions. And the hospital where most of the procedures take place says it plans to conduct an independent review.

As it turns out, nearly all the procedures at the Elyria hospital are performed by a group of cardiologists who dominate coronary care in this city and have an unabashed enthusiasm for angioplasties, the highly profitable procedure in which they specialize.

Whether the preference for angioplasty is good for the patients of Elyria is open to medical debate. The cardiology group's leader says the high rate of angioplasties is simply a function of his doctors' detecting disease more often in their patients than physicians elsewhere might spot, and being quicker to intervene.

“We do manage very aggressively the patients we care for,” said Dr. John W. Schaeffer, the founder and president of the group, the North Ohio Heart Center, which employs 31 cardiologists.

But some outside experts say they are concerned that Elyria is an example, albeit an extreme one, of how medical decisions in this country can be influenced by financial incentives and professional training more than by solid evidence of what works best for a particular patient.

“People are rewarded for erring on the side of an aggressive, highly expensive intervention,” said Dr. Elliott S. Fisher, a researcher at Dartmouth Medical School, which analyzed Medicare data and found Elyria to be an outlier.

Medicare pays Elyria’s community hospital, EMH Regional Medical Center, about \$11,000 for an angioplasty involving use of a drug-coated stent.

The cardiologist might be paid an additional \$800 for the work. That is well above the fees for seeing patients in the office. And with the North Ohio doctors performing thousands of angioplasties a year — about 3,400 in 2004, for example — the dollars can quickly add up.

Some medical experts say Elyria’s high rate of angioplasties — three times the rate of Cleveland, just 30 miles away — raises the question of whether some patients may be getting procedures they do not need or whether some could have been treated just as effectively and at lower cost and less risk through heart drugs that may cost only several hundred dollars a year. Or whether, in some cases, patients might be even better off with bypass surgery — even though a bypass is a riskier, more invasive and more expensive procedure. At EMH Regional, Medicare pays the hospital about \$25,000 for a bypass operation, and as much as \$2,200 to the surgeon.

The Elyria cardiologists do not perform bypasses. Because they are not surgeons, the North Ohio cardiologists must refer a patient to another doctor if they conclude that bypass surgery is that patient’s best option. The bypasses are performed at the Elyria hospital by surgeons from the Cleveland Clinic who have operating privileges there.

But even in cases of extensive disease where other doctors might typically recommend bypass surgery, the Elyria doctors say they frequently favor the use of stents.

For patients with less serious disease, the doctors say they do prescribe drug-only treatment.

But generally, Dr. Schaeffer argues, the group’s aggressive use of angioplasty provides the best results for its patients. “We have excellent outcomes,” he said.

No Definitive Studies

When it comes to treating blocked arteries, there are no definitive studies showing which approach most benefits patients in the long term. And some local insurers agree that the Elyria hospital provides high-quality care.

But there is little doubt that hundreds of Elyria patients each year are getting angioplasties that they would not be getting if they lived elsewhere in Ohio — or in any other part of the country for that matter — at a cost of millions of dollars a year to Medicare, the federal insurance program for the elderly. Elsewhere in the state, some of the sickest of these patients might have received bypass surgery, while

many others might have simply been treated with drugs. Or, for those whose conditions were not diagnosed or were not deemed serious enough, there might have been no treatment at all. .

Experts know that changing the financial incentives can change the way medicine is practiced.

For example, Kaiser Permanente, the big health system that employs its own doctors, says its patients in Ohio, including some in Elyria, are slightly less likely than the national average to undergo the type of cardiac procedures the North Ohio Heart Center doctors perform so prolifically.

Kaiser's cardiologists, who work on salary instead of being paid by the procedure, typically treat patients in that region at the Cleveland Clinic, where they have hospital privileges. And they follow established protocols about when a patient should undergo an angioplasty, when drugs might suffice and when bypass surgery might be the best resort.

"It's not just individual doctors making up their minds," explained Dr. Ronald L. Copeland, the executive medical director for Kaiser's medical group in Ohio. With no financial reason to perform expensive procedures, the Kaiser doctors frequently choose to manage the patients' [heart disease](#) with drugs only. "Our doctors have no disincentive to do that," Dr. Copeland said.

EMH Regional, the small, nonprofit Elyria hospital where North Ohio doctors perform most of their angioplasties, says it is aware that the volume of procedures is higher than it is elsewhere.

"We believe we're doing a good job," said Dr. Donald Sheldon, the hospital's vice president for medical affairs. But he conceded that the high rates raise questions. He said the hospital had decided to ask a professional society of heart specialists to review the cardiac program and "give us an honest and objective outside look."

Medicare officials, after being asked about the Elyria data by a reporter, said they intended to take a closer look. And at least one commercial insurer that covers patients in Elyria, [Anthem](#) Blue Cross and Blue Shield, said it had discussed with the hospital whether all the procedures were appropriate.

Among Dartmouth's findings is that for the years 2001 through 2003, the approximately 3,000 angioplasty procedures performed on Medicare patients in Elyria were nearly triple the number that might have been expected if the same people had lived elsewhere in Ohio. Elyria's statistics have stood out at least since 1998, according to the Dartmouth researchers. By 2003, the most recent year for which information is available, Elyria had 42 procedures per 1,000 Medicare patients, compared with an average of 13.5 throughout Ohio and 11.3 in the rest of the nation, according to Dartmouth's analysis.

A Lucrative Area of Medicine

Experts say that cardiac care is one of the most lucrative areas of medicine. EMH Regional says it generates nearly half its profit from cardiac services.

Government officials had recently discussed significantly lowering Medicare payments for heart care. But they ended up proposing only modest changes, allowing cardiac care to remain an important source of hospital income. EMH Regional says it does not expect the new Medicare rates to have a significant impact on its revenue.

In Elyria and its environs, where Dr. Schaeffer says there are perhaps only two cardiologists not affiliated with his practice, patients appear highly likely to get their cardiac advice from the North Ohio group. In some cases, they may even be referred to the North Ohio cardiologists by doctors from the separate primary care practice that the group also operates.

For many cardiologists, the natural tendency when they see a patient with heart disease is to perform a procedure to try to clear arterial blockages. And patients, cardiologists say, tend to rely on their doctors' judgment.

"It's sort of like, you go to a barber and ask if you need a haircut," said Dr. David D. Waters, chief of cardiology at San Francisco General Hospital, who is currently studying the effectiveness of different kinds of treatment for heart disease. "He's likely to say you do."

But the Dartmouth data also shows that the Elyria doctors have a higher than average tendency to perform diagnostic coronary angiographies on patients — the primary test that is used to detect blockages in the first place.

"People are just geared to be looking at things, and they find them," said Dr. John E. Wennberg, who pioneered the Dartmouth data analysis.

Aggressive Treatment

Dr. Schaeffer says the North Ohio doctors follow medical guidelines in determining treatments. And he argues adamantly that patients with coronary artery disease are best served when doctors intervene quickly. "With absolutely no exception," he said, "patients given aggressive treatment will come out with a better outcome."

Among the insurers that say the doctors and hospital deliver good care is UnitedHealth, one of the state's largest insurers, which has designated the Elyria hospital as one of its centers of excellence for heart care.

Richard Waldron, the director of hospital contracting for another insurer, Medical Mutual of Ohio, says that EMH scores well on traditional quality measures like the number of patients readmitted, complications and mortality. "They are a very high-quality provider," he said.

Although Medical Mutual says it is aware of Elyria's unusually high rates of angioplasties, Mr. Waldron said the insurer tended to leave clinical decisions to the doctors and patients involved.

Elyria's reputation in heart care has also become a matter of community pride. Harvey Gittler, a columnist for the local newspaper, The Chronicle-Telegram, wrote glowingly last year of the doctors and hospital, saying there was no reason to travel to the Cleveland Clinic, which has a world-renowned heart center.

Mr. Gittler, who is 83 and insured through Medicare and his former employer, received a stent and a pacemaker last summer after being taken to EMH by ambulance, suffering from pneumonia and an irregular heart beat.

"The care in that hospital is excellent," he said in an interview, adding that the doctors at North Ohio Heart Center "have this thing down to such a science."

But outside experts say such a locally dominant cardiology group could make it hard for patients to be aware of other treatment options. They also say there is no clear medical reason for so many patients in Elyria to be so much more likely than heart patients elsewhere to require angioplasty.

The high rates do not have "a good explanation," said Dr. Eric J. Topol, a nationally known cardiologist at Case Western Reserve University in Cleveland. He said Elyria did not appear to have significant differences in risk factors and demographics from Cleveland and the rest of Ohio that would explain the sharply higher rates.

One clear reason for the high number of angioplasties in Elyria, though, is the way the doctors tend to perform the procedures. In many other parts of the country, doctors who perform angioplasties try to unblock all of the blood vessels during a single session. Or they may elect not to put a stent in another vessel that might require an additional session because there is only a minor blockage.

But in Elyria, patients are more likely to undergo two or more procedures, sometimes requiring separate hospital stays and additional bills. As many as 31 percent of patients there who receive treatment undergo additional procedures, according to Dr. Scott Sheldon, a North Ohio Heart Center cardiologist, who is not related to the hospital's Dr. Sheldon. That would be three times the national average.

"There's a safety issue," Dr. Sheldon said. North Ohio doctors, he said, do not want to endanger patients by operating on too many vessels during a single procedure. Among other concerns, he said, it could mean subjecting them to too much of the contrast agent that enables doctors to see the arteries.

Using separate procedures, a practice known as staging, "is a reasonable option for patients," said Dr. Howard C. Herrmann, the director of interventional cardiology at the Hospital of the [University of Pennsylvania](#). But Dr. Herrmann emphasized that in all of these decisions, much is left to the cardiologist's own judgment.

“The cardiologists are the gatekeepers about who gets stents or surgeries,” he said.

Even the North Ohio doctors, who say they believe their patients do well, concede that there is no conclusive long-term evidence about what actually works best. They say they, too, want to know what the long-term outcomes are going to be.

Patterns of Activity

No one has accused the North Ohio doctors of inappropriate conduct. But there have been cases in which unusual patterns of medical activity that also showed up in the Dartmouth data have prompted federal law enforcement investigators to look into whether unnecessary procedures have been performed.

In one well-known instance, doctors at a community hospital in Redding, Calif., owned by [Tenet Healthcare](#) were accused of defrauding Medicare by performing unnecessary heart operations on hundreds of healthy patients. Without admitting wrongdoing, Tenet settled the accusations with the federal government in 2003 for \$54 million.

Earlier this year, a doctor in Lafayette, La., Dr. Mehmood M. Patel, was indicted on federal charges that he committed Medicare fraud by performing unnecessary heart procedures. Residents of Lafayette had more than twice the national rate of angioplasties in 2003, the second highest in the country behind Elyria, according to the Dartmouth researchers.

A lawyer for the physician, J. Michael Small, said Dr. Patel had pleaded not guilty to all of the government’s counts. “He intends to vigorously contest the allegations,” Mr. Small said. The Doctor’s Decision

Experts say it can be difficult to detect cases in which doctors cross a medical line and are clearly performing unnecessary treatments.

“A lot of decisions are discretionary,” said Dr. Harlan M. Krumholz, a cardiologist and professor at [Yale](#).

“It’s about where the thermostat is set,” he said, arguing that doctors in a particular geographic area tend to be unaware if the way they are treating their patients is markedly different from the practices of their peers in other areas.

Traditional measures of medical quality are not set up to detect whether patients are being treated too much, he said, unlike the kinds of safeguards that prompt credit card companies to call their customers to discuss unusual spending activity. “Right now there are no ‘smart’ systems in place,” Dr. Krumholz said.

In the absence of any real monitoring or oversight, doctors in most places, including Elyria, have few incentives not to favor the treatments that provide them the most reimbursement. Dr. Waters, the San

Francisco cardiologist, said that the way physicians are typically paid — more money for more procedures — results in too many decisions to give a patient a stent.

“You can’t be paying people large sums of money to do things without checks and balances,” he said.

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Drug Makers Pay for Lunch as They Pitch

By [STEPHANIE SAUL](#)

Anyone who thinks there is no such thing as a free lunch has never visited 3003 New Hyde Park Road, a four-story medical building on Long Island, where they are delivered almost every day.

On a recent Tuesday, they began arriving around noon. Steaming containers of Chinese food were destined for the 20 or so doctors and employees of Nassau Queens Pulmonary Associates. The drug maker [Merck](#) paid the \$258 bill.

A deliveryman carrying trays of gourmet sandwiches sashayed past patients at Advanced Internal Medicine. The bill showed that Takeda [Pharmaceuticals](#) was picking up the bill. The doctors in the group must have liked the sandwiches. The next day, the exact same delivery came in, paid for by [Cephalon](#).

Free lunches like those at the medical building in New Hyde Park, N.Y., occur regularly at doctors' offices nationwide, where delivery people arrive with lunch for the whole office, ordered and paid for by drug makers to the tune of hundreds of millions of dollars a year.

Like the "free" vacation that comes with a time-share pitch attached, the lunches go down along with a pitch from pharmaceutical representatives hoping to bolster prescription sales. The cost of the lunches is ultimately factored in to drug company marketing expenses, working its way into the price of prescription drugs.

Doing business over lunch is a common practice in many fields, but drug makers have honed it to perfection, particularly since 2002, when the drug industry adopted a new code banning many other free enticements — golf outings, athletic tickets, trips and lavish dinners for doctors. The code gives approval to modest meals in the course of business. And conventional wisdom in both the pharmaceutical industry and the medical profession is that a lunch is too small to pose an ethical problem. But a growing number of critics say that even those small lunches should be banned.

A former pharmaceutical representative, Kathleen Slattery-Moschkau, called lunch "incredibly effective" in lifting pharmaceutical sales for the companies where she worked, [Bristol-Myers Squibb](#) and [Johnson & Johnson](#).

“We got the numbers of what the physicians were prescribing. If I brought in lunch one week, I could see the following week if that lunch had an impact,” Ms. Slattery-Moschkau said.

Dr. John G. Scott, assistant professor of family medicine at the [University of Medicine and Dentistry of New Jersey-Robert Wood Johnson Medical School](#) in New Brunswick, N.J., is examining the interaction between medical practices and pharmaceutical representatives.

“We found that some offices get breakfast and lunch every day,” said Dr. Scott, who calls lunch the “currency” that buys access to doctors’ offices for drug representatives. He also noted that some doctors were hard pressed to meet payrolls and that the lunches provided an added benefit for their employees.

“Essentially, we feel that most of what the pharmaceutical reps do works at an unconscious level,” Dr. Scott said. He said most doctors said they were not influenced by the food deliveries and other small gifts. But, he added, “They do influence prescribing.”

The \$258 Merck lunch, for example, cost the company only \$10.75 a person and fell clearly within industry guidelines allowing modest meals. But it could easily return thousands of dollars for the drug maker in prescriptions for the [osteoporosis](#) medication Fosamax and the [asthma](#) treatment Singulair, the two drugs discussed during lunch with two Merck representatives.

An official of Merck’s sales and marketing division, Patrick T. Davish, says his company views lunch meetings as appropriate and “a good time to sit around and talk about the clinical properties of your drug and the disease categories you deal with.” Spokesmen for both Takeda and Cephalon emphasize that the lunches they pay for are modest.

Dr. Scott cited several studies that show that the lunches — plus small gifts like pens and sticky notepads, along with drug samples — can lead doctors to prescribe the more expensive brand names when cheaper generic drugs would be as effective.

Such concerns have spurred the effort to ban lunches. The movement is making headway nationwide, as opponents of the practice cite ethics questions. The hospital at the [University of Pennsylvania](#) became the latest large institution barring industry-paid lunches, effective July 1, according to its medical director, Dr. Patrick J. Brennan.

“It curries favor and it creates influence, and it introduces influences into decision-making processes that we think ought not to be there,” Dr. Brennan said.

Similar rules have been adopted recently at several other academic medical centers. When the [University of Michigan](#) Health System banned industry lunches last year, officials calculated that they had been worth \$2.5 million annually.

In Madras, Ore., meanwhile, a group of internists earlier this year banned not only lunch but also visits by drug representatives. Even in Madras, a rural town of about 5,000, the group got visits from more than 30 drug representatives a month, including two or three lunches.

“The complaints that I would get from my patients were, ‘You’re 15 minutes late to see me.’ ” said Dr. David V. Evans, a member of the group. “ ‘O.K., I was back there talking to a drug rep.’ That wasn’t such a good thing.”

Dr. Evans added, “It’s an issue of professionalism and integrity, really.”

The pharmaceutical industry employs about 90,000 representatives. While some patients grumble about their ubiquitous presence in medical office waiting rooms — and many are aware of lunch deliveries — others say the intrusion is worthwhile in exchange for the free drug samples.

“The doctors I go to only see them at certain times,” said Arnold Dimond of Glen Oaks, N.Y., who was leaving the New Hyde Park building recently, carrying a plastic bag of drug samples. “The samples save you quite a bit of money, too.”

One of the most vocal opponents of free lunch is Dr. Bob Goodman, a Manhattan internist who formed an organization called No Free Lunch.

“I’d say that lunches are going to be one of the last things to go,” Dr. Goodman said. “The interesting thing is that it’s generally not something doctors are ashamed about. That’s why I find this thing so fascinating. They don’t think they’re doing anything wrong.”

At 3003 New Hyde Park Road most of the doctors contacted declined to be interviewed for this article. But one, Dr. Javier Morales, said the samples that representatives bring to his office are helpful for low-income patients.

And Scott M. Lassman, senior assistant general counsel for the Pharmaceutical Research and Manufacturers of America, said: “It’s our feeling that a modest meal is not the type of thing that is going to interfere with the independence of a health care practitioner. It’s really a recognition that these folks are extremely busy. They don’t have time to talk. Perhaps the only time they do have time to talk is over lunch or dinner. So we thought it was appropriate for the sales rep to pay for that.”

Not every doctor’s office gets free lunches at 3003 New Hyde Park Road, though many do. The deliveries often start even before lunchtime, with representatives bringing in pastries and large containers of coffee from [Starbucks](#) or Dunkin’ Donuts.

Ms. Slattery-Moschkau, the former pharmaceutical representative, said that nurses and staff members in some offices were quite demanding about lunch.

“It was almost a game, and it was unbelievable the animosity they would show if you did not bring the right kind of food, or if it was the third time they had pizza that week,” said Ms. Slattery-Moschkau, who left the industry in 2002 and recently wrote and directed the documentary “Money Talks,” in which the practice of lunch is discussed.

Midweek lunches, when all the doctors are sure to be in the office, are considered prime time.

“Wednesdays are big,” said Larry Plompen of West Islip, N.Y., who peddles lunch and coffee out of a refrigerated truck at 3003 New Hyde Park Road. Several years ago, Mr. Plompen said, a drug company purchased lunch from his truck for the entire staff of a large practice in the building.

Other entrepreneurs have also capitalized on the business — a segment of the restaurant industry that one national lunch-ordering company, Lunch and Earn, estimates is worth \$4 million a day, or as much as \$1 billion a year. A founder of that company, Amy Kristjanson, a former pharmaceutical representative, said her numbers were based on a calculation of lunch spending by representatives for the top 10 pharmaceutical companies.

Mr. Lassman said he was not aware of any industrywide figure for the cost of such lunches. But various sales representatives, pharmaceutical companies and the lunch delivery industry supplied estimates of how much is spent for lunch. Judy Kay Moore, spokeswoman for [Eli Lilly](#), for instance, said that company’s representatives spend \$500 to \$750 a month for lunches. Joseph R. Carolan, an owner of Casa Mia’s in Nottingham, Md., which does a large pharmaceutical lunch delivery business in the Baltimore area, said the average representative he deals with has a monthly lunch budget of close to \$2,000.

Mr. Carolan said his lunch business — about 30 to 40 orders a day — exploded after the new industry marketing code was adopted in 2002.

“I got into this because the feds cracked down on the more extravagant things they were doing: the dinners, courtside N.B.A. games, flying them to the islands.” Mr. Carolan said.

He is also on the forefront of another marketing trend: rewards programs for pharmaceutical representatives.

One who spends \$5,000 at Casa Mia’s, for example, can get a \$100 gift certificate to Nordstrom, one month of tanning, or a Swedish massage with a manicure and pedicure.

Ms. Kristjanson, the former representative who founded Lunch and Earn, said that lunch represented a fundamental shift in the business.

“Reps used to have more freedom,” Ms. Kristjanson said. “Lunch is sort of what it’s come down to.”

July 22, 2006

Indictment of Doctor Tests Drug Marketing Rules

By [ALEX BERENSON](#)

At first, Dr. Peter Gleason thought his arrest was a joke.

In the early afternoon of Monday, March 6, half a dozen men in suits surrounded Dr. Gleason, a Maryland psychiatrist, at a train station on Long Island and handcuffed him.

“I said, ‘Well, this is a gag,’ ” Dr. Gleason recalled in a recent interview. “They said, ‘No, this isn’t.’ ”

Dr. Gleason, 53, was taken aback because he was arrested, and later charged, for doing something that has become common among doctors: promoting a drug for purposes other than those approved by the federal government.

But prosecutors say that Dr. Gleason went too far. At hundreds of speeches and seminars where he was rewarded with generous fees, Dr. Gleason advised other physicians that a powerful drug for narcolepsy could be prescribed for [depression](#) and pain relief. In doing so, he conspired with the drug’s manufacturer to recommend it for potentially dangerous uses, the prosecutors claim.

The case has put the spotlight on the murky financial relationships between drug companies and the physicians they use to promote their medicines. Companies cannot directly advertise drugs for purposes not approved by the [Food and Drug Administration](#). But getting drugs prescribed for unapproved uses can increase a drug’s sales, so companies often skirt the rules by sponsoring seminars where doctors are paid to make presentations promoting their drugs, including the “off label” uses.

For doctors, these and other payments they receive for discussing drugs can be very lucrative. Dr. Gleason acknowledges that he received more than \$100,000 last year alone from Jazz [Pharmaceuticals](#), which makes Xyrem, the narcolepsy drug he has promoted.

His case could establish limits on what doctors can do to help companies sell their drugs. But any precedent could be complicated by the history of Xyrem, which differs in one important way from other

drugs. Because the active ingredient in Xyrem is gamma hydroxybutyrate, or GHB, an illegal street drug with a history of use in date rape and of overdose hazards, Xyrem is listed as a federally controlled substance, with distribution tightly monitored.

Some doctors who have researched Xyrem say that Dr. Gleason, in his enthusiasm for the drug, may have understated its very real risks. Still, at least one former F.D.A. official says that the government appears to be overreaching in going after Dr. Gleason and may chill a common and legitimate form of medical discussion. “This is a very, very scary development,” said Daniel E. Troy, a partner at Sidley Austin and the former chief counsel of the F.D.A.

Dr. Steven Nissen, the interim chairman of cardiovascular medicine at the Cleveland Clinic, said the case could “have a chilling effect on physicians, because when we give lectures, we assume that giving an opinion about the use of a drug is not going to get us into legal difficulty.” The F.D.A. and federal lawyers, he said, need to restrict criminal prosecutions to especially egregious cases of off-label promotion.

Continuing to Practice

Dr. Gleason, who is now free on bail and continues to practice medicine, insists that he is not guilty of conspiracy. He says that he was charged only after he refused to help the government build a case against the drug’s maker, Jazz Pharmaceuticals — a sequence of events that court documents seem to support.

Dr. Gleason freely acknowledges that in meetings with other doctors, he advocated Xyrem as a treatment for many conditions, including depression and fibromyalgia, a poorly understood pain disorder.

In a news release about the indictment, an assistant [F.B.I.](#) director compared Dr. Gleason to a “carnival snake-oil salesman.”

But the doctor says that based on his own experience giving Xyrem to patients, he believes everything he said about the drug and that his right to express his views are protected by both F.D.A. rules and the First Amendment.

Some lawyers who have reviewed Dr. Gleason’s case, but are not representing him, say they agree.

Dr. Gleason has been trapped in the complex rules that cover what doctors and drug manufacturers are allowed to say about prescription drugs, according to Harvey A. Silverglate, a lawyer in Boston who specializes in civil liberties cases.

“What they are doing is criminalizing conduct that is not clearly criminal,” said Mr. Silverglate, who is not involved in Dr. Gleason’s defense.

Neither the F.D.A. nor the United States attorney’s office in Brooklyn, which indicted Dr. Gleason,

would comment on the case. Nor would David Loftus, a public defender who took over the case after Dr. Gleason determined he could not afford a private lawyer. Jazz Pharmaceuticals, which has not been charged, also declined to comment.

F.D.A. rules allow doctors to prescribe federally approved drugs for any purpose, even if it is not indicated on the medicine's label. But drug companies are tightly constrained in what they can say about their medicines. Companies can promote drugs only for their federally approved purposes — their so-called “on label” use.

“Off label” promotion by drug companies is illegal, and since 2000 drug makers have paid large fines to settle federal criminal cases over off-label prescriptions.

[Pfizer](#), for example, paid \$430 million in 2004 to settle allegations that it had promoted Neurontin, an anti-[epilepsy](#) medicine, for pain and [bipolar disorder](#).

Despite the F.D.A.'s constraints on drug makers, though, the companies are allowed to hire independent doctors to talk to other physicians about their medicines. Companies can also sponsor “continuing medical education” sessions, ranging from lunches to weeklong conferences, where specialist doctors tell other physicians about the latest developments in their fields — including off-label uses for drugs already on the market. For such speaking engagements, doctors can receive \$3,000 or more a day from the companies.

In other words, the F.D.A. rules allow drug makers to pay independent doctors to discuss medicines in ways that might be illegal for the companies themselves. Beyond the federal rules, guidelines by doctors' groups give physicians wide latitude to talk about off-label use.

The [American Medical Association](#) considers continuing-education sessions valuable and believes that doctors should be free to prescribe drugs for off-label use, according to Dr. Edward Langston, a member of the A.M.A. board.

In general, though, he said, the A.M.A. believes doctors should rely on peer-reviewed research, not anecdotal evidence, when they write off-label prescriptions.

The Accreditation Council for Continuing Medical Education, which oversees the groups that create medical education sessions, loosened its rules in 2004 so that speakers would not have to disclose whether a recommended use is on-label or off-label, said Dr. Murray Kopelow, the council's chief executive.

“The A.C.C.M.E. abandoned the distinction between off-label and on-label,” Dr. Kopelow said. Instead speakers should make recommendations based on accepted medical and scientific evidence, he added.

Dr. Gleason acknowledges that he did not follow those evidence-based guidelines when discussing Xyrem in hundreds of speeches and seminars from 2003 to 2006. The talks were paid for by the original maker of Xyrem, a company called Orphan Medical. Orphan was acquired by Jazz Pharmaceuticals in June 2005.

In one seminar cited in the federal indictment, a session last August in Denver, Dr. Gleason told doctors that “table salt is more dangerous” than Xyrem — a statement scoffed at by other experts on the drug.

An Aid to Sleep Quality

Xyrem’s active ingredient GHB is a fast-acting central nervous system depressant developed as an [anesthetic](#) in the 1960’s. The drug improves sleep quality, enabling narcoleptics to stay awake the next day, according to physicians who specialize in treating [sleep disorders](#). But because GHB can suppress breathing, overdoses can cause coma or death.

“It has the potential to do a lot of good if it’s used properly, the potential to do a lot of harm if it’s used improperly,” said Dr. Martin Scharf, the director of the Tri-State Sleep Disorders Clinic in Cincinnati, who said he had studied GHB in hundreds of patients since the early 1980’s.

In 2000, after highly publicized cases in which young women died or were raped after GHB was slipped into their drinks, Congress designated the drug a Schedule I controlled substance, in the same class as heroin.

But by then, doctors had shown that GHB could treat cataplexy, a variant of narcolepsy that causes people to suffer temporary paralysis. After lobbying from doctors and Orphan Medical, Congress said that if the F.D.A. chose to approve prescription GHB, it would be designated as a Schedule III controlled substance, legal for medical use, like the painkiller Vicodin or [steroids](#).

In 2002, after Orphan presented clinical trial data showing GHB’s effectiveness against cataplexy, the F.D.A. approved the drug, under the brand name Xyrem, as a cataplexy treatment. In 2005, the agency approved Xyrem for the treatment of all forms of narcolepsy.

To help persuade the F.D.A. to approve Xyrem, Orphan Medical agreed to make the drug available only from a single pharmacy in Missouri, which ships it to patients nationally. No other prescription drug, even other Schedule III medicines, is so tightly controlled. For now, Xyrem, which costs more than \$600 a month, is a niche product, with sales of about \$25 million last year.

Dr. Gleason said he had been interested in Xyrem even before the drug was officially approved because he believed that other medicines for [insomnia](#) and depression were addictive or had serious side effects. “I immediately just started prescribing this stuff in 2002,” he said.

He prescribed the drug to about 100 of the patients he saw in his private practice in Maryland, almost always for off-label conditions like insomnia and severe depression. Xyrem seemed to work better than existing treatments, he said.

By early 2003, a sales representative for Orphan Medical, noting Dr. Gleason's high rate of prescriptions, asked him if he would give talks to other doctors about Xyrem.

"I started doing those, and I started getting requested a lot," Dr. Gleason said. He received \$450 to visit a doctor in the office, \$750 for speaking at a luncheon and \$1,500 for a dinner speech. He made as much as \$3,000 a day, he said.

Although he continued to see some patients, the Xyrem talks gradually became his primary source of income.

In April 2005, after a tip from a whistleblower inside Orphan Medical, the government began investigating Dr. Gleason and the company, according to an affidavit that Darren Petri, a criminal investigator for the F.D.A., filed in February in support of an arrest warrant for Dr. Gleason.

The affidavit says that a cooperating witness repeatedly taped Dr. Gleason as he discussed Xyrem, including the Denver talk where he compared Xyrem to table salt and a meeting in November where he said Xyrem was safe for children.

The indictment also charges that Dr. Gleason committed fraud against insurance companies by advising doctors to leave blank an area on the Xyrem prescription form that asked for a disease diagnosis. Dr. Gleason acknowledges that he told doctors not to offer a diagnosis but says he never told them to lie if they were asked for one.

Dr. Gleason says he did not know he was under investigation when he went to Great Neck, N.Y., on March 5 to talk to doctors about Xyrem during a lunch meeting at the office of Dr. Richard Blanck, a neurologist. The meeting had been arranged by a Jazz Pharmaceuticals salesman, Al Caronia, Dr. Gleason said.

An Unexpected Arrest

Dr. Blanck confirmed the meeting and said Dr. Gleason's comments seemed typical for a sales presentation sponsored by a drug company. Mr. Caronia did not return calls seeking comment.

Afterward, Dr. Gleason says that Mr. Caronia drove him to the Long Island Rail Road station in the village center, to begin his journey home. When he stepped out of the car, Dr. Gleason says, Mr. Petri and other investigators surrounded him, bundled him into a sport utility vehicle and drove him to the Great Neck police station.

Mr. Caronia was not arrested.

The federal agents said he would have to cooperate in their investigation into Jazz Pharmaceuticals, Dr. Gleason contends. “They said, ‘Who in this company roped you into this conspiracy?’ ”

Insisting that he had broken no laws, Dr. Gleason said he tried to persuade Mr. Petri and the others that his views on Xyrem were scientifically based. He was released later that day.

Dr. Gleason’s account is at least partly supported by a letter on March 13 from Geoffrey Kaiser, an assistant United States attorney, to Lois Bloom, the federal magistrate judge overseeing the case. In the letter, Mr. Kaiser asks that the case be kept quiet because Mr. Gleason may “be willing to cooperate with this office in its broader investigation.”

On Bail and Short on Work

The same day, Dr. Gleason was arraigned in Federal District Court in Brooklyn, where he was released on a \$150,000 bond.

It was not until three weeks later, on April 5, that the federal attorney’s office announced Dr. Gleason’s arrest, with the news release comparing him to a snake-oil salesman. As he awaits further hearings and trial, Dr. Gleason, who is divorced, is supporting himself by working as an in-house doctor on short-term contracts. For a brief period, he worked at a Maryland state hospital, before being let go. He said the hospital told him he had been fired because of the indictment; a spokesman for the hospital declined to comment.

Now he is filling in at various hospitals in Western states, which he did not want to identify for fear of losing the work.

As for his former benefactor, Jazz, Dr. Gleason says the company told him it was now cooperating with the investigation and that he would have to face the indictment on his own.

“They’re just cutting me loose,” he said.

For all that, Dr. Gleason said he still believed in Xyrem. “The only thing symmetrical with the efficacy and safety of GHB is the hysteria about it.”

Those sorts of claims discomfort even other doctors and researchers who agree that the drug may be useful.

“He is a very smart man, and I believe he is extremely well intentioned,” Dr. Scharf said. “But this is not candy. It’s not a cure-all.”

June 28, 2006

Charities Tied to Doctors Get Drug Industry Gifts

By [REED ABELSON](#)

As she presented research results indicating that a new medical device was "an important breakthrough," the doctor's enthusiasm was clear. Less evident were some of the financial links between the researchers and the device's maker.

Dr. Maria Rosa Costanzo, making her presentation at a March conference of cardiologists, said the study found that a \$14,000 blood filtering device was better than intravenous diuretic drugs at removing excess fluid from patients with heart failure.

Although outside researchers raised questions about the study's conclusions, the doctor betrayed little doubt. "We believe these results challenge current medical practice and recommendations," said Dr. Costanzo, who predicted many patients might benefit.

Dr. Costanzo did disclose to the audience that she was a paid consultant with stock in the device's maker, a Minnesota company called CHF Solutions. But she omitted another potentially important detail: CHF Solutions was also one of the largest donors to the nonprofit research foundation that had overseen the study. The company contributed about \$180,000 in 2004, according to the foundation's federal filings.

Nor did she note that the nonprofit entity, the Midwest Heart Foundation, was in turn an arm of the thriving for-profit medical group outside of Chicago where Dr. Costanzo and more than 50 of her fellow doctors treat heart patients — in many cases using products and drugs made by CHF Solutions and other big donors to their charity. Although the CHF Solutions device has generally been slow to catch on, physicians at Dr. Costanzo's medical group have treated many patients with the company's filtration system.

The Midwest Heart Foundation, and the way it has become quietly interwoven into its doctors' professional lives, is far from unique. Around the country, doctors in private practice have set up tax-exempt charities into which drug companies and medical device makers are, with little fanfare, pouring donations — money that adds up to millions of dollars a year. And some medical experts see that as a big problem.

The charities are typically set up to engage in medical research or education, and the doctors involved defend those efforts as legitimate charitable activities that benefit the public. But because they operate mainly under the radar, the tax-exempt organizations represent what some other doctors, as well as regulators and industry consultants, say is a growing conduit for industry money. The payments, they say, can bias the treatment decisions of physicians, may lead to suspect research findings and at times may even risk running afoul of anti-kickback laws.

Federal officials are starting to take notice of such tax-exempt charities, which critics say are becoming increasingly popular as other forms of industry support to physicians — like lucrative consulting agreements that involve little actual work — have come under scrutiny from regulators and others worried about the potential conflicts.

The potential for abuse by these charities is clear, critics say. "It obviously sets a fertile ground for conflict of interest and misuse of funds," said Dr. Robert M. Califf, vice chancellor for clinical research at Duke University Medical Center.

The charities at issue are not philanthropies like the [Bill and Melinda Gates Foundation](#) that dispense grants for medical research but remain independent of any one group of doctors or medical practice. Instead, the charities drawing scrutiny are set up by doctors in private practice and are closely linked to those doctors' for-profit medical groups.

The Midwest Heart Foundation, which has received millions of dollars from medical industry donors, including the drug makers [Amgen](#) and [AstraZeneca](#), and the Cordis and Scios units of [Johnson & Johnson](#), says it stands behind its charitable work, which currently involves about 30 studies and dozens of doctor-education lectures each year.

Dr. Mark Goodwin, a managing partner for the Midwest Heart for-profit practice, said the foundation was created to help prevent potential conflicts by keeping the industry money separate from the doctors' private practice. Companies contribute to the foundation, he said, because they can rely on its research and the doctors involved can enroll large numbers of patients in studies. "We are able to deliver excellent research to our community in a timely fashion," Dr. Goodwin said, "and we are proud of it."

But some of its research has drawn criticism from federal regulators. Earlier this year, moreover, the foundation received a Justice Department subpoena as part of an investigation into the marketing activities of one of its big contributors, Scios.

Experts aware of the various doctor-run charities say that even if much of the donated money is spent on legitimate medical research or education, the funds can also go toward studies that while lending prestige to the doctors and luster to the companies, may do little to advance scientific understanding. The tax-exempt money also sometimes flows to the for-profit medical groups affiliated with the charities, sometimes covering business expenses or even paying parts of the salaries of doctors.

Too often, the critics contend, the industry donations amount to a form of "relationship funding" — to use one skeptical doctor's term — in which companies hope to sell more drugs and devices by currying favor with the doctors. That skeptic, Dr. John Cherf, is a knee surgeon at the Neurologic and Orthopedic Institute of Chicago who also consults for a market research firm specializing in health care topics. He says the donor arrangements are fraught with potential conflicts of interest and are likely to come under greater scrutiny as the costs of devices and drugs rise.

"There's undoubtedly corruption in the system," Dr. Cherf said. "We need healthy relationships between physicians and industry. Both parties have been too aggressive."

Number of Charities Is Unknown

No one knows precisely how many of these doctor-run charities exist. Although each one files with the federal government as a tax-exempt entity, they are hard to discern among other health-related charities. And because in many cases each has no more than a few hundred thousand dollars in annual revenue, they tend to escape the attention of the federal and state regulators who oversee charities.

"The reality of it is that these are small organizations that are off the radar screen," said Douglas M. Mancino, a lawyer at McDermott Will & Emery in Los Angeles who specializes in health care law and nonprofit groups.

As long as the activities being financed benefit the public rather than the doctors or companies involved, they are legitimate charities, according to lawyers who specialize in nonprofits.

But concerns can arise when a corporate donation appears to be helping pay the salary of an additional doctor at a for-profit medical practice — through a fellowship, for example — that brings in additional revenue to the practice. Another problem area, they say, would be when donations go toward expenditures that would normally be part of the practice's business cost.

Lawyers say that determining whether a charity's activities are legitimate tax-exempt activities would typically require a close look at the facts in each case.

"If they're really underwriting normal business expenses to the group, then I think you have a problem," Mr. Mancino said.

As a group, these relatively obscure charities are attracting sizable amounts of corporate money. And many of their activities focus on the companies that have made the donations or the doctors' medical groups.

Consider the Arizona Orthopedic Education Foundation, which was created by a surgeon in Phoenix and which in 2003 received a \$200,000 donation from a unit of the orthopedic device company Stryker. Most of the charity's efforts are devoted to public education, according to the founder, Dr. Anthony K. Hedley.

But its activities also include teaching other doctors how to use Stryker products.

Stryker said this training was "critical" for surgeons.

Dr. Hedley says the fact that he mainly uses Stryker devices with his own patients may account for Stryker's contributions. "That was probably why I was able to leverage support," Dr. Hedley said.

Another charity is the Blue Ridge Bone and Joint Research Foundation, run by Dr. Joseph T. Moskal, an orthopedic surgeon in Roanoke, Va. It received a \$75,000 contribution from the DePuy Orthopaedics unit of Johnson & Johnson in the year ended July 31, 2004, according to federal filings. The Blue Ridge foundation appears to have paid \$30,000 of that money to the for-profit Roanoke Orthopaedic Center, where Dr. Moskal practices, to defray the costs of a fellowship program there.

Dr. Moskal did not return repeated phone calls seeking comment. DePuy, in a brief response to questions, said in part, "Fellowships are vital to advance the education and training of orthopaedic surgeons."

Corporate donors are also major contributors to the Vascular Specialists Education Foundation, which is led by a vascular surgeon in Norfolk, Va., Dr. Marc H. Glickman. The foundation spent \$30,000 in 2003 to pay for the further medical education of doctors in his for-profit practice.

Although the public filings offer few details about the charity's activities, Dr. Glickman said such expenditures are part of the foundation's mandate, which includes offering fellowships to doctors being trained and paying for continuing medical education for those doctors. One of Vascular Specialists' two big donors, the device maker [Guidant](#), now part of [Boston Scientific](#), said it contributed \$25,000 in 2003 and \$40,000 the next year, through its own foundation. The company says the money was given with the understanding that it would go to finance the group's fellowship program.

The other big donor, the device maker [Medtronic](#), says it gave Dr. Glickman's charity \$80,000 last year to help pay for the group's fellowship program. "Dr. Glickman and his colleagues have trained hundreds of physicians and fellows on life-saving procedures associated with vascular disease — a notable accomplishment," Medtronic said in a written statement.

Donors have been so generous to Dr. Glickman's foundation that he says it is currently sitting on \$100,000 he has not yet decided how to spend. "I'm very cautious with what I do," he said.

Whatever the issues of tax-exempt status among the various charities, federal regulators say the groups could find themselves in trouble in another way — in violation of federal anti-kickback laws — if donations appear to be little more than a way for companies to funnel money to doctors.

If the contributions amount to payments or gifts to doctors who then use or recommend a certain drug or device, companies could be breaking the law, said Vicki Robinson, a top lawyer in the Office of Inspector General at the federal [Health and Human Services Department](#).

"From a legal perspective, it's really no different," Ms. Robinson said.

Patrick L. Meehan, the United States attorney in Philadelphia, whose office has a long history of prosecuting health care fraud, said the doctors' charities could warrant scrutiny. "What we would be concerned about are end runs around the system," Mr. Meehan said. "We want to be sure there is independent and fully informed medical judgment at the heart of the physician-patient relationship."

For their part, Midwest Heart officials defend the activities of their foundation. Contributions to the charity, which was created in 1988, have more than doubled in the last few years — to \$1.7 million in 2004, the most recent period for which federal filings are available.

In a written statement, the foundation said it had "strict internal controls and systems in place to ensure the independence and integrity of all research and education activities."

Questions About Research

Outside researchers have questioned some of the foundation's work. Some doctors say the study of the CHF Solutions filtration device that Dr. Costanzo presented in March may have been flawed, for example, because heart failure patients who were given conventional diuretic drugs may not have received enough medicine to provide meaningful comparisons.

One heart doctor critical of those findings was Dr. JoAnn Lindenfeld, who was quoted in a cardiology publication, *Heartwire*, in March as saying, "I wouldn't view these data as persuasive enough to use it full-scale in a million patients a year with acute decompensated heart failure." Dr. Lindenfeld did not dispute the accuracy of that quote but declined to comment further.

Through the Midwest Heart Foundation, Dr. Costanzo declined to comment. Both CHF Solutions and the foundation say she no longer has stock or stock options in the company.

CHF Solutions said that most of its contributions to the Midwest Heart Foundation covered the cost of conducting the research project that Dr. Costanzo led and the company helped design.

John L. Erb, CHF's chief executive, said "we were very careful" in designing the research, but he conceded that it was "not the perfect study where we could answer all the questions."

Dr. Goodwin, at the foundation, said the research was only a starting point. "We fully agree that further investigation is needed to validate the findings and carry them forward to a larger number of patients," he said.

Some of Midwest Heart's research has also fallen short of federal rules governing clinical studies. In August 2004, the [Food and Drug Administration](#) sent the foundation a warning letter about a study of a

new carotid stent — a device designed to open up a major artery in the head and neck.

The F.D.A. said Midwest Heart had failed to get necessary approval before beginning its research, which involved different types of [stents](#) and 168 patient procedures. The regulators also found that some patients were not properly informed and that the foundation was too slow in reporting serious complications. The results of the study were never published, although the foundation says they were submitted to the F.D.A.

The shortcomings were simply "record keeping" issues, said Wendy Landow, the chief executive of the Midwest Heart Foundation, who said her organization had in fact received the necessary approval to do the study but had poorly documented it. The issue has been resolved, she said, adding that the foundation had adopted tighter procedures to avoid future lapses.

A separate controversy surrounds the heart failure drug Natrecor made by Scios, which gave the Midwest Heart Foundation a total of more than \$300,000 for the years 2003 and 2004, according to federal filings. The Justice Department, which is investigating whether Scios improperly marketed Natrecor, has issued a subpoena to the foundation.

Scios said that most of its Midwest Heart contributions went toward educational programs that Scios had no influence over. It said it could not comment on the Justice Department investigation. Midwest Heart said it was cooperating with federal officials and had been told it was not a target of the investigation.

Natrecor was approved by the F.D.A. in 2001 for use in hospitals for patients only in an extreme, or decompensated, stage of heart failure. But it also became heavily used by doctors who administered it intravenously in outpatient clinics for periodic patient "tune-ups," as they were sometimes known. Natrecor's enthusiasts included some Midwest Heart doctors, who participated in studies of the drug and also used it in outpatient settings.

While doctors can use federally approved drugs for any purpose they see fit, a pharmaceutical company is prohibited from actively encouraging such off-label uses.

A Debate Over Drug's Merits

In mid-2005, after researchers elsewhere published an article in a scholarly medical journal raising concerns that Natrecor could seriously impair kidney function, one of Midwest Heart's cardiologists, Dr. Mitchell T. Saltzberg, continued to staunchly defend the drug. Dr. Saltzberg, who has also been a paid Scios consultant, wrote to Medicare officials in July 2005 to argue that the drug was being "unfairly targeted."

Dr. Saltzberg's letter cited a study of Natrecor's outpatient use — a study for which the foundation had provided some work — saying that this research and "the body of anecdotal experience" indicated the drug posed no kidney risks.

His comments to Medicare, though, came a few days after Scios itself sent a safety alert to doctors warning against the outpatient use of Natrecor. The Scios alert, issued in consultation with the F.D.A., relied on the findings of an expert panel that the company had asked to look into issues involving the drug's safety.

The Scios alert referred to the very study Dr. Saltzberg had cited and found it lacking. That study "was not powered to adequately assess the effectiveness or safety of serial infusions of Natrecor," the alert said. "The size of the study, its design and its findings provide an inadequate basis to recommend the use of intermittent, serial or scheduled repetitive infusions of Natrecor." Through the foundation, Dr. Saltzberg declined to comment. Foundation officials, though, said they agreed with the Scios panel's findings.

Outpatient use of Natrecor around the country has fallen precipitously. Scios has said it plans to conduct further research into the drug's safety.

The Midwest Heart Foundation said that only one of its patients, who is part of a study, is still being given the drug as an outpatient. But while the foundation says it believes more research is needed, Dr. Goodwin also said that he believes that many doctors had positive results with the drug and that he had seen it keep patients out of the hospital.

"It worked great," he said.

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October 20, 2006

Side Effects

New Nerve Test, a Moneymaker, Divides Doctors

By [REED ABELSON](#)

For many doctors, it's an irresistible pitch: a \$250 profit from a 15-minute test.

With that lure, some 12,000 of the nation's physicians have purchased an automated device that checks patients for nerve disease. Such a diagnosis might otherwise require extensive testing by specialists.

Indeed, many neurologists, who stand to lose money and patients from the growing popularity of the device, say that the general practitioners who use it are not always capable of discovering the true cause of a patient's symptoms. Some insurers and other doctors also have qualms about use of the automated test to diagnose possible nerve damage.

One neurologist cites an extreme case, in which a general practitioner diagnosed arm numbness as carpal tunnel syndrome but missed the main cause: a brain [tumor](#).

The system, made by a company called Neurometrix, "is being marketed to and utilized by physicians who are not qualified to do these tests," said Dr. John D. England, a neurologist at the Billings Clinic in Montana who is also an officer for a national professional society of specialists and was the doctor who discovered the brain tumor.

The popularity of Neurometrix's nerve-testing system, called the NC-stat, speaks to the zealous sales practices that some makers of medical devices employ to build the largest possible market for their products. The company's marketing is the subject of an investigation by federal regulators, with which the company says it is cooperating. But the product's success among general practitioners — the company's primary customers — also touches on a more fundamental fact of the American health care system. Medicare and other insurers tend to pay doctors much more for performing diagnostic tests and other billable procedures than for spending time talking with patients about their symptoms and figuring out how best to treat them.

"NC-stat is a Billable Procedure," says one slide in a Neurometrix marketing DVD obtained by The New

York Times.

A worksheet prepared by one former Neurometrix salesman, labeled “CONFIDENTIAL OPPORTUNITY,” showed how a doctor could realize an annual profit of \$46,588.80 by testing 10 patients a week.

“The doctor’s making margin, the company’s making money,” said the former salesman, who shared the document and spoke only on condition of anonymity.

For physicians, who might be able to bill only \$80 or so for a routine 30-minute office visit, Neurometrix’s promise of a profit as high as \$250 for 15 minutes, is compelling. So was a customer-referral program in which physicians could receive hundreds of dollars in free products for steering other doctors to Neurometrix.

Dr. Shai N. Gozani, Neurometrix’s founder and chief executive, said he could not comment on the specific marketing materials but said the company was “very ethical.”

And he said the company’s marketing efforts stressed the medical over the monetary. “I think our messaging to physicians is clinical first,” Dr. Gozani said.

Neurometrix says there is no evidence that doctors are using the tests inappropriately and that, on average, they are testing only a handful of patients a month.

“By no means do we believe this is a replacement for neurologists,” said Dr. Gozani, who said the doctors referred patients to specialists whenever necessary.

The company says it plans within the next six months to publish research on how doctors are using the test, based on their experience with thousands of patients.

While Medicare and many insurers are paying for the Neurometrix test, other insurers have rejected it as unproven or are now having second thoughts about covering it.

And a Chicago surgeon, to whom doctors have referred cases based on Neurometrix exams, also says he is wary of the diagnoses.

Whenever carpal tunnel syndrome has been found with a Neurometrix test, “it always makes me more uncomfortable,” said the surgeon, who noted that he sometimes referred such patients to a neurologist to rule out more complex problems. The surgeon insisted on anonymity for fear of offending doctors who refer patients to him.

General practitioners who have purchased the device, which sells for around \$5,000, say they are qualified to use it. The test is generally used to check for signs of nerve damage associated with carpal

tunnel syndrome, [diabetes](#) or low-back pain. The company says the system enables patients to be screened more quickly, and to start treatment sooner, than if they must wait to be seen by specialists.

Since the [Food and Drug Administration](#) approved the NC-stat in 1998, the company estimates that more than 500,000 patients have been tested with the system, in which biosensors are attached to the skin to stimulate nerves, and a hand-held device records the results. The doctor can transmit the readings to the company and within minutes receive the findings by a fax or e-mail message.

The device is “a good revenue maker,” said John Poole, a manager at the family practice Colstrip Medical Center in Montana, but, he added, “we don’t want to abuse it.”

Neurometrix, a small medical device maker with billion-dollar ambitions, says that its system has removed much of the complexity inherent in traditional neurology exams.

“We’ve put that technology in the hands of all physicians, allowing them to replicate the diagnostic accuracy of the specialist,” Dr. Gozani told financial analysts and others at a recent meeting.

Dr. Gozani, a medical doctor with advanced degrees in biomedical engineering and neurobiology, said the company’s device represented “a new standard of care.”

Still, some former employees and Neurometrix’s own sales materials portray a company willing to go to great lengths to sell its device.

In May, Neurometrix said the [Department of Health and Human Services](#) had issued a subpoena for documents from the company in connection with potential kickbacks and possible fraud against the federal government. The company offered no further details, and federal regulators declined to comment.

Several former employees and Neurometrix documents also describe a program to reward physicians who are already customers, if they find other doctors who will purchase the system. The company gave away boxes of the disposable biosensors that are used with the system — which Neurometrix typically sells to the doctor for around \$200 a box.

“Allow us to thank you for your loyalty,” reads a document from this year. If a prospective customer agreed to meet with a sales representative, the referring doctor got one box of sensors — and a second if the prospect became a customer.

Giving doctors something of value for referrals is an industry practice that can potentially violate federal antikickback laws, said Bruce A. Levy, a lawyer in Newark who used to work for the United States attorney there.

Dr. Gozani said the giveaway program had been “extremely small,” involving a tiny fraction of the

sensors the company sells. He said Neurometrix had recently stopped it, but declined to comment further.

Neurometrix, based in Waltham, Mass., is eager to please Wall Street and investors with fast growth. The company went public in 2004. Sales last year doubled, to \$34 million, and are expected to be \$55 million or so this year.

Neurometrix cites numerous studies, written up in medical journals, that compared its nerve tests with traditional methods and found them just as accurate.

Medicare and many other insurers, including some Blue Cross/Blue Shield plans, have paid for many of the tests. But some large insurers, including [Aetna](#) and [Cigna](#), say they do not generally cover the Neurometrix test because there is inadequate clinical evidence to support it. Cigna says it is reluctant to cover a new test when there are existing methods that have proven reliable in making a diagnosis.

The federal Medicare program leaves the coverage decision to the nearly 20 regional insurers that oversee payments to physicians. Some of these regional Medicare offices are currently reviewing their coverage policies on the Neurometrix test.

Physicians using the device have not told the company they are having trouble getting reimbursed for the tests, Dr. Gozani said. But doubts about insurance coverage have contributed to the volatility of Neurometrix's stock price in recent months. Short-sellers — investors who bet that a stock's price will fall — have a large position in the stock.

The debate within the medical community has been muted in part by letters from Neurometrix threatening legal action against some doctors who criticized its technology.

One target was the Arizona Neurological Society, after its Web site posted a sharp critique, according to the society's president, Dr. Terry D. Fife. The critique claimed that the Neurometrix system produced "results that may be misleading or even wrong" and suggested doctors "are likely to use it excessively for the sole purpose of generating income."

Dr. Fife said he received a threatening letter in August from the company's lawyers, saying questions about the test's accuracy were "unsubstantiated innuendo." If the Web site continued to post the commentary, the letter said, the society would risk "legal claims both for violations of the antitrust laws and for defamation and for miscellaneous other intentional torts."

Dr. Fife said that he removed the critique and that the society did not plan to publicly comment on the technology again, because it did not want to risk a lawsuit.

The company says it has sent letters only in isolated cases. "We are by no means trying to limit the discussion," Dr. Gozani said.

For some health policy analysts, the popularity of such procedures illustrates why primary care doctors should be paid more for basic office visits and less for money-making procedures. Earning \$250 from a diagnostic test “is obviously out of line with what physicians can earn from office visits,” said Paul Ginsburg, the president of the Center for Studying Health System Change, a Washington research group.

But many primary care doctors, including family physicians, defend their adoption of the Neurometrix test and say they are not overusing it.

“Family physicians can safely and reliably administer the tests,” said Dr. Keith Lehman, an official with the Ohio Academy of Family Physicians, which has been fighting efforts by the Medicare administrator in that state to curtail use of the tests. “It’s more convenient for the patients,” he said, “and it’s quicker.”

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Diabetes & Endocrinology Specialists

I. Patients

10 Patients per Week	40 Patients per Month
3 Sensors per Patient	120 Sensors per Month
(Protocol: 2 Peroneals, 1 Median M/S)	

II. Sensors Required

12 boxes (84 sensors) Peroneal @ \$192.00 per box	\$1,152.00
6 boxes (42 sensors) Median M/S @ \$258.00	<u>\$1,548.00</u>
Total Cost:	\$3,852.00

III. Revenue and Profit

50% Medicare, 50% Private	
1 DPN Study (3 of 95903 + 1 of 95904)	\$204.06
3 Sensors	+ \$107.00
Net Profit per Patient	\$97.06
Net Profit per Month	\$3,882.40
Net Profit per Year	\$46,588.80

IV. Volume Incentives

A. Cost	
2 boxes Free-Median M/S @ \$258	\$516.00
Discount on Purchase:	13.4%
B. Economic Value	
2 boxes = 12 tests @ \$96.53 (Profit)	\$1158.36
Discount on Purchase:	30.1%

V. Business Opportunity

A. Offer	
Buy 18 Boxes; Receive 2 Boxes Free	
Buy 12 Boxes Peroneal	\$2,304.00
Buy 6 Boxes Median M/S	<u>+\$1,548.00</u>
	\$3,852.00

B. Value
Receive 2 Boxes Median M/S FREE

Discount on Purchase

Cost	\$516.00	13.4%
Economic Value	\$1,158.36	30.1%

CONFIDENTIAL OPPORTUNITY

INTRODUCING THE NEUROMetrix REFERRAL REWARDS PROGRAM

Dear Valued NEUROMetrix Customer,

You recently indicated a willingness to recommend the NC-stat System to a colleague.
By enabling us to contact your colleagues and communicate the practice benefits you have enjoyed with the NC-stat System, you will receive a special thanks.



It's Easy...

1. Provide us with names of colleagues you feel would benefit from the NC-stat System.
 Please provide each colleague with a courtesy phone call, to alert them of upcoming call from NEUROMetrix.
2. Receive 1 **FREE BOX** of sensors after your colleague's appointment with NEUROMetrix.
 Receive 1 **ADDITIONAL** free **BOX** of sensors when your colleague becomes a customer.
3. Your colleague will receive 1 **FREE BOX** of sensors when they become a NEUROMetrix customer.

**ALLOW US TO
 THANK YOU
 FOR YOUR
 LOYALTY.**

ACT NOW...All Referrals Must Be Received by March 31, 2006 to Qualify.

<u>Colleague 1:</u>	<u>Colleague 2:</u>
Name:	Name:
Practice Name:	Practice Name:
City/State:	City/State:
Telephone: (Check if appropriate): Has Been Contacted by phone ?	Telephone: (Check if appropriate): Has Been Contacted by phone ?
<u>Colleague 3:</u>	<u>Colleague 4:</u>
Name:	Name:
Practice Name:	Practice Name:
City/State:	City/State:
Telephone: (Check if appropriate): Has Been Contacted by phone ?	Telephone: (Check if appropriate): Has Been Contacted by phone ?

PLEASE FAX TO: 781-207-1095

BONUS: Any colleague who BUYS NC-stat by March 31, 2006 will receive 2 FREE BOXES of sensors.