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BRYAN VROON AND THE FALSE CLAIMS CASES AGAINST MORE THAN 500 HOSPITALS

If you look at Bryan Vroon's web site, you might think it's the web site of a political philosopher.

There's a quote from Kierkegaard: We create ourselves by our choices.

And then one from Teddy Roosevelt: Far away the best prize that life has to offer is the chance to work hard at work worth doing.

One from Victor Hugo: Life, misfortunate, isolation, abandonment, poverty are battlefields that have their heroes -- obscure heroes, sometimes greater than the illustrious heroes.

And from Benjamin Franklin -- There is no kind of dishonesty into which otherwise good people more easily and frequently fall than that of defrauding the government.

Bryan Vroon for years was a partner at the corporate law firm of Alston & Bird in Atlanta.

Then he jumped ship and opened his own plaintiff side law firm.

Since going out on his own, Vroon has brought cases against more than 500 hospitals for defrauding Medicare.

Those cases resulted in over \$280 million in settlements under the False Claims Act. Just last week, fifty-one more hospitals settled for \$24 million.

Vroon represented two whistleblowers -- Leatrice Richards, a registered cardiovascular nurse and Medicare-compliance and reimbursement consultant, and Thomas Schuhmann, also a Medicare-compliance and reimbursement consultant, both from Louisville, Kentucky.

They alleged that the hospitals improperly billed Medicare for surgical procedures to implant cardioverter defibrillators (ICDs).

The Justice Department negotiated 81 separate settlements with the hospital systems, including some of the largest systems in the country. HCA and Tenet Healthcare, for example, agreed to pay \$15.8 million and \$12.1 million, respectively.

The announcement includes a \$5.9 million settlement with a San Francisco-based hospital

system.

"This investigation is critically important to patient care now and in the future," Vroon said. "Science-based medicine protects elderly patients and the Medicare Program."

The federal investigation led by Department of Justice attorneys Jeffrey Dickstein and Amy Easton dramatically influenced cardiac care by requiring adherence to Medicare's science-based coverage conditions.

Vroon said that the federal investigation has resulted in major reductions in the numbers of patients undergoing surgeries to implant ICDs -- approximately 20,000 fewer each year.

Since the beginning of the Department's investigation, surgeries to implant ICDs in Medicare patients have decreased by approximately 28 percent, representing a savings of over 2 billion dollars to the Medicare Program during the last five years, Vroon estimated.

The ICDs at issue were implanted in patients' chests within days after the patients had suffered heart attacks or undergone cardiac bypass or angioplasty procedures.

Scientific studies have demonstrated that in many patients, implanting an ICD in the weeks after a heart attack is not beneficial and is potentially harmful to the heart as it heals. Such harm includes worsening heart failure. Additionally, the heart may recover function in time, rendering an ICD not only premature but never needed.

The waiting periods -- 40 days after a heart attack and three months after a bypass or angioplasty procedure -- are generally established in the National Coverage Determination (NCD), Medicare's requirements for coverage. The National Coverage Determinations ensure that Medicare patients receive "reasonable and necessary" medical treatment based on science.

Numerous published studies have confirmed the importance of following the established indications and contraindications for implanting an ICD.

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(VROON, from page one)

For example, a major study led by medical researchers at Duke University reported, "Patients who received a non-evidence-based ICD had significantly more comorbidities than patients who received an evidence-based device and were at a higher risk of post-procedural complications (including death)."

The Department of Justice worked with leading cardiology experts to develop a settlement model that permitted the hospitals to present potential evidence justifying the surgeries at issue.

Still there were approximately 10,000 surgeries found nationally where ICDs were implanted in violation of science-based medicine or the National Coverage Determination.

Vroon said that the case is a prime example of what Donald Berwick, the former Administrator of the Centers for Medicare and Medicaid Services, called "overtreatment" – or "care rooted in outmoded habits, supply-driven behaviors, and ignoring science" – which he estimated cost Medicare and Medicaid \$87 billion in 2011 alone.

"The settlements in this case are a window into a much larger problem in American healthcare," Vroon said.

Vroon praised Dickstein and Easton for the success of the case.

"Jeffrey Dickstein and Amy Easton led this investigation with extraordinary dedication to Medicare and the medical care of elderly patients," said Vroon. "Their work over eight years was tireless and determined to ensure that Medicare patients receive needed treatment based on science."

Vroon said that his move from Alston & Bird to private practice was not an easy one.

"I had three small children," Vroon told *Corporate Crime Reporter* in an interview last week. "They have school tuition. We have mortgages. I took out a second mortgage on my house. I leveraged my house to the max. I cashed in my retirement. There was a huge amount of risk. Ted Turner said -- follow your heart but make sure you are right. I knew I was following my heart, but there were many times when I didn't know whether I was right or not."

(For the complete interview with Bryan Vroon, see page 12.)

INTERVIEW WITH BRYAN VROON, FALSE CLAIMS ACT ATTORNEY, ATLANTA, GEORGIA

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Bryan Vroon for years was a partner at the corporate law firm of Alston & Bird in Atlanta.

Then he jumped ship and opened his own plaintiffs firm.

Over the past year, he has settled cases against more than 500 hospitals for defrauding Medicare and recovered over \$250 million in settlements under the False Claims Act.

We interviewed Vroon on February 15, 2016.

CCR: You graduated from Vanderbilt University Law School in 1987.

VROON: I came back to Atlanta and joined Alston & Bird. I then joined a smaller firm before rejoining Alston & Bird as a partner. I left Alston & Bird in 2004 and started my own firm to pursue health care fraud cases.

CCR: What was your work at Alston & Bird?

VROON: I was in the Litigation Department. I did product liability defense work and some class action defense work.

CCR: How long were you at Alston & Bird?

VROON: I was at Alston & Bird combined for about eight years. And I was at the smaller firm for about seven years.

CCR: That is an unusual career trajectory -- lawyers going from doing defense work at a big corporate firm to going out on their own to do plaintiffs' side work. What led you to that?

VROON: There was a speech by the former director of the Centers for Disease Control and

Prevention. He was talking about pursuing public health issues. And he said -- you are not going to run out of money. You are going to run out of time. It was maybe idealistic on my part. I had three young sons at the time. In hindsight, I'm not sure I would do it again. But I did it and it worked out well, fortunately.

CCR: Were you introduced to the False Claims Act at Alston & Bird?

VROON: No. I stumbled on one False Claims Act in 2005. One thing led to another. There were some failed efforts to file these cases. I was fortunate to meet some people who were interested in working on those cases.

CCR: When you decided to go out on your own, was it in your mind to pursue False Claims Act cases?

VROON: Not really. It was in my mind to do cases in the public health arena -- whether that be medical cases, product liability cases, pharmaceutical cases. At Alston & Bird, I had done a lot of science work. I was on a team of people who looked at the public scientific studies and determined legal strategies from those studies. I wanted the option to follow the science wherever it led -- whether it be plaintiffs or defense. While at Alston, I was locked into doing only defense work and I couldn't choose the issue of science. Coming out of Alston & Bird, I had that freedom, but also had a lot of insecurity and risk and major stress.

When I left, I left with nothing. I had no clients I could take with me. My clients at Alston were major medical device or pharmaceutical companies. None of those clients would go with an attorney who wants to go out on his own. I had no clients when I left. I had no work. Since I left in 2004, I don't know how it happened, but I never had a day without plenty of work. Not all of it paid off, but at least I was trying.

CCR: Was your leaving Alston & Bird a matter of conscience?

VROON: There is nothing unethical about Alston & Bird. It's a phenomenal and fantastic firm. I wouldn't say it was a matter of conscience or protest. It was a matter of desire, interest and passion to do something a little different.

CCR: Were these hospital cases your first big settlement?

VROON: I had a False Claims Act case settled in 2010 for \$13 million. That was a single hospital case. That was my first False Claims Act settlement.

CCR: Was that an ICD settlement also?

VROON: No it wasn't. It was a case involving a hospital submitting false claims to the government to get extra funding from federal subsidies. I also had a case last fall -- it was a \$70 million Stark settlement against Broward Health in Miami. At the time, it was the largest Stark settlement without litigation. That was a major case. I was fortunate to represent a doctor down in Miami who brought that case.

CCR: Was there anytime after leaving Alston & Bird when you were up against it financially and wondering whether you done the right thing to leave?

VROON: Absolutely. I had three small children. They have school tuition. We have mortgages. I took out a second mortgage on my house. I leveraged my house to the max. I cashed in my retirement. There was a huge amount of risk. Ted Turner said -- follow your heart but make sure you are right. I knew I was following my heart, but there were many times when I didn't know whether I was right or not.

CCR: Is your practice primarily False Claims Act right now?

VROON: One hundred percent right now. It is really what I want to do.

CCR: But it wasn't just False Claims Act coming out of the box?

VROON: No, coming out of the box it was looking at everything. I did class actions on behalf of uninsured patients against hospitals. We filed cases in 23 states.

The uninsured patients were charged master rates, which are much higher than any other patient category. I was involved with a group of plaintiffs' attorneys pursuing those cases. I thought those cases were very viable and had a lot of merit. But we failed. We got beat everywhere.

CCR: What was your argument?

VROON: These patient entering the hospitals are given consent to treatment forms and the hospitals did not disclose the rates, the itemized bill, there is no estimate of the bill. When the patients are discharged, they get a bill that is multiple times what other Medicare patients, insured patients have to pay. These were non profit hospitals charging those rates. We argued that that practice violated fundamental contract law. But we did not win on that issue.

CCR: This ICD cases -- this is your biggest

settlement to date, by far. How did these cases come in the door for you?

VROON: I was doing other cases and was recommended to what would become my future clients. One thing led to another. I was fortunate and lucky.

CCR: What were the allegations?

VROON: The allegations were that the hospitals were implanting these ICDs into Medicare patients in violation of the National Coverage Determination.

CCR: What is an ICD?

VROON: An ICD is a device that is planted below the heart. It has wires that connect to the heart. When a patient's heart experiences a rapid heart rate, fibrillation, the ICD device will send an electrical shock to the heart and hopefully shock it back into a rhythm. But some of the patients getting these devices had never experienced ventricular tachycardia -- which is rapid heart rate -- or ventricular fibrillation -- which is where the heart shudders and shuts down.

But the ICDs were implanted in these patients as a precaution -- in the event that they ever did experience those episodes. There are science based conditions under which these ICDs should be implanted. And those science based conditions are based on published studies. And the NCD is based on those published scientific studies.

We alleged in this case that many hospitals were implanting these devices under clinical conditions that were not indicated. The studies had indicated that the device should not be implanted under those conditions because it is not helpful and it can be harmful.

CCR: Under which conditions were they being implanted where the standards were not being met?

VROON: One was within weeks after an acute heart attack. When a patient has a heart attack, the heart muscle experiences severe trauma and bruising. The heart muscle can recover. But it takes time. In these cases, the hospitals and physicians implanting these devices were doing it in the same hospital admission as the patient experiencing the heart attack. And the scientific studies showed that that is not helpful and it can be harmful.

CCR: When was the lawsuit filed?

VROON: We filed it under seal in January 2008 in Miami against hundreds of hospitals.

CCR: Did the federal government intervene?

VROON: There was never an official intervention.

But they took over the investigation, they led the investigation to reach the settlements. Once the settlements were reached, there were stipulations of dismissal filed with the court as the settlements occurred.

CCR: You were working with Justice Department attorneys out of Washington or Miami?

VROON: Jeffrey Dickstein out of Miami and Amy Easton out of Washington. They were the only two attorneys from the Justice Department, to my knowledge, who worked on this case. They travelled extensively. They worked incredible hours for years, many sacrifices, being away from their families, their homes. And they did brilliant work.

CCR: After the federal investigation began, a major study was released from Duke University. They looked at more than 100,000 patients who received ICDs and found that almost a quarter of them were non-evidenced based ICD implants.

VROON: The authors of the study concluded that there needed to be more vigilance to adhere to the science based conditions of implanting these devices. They found that 22 percent were implanted in situations that were not supported by the science.

That study came out in 2011. That was three years into the investigation by the Justice Department. And it was an important study that confirmed and validated our case in a major way.

CCR: Since the Department opened its investigation in 2008, these ICD procedures in Medicare patients decreased by about 28 percent. You have estimated that saved the federal government \$2 billion.

VROON: Just in the last five years. The hospitals received notices of the investigation roughly in 2010. The Justice Department issued those subpoenas. Once they were on notice of the investigation and what the Justice Department was looking at, you begin to see ICD implants decline dramatically. The \$2 billion savings estimate is a conservative estimate. That was just based on a \$25,000 cost per implant to the Medicare program. I didn't include the follow up care, the lifetime care that's required for these devices. It was a conservative estimate. The number is really much higher than \$2 billion.

CCR: What is the defense of the hospitals?

VROON: The Justice Department gave them a chance to present whatever defense they had. They created a system that would allow the hospitals to bring their experts to settlement meetings and audit

meetings and present whatever evidence they wanted to present. The Justice Department took an open approach to allowing the hospitals to do that. They listened to their arguments on the medicine and they still found all of these violations that were either against the NCD or a violation of science based medicine or both.

The Justice Department developed a resolution model that allowed for some of these considerations to get a pass. But they still found thousands of violations.

CCR: Are you convinced that the hospitals were doing this just to rake in the money?

VROON: I don't want to make that allegation. Motivations in medicine are complex and complicated. We are convinced that the science didn't support it, the NCD didn't support it. I can't go into every clinical situation and determine the motivation of the doctors who did this. I know the science and the NCD didn't support these devices going in at the times they went in.

CCR: The Duke researchers reported that patients who received a non evidence based ICD had significantly more comorbidities than patients who received an evidence based device and were at a higher risk of postprocedural complications including death. Is there a death figure?

VROON: I wouldn't have access to those figure. We looked at single admission hospitalizations for Medicare patients. We had access to the clinical and procedure codes submitted for a single hospital admission. We were not able to see what happened to the patient in the weeks and months after that.

CCR: Were you the only attorney on these cases?

VROON: I was the lead attorney on the plaintiffs side. These were the only two whistleblowers.

CCR: The two whistleblowers went against 500 hospitals. How did they know?

VROON: They had restricted access to Medpar data, which included the procedure and diagnostic codes submitted by hospitals to Medicare. There are many codes submitted. We studied those codes and determined that the NCD was being violated.

CCR: What were the big hospital systems that were involved?

VROON: All the major systems in the country. HCA, Tenet, Adventist, Ascension, Dignity Health.

CCR: You were sitting across the table from a string of corporate lawyers representing these hospital chains?

VROON: Amy Easton and Jeffrey Dickstein were, I

was not. As relator's counsel, I was not privy to the settlement meetings. That's typical.

CCR: The plaintiff's attorney doesn't have a say in the settlement?

VROON: We can review the settlement. And Jeffrey Dickstein and Amy Easton provided us full information about the settlements. And we were given a chance to give feedback. But we did not participate in the settlement meetings. We did not participate directly in the negotiations.

CCR: Let's say you don't like the deal the government agrees to. Is there anything you can do about it?

VROON: You can go to the court. A relator has a right to object to a settlement. You can request a hearing to present the basis for your objection.

CCR: Over 500 hospitals have settled. About 505 hospitals The total settlement amount is what?

VROON: \$281 million.

CCR: What is the relator's share?

VROON: Fifteen percent. So the relator's share is about \$41 million.

CCR: We opened the interview and you were talking about a person from the CDC who said -- you will run out of time before you run out of money. Was this person encouraging people to get into the False Claims Act field?

VROON: No, I don't think so. He's a scientist. And he was encouraging people to do things in the public interest, in public health. I am not a scientist. I don't have a degree in science or medicine. But this was my small way of following his advice.

CCR: In terms of deterrence, once the government, as a result of your lawsuit, began investigating, the system reacted.

These unauthorized procedures began to drop remarkably, saving the system more than \$2 billion. It had direct deterrent effect.

VROON: I'm convinced it's because of the federal investigation. The federal investigation started three years before the Duke study came out in 2007. Hospitals were aware of this investigation before this Duke study came out. You can imagine when you have an investigation of this scope, word travels fast. I'm convinced it was the federal investigation, but I don't have access to interviews of hospital executives, of course.

CCR: Tell us about the relators -- Leatrice Richards and Thomas Schuhmann.

VROON: Leatrice is a cardiovascular nurse. She had her own consulting firm for a number of years.

She had worked within hospital systems and had audited charts and looked at indications for procedures.

Tom Schuhmann is a reimbursement consultant and had been in the Medicare field for years. It was a risk for both of them. If you look back on this case, in hindsight, you would say -- that's impossible.

CCR: What's impossible?

VROON: The feasibility of filing and winning a case like this looked to be impossible. It was very challenging. Historically, the Justice Department is not in a position to go in and look at medical charts. That's not what the Medicare program or the Justice Department typically does. It's a difficult challenge to do that -- for obvious reasons. Thanks to two attorneys -- Jeffrey Dickstein and Amy Easton -- this case had enormous success against impossible odds.

CCR: You call this a landmark case. Not just in terms of the numbers -- but it's a landmark case because --

VROON: So much happens to Medicare patients that is never reviewed. There are so many tests, so many procedures, so many surgeries. It's difficult for any governmental body that is paying the bills to review all of those cases. In this case you had multiple indicators from the codes being submitted by the hospitals that there were major compliance problems with respect to these surgeries.

And the Justice Department tracked those codes, went in and looked, audited the medical codes and they found major violations. I don't know another case where the Justice Department was able to do this on a systematic national basis for Medicare patients.

CCR: What percentage of these cases are now settled?

VROON: Nearly all of the hospitals that were in the third complaint. A few will be dismissed. They have too few claims. Nearly 90 percent have settled.

CCR: And the rest will be settled here soon?

VROON: Yes, with a few exceptions.

CCR: What are the implications for your practice? Where do you want to focus your attention?

VROON: Health care fraud cases. It's the work I love to do. I'm looking at a lot of Stark cases and all kinds of other cases. You get a lot of calls when you get some publicity. But health care fraud cases are what I want to focus on.

CCR: What cases do you have in the pipeline?

VROON: I can't get into it. They are under seal. These are not isolated problems. The calls come

from all over the country. I've gotten calls from faraway places -- every region of the United States.

CCR: What percentage of the cases do you take?

VROON: You learn as you go. Ten years ago, I would have taken a much higher percentage. I have had some losses. I have learned and gotten a little wiser, I hope. The percentage is fairly small now -- maybe I'll take one or two out of ten cases.

CCR: Of the cases that you take, what's your batting average?

VROON: The ICD settlements pushed my batting average up pretty high.

CCR: What was your batting average before the ICD cases?

VROON: Probably .300.

CCR: Now it is going to get better because you can be more selective.

VROON: And smarter and wiser, we can hope.

CCR: You have to admit that you generally don't see that jump from big corporate law firm to plaintiffs firm.

VROON: I was 42 when I did it. I had thought about it for a number of years and probably should have done it earlier. It depends on the disposition of the person or the passion of the person. For me, I waited too long, based on my own instincts and drive.

But I also waited so long that I had young children, which wasn't optimal. But I survived.

CCR: Do you know of any others who made a similar move from defense to plaintiffs firm?

VROON: Not many. We are all looking for freedom. And if you have major bills to pay and you have overhead, which we all do, it eliminates a lot of options from your freedom. Sometimes, you just have to take a major leap and a major risk to try and find that freedom. It's a hard thing to do.

CCR: I noticed on your web site, you quote Kierkegaard, Teddy Roosevelt, Benjamin Franklin, Victor Hugo, da Vinci.

Is that you? Or some PR firm?

VROON: That's all me. I don't know if my web site is effective or not. But it's me. I see so many lawyers who are braggadocious on their web sites. To me it's like listening to the presidential debates -- it's nauseating. I wanted to do something different. You hope your work can inspire you. You hope you do things that are inspiring. For me, those quotes are just trying to keep me on track.

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