THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLORADO

Criminal Action No.

UNITED STATES OF AMERICA,

Plaintiff,

v.

1. GEORGE JOHN SCHULTE, aka JOHN SCHULTE,
2. OBINNA ADIGHIJE, aka LARRY ADIGHIJE,
3. TRUNG PHAM, and
4. HERNAN RICAURTE,

Defendants.

INDICTMENT
18 U.S.C. § 371
(Conspiracy to Defraud the United States)
18 U.S.C. § 545
(Receipt of Merchandise Brought Into the United States Contrary to Law)
18 U.S.C § 1001
(False Statements)
21 U.S.C. § 331(a)
(Introduction Into Interstate Commerce of Adulterated and Misbranded Medical Devices)
21 U.S.C. § 331(c)
(Receipt In Interstate Commerce of Adulterated and Misbranded Medical Devices and the Delivery Thereof For Pay or Otherwise)
and
18 U.S.C § 2
(Aiding and Abetting)

The Grand Jury charges:

At all times relevant to this Indictment:

INTRODUCTION

1. The United States Food and Drug Administration ("FDA") was the agency of the United States responsible for enforcing the provisions of the Federal Food, Drug, and Cosmetic Act

(the "FDCA"). The FDA's responsibilities included regulating the manufacture, labeling, and distribution of medical devices shipped or received in interstate commerce.

2. The FDCA defined a "device" as "an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is . . . intended for use in the . . . the cure, mitigation, treatment, or prevention of disease, in man . . . or . . . intended to affect the structure or any function of the body of man . . ., and which does not achieve its primary intended purposes through chemical action within or on the body of man . . . and which is not dependent upon being metabolized for the achievement of its primary intended purposes." "Devices" are interchangeably referred to as "medical devices."

3. Under the FDCA, medical devices like medical lasers, excimer lasers, laser catheters, laser guide catheters and peripheral devices associated with them such as guidewires used in coronary and perpherial angioplasty or atherectomy procedures, percutaneous transluminal angioplasty ("PTA") balloons, and other types of catheters, must be either cleared or approved by FDA for each intended use prior to being distributed in interstate commerce, unless they are exempt from clearance or approval.

4. United States Customs and Border Protection ("CBP") was the agency of the United States responsible for assessing duties, collecting duties on imported goods and preventing the smuggling of goods into the United States. By agreement with the FDA, CBP also cooperates in the enforcement of provisions of the FDCA relative to the importation of medical devices.

CORPORATE ENTITIES

5. **"SPNC"** was a corporation formed and existing under the laws of the State of

Colorado and located in Colorado Springs, Colorado. SPNC manufactured medical lasers and related devices associated with them. Those related devices included catheters that serve as intravenous sleeves that contain the lasers. Physicians used the lasers to perform atherectomies, which are types of procedures that remove plaque buildup from arteries or vein grafts in order to ease blood flow.

6. **"BMT"** was a German corporation. BMT manufactured medical devices including PTA balloons. The PTA balloons were intended to be inserted into vascular tissue through catheters and inflated in order to compress arterial plaque against the vessel walls.

7. **"FMD"** was a corporation operating in Japan. FMD manufactured guidewires used in coronary and perpherial angioplasty or atherectomy procedures. The guidewires were intended to be inserted into blood vessels to guide catheters through the vessels.

8. **"BAC"** was a corporation formed and existing under the laws of the State of Florida. BAC was a medical device consulting firm contracted by SPNC to, among other duties, identify potential sourcing partners for medical products that may be complementary to SPNC products.

THE DEFENDANTS

9. **GEORGE JOHN SCHULTE, aka JOHN SCHULTE,** was the Chief Executive Officer ("CEO") of SPNC, and was active in and responsible for the daily operations of SPNC, including directing its employees in the purchase, promotion, distribution and clinical evaluation of medical devices, including but not limited to guidewires and balloons.

10. **OBINNA ADHIGIJE, aka LARRY ADIGHIJE,** was the Vice President of Business Development at SPNC. He reported directly to **SCHULTE** and was the direct supervisor of **TRUNG PHAM**.

11. **TRUNG PHAM** was a Business Development Manager at SPNC. He reported to and was a subordinate of **ADIGHIJE** and **SCHULTE**.

12. **HERNAN RICAURTE** was a representative of **BAC** who at times was contracted by SPNC to obtain guidewires and other products from FMD.

THE DOCTORS

13. **R.G.** was a medical doctor licensed in the State of Maryland and the District of Columbia who clinically evaluated medical devices provided by defendants **SCHULTE**, **ADHIGIJE** and **PHAM** in patients, including L.K., B.W., and C.H.

14. **C.W.** was a medical doctor licensed in the State of Louisiana who clinically evaluated medical devices provided by defendants **SCHULTE, ADHIGIJE** and **PHAM** in patients, including W.S., F.T., and E.M.

15. **B.M.** was a medical doctor licensed in the State of Arkansas who clinically evaluated medical devices provided by defendants **RICAURTE**, **SCHULTE**, and other SPNC employees or representatives, in patients, including V.S., M.M., L.B., E.W., and C.A.

COUNT ONE
18 U.S.C. § 371
(Conspiracy to Defraud the United States)

THE CONSPIRACY

16. The allegations in paragraphs 1-15 are incorporated by reference as if fully rewritten herein.

17. In or about January 2004 and continuing until in or about October 2008, within the State and District of Colorado and elsewhere, the defendants,

1.GEORGE JOHN SCHULTE, aka JOHN SCHULTE
2.OBINNA ADIGHIJE aka LARRY ADIGHIJE,
3.TRUNG PHAM, and
4.HERNAN RICAURTE,

did knowingly conspire, confederate, and agree with each other and others known and unknown to the Grand Jury to defraud the FDA and the CBP, agencies of the United States, for the purpose of impeding, impairing, obstructing, and defeating their lawful governmental functions of inspecting, taxing, approving, evaluating and clearing medical devices imported into the United States and further distributed in interstate commerce.

MANNER AND MEANS

18. As part of the conspiracy, the defendants, aiding and abetting each other, imported medical devices into the United States by false declarations regarding the description, value or uses for which the medical devices were imported, thereby defeating the lawful governmental functions of CBP and the FDA.

19. As part of the conspiracy, the defendants, aiding and abetting each other, introduced and delivered for introduction into interstate commerce medical devices that were adulterated and misbranded in that they were not approved nor cleared by the FDA, nor exempt from approval or clearance, thereby defeating the lawful governmental functions of the FDA.

20. As part of the conspiracy, the defendants, aiding and abetting each other, unlawfully promoted medical devices for unauthorized uses.

21. As part of the conspiracy, the defendants, aiding and abetting each other, concealed their conduct from internal investigators at SPNC and investigators from the FDA and Department of Homeland Security.

OVERT ACTS

22. To effect the object of the conspiracy, the defendants and other co-conspirators performed overt acts in the State and District of Colorado and elsewhere, including but not limited to the following acts:

A. FMD Guidewires

(1) On or about March 20, 2005, **RICAURTE** sent an electronic mail message wherein he wrote: *"I have FedEx'd the wires to your attention. As thorough a review as possible by the SPNC engineers and by a couple of trusted physicians may be helpful in our efforts moving forward."*

(2) On or about June 26, 2005, **SCHULTE** traveled from Colorado to Japan and met with **RICAURTE**, **B.M.**, and representatives of FMD.

(3) On or about July 4, 2005, **SCHULTE** imported into the United States in San Francisco, California, a non-sterile thirty-five gram peripheral FMD guidewire.

(4) On or about July 5, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** wherein he wrote: *"Terashi-san also stressed that the sample he provided you is non hydrophilic . . . . The sample of the FMD 35g I gave Mr. SCHULTE is non Hydrophilic coating."*

(5) On or about July 5, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** discussing the June 2005 visit to FMD wherein he wrote: *"FMD will provide 10 sterile samples of each wire (50 samples) Schedule 2 months (September 15) SPNC will conduct a review after receiving sterile sample wires and will provide comments for potential design changes . . . . SPNC would submit for FDA approval by December 2005 . . . ."*

(6) On or about July 18, 2005, an employee of SPNC sent **SCHULTE** an electronic mail message wherein he wrote: *"I would like to proceed with cutting the po* [purchase order] *for the FMD wires. If have 2 minutes today, can you give me a call."*

(7) On or about July 20, 2005, SPNC submitted a purchase order for $18,400.00 to FMD for fifty sterile FMD coronary guidewires.

(8) On or about July 21, 2005, an employee of SPNC sent **SCHULTE, RICAURTE** and others an electronic mail message wherein he indicated he had faxed the purchase order to FMD.

(9) On or about August 3, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** and others wherein he described a recent meeting he had with representatives from FMD and stated that a representative planned to visit SPNC facilities in October 2005. **RICAURTE** further wrote: *"His hope is to have already signed an agreement with SPNC by this time and to review feedback from wire sample evaluations as well as peripheral wire opportunities. . . . How does SPNC want the 50 wire samples shipped? Sample product with separate invoice? Please confirm."*

(10) On or about August 24, 2005, **SCHULTE** sent an electronic mail message to **RICAURTE**, and a representative of FMD stating, *"I believe that having you visit our headquarters in Colorado Springs October 14th would be very productive, especially if we receive the prototype wires sometime next month. This will give us the opportunity to perform internal testing and have some physicians trial the wires."* The message further stated that **SCHULTE** misplaced the 35 gram wire he imported from Japan on or about July 4, 2005.

(11) On or about September 5, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** and others wherein he wrote: "*Regarding the sample wires (sterilized samples), Terashi-san needs confirmation on how they should be shipped and labeled. Please advise accordingly as they will be ready by the end of the month or earlier*."

(12) On or about September 8, 2005, an employee of SPNC sent an electronic mail message to **RICAURTE** and **SCHULTE** wherein he wrote: *"Given that we have not yet had the opportunity to evaluate the new prototype wires (those expected later this month), it would seem wise to proceed cautiously with any discussion with FMD about volume. . . . With respect to shipment recommendations for the prototype wires, please: * Address to my attention, *Provide shipment tracking number to ensure clear traceability from point to point, *Provide detailed label on each wire/package (specifications, coating, tip stiffness, etc.), * provide documentation of complete/passed sterilization process."*

(13) On or about September 12, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** and others wherein he wrote: *"As for shipment of the sample wires. I saw the boxes just prior to sterilization at the FMD office last week. What price would you like listed on the documentation? They will be labeled 'Not for Human Use'. Correct? Please confirm."*

(14) On or about September 13, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** and others wherein he noted the shipment recommendations from September 8, 2005 and added: *"* Please do not add any additional labeling which specifies use etc."*

(15) On or about September 15, 2005, **RICAURTE** sent an electronic mail message to

an employee of FMD wherein he wrote, *"...FMD will put actual price on the invoice-SPNC: PLEASE place a lower price..."Coronary wire" will not be on the box to avoid regulatory issues-SPNC:Okay...An easy to peel off "Not for Human Use" label will be placed on boxes. Terashi-san mentioned that he needed to have this label on.-SPNC:Okay..."*

(16) On or about September 20, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** and others wherein he asked the recipients to confirm that SPNC would use two different invoices for the importation of a single shipment of guidewires; **RICAURTE** attached two documents to the email, entitled "Package Invoice.doc" and "Accurate Invoice.doc."

(17) On or about September 21, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** and others wherein he wrote that the sample guidewires had been shipped to SPNC from FMD.

(18) On or about September 21, 2005, FMD representatives sent via UPS a shipment of fifty coronary guidewires from Japan to SPNC with a total declared value of $150.00, when the actual price of the guidewires was $18,400.00. The shipment was declared as a "wire rope sample" for customs purposes.

(19) On or about September 25, 2005, an employee of SPNC sent an electronic mail message to **RICAURTE**, **SCHULTE**, and others, wherein he acknowledged receipt of the sample guidewires.

(20) On or about October 21, 2005, SPNC paid FMD $18,400.00 via wire transfer for the guidewires shipped on or about September 21, 2005.

(21) On or about October 26, 2005, **SCHULTE** sent an electronic mail message wherein

he wrote: *"Have you been able to contact* [B.M.] *to see if he will try the FMD wires in the heart and the legs. John."*

(22) On or about October 26, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** wherein a representative of FMD expressed concerns about the clinical evaluation of the FMD chronic total occlusions ("CTO") ten gram guidewire, writing: *"However I worry that FMD CTO 10 is used for clinical."*

(23) On or about October 26, 2005, **SCHULTE** sent an electronic mail message to **RICAURTE** requesting his assistance with contacting **B.M.** to obtain clinical evaluation of the FMD guidewires, wherein he wrote: *"Can yoi* [sic] *help Anton with contacting* [B.M.] *to see if he will try the FMD wires on a few coronaries and peripherals so we can get feedback on their performance relative to the Asahi wires. Clearly you know the sensitivity here so we would appreciate your help. If* [B.M.] *is not comfortable, no problem. Thanks John";* to which **RICAURTE** replied *"Absolutely . . . ."*

(24) On or about November 2, 2005, **RICAURTE** sent an electronic mail message to an employee of SPNC requesting the employee ship the FMD guidewires to **B.M.** via his assistant at the Little Rock Cardiology Clinic in Little Rock, Arkansas.

(25) On or about November 3, 2005, **SCHULTE** sent an electronic mail message to an employee of SPNC wherein he wrote: *"Did you have a chance to send the fmd wires to* [B.M.] *for evaluation. John"*. The employee responded *"yes, I sent him 2 of each tip. Hernan will coordinate getting the feedback."*

(26) On or about November 4, 2005, an employee of SPNC ordered 10 peripheral

guidewires from FMD for a total purchase price of $3,480.00, and that same day, **RICAURTE** sent two invoices, one reflecting a "value for customs purposes only" of $30.00, and the other reflecting the actual sale price of $3,480.00.

(27) On or about November 6, 2005, FMD sent SPNC via UPS ten peripheral guidewires from Japan to the United States with a total declared value of $30.00, when the true value of the guidewires was $3,480.00, which was declared for customs purposes as "wire rope."

(28) On or about November 10, 2005, patient V.S. was treated with an FMD guidewire in Arkansas which was provided to the treating physician by **B.M.**; said guidewire was not cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither FMD nor any other entity had submitted the device or documentation regarding the device to FDA before that guidewire was introduced in interstate commerce.

(29) On or about November 14, 2005, patient M.M. was treated with an FMD guidewire in Arkansas; said guidewire was not cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither FMD nor any other entity had submitted the device or documentation regarding the device to FDA before that guidewire was introduced in interstate commerce.

(30) On or about November 14, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** and others wherein **RICAURTE** provided feedback from B.M. about the use of the FMD guidewires. Referring to the physician as the "operator" and to patients as "models," **RICAURTE** wrote: *"The operator also went sub-intimal and back into the true lumen with the model." . . . "In general, the operator stressed that the wires far exceeded his expectations. 'I knew they would be good, but this is incredible.' The operator will use*

all week in various models."

(31) On or about November 16, 2005, patient L.B. was treated with an FMD guidewire in the United States by **B.M.**; said guidewire was not cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither FMD nor any other entity had submitted the device or documentation regarding the device to FDA before that guidewire was introduced in interstate commerce.

(32) On or about November 16, 2005, **RICAURTE** sent an electronic mail message to **SCHULTE** and others wherein he wrote *"HR NOTE:* [B.M.] *used the 4.5 and 9.0 in a model and confirmed again yesterday that the 4.5 broke through a cap that none of the Miracle Bros wires would have been able to penetrate. This was achieved with far superior torque and control. Though these comments are very early and further evaluations are necessary, they are extremely promising . . . ."*

(33) On or about November 17, 2005, patient E.W. was treated with an FMD guidewire in the United States by **B.M.**; said guidewire was not cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither FMD nor any other entity had submitted the device or documentation regarding the device to FDA before that guidewire was introduced in interstate commerce.

(34) On or about November 23, 2005, **RICAURTE** sent an electronic mail message wherein he wrote: *"John spoke to* [B.M.] *yesterday evening regarding the FMD performance and realized that I wasn't exaggerating about his rave reviews of the product. With every use,* [B.M.] *just seems to get more excited."* The recipient replied,*"You are correct. John was quite excited after his call with* [B.M.]*."*

(35) On or about November 23, 2005, an employee of SPNC sent an electronic mail message to **RICAURTE** detailing the UPS shipment of peripheral FMD guidewires from SPNC to **B.M. RICAURTE** sent an electronic mail message in response wherein he wrote: *"GREAT! It will be a nice surprise for him when he returns to the cath lab over the weekend or on Monday. You may know that he does cases on the weekends too."*

(36) In or about November 2005, **SCHULTE**, **RICAURTE**, and others participated in a conference call discussing **B.M.**'s use of FMD guidewires inside human patients in the United States.

(37) In or about November 2005, an officer of SPNC expressed his concern to **SCHULTE** about the clinical evaluation of unapproved and uncleared FMD guidewires, and **SCHULTE** replied that **B.M.** used the FMD guidewires often and imported them from Japan, that **B.M.** is a friend of both **SCHULTE** and the representative of FMD, and **B.M.** does similar evaluations for other companies.

(38) On or about December 1, 2005, patient C.A. was treated with an FMD guidewire in the United States by **B.M.**; said guidewire was not cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither FMD nor any other entity had submitted the device or documentation regarding the device to FDA before that guidewire was introduced in interstate commerce.

(39) On or about December 10, 2005, **RICAURTE** sent an electronic mail message to a SPNC employee discussing FMD, wherein **RICAURTE** wrote: *"I will be in Little Rock on Monday and hope to see the peripheral wire in action at that time."*

(40) On or about January 20, 2006, SPNC transferred via wire $3,480.00 to FMD as

payment for peripheral guidewires.

(41) On or about May 25, 2006, **RICAURTE** sent an electronic mail message to a SPNC employee explaining the double invoicing of international shipments and wrote: *"There are two versions of the invoices, the Commercial Invoice and the Actual. We've been doing this for the past two years on Physician License orders to save Japanese tax. We may want to do the same for the FMD wires since SPNC will be paying tax on the US side."*

(42) On or about August 23, 2006, in an email to **PHAM** and another SPNC employee, **SCHULTE** sent an electronic mail message to **PHAM** and another employee of SPNC wherein he wrote: *"I have three .018 perpherial wires which have tip stiffness ranging from 6gm to 15gm. to 45gm."*

(43) On or about August 24, 2006, **SCHULTE** imported three FMD guidewires from Japan into the United States in San Francisco, California.

(44) In or about November 2006, a SPNC employee told **SCHULTE** and another employee that he was concerned about the clinical use of the unapproved and uncleared FMD guidewires in patients.

(45) On or about June 29, 2007, **SCHULTE** returned from Japan and imported three FMD "Truefinder" guidewires at Los Angeles International Airport.

(46) On or about July 3, 2007, **RICAURTE** sent an electronic mail message confirming **SCHULTE** was provided with three FMD "Truefinder" guidewires.

(47) In or about July 2007, **SCHULTE** sent **R.G.** an electronic mail message wherein he wrote that he possessed *"new wires from Japan that I would like you to try. They are approved there. Would you be willing?"* **R.G.** replied *"for you."*

(48) On or about July 14, 2007, **R.G.** stayed at **SCHULTE's** residence in Massachusetts for a conference at a hospital in Boston.

(49) On or about April 1, 2008, a SPNC employee sent an electronic mail message to **SCHULTE** entitled "Questionable Business Practices at [SPNC] and Resulting Employment Concerns," wherein the employee alleged that SPNC was involved in "*The evaluation of multiple non-FDA approved medical products in humans at several US clinical sites by our Business Development Group during and prior to my employment at* [SPNC]."

(50) In or about April 2008, an employee of SPNC proposed an internal company investigation into the clinical evaluation of non-FDA approved medical products, which was subsequently initiated in or about April 2008.

(51) On or about April 14, 2008, **PHAM** traveled to Maryland and met with **R.G.** at a hospital in Maryland.

(52) On or about April 15, 2008, patient B.W. was treated with an FMD "Truefinder" guidewire by **R.G.** in the United States; said FMD guidewire was neither cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither FMD nor any other entity had submitted the device or documentation regarding the device to FDA before that guidewire was introduced in interstate commerce.

(53) On or about April 28, 2008, patient C.H. was treated with an FMD "Truefinder" guidewire by **R.G.** in the United States; said FMD guidewire was neither cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither FMD nor any other entity had submitted the device or documentation regarding the device to FDA before that guidewire was introduced in interstate commerce.

(54) In or around August 2008, **SCHULTE** stated to a SPNC employee that he wanted to reduce the company's expenditures on the internal investigation, and to that end he did not want the internal investigation at SPNC to include interviews of **C.W.**, **B.M.**, or **R.G.**

B. The BMT PTA Balloons

(1) On or about May 21, 2007, defendants **SCHULTE** and **ADIGHIJE** attended the Percutaneous Cardiovascular Interventions ("PCR") conference in Barcelona, Spain, where they discussed BMT as a potential supplier of medical devices for SPNC.

(2) On or about June 18, 2007, SPNC held a Board of Directors meeting, which **SCHULTE** attended as the CEO, where BMT was discussed as a potential medical device supplier.

(3) On or about June 18, 2007, a Mutual Non-Disclosure Agreement was executed between SPNC and a representative of BMT.

(4) In or about June 2007, **ADIGHIJE** traveled to Germany and met with representatives of BMT.

(5) On or about July 10, 2007, a representative of BMT sent an electronic mail message to **ADIGHIJE** and **SCHULTE** discussing PTA Balloon transfer pricing and FDA approval time lines.

(6) On or about July 13, 2007, a BMT representative sent an electronic mail message to **ADIGHIJE** and others asking about the regulatory approval process, noting that BMT has never made an FDA submission for the PTA balloons.

(7) On or about August 16, 2007, **PHAM** sent an electronic mail message to **ADIGHIJE**

and others wherein he wrote: *"I'm excited to get going on the evaluations of your PTA catheters. Attached is a copy of the evaluation form I just completed. Please take a look and let me know your thoughts! I'll begin thinking about potential sites for the assessment; upon availability of the units, I can hit the ground running."* Attached to the email was a document entitled "BMT PTA Catheter Evaluation Form.doc" which was to be completed by interviewing a doctor after a clinical evaluation of the BMT PTA Balloons.

(8) On or about August 29, 2007, **PHAM** sent an electronic mail message to **ADIGHIJE** discussing a recent phone conversation with a representative of BMT regarding the labeling requirements for "evaluation units," wherein **PHAM** wrote that he told a BMT representative that *"there isn't any SPNC specific requirements for him to worry about and that these evaluations will be done by a small number of close friends*." **PHAM** also wrote that the BMT representative viewed the upcoming Transcatheter Cardiovascular Therapies ("TCT") conference in Washington D.C., that would occur from October 20-25, 2007, *"as the target time and place to discuss the evaluation outcomes . . . ."*

(9) On or about October 3, 2007, **PHAM** sent **C.W.** an electronic mail message through **C.W.'s** administrative assistant, asking him to assess the sterile BMT balloons in procedures above the knee and below the knee.

(10) On or about October 3, 2007, **ADIGHIJE** sent an electronic mail message to **PHAM** wherein he wrote: *"I am really concerned about these PTA balloons on humans. I will prefer animal studies instead. Please hold off for now."*

(11) On or about October 9, 2007, **ADIGHIJE** and PHAM received an electronic mail

message confirming that thirty BMT balloon catheters were sent to them at SPNC. Therein, a representative of BMT wrote: *"As announced last week, we received the catheters today from sterilization and shipped them immediately to your attention. The FedEx tracking # is: 7992 0092 7365 . . . . We added to this shipment a FDA/Customs letter . . . I hope it will work for this shipment and that the catheters do not get stucked* [sic] *in customs."* Attached to the email was a letter addressed to *"Customs, FDA Compliance Officers,"* which reads in part, *"The PTA Catheters provided to* [SPNC] *are prototypes and intended to be used for benchmark testing and R&D purpose only . . . .* [SPNC] *does not currently distribute these PTA catheters."*

(12) On or about October 10, 2007, the thirty sterile PTA balloons from BMT in Germany were received at the SPNC office in Colorado via Federal Express.

(13) On or about October 10, 2007, **PHAM** sent an electronic mail message to confirm whether **ADIGHIJE** had received the BMT balloons. **ADIGHIJE** responded, *"I have the package in my office."*

(14) On or about October 11, 2007, **PHAM** sent an electronic mail message to **ADIGHIJE** confirming their meeting at the TCT conference, wherein the BMT representative wrote: *"We will have a little conference room in the Renaissance Hotel, that we can use . . . I cross my fingers for the trials and I am looking very much forward to seeing you in Washington."*

(15) On or about October 12, 2007, **PHAM** sent an electronic mail message to **ADIGHIJE** wherein he wrote: *"Please see attached Larry!"* The document named "BMT PTA Catheter Evaluation Form.doc" was attached to the email.

(16) On or about October 13, 2007, **ADIGHIJE** sent an electronic mail message to a representative of BMT wherein he wrote: *"The first case went well. I will know more next week with more cases."*

(17) On or about October 15, 2007, **ADIGHIJE** sent an electronic mail message to another SPNC employee wherein he wrote: *"I am doing clinical evaluations on BMT balloons."*

(18) On or about October 16, 2007, **PHAM** sent an electronic mail message to **SCHULTE** with the document "BMT PTA Catheter Evaluation Form.doc" attached. In a subsequent email sent by **SCHULTE** to **PHAM** and **ADIGHIJE**, **SCHULTE** approved the balloon catheter evaluation form, writing, *"On the money! I look frward* [sic] *to the results."*

(19) On or about October 18, 2007, **PHAM** sent an electronic mail message to a BMT representative and **ADIGHIJE** about the BMT balloons, wherein **PHAM** wrote: *"I'm heading out in a few to start collecting user experience and clinical feedback. With good data, we can start discussing marketing needs, design trade-offs, and any and all possible modifications."*

(20) On or about October 18, 2007, **PHAM** traveled from Colorado to Louisana.

(21) On or about October 19, 2007, patient W.S. was treated with a BMT balloon by **C.W.** in Louisiana that was hand-delivered to him by **PHAM;** said BMT balloon was neither cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither BMT nor any other entity had submitted the device or documentation regarding the device to FDA before that balloon was introduced in interstate commerce.

(22) On or about October 19, 2007, patient F.T. was treated with a BMT balloon by **C.W.**

in Louisiana that was hand-delivered to him by **PHAM**; said BMT balloon was neither cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither BMT nor any other entity had submitted the device or documentation regarding the device to FDA before that balloon was introduced in interstate commerce.

(23) On or about October 19, 2007, patient E.M. was treated with a BMT balloon by **C.W.** in Louisiana that was hand-delivered to him by **PHAM**; said BMT balloon was neither cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither BMT nor any other entity had submitted the device or documentation regarding the device to FDA before that balloon was introduced in interstate commerce.

(24) On or about October 22, 2007, **PHAM** traveled from Colorado to Washington, D.C.

(25) On or about October 23, 2007, patient L.K. was treated with a BMT balloon by **R.G.** in the United States that was hand-delivered to him by **PHAM**; said BMT balloon was neither cleared nor approved by the FDA, it was not exempt from clearance or approval, and neither BMT nor any other entity had submitted the device or documentation regarding the device to FDA before that balloon was introduced in interstate commerce.

(26) On or about October 23, 2007, **PHAM**, **SCHULTE**, **ADIGHIJE**, and others met at the Renaissance Hotel during the TCT conference and were briefed by **PHAM** on the use of the unapproved and uncleared BMT balloons by **C.W.** and **R.G.**

(27) On or about October 29, 2007, a representative of BMT sent an electronic mail message to **SCHULTE**, **PHAM**, and **ADIGHIJE**, wherein he wrote: *"It was a pleasure meeting with you in Washington, especially with the good clinical feedback from the physicians regarding the PTA catheters. We hope that the baseline for a fruitful*

collaboration between [SPNC] *and BMT is made."*

(28) On or about October 31, 2007, replying to the email of October 29 and copying **SCHULTE** and **PHAM**, **ADIGHIJE** wrote: "*The evaluation is still ongoing and we continue to learn more about the balloon. The reasonable call at this particular time regarding the performance of the product is that we are pleased. I do still want to have all of the evaluations completed before the end of November."*

(29) On or about November 2, 2007, the Director of Global Clinical and Regulatory Affairs for SPNC sent an electronic mail message to a representative of BMT, copying **SCHULTE** and **ADIGHIJE**, wherein he discussed the materials needed to file for 510(k) clearance for BMT balloons with the FDA.

(30) On or about November 6, 2007, **PHAM** sent an electronic mail message directing an employee of SPNC to ship a box of BMT balloons to **R.G.**, writing: "*[P]lease ship the boxes (balloon catheters) on your chair to* [R.G.'s] *personal address next-day delivery for me."*

(31) On or about November 7, 2007, **PHAM** sent an electronic mail message to **ADIGHIJE** and another SPNC employee, sharing an attachment pertaining to a procedure using the SPNC TurboBooster laser catheter, wherein **PHAM** wrote: "*Rob showed me this during the TCT week on the day we did the BMT case.*"

(32) On or about November 13, 2007, **PHAM** inquired in an email to **R.G.** if he had received balloon catheters **PHAM** sent to him and asking for **R.G.**'s feedback; attached to the email was the evaluation document "BMT PTA Catheter Evaluation Form.doc."

(33) On or about November 13, 2007, **PHAM** sent an electronic mail message to **ADIGHIJE** with the document "BMT PTA Catheter Evaluation Form.doc"attached, wherein **PHAM** wrote: "*You may find the attached evaluation form useful for the evaluations the next couple of days."*

(34) On or about December 8, 2007, **PHAM** traveled from Colorado to Germany and met with representatives of BMT.

(35) On or about December 12, 2007, **PHAM** returned to Colorado from Germany.

(36) In or about April 2008, a SPNC employee proposed an investigation into the clinical evaluation of non-FDA approved medical products which was subsequently initiated.

(37) In or around April 2008, **ADIGHIJE** told another SPNC employee, *"Just so you know, we didn't do any evaluations of balloons."* **ADIGHIJE** also told the employee that he spoke to **C.W.** and was assured that **C.W.** did not use BMT balloons in any patients.

(38) On or about May 7, 2008, during an interview as part of the internal investigation at SPNC, **SCHULTE** stated to investigators that he was unaware of any use of BMT balloons in humans.

(39) On or about May 14, 2008, during an interview as part of the internal investigation at SPNC, **PHAM** stated to investigators that he was unaware of any use of BMT balloons in humans.

(40) On or about May 21, 2008, during an interview as part of the internal investigation at SPNC, **ADIGHIJE** stated to investigators that he was unaware of any use of BMT balloons in humans.

C. Off-Label Promotion for In-Stent Restenosis (ISR)

(1) On or about July 9, 2007 **SCHULTE** sent an electronic mail message to a doctor in Massachusetts, wherein he wrote: *"Hi Matt: Thanks for taking time to meet with me during my recent visit to Boston. I enjoyed our discussion regarding the possible use of laser for treating SFA [superficial femoral artery] ISR. This may be the most difficult to get a lasting result and debulking with the laser is very safe and can remove a lot of tissue, particularly with the recently approved Turbo Booster."* **SCHULTE** continued, *"Before you use the Booster, I would suggest you do a few cases with the standard Turbo Elite catheters to get a feel for the technology. ISR is a perfect place to start as te* [sic] *safety profile is unparralled."*

(2) On or about August 24, 2007 **SCHULTE** sent an electronic mail message to a doctor in Oklahoma wherein he wrote: *" I want to thank you for braving the inclement weather to visit our HQ in the inaugural VIP visit. It was great meeting you and I thoroughly enjoyed our dinner conversation . . . Thanks for your continued support of SPNC. It was great to hear of your succesful* [sic] *turbo booster cases. We are excited by the potential of this device for ISR and debulking prior to stenting in calcified vessels."*

(3) On or about August 24, 2007 **SCHULTE** sent an electronic mail message to a doctor in California wherein he wrote: *"It was really great seeing you this week during my visit to Ca . . . I am delighted that you are willing to try the new Turbo Booster. I think you will find it an excellent choice to SFA ISR and marries nicely with Viabahn . . . ."*

(4) On or about September 28, 2007 **SCHULTE** sent an electronic mail message to a doctor in Iowa wherein he wrote: *"It was great seeing you at VIVA . . . . I appreciated your*

honest feedback on our technology versus CSI. We continue to try to improve our effectiveness versus calcium and believe it represents a great workhorse device for tibials, popliteals, ISR and possibly debulking before stenting in calcified vessels. While we don't have an indication for ISR, we are the only atherrectomy device without a contraindication and are currently doing two studies to evaluate its effectiveness here."

(5) On or about November 27, 2007 **SCHULTE** sent an electronic mail message to a second doctor in Massachusetts, wherein he wrote: *"Great seeing you today. I enjoyed your technique on the ISR case. I thought it was a nice result. Did you end up spot stenting? I hope you have more opportunities to try the Turbo Booster. I trhink [sic] you will be impressed by the debulking capability in addition to ISR, pls give it a try in a long calcified SFA prior to stenting to facilitate stent expansion."*

(6) On or about December 20, 2007 the Clinical Affairs Manager for SPNC sent an electronic mail message to SPNC executive staff, including **SCHULTE**, wherein she wrote: *"I love you guys and I want to keep your butts out of hot water, jail, and bankrupcy* [sic] *court. Therefore please keep this in the forefront of your minds . . . . 3. Any email related to off-label uses should be limited to the clinical affairs/regulatory affairs channels to avoid the implication of PROMOTION, which could lead to fines/jail time. 4. Any materials related to the off-label use of the laser (articles, PPT, abstracts, etc.) should NOT be distributed through Sales and Marketing channels-this implies PROMOTION, which could lead to fines/jail time."*

(7) On or about December 22, 2007 **SCHULTE** sent an electronic mail message to **R.G.** discussing his upcoming presentation at the International Congress XXI on Endovascular

Interventions, February 10-14, 2008 in Scottsdale, Arizona, wherein SCHULTE stated, *"We will od* [sic] *everything possible to get you to do a live ISR TB John."*

(8) On or about December 22, 2007, **SCHULTE** sent an electronic mail message to a doctor in Chicago, Illinois wherein he wrote: *"Thanks for making time to visit with me during my recent visit to Chicago. I must say that I was a bit surprised that you chose to FH that ISR case moments after we discussed the possible clinical benefits of using the turbo booster in that situation. While I am sure that you didn't do it on purpose, you might imagine that it was embarrassing for Bucky to be in the lab with me, his manager (and with the CSI rep watching) while you did the case with FH. I sincerely hope you will give our technology a try in those situations where it can add clinical value, reduce complications or save you time and the hospital money. Bucky doesn't know I sent this email so I hope you wont hold it against him. He is one of our best guys. Thanks for listening. John."*

(9) On or about December 24, 2007, **SCHULTE** received an electronic mail reply from the same doctor in Chicago, Illinois to **SCHULTE's** electronic mail message, wherein the doctor wrote: *"I really don't think you are that ignorant, but do you really think I use devices/equipment based on who is in the lab that day? Come on, I'm a doctor, not a device whore. I use what I think is the best for the patient. Even if I had* [C.W.'s] *shares in* [SPNC], *I wouldn't have used LASER on that case . . . . the patients SFA was fairly large and I did not think the turbo booster would have much of an effect . . . . Just because you think the LASER is good for ISR, doesn't mean it is. There is absolutely no clinical data that LASER is any better than* [FH] *for ISR (or vice versa). If you want to visit when I plan on using the LASER, let Bucky know and I will try to set up a case."*

(10) On or about December 26, 2007, **SCHULTE** sent an electronic mail message to the previously-described doctor in Chicago, Illinois, wherein he wrote: *"Dear Jack . . .I clearly understand that clinical judgement drives decision making as it relates to device selection and would never expect that a device would be used simply because of who was present in the lab. I have gone on record many times with our salesforce that our technology should be recommended only in those situations where it adds value. I realize your experience with the Turbo Booster has been somewhat limited and would simply ask that you give it a try in 5-10 cases so that you might be able to make a better judgement as to where it might fit in your practice (if anywhere). With regard to ISR, we have initiated two studies, one in the US and one in Germany to get some data on the Booster . . . . PS. Its my job to be the device whore, not yours. (hope you at least cracked a smile) John."*

(11) On or about December 26, 2007, **SCHULTE** wrote an electronic mail message to SPNC sales management discussing the upcoming Global Sales Meeting, as follows: *"ISR is our meal ticket as we are the only atherectomy device not contraindicated. In addition we are the only atherectomy device indicated for coronary ISR and have two studies underway to gather clinical evidence. If we could become synonymous with ISR, the laser would be in the lab for every ISR case, just as the Rotablator was there for every calcium case. Once we got that lesion, the other 5 types of cases would be easier to get."*

(12) On or about January 12, 2008, **SCHULTE** sent an electronic mail message to a doctor in Georgia, wherein he wrote: *"It was a real pleasure spending time with you this week in Atlanta . . . . I am delighted that I was in the lab to see your first laser case. It was a challenging ISR case but perfectly suited to our technology. Your technique was perfect and the result was excellent. Thanks so much for giving us a chance. Price has often told me*

how important you and your group is in the Atlanta area. We believe our technology is perfectly suited to your practice in many areas, including: SFA ISR . . . .”

(13) On or about January 14, 2008, **SCHULTE** sent an electronic mail message to a second doctor in Georgia, wherein he wrote: *“It was a pleasure meeting you during my recent visit to Atlanta . . . We have much more efficient catheters, understand the science of laser ablation, thus have enhanced techniques and most importantly, have a new application-PAD. As we discussed, Laser atherectomy may be an ideal way to treat ISR. We have two clinical trials underway and are the only atherectomy device which is not contraindicated for ISR.”*

(14) On or about January 15, 2008, **SCHULTE** sent an electronic mail message to a third doctor in Georgia, wherein he wrote: *“Great seeing you (if only for a short time) during my recent visit to Atlanta. I want to thank you for giving the Turbo Booster a try a few weeks ago with* [another doctor]. *He told me the case went well. I hope you will try it for ISR as that's where I think it really shines. We are the only atherectomy technology not contra-indicated here and currently have two prospective clinical studies underway.”*

(15) On or about January 27, 2008 SPNC held a Global Sales Meeting in La Jolla, California, wherein employees of SPNC and others presented the TurboBooster LITE promotion that included promotion for In-Stent Restenosis of the TurboBooster catheter.

(16) On or about February 13, 2008, **SCHULTE** sent an electronic mail message to a doctor in Arizona wherein he stated, *“It was great meeting you for lunch today. It was clear from our discussion that you handle the toughest Cli* [Critical Limb Ischemia] *cases. As a*

believer in Atherectomy, I am confident that we can demonstrate the clinical benefits of our technology, particularly for diffuse tibial disease, ISR, CTOs and lastly thrombus . . . . Rob Gallino will sent [sic] *you some representative cases for your review and we would be happy to have him visit your lab when you have some cases that are appropriate."*

(17) On or about June 16, 2008 a Product Development Engineer at SPNC wrote an electronic mail message to **SCHULTE** and others describing testing done by him in an effort to understand how their laser interacted with the nitinol stent when treating ISR, as follows: *"From a fatigue standpoint we did pass. There were no gross failures in the test and control group, which makes the statistical analysis more difficult. There is evidence, however of laser interaction with the nitinol, but that interaction did not result in fatigue failure . . . ."*

(18) On or about May 7, 2008, during an interview as part of the internal investigation at SPNC, **SCHULTE** stated to investigators that he was unaware of any off-label promotion of medical devices by SPNC employees.

(19) On or about August 7, 2008, **SCHULTE** sent an electronic mail message to a doctor in Springfield, Illinois, wherein he wrote: *"It was a real pleasure meeting you during my recent trip to Springfield . . . Lastly, I understand your skepticism regarding the value of atherectomy in the treatment of PAD* [Perpherial Artery Disease]. *The three areas where it may add value are: Long diffuse BTK leions* [sic], *ISR (we are doing two studies here) and possibly debulking prior to stenting for calcified lesions..."*

(20) On or about August 7, 2008, **SCHULTE** sent an electronic mail message to a

second doctor in Illinois wherein he wrote: *"Tyler told me you have done a few nice laser leg cases. We think it adds clinical benefit in long BTK lesions, possibly ISR (we are doing two studies here) and in conjunction with SFA stenting in long calcified lesions."*

All in violation of Title 18, United States Code, Sections 371 and 2.

COUNT TWO
Title 18, United States Code, Section 1001(a)(2)
(False Statements)

23. The allegations in paragraphs 1-15 are incorporated by reference as if fully rewritten herein.

24. On or about September 4, 2008 in the District of Colorado, in a matter within the jurisdiction of the executive branch of the government of the United States,

1. GEORGE JOHN SCHULTE aka JOHN SCHULTE,

knowingly and willfully did make the below materially false statement to Special Agent Daniel Burke of the United States Food and Drug Administration, when in truth, he knew the below-described facts:

FALSE STATEMENT	THE TRUTH IN FACT
SCHULTE told Special Agent Burke that he was never given FMD guidewires while in Japan and did not physically carry any with him when returning to the United States.	In truth and in fact: 1. On 7/4/2005, **SCHULTE** imported a guidewire given to him by representatives of FMD in Japan. 2. On 8/24/2006, **SCHULTE** imported three FMD guidewires given to him by representatives of FMD in Japan; and 3. On 6/29/2007, **SCHULTE** imported three FMD Truefinder guidewires given to him by representatives of FMD in Japan.
SCHULTE told Special Agent Burke that the FMD guidewires provided to physicians were not provided for use in human patients.	When in truth and in fact **SCHULTE** was aware that FMD guidewires were implanted into human patients.

SCHULTE told Special Agent Burke that he was not aware that FMD guidewires were provided to **B.M.** by members of his staff or by **RICAURTE** for use inside human patients.	When in truth and in fact **SCHULTE** was aware that members of his staff and **RICAURTE** provided FMD guidewires to **B.M.** for use inside human patients
SCHULTE told Special Agent Burke that he did not know that **C.W.** or **R.G.** were supplied BMT balloons by employees to use inside human patients.	When in truth and in fact **SCHULTE** was aware that **C.W.** and **R.G.** were supplied BMT balloons for use in human patients by employees.
Special Agent Burke showed **SCHULTE** a copy of the evaluation forms entitled "BMT PTA Catheter Product Evaluation," and SCHULTE told Special Agent Burke that he had never seen the forms.	When in truth and in fact **SCHULTE** had seen the BMT PTA Catheter Product Evaluation form on at least one prior occasion.

In violation of Title 18, United States Code, Section 1001(a)(2).

COUNTS THREE and FOUR
18 U.S.C. § 545 and 18 U.S.C. § 2
(Receipt of Merchandise Brought Into the United States Contrary to Law and Aiding and Abetting)

25. The allegations in paragraphs 1-15 are incorporated by reference as if fully rewritten herein.

26. On or about the dates stated below, within the State and District of Colorado and elsewhere, the defendants,

1. GEORGE JOHN SCHULTE, aka JOHN SCHULTE, and
4. HERNAN RICAURTE,

did knowingly receive merchandise brought into the United States, FMD guidewires, knowing the same to have been brought into the United States contrary to law in violation of Title 18, United States Code, Section 542 (relating to the entry of merchandise by means of false statements), in violation of Title 18, United States Code, Section 541 (relating to the entry of goods falsely invoiced or valued), and did aid and abet same.

COUNT	"On or About Date"/Date Received	UPS Tracking Number:	Declared As:	Shipped From:
3	9/24/2005	M0376759901	"Wire Rope Sample"	Japan
4	11/9/2005	M0376759885	"Wire Rope"	Japan

All in violation of Title 18, United States Code, Section 545; and Title 18, United States Code, Section 2.

COUNT FIVE
18 U.S.C. § 545 and 18 U.S.C. § 2
(Receipt of Merchandise Brought Into the United States Contrary to Law and Aiding and Abetting)

27. The allegations in paragraphs 1-15 are incorporated by reference as if fully rewritten herein.

28. On or about October 9, 2007, within the State and District of Colorado and elsewhere, the defendants,

1. GEORGE JOHN SCHULTE, aka JOHN SCHULTE
2. OBINNA ADIGHIJE aka LARRY ADIGHIJE, and
3.TRUNG PHAM,

did knowingly receive merchandise brought into the United States, BMT PTA Balloons, knowing the same to have been brought into the United States contrary to law in violation of Title 21, United States Code, Section 331(a) (prohibiting causing the introduction into interstate commerce of an adulterated or misbranded device), and did aid and abet same:

COUNT	"On or About Date"/Date Received	FedEx Tracking No:	Declared As:	Shipped From

5	10/9/2007	79920092 7365	PTA-Catheter- Samples for benchmark and R&D purposes only	Germany

All in violation of Title 18, United States Code, Section 545; and Title 18, United States Code, Section 2.

COUNTS SIX and SEVEN
(Introduction Into Interstate Commerce of an Adulterated and Misbranded Medical Device - FMD Guidewires)
21 U.S.C. §§ 331(a) and 333(a)(2); and 18 U.S.C. § 2

29. The allegations in paragraphs 1-15 are incorporated by reference as if fully rewritten herein.

30. On or about the dates stated below, within the District of Colorado and elsewhere, the defendants,

1. GEORGE JOHN SCHULTE, aka JOHN SCHULTE, and
4. HERNAN RICAURTE,

with the intent to defraud and mislead the FDA, doctors and patients, introduced and delivered for introduction into interstate commerce and caused to be introduced and delivered for introduction into interstate commerce from Japan to the United States, FMD Guidewires specifically described below, medical devices, that were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) (relating to the requirement of pre-market approval of medical devices by the FDA) and misbranded within the meaning of 21 U.S.C. §§ 352(o) and 360(k) (relating to notifying the FDA regarding certain information about the device at least 90 days prior to its introduction), and did aid and abet same.

COUNT	"On or About Date"/Date Received	Medical Device	Received in Colorado from:
6	9/24/2005	FMD Coronary Guidewire	Japan
7	11/9/2005	FMD Peripheral Guidewire	Japan

All in violation of Title 21 United States Code, Sections 331(a) and 333(a)(2) and Title 18, United States Code, Section 2.

COUNTS EIGHT and NINE
(Receipt in Interstate Commerce of an Adulterated and Misbranded Medical Device and Delivery or Proffered Delivery for Pay or Otherwise - FMD Guidewires)
21 U.S.C. §§ 331(c) and 333(a)(2); and 18 U.S.C. § 2

31. The allegations in paragraphs 1-15 are incorporated by reference as if fully rewritten herein.

32. On or about the dates described below, within the District of Colorado and elsewhere, the defendants,

1. GEORGE JOHN SCHULTE, aka JOHN SCHULTE, and
4. HERNAN RICAURTE,

with the intent to defraud and mislead the FDA, doctors and patients, received in interstate commerce, and caused the receipt in interstate commerce, from Colorado to Arkansas, FMD Guidewires specifically described below, medical devices, that were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) (relating to the requirement of pre-market approval of medical devices by the FDA) and misbranded within the meaning of 21 U.S.C. §§ 352(o) and 360(k) (relating to notifying the FDA regarding certain information about the device at least 90 days prior to its introduction), and caused the delivery and proffered delivery of said medical devices for clinical feedback and product evaluation, and did aid and abet same.

Count	On or About	Medical Device	Patients (Initials)	Doctor (Initials)	Received In Colorado From	Delivered From Colorado To
8	11/4/05	FMD Coronary Guidewire	V.S., M.M., L.B. and E.W.	B.M. (J.S.)	Japan	Arkansas
9	12/1/05	FMD Peripheral Guidewire	C.A.	B.M.	Japan	Arkansas

All in violation of Title 21 United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2.

COUNT TEN
(Introduction Into Interstate Commerce of an Adulterated and Misbranded Medical Device - BMT PTA Balloons)
21 U.S.C. §§ 331(a) and 333(a)(2); and 18 U.S.C. § 2

33. The allegations in paragraphs 1-15 are incorporated by reference as if fully rewritten herein.

34. In or about October 2007, within the District of Colorado and elsewhere, the defendants,

1. GEORGE JOHN SCHULTE, aka JOHN SCHULTE
2. OBINNA ADIGHIJE aka LARRY ADIGHIJE, and
3. TRUNG PHAM,

with the intent to defraud and mislead the FDA, doctors and patients, introduced and delivered for introduction into interstate commerce and caused to be introduced and delivered for introduction into interstate commerce from Germany to the United States, BMT PTA Balloons, medical devices, that were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) (relating to the requirement of pre-market approval of medical devices by the FDA) and misbranded within the meaning of 21 U.S.C. §§ 352(o) and 360(k) (relating to notifying the FDA regarding certain information about the

device at least 90 days prior to its introduction), and did aid and abet same.

All in violation of Title 21 United States Code, Sections 331(a) and 333(a)(2) and Title 18, United States Code, Section 2.

COUNTS ELEVEN and TWELVE
(Receipt in Interstate Commerce of an Adulterated and Misbranded Medical Device and Delivery or Proffered Delivery for Pay or Otherwise)
21 U.S.C. §§ 331(c) and 333(a)(2); and 18 U.S.C. § 2

35. The allegations in paragraphs 1 - 34 are incorporated by reference as if fully rewritten

herein.

36. In or about the dates below, within the District of Colorado and elsewhere, the defendants,

1. GEORGE JOHN SCHULTE, aka JOHN SCHULTE,
2. OBINNA ADIGHIJE aka LARRY ADIGHIJE, and
3. TRUNG PHAM,

with the intent to defraud and mislead the FDA, doctors and patients, received in interstate commerce, and caused the receipt in interstate commerce, from Colorado to Louisiana and Maryland, BMT PTA Balloons, medical devices, that were adulterated within the meaning of 21 U.S.C. § 351(f)(1)(B) (relating to the requirement of pre-market approval of medical devices by the FDA) and misbranded within the meaning of 21 U.S.C. §§ 352(o) and 360(k) (relating to notifying the FDA regarding certain information about the device at least 90 days prior to its introduction), and caused the delivery and proffered delivery of said medical devices for clinical feedback and product evaluation, and did aid and abet same:

Count	On or About	Medical Device	Patients (Initials)	Doctor (Initials)	Received In Colorado From	Delivered From Colorado To
11	**10/19/07**	BMT PTA Balloons	W.S., F.T., and E.M.	C.W.	Germany	Louisiana
12	**10/23/07**	BMT PTA Balloons	L.K.	R.G.	Germany	Maryland

All in violation of Title 21 United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2.

A TRUE BILL:

Ink signature on file in the Clerk's Office
FOREPERSON

DAVID M. GAOUETTE
Acting United States Attorney

s/ Jaime A. Pena
By: Jaime A. Pena
Assistant U.S. Attorney
1225 Seventeenth Street, Suite 700
Denver, CO 80211
Telephone: 303-454-0100
Facsimile: 303-454-0402
Email: jaime.pena2@usdoj.gov
Attorney for the Government

INFORMATION SHEET

DEFENDANT : George John Schulte aka John Schulte

YEAR OF BIRTH: 1948

ADDRESS: Wellesley, MA

COMPLAINT FILED? _____ YES _____ NO

IF YES, PROVIDE MAGISTRATE CASE NUMBER: _____

HAS DEFENDANT BEEN ARRESTED ON COMPLAINT? _____ YES _____ NO

OFFENSE: Count 1: Title 18, United States Code, Section 371 - Conspiracy to Defraud the United States.

Count 2: Title 18, United States Code, Section 1001 - Making False Statements.

Counts 3 and 4: Title 18, United States Code, Sections 545 and 2 - Receipt of Merchandise Brought Into the United States Contrary to Law and Aiding and Abetting).

Count 5: Title 18, United States Code, Sections 545 and 2 - Receipt of Merchandise Brought Into the United States Contrary to Law and Aiding and Abetting).

Counts 6 and 7: Title 21, United States Code, Sections 331(a) and 333 (a)(2) and Title 18, United States Code, Section 2 - Introduction Into Interstate Commerce of an Adulterated and Misbranded Medical Device - FMD Guidewires.

Counts 8 and 9: Title 21, United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2 - Receipt in Interstate Commerce of an Adulterated and Misbranded Medical Device and Delivery or Proffered Delivery for Pay or Otherwise - FMD Guidewires.

Count 10: Title 21, United States Code, Sections 331(a) and 333(a)(2) and Title 18, United States Code, Section 2 - Introduction Into Interstate Commerce of an Adulterated and Misbranded Medical Device - BMT PTA Balloons.

Counts 11 and 12: Title 21, United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2 - Receipt in Interstate Commerce of an Adulterated and Misbranded Medical Device and Delivery or Proffered Delivery for Pay or Otherwise.

LOCATION OF OFFENSE: El Paso County, CO

PENALTY: Count 1: NMT 5 years imprisonment, NMT $250.000.00 fine, or both; $100 Special Assessment Fee.

Count 2: NMT 5 years imprisonment, NMT $250.000.00 fine, or both; $100 Special Assessment Fee.

Counts 3 and 4: NMT 20 years imprisonment, NMT $250,000 fine, or both; $100 Special Assessment Fee.

Count 5: NMT 20 years imprisonment, NMT $250,000 fine, or both; $100 Special Assessment Fee

Counts 6 and 7: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special assessment fee.

Counts 8 and 9: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special assessment fee.

Count 10: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special assessment fee.

Counts 11 and 12: NMT 3 years imprisonment, NMT $100,000 fine, or both; $100 Special assessment fee.

NMT

AGENT: Daniel Burke, Special Agent
U.S. Food and Drug Administration

AUTHORIZED BY: Jaime A. Peña
Assistant U.S. Attorney

ESTIMATED TIME OF TRIAL:

____ five days or less ___ over five days ____ other

THE GOVERNMENT will (X) will not ( ) seek detention in this case.

INFORMATION SHEET

DEFENDANT : Obinna Adighije aka Larry Adighije

YEAR OF BIRTH: 1959

ADDRESS: Encinitas, CA

COMPLAINT FILED? _____ YES _____ NO

IF YES, PROVIDE MAGISTRATE CASE NUMBER: _____

HAS DEFENDANT BEEN ARRESTED ON COMPLAINT? _____ YES _____ NO

OFFENSE: Count 1: Title 18, United States Code, Section 371 - Conspiracy to Defraud the United States.

Count 5: Title 18, United States Code, Sections 545 and 2 - Receipt of Merchandise Brought Into the United States Contrary to Law and Aiding and Abetting).

Count 10: Title 21, United States Code, Sections 331(a) and 333(a)(2) and Title 18, United States Code, Section 2 - Introduction Into Interstate Commerce of an Adulterated and Misbranded Medical Device - BMT PTA Balloons.

Counts 11 and 12: Title 21, United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2 - Receipt in Interstate Commerce of an Adulterated and Misbranded Medical Device and Delivery or Proffered Delivery for Pay or Otherwise.

LOCATION OF OFFENSE: El Paso County, CO

PENALTY: Count 1: NMT 5 years, $250.000.00 fine, or both; $100 Special Assessment Fee.

Count 5: NMT 20 years imprisonment, NMT $250,000 fine, or both; $100 Special Assessment Fee.

Count 10: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special assessment fee.

Counts 11 and 12: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special Assessment fee.

AGENT: Daniel Burke, Special Agent
U.S. Food and Drug Administration

AUTHORIZED BY: Jaime A. Peña
Assistant U.S. Attorney

ESTIMATED TIME OF TRIAL:

____ five days or less ___ over five days ____ other

THE GOVERNMENT will (X) will not ( ) seek detention in this case.

INFORMATION SHEET

DEFENDANT : Trung Pham

YEAR OF BIRTH: 1972

ADDRESS: Colorado Springs, CO

COMPLAINT FILED? _____ YES _____ NO

IF YES, PROVIDE MAGISTRATE CASE NUMBER: _____

HAS DEFENDANT BEEN ARRESTED ON COMPLAINT? _____ YES _____ NO

OFFENSE: Count 1: Title 18, United States Code, Section 371 - Conspiracy to Defraud the United States.

Count 5: Title 18, United States Code, Sections 545 and 2 - Receipt of Merchandise Brought Into the United States Contrary to Law and Aiding and Abetting).

Count 10: Title 21, United States Code, Sections 331(a) and 333(a)(2) and Title 18, United States Code, Section 2 - Introduction Into Interstate Commerce of an Adulterated and Misbranded Medical Device - BMT PTA Balloons.

Counts 11 and 12: Title 21, United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2 - Receipt in Interstate Commerce of an Adulterated and Misbranded Medical Device and Delivery or Proffered Delivery for Pay or Otherwise.

LOCATION OF OFFENSE: El Paso County, CO

PENALTY: Count 1: NMT 5 years imprisonment, NMT $250.000.00 fine, or both; $100 Special Assessment Fee.

Count 5: NMT 20 years imprisonment, NMT $250,000 fine, or both; $100 Special Assessment Fee.

Count 10: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special assessment fee.

Counts 11 and 12: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special assessment fee.

AGENT: Daniel Burke, Special Agent
U.S. Food and Drug Administration

AUTHORIZED BY: Jaime A. Peña
Assistant U.S. Attorney

ESTIMATED TIME OF TRIAL:

____ five days or less ___ over five days ____ other

THE GOVERNMENT will (X) will not ( ) seek detention in this case.

INFORMATION SHEET

DEFENDANT : Hernan Ricaurte

YEAR OF BIRTH: 1969

ADDRESS: Ladera Ranch, CA

COMPLAINT FILED? _____ YES _____ NO

IF YES, PROVIDE MAGISTRATE CASE NUMBER: _____

HAS DEFENDANT BEEN ARRESTED ON COMPLAINT? _____ YES _____ NO

OFFENSE: Count 1: Title 18, United States Code, Section 371 - Conspiracy to Defraud the United States.

Counts 3 and 4: Title 18, United States Code, Sections 545 and 2 - Receipt of Merchandise Brought Into the United States Contrary to Law and Aiding and Abetting).

Counts 6 and 7: Title 21, United States Code, Sections 331(a) and 333 (a)(2) and Title 18, United States Code, Section 2 - Introduction Into Interstate Commerce of an Adulterated and Misbranded Medical Device - FMD Guidewires.

Counts 8 and 9: Title 21, United States Code, Sections 331(c) and 333(a)(2) and Title 18, United States Code, Section 2 - Receipt in Interstate Commerce of an Adulterated and Misbranded Medical Device and Delivery or Proffered Delivery for Pay or Otherwise - FMD Guidewires.

LOCATION OF OFFENSE: El Paso County, CO

PENALTY: Count 1: NMT 5 years imprisonment, NMT $250.000 fine, or both; $100 Special Assessment Fee.

Counts 3 and 4: NMT 20 years imprisonment, NMT $250,000 fine, or both; $100 Special Assessment Fee.

Counts 6 and 7: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special assessment fee.

Counts 8 and 9: NMT 3 years imprisonment, NMT $10,000 fine, or both; $100 Special assessment fee.

AGENT: Daniel Burke, Special Agent
U.S. Food and Drug Administration

AUTHORIZED BY: Jaime A. Peña
Assistant U.S. Attorney

ESTIMATED TIME OF TRIAL:

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