UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES OF AMERICA	:	CRIMINAL NO.: 15cr 10076
v.	:	VIOLATIONS:
		18 U.S.C. § 371 (conspiracy)
(1) WILLIAM FACTEAU,	:	15 U.S.C. §§ 78j(b), 78ff (securities fraud)
(2) PATRICK FABIAN		18 U.S.C. §§ 1343, 1349 (wire fraud)
	:	21 U.S.C. §§ 331(a), 333(a)(1)-(2), 351, 352 (distributing adulterated and misbranded medical devices)
		18 U.S.C. § 2 (aiding and abetting)
		Forfeiture Allegations: 18 U.S.C. §§ 981(a)(1)(C), 982(a)(7); 28 U.S.C. § 2461(c)

INDICTMENT

THE GRAND JURY CHARGES:

At all times relevant to this Indictment:

The Defendants

1. WILLIAM FACTEAU ("FACTEAU") was an individual residing in Atherton, California and was the President and Chief Executive Officer ("CEO") of a medical device manufacturer and distributor known as Acclarent, Inc. ("Acclarent").

2. PATRICK FABIAN ("FABIAN") was an individual residing in Lake Elmo, Minnesota and was the Vice President of Sales for Acclarent from August 2007 and until November 2011.

3. The United States Food and Drug Administration ("FDA") is an agency of the United States responsible for protecting the health and safety of the public by assuring, among other things, that drugs and medical devices intended for use in people are safe and effective for their intended uses and that the labeling of the drugs and devices is true and accurate. The FDA regulates the manufacture, labeling, and shipment in interstate commerce of drugs and devices.

4. Every manufacturer of a medical device distributed in the United States is required by law to obtain marketing authorization from FDA before distributing its device in interstate commerce, unless subject to an exemption not applicable here.

Overview of the Fraud

5. FACTEAU and FABIAN and others known and unknown to the Grand Jury engaged in a scheme to fraudulently drive up Acclarent revenues and stock valuation by illegally selling a medical device known as the Relieva Stratus Microflow Spacer ("Stratus") for intended uses for which Acclarent had not obtained required approvals from the FDA.

6. Stratus, with its access system, was a medical device for implanting a small balloon with tiny holes in the nasal sinuses.

7. FACTEAU, FABIAN and others knew that the Stratus was designed and intended to provide sustained delivery of drugs and, in particular, steroids, to the sinuses.

8. FACTEAU, FABIAN and others at Acclarent agreed to and did deceive the FDA regarding the real intended use of the Stratus by falsely claiming that the intended use of the Stratus was to mechanically maintain an opening to the sinus for 14 days and that the Stratus was to be used with saline.

9. From in or around 2008 through 2011, FACTEAU, FABIAN and others at Acclarent distributed the Stratus in the United States intending it to be used as a steroid delivery device, without having received the requisite marketing authorization from the FDA for that use.

10. FACTEAU, FABIAN and others at Acclarent also concealed from potential purchasers such as Johnson & Johnson and its subsidiary, Ethicon, Inc. (together, "Ethicon"), Acclarent's illegal conduct in promoting and distributing the Stratus as a steroid delivery device. Ethicon purchased Acclarent stock in early 2010 for approximately $785 million.

11. Ethicon, when it purchased Acclarent, directed Acclarent and FACTEAU and FABIAN to stop promoting the Stratus at all, in light of the extensive off-label use of the product of which Ethicon became aware through its due diligence process.

12. Despite these explicit instructions from Ethicon in early 2010 and despite purporting to implement those instructions, FACTEAU and FABIAN continued to cause Acclarent employees to market the Stratus for use as a steroid delivery device in 2010 and 2011.

13. FACTEAU, FABIAN and others at Acclarent received millions of dollars for stock, options and other compensation in connection with the merger of Acclarent into Ethicon.

Acclarent Background and Stratus Strategy

14. Acclarent was a start-up company with headquarters in Menlo Park, California. It was founded in 2004 to develop new medical devices in the area of the treatment of the ears, nose and throat ("ENT").

15. FACTEAU, FABIAN and others at Acclarent sought to quickly develop and market products to, among other things, create a projected revenue stream that would make Acclarent an attractive target for either an initial public offering ("IPO") or acquisition.

16. Many employees of the company, including FACTEAU and FABIAN, received significant stock options, which, if the company went public or was acquired, would be potentially worth millions of dollars.

17. As part of a strategy to market Acclarent as the future preeminent medical device company in the ENT space, FACTEAU, FABIAN and others at Acclarent sought to develop and sell products to be implanted in the sinuses to provide sustained drug delivery to the sinuses.

18. FACTEAU, FABIAN and others at Acclarent understood that Acclarent needed marketing authorization from the FDA for a medical device's intended use in order to legally market any such device to be placed in the human body in the United States.

The Development of the Stratus and Distribution Strategy

19. Beginning in or about 2005, FACTEAU and others at Acclarent caused Acclarent and its engineers to develop and design the Stratus to provide sustained release of the steroid Kenalog-40 in the nasal passages by designing a reservoir with a pattern of micropores or holes that would slowly release the Kenalog-40 over an extended period of time. It did not elute saline for any significant period of time.

20. Kenalog-40 is a brand name version of triamcinolone acetonide injectable suspension ("TA"), a steroid used as an anti-inflammatory drug. Kenalog-40 has solid ingredients suspended in liquid and has an opaque, milky appearance when prepared for injection.

21. FACTEAU, FABIAN and others at Acclarent understood that the FDA would likely require significantly more testing and clinical data to permit the interstate distribution of the Stratus as a steroid delivery device than it would require for a device that did nothing more than maintain a space in the sinuses and release saline.

22. FACTEAU and others at Acclarent therefore developed and implemented a strategy to more quickly obtain marketing authorization by concealing from FDA that they intended the Stratus to be used as a steroid delivery device and by falsely claiming that the Stratus was a sinus spacer that was substantially equivalent to an existing legally marketed spacer.

23. The Stratus device, however, was not designed to work as a spacer and had no design specifications to ensure that it would mechanically maintain any particular space and or permit drainage in the sinuses.

FDA Requirements for Marketing Medical Devices

24. The Food, Drug and Cosmetic Act, 21 U.S.C. § 301 et seq. ("FDCA"), and its

implementing regulations establish a process for FDA to evaluate medical devices and determine if they can be lawfully marketed in the United States.

25. Under the FDCA, with some exceptions not applicable here, a medical device cannot be introduced into interstate commerce unless it has either an FDA-approved premarket application (a "PMA") or a form of FDA marketing authorization known as "510(k) clearance."

26. A PMA approval means that the device has been approved by the FDA based upon an application by the manufacturer that demonstrates to the FDA's satisfaction a reasonable assurance that the device is safe and effective when used according to its labeling.

27. A 510(k) clearance means that the device has been "cleared" by the FDA for marketing based upon a pre-market notification (a "510(k) notification") submitted by the proposed manufacturer to the FDA that demonstrates that the device is "*substantially equivalent*" to a device that is already legally marketed (a "predicate device").

28. A 510(k) clearance allows manufacturers who want to market products that are not required to have a PMA, are substantially the same and serve substantially the same purpose as products already legally on the market, and therefore not believed to raise new issues of safety and effectiveness, to have the products reach the market more quickly.

29. A determination that a device is "substantially equivalent" to a legally marketed predicate device requires that the manufacturer demonstrate, among other things, that the device has the same intended use as the predicate. The manufacturer must also demonstrate that the device has the same technological characteristics or that the device is as safe and effective as the predicate device and does not raise different questions of safety and effectiveness.

30. FDA regulations require manufacturers to submit to FDA a new 510(k) notification and clearance for "a change or modification in the device that could significantly affect the safety or effectiveness of the device, or a major change or modification in the intended use of a device."

31. Thus, if a manufacturer intends to market a medical device such as the Stratus for a new or different intended use other than the intended use cleared by FDA, the manufacturer must request and obtain FDA marketing authorization for that new intended use and support any claims made regarding the new use with scientific data when necessary.

Adulterated and Misbranded Devices

32. Medical devices such as the Stratus are authorized for marketing by the FDA on the basis of the particular proposed intended use or uses.

33. A device is "adulterated" if it is required to have, but lacks, PMA approval for its intended use. A 510(k) clearance cannot substitute for a PMA approval where PMA approval is required.

34. A medical device is "misbranded" if a 510(k) notification (or other required information not relevant here) was not provided to the FDA at least ninety days before such device is introduced into interstate commerce for commercial distribution or if it is intended for a new use for which a 510(k) notification was required but not filed with the FDA.

35. A medical device is also misbranded if its labeling is false or misleading. Labeling can be misleading if, among other things, it fails to reveal facts that are material in light of other representations in the labeling or customary or usual conditions of use.

36. A medical device is also misbranded if its labeling lacks the required adequate instructions and warnings for all of the product's intended uses.

37. The FDCA prohibits the introduction, or delivery for introduction, or causing the introduction or delivery for introduction, of adulterated medical devices and misbranded medical devices into interstate commerce.

The First False 510(k) Notification

38. In August 2006, Acclarent, under the leadership of FACTEAU, submitted a 510(k) notification to the FDA requesting clearance to market the Stratus as a post-operative "Ethmoid Sinus Spacer" intended to mechanically maintain an opening to the ethmoid sinus and prevent obstruction within the first 14 days following surgery. (The ethmoid sinuses are one of four pairs of human sinuses – the ethmoid, the frontal, the maxillary and the sphenoid).

39. The 510(k) notification represented that the perforated membrane of the device "allows saline to moisten the area around the Ethmoid Sinus Spacer" and included as one step of the instructions for use "inject 0.3ml of saline . . . into the perforated membrane."

40. Acclarent represented to the FDA that the Stratus, including its intended use, was substantially equivalent to an existing nasal stent, which the FDA had previously cleared for the intended use of mechanically maintaining an opening to the sinus during the first days after surgery. Acclarent also represented that the Stratus did not raise any new issues of safety and effectiveness.

41. In its August 2006 510(k) notification, Acclarent did not disclose to the FDA that its real goal was to sell Stratus as a steroid delivery device. Nor did Acclarent tell the FDA that it did not intend to market the product to deliver saline or mechanically maintain an opening to the sinus.

42. In its August 2006 510(k) submission, Acclarent also did not tell the FDA that the pores in the device were designed to elute Kenalog-40, not saline, and that most of the saline would run right out of the device.

43. Based upon Acclarent's false representations that the device was intended to mechanically maintain an opening to the sinus following surgery and could moisten the sinus with saline, the FDA concluded that the device was substantially equivalent to a legally marketed

device, and cleared the device to be marketed for that intended use only, that is, to mechanically maintain an opening to the sinus. The FDA clearance covered only the use of saline in the device.

The FDA Rejects a Broader Indication for Stratus

44. On or about April 16, 2007, Acclarent wrote to the FDA and asked to expand the indications for use for Stratus by adding the following language: "The Ethmoid Sinus Spacer is also indicated for use to irrigate the sinus space for diagnostic and therapeutic procedures."

45. On or about May 21, 2007, the FDA wrote to Acclarent to inform it that such changes could not be made based upon the existing submissions and evidence and stated:

> Based solely on the change or modifications that you have described, it appears that you have significantly changed or modified the design, components, methods of manufacture, device labeling or intended use of the device referenced above.

Acclarent Prepares to Study and Launch the Stratus for Drug Delivery

46. From April through November 2007, Acclarent enrolled patients in a clinical study ("the SPACER study") pursuant to which Acclarent instructed physicians to use the Stratus to deliver Kenalog-40 to the sinuses. Acclarent did not notify the FDA about the study or seek approval from the FDA before beginning the study.

47. FACTEAU and others at Acclarent intended that physicians in the SPACER study use the Stratus to deliver Kenalog-40, which was an unapproved intended use of the product.

48. In the fall of 2007, one of the proposed study sites notified the FDA of the ongoing clinical study and asked if the FDA considered it a "significant risk" study. A significant risk study is a study which, according to FDA regulations, requires FDA approval before it begins because it presents a potential for serious risk to the health, safety, or welfare of a subject of the clinical trial.

49. On or about December 5, 2007, the FDA determined that the study of the Stratus for Kenalog-40 delivery raised significant risks and required Acclarent to halt the study.

FACTEAU and FABIAN Approve the Launch of Stratus Intending It to Be Used for Steroid Delivery Without FDA Approval or Clearance

50. In or about January 2008, Acclarent, under the leadership of FACTEAU, FABIAN, and others, decided to launch the Stratus, starting with distribution to those physicians whom Acclarent had already trained or was training to use the device for steroid delivery.

51. FACTEAU, as the CEO of Acclarent, had final authority over whether Acclarent began to distribute the Stratus and ultimately approved the decision to launch the Stratus without FDA clearance or approval for its intended use as a steroid delivery device.

52. FABIAN, as Acclarent's Vice President of Sales, participated in the decision to distribute the Stratus without FDA approval or clearance for its intended use as a steroid delivery device and led the sales team that promoted and sold the Stratus as a steroid delivery device.

53. FACTEAU, FABIAN, Acclarent and its representatives intended physicians to use the Stratus for steroid delivery at the time it was distributed.

54. Under the direction and leadership of FACTEAU and FABIAN, beginning in February 2008 and continuing through 2011, Acclarent distributed the Stratus to physicians intending that it be used for steroid delivery and for implantation longer than 14 days, while purporting to be distributing it for its FDA-cleared use as a mechanical spacer that could be implanted for up to 14 days following surgery and used with saline.

55. Multiple Acclarent representatives attended most of the early implantations of the Stratus, and Acclarent managers often personally carried the Stratus to the physician's office or hospital, knowing and intending that it would be used in a manner not cleared or approved by the FDA, that is, to, among other things, deliver Kenalog-40.

56. FACTEAU, FABIAN and others at Acclarent did not intend to market the Stratus for its FDA-cleared use to mechanically maintain an opening and understood that it would not function to elute saline to the sinus over the implantation time since the holes in the device were specifically designed to elute a thicker substance, Kenalog-40.

57. In fact, FACTEAU, FABIAN, and others at Acclarent understood that the device would not function as an extended release delivery system for saline and that most of the saline injected into the device would run right out after injection.

The Full Launch Preparation

58. In and prior to the summer of 2008, Acclarent made modifications to the Stratus device and access system it had submitted to the FDA.

59. In or about the summer of 2008, FACTEAU, FABIAN and others at Acclarent prepared for a full commercial launch of the modified Stratus device and access system and trained the sales force and physicians to use the product as a Kenalog-40 delivery device

60. In or about the summer of 2008, Acclarent prepared sales and promotional materials for the Stratus. Those materials did not promote the FDA-cleared intended use of the Stratus as a spacer to mechanically maintain an opening, but instead promoted it as a device to deliver a fluid to bathe the sinuses.

61. The primary Stratus promotional brochure, which is a piece of labeling under the FDCA, had a picture of the Stratus inflated with a milky white substance that looks like Kenalog-40, not like clear saline.

62. Acclarent also prepared product introduction slides that were provided to the sales force to distribute or show to physicians. These slides also constitute labeling under the FDCA.

63. The product introduction slides failed to mention the FDA-cleared use of the Stratus as a spacer to mechanically maintain an opening or to moisten the sinus with saline.

Instead, the slides describe Stratus as a "temporary implant to . . . enable targeted local bathing of the paranasal sinus cells." The slides reference fluid delivery but do not mention saline, the only fluid cleared by FDA for use in the Stratus.

64. The only fluid mentioned in these slides is Kenalog-40. The slides state that the Stratus is being studied with Kenalog-40.

65. In or about the summer of 2008, Acclarent distributed to its sales force a video to show to physicians that portrayed a physician, who was paid by Acclarent and on Acclarent's Scientific Advisory Board, implanting the Stratus in a patient and filling it with Kenalog-40. The video states in the introduction that this is an off-label use of the Stratus with Kenalog-40 in a clinical study and that the product is only FDA-cleared for use with saline.

66. Beginning in or about the summer of 2008, under the direction of FACTEAU and FABIAN, Acclarent representatives shared these promotional pieces with physicians to whom they were marketing the Stratus for use as a steroid delivery device.

67. In July 2008, Acclarent sponsored a meeting called "Sinus Forum" to which it invited ENT physicians and presented information about issues in ENT, including the use of Acclarent's products. The meeting included panel discussions on local drug delivery and a live demonstration of a sinus surgery where the Stratus was implanted by a surgeon and filled with Kenalog-40 in front of hundreds of physician attendees.

68. On numerous occasions, Acclarent distributed the Stratus to physicians after the physicians had informed Acclarent in writing (and before Acclarent distributed the Stratus to physicians) that the physicians intended to use the Stratus with Kenalog-40, and Acclarent representatives were present while the physician used the product with Kenalog-40.

Acclarent Fully Launches Stratus Despite Lack of FDA Approval or Clearance for Intended Use

69. In the summer of 2008, one or more of the members of Acclarent's Scientific Advisory Board questioned whether the Stratus was ready for full launch at the annual meeting of the American Academy of Otolaryngologists ("AAO") in the fall of 2008.

70. One physician from Massachusetts wrote to FACTEAU and others known and unknown to the Grand Jury, and objected to the launch of the Stratus on the following grounds, among others:

> -- Acclarent is marketing and making available for sale a new sinus implant for delivery of medications intended to eliminate the need for traditional surgery on the target sinus . . .
> -- The device is NOT FDA approved for use with any medication,
> -- The device has no efficacy data to support its use for any degree of sinus inflammation
> – The device has limited safety data derived primarily from experienced rhinologists
> -- The 2 papers being presented at AAO do not reliably address any of the above concerns and are pilot data at best.

71. FACTEAU replied to this physician in Massachusetts and others and agreed that the Stratus was not FDA-approved for use with any medication in the United States and also conceded that the "SPACER [was] not ready for prime time." In this email exchange, FACTEAU also stated:

> There has been a tremendous amount of interest from the physician community to use this as a mechanism to deliver drugs locally, the device being discussed in the presentation is specifically developed for the ethmoid sinuses and has only been studied with Kenalog-40. The efficacy and indications have not yet been determined. The best way to think about this technology today is as another tool in your armamentarium to manage your surgical patients where you think they may benefit from a local dose of steroid to reduce inflammation . . .

72. Also in or about September 2008, FACTEAU and others at Acclarent distributed to a group of physicians on Acclarent's Scientific Advisory Board, including

one in Massachusetts, as well as to FABIAN and other managers at Acclarent, a set of slides regarding the market positioning of the Stratus. These slides stated:

> Stratus is simply a way to obtain sustained drug delivery to a targeted sinus or sinus complex . . . The goal of Stratus is to address the need expressed by most if not all ENT physicians – to find a way to get sustained local delivery of a drug to the sinus of interest.

73. On or about September 16, 2008, FACTEAU conducted two nationwide sales conferences with the Acclarent sales and marketing teams, including FABIAN. In these calls, he discussed what physicians should expect when they decide to use the Stratus to deliver Kenalog-40 and instructed the sales force to tell physicians that local drug delivery has a role in treating ethmoid disease and to position the Stratus as a more effective way to deliver an agent.

74. In or about September 29, 2008, Acclarent announced the launch of the Stratus at the annual AAO meeting.

75. At the time of this launch, the head of Research and Development at Acclarent trumpeted the fact that Acclarent had launched a drug delivery device. In an email to many at Acclarent, including FACTEAU and FABIAN, he wrote: "Congratulations, Team Condor [the internal project name for Stratus], Acclarent has planted the flag for sustained local drug delivery for our ENT customers and their patients."

76. Some physicians had difficulty placing the Stratus device initially launched in 2008 in the frontal sinuses and some physicians experienced problems with the device migrating or slipping out, and also experienced problems with the Stratus' retention wings on the device detaching from the device and remaining in the patient.

77. In or about February 2009, Acclarent also launched for commercial sale a physically modified version of the Stratus that it marketed in particular for use in the frontal sinuses. This new device was also called the Stratus and was also intended to deliver

Kenalog-40 to the sinuses, but was 510(k) cleared by the FDA in December 2008 based upon the false claim that it was intended to maintain an opening to the frontal sinus post-operatively and could moisten with saline.

The Sale of Acclarent

78. From the beginning, an overarching goal of the Acclarent management team and board of directors was to develop the company to a point where its investors and shareholders could make a substantial profit by selling their shares.

79. Starting in 2007, Acclarent and its executive team, including FACTEAU and FABIAN, began taking steps, including engaging investment bankers, to profit from Acclarent either by an IPO of Acclarent shares or by selling the company outright.

80. On or about June 5, 2008, FACTEAU signed and caused to be submitted to the United States Securities and Exchange Commission (the "SEC") and posted on the internet, on behalf of Acclarent, a Form S-1, Registration Statement to list Acclarent stock with the SEC. In this statement, FACTEAU and others at Acclarent acknowledged:

> Risks of using our products include risks related to using instruments in close proximity to the brain, eyes and other critical structures. In addition, our currently marketed products have been cleared by the FDA for certain uses. We are prohibited from marketing our products for uses outside of those cleared or approved by the FDA, but physicians may use our product for an off-label indication. There may be increased risk of injury if physicians attempt to use our products for an off-label indication, or if they misuse any of our products, such as reusing any of our single-use products. . . . Furthermore, if we are deemed by the FDA to have engaged in the promotion of off-label use of our products, we could be subject to FDA prohibitions on the sale of our products or significant fines and penalties, and the imposition of these sanctions could also affect our reputation and position within the industry. Any of these events could harm our business and results of operations and cause our stock price to decline.

81. In the S-1, FACTEAU also acknowledged:

> The FDA and state authorities have broad enforcement powers. Our failure to comply with applicable regulatory requirements could result in enforcement action by the FDA or state agencies, which may include any of the following sanctions . . . withdrawing 510(k)

clearances, . . . or criminal prosecution.

82. In the S-1 FACTEAU also disclosed his knowledge that:

> If we materially modify our FDA cleared devices, we may need to seek and obtain new clearances, which, if not granted, would prevent us from selling our modified products. . . . Medical devices can be marketed only for the indications for which they are cleared or approved. After a device received 510(k) clearance, any modification that could significantly affect its safety or effectiveness, or that would constitute a new or major change in its intended use, will require a new 510(k) clearance, or depending on the modification, pre-market approval.

83. Due to the unfavorable market conditions in the fall of 2008, Acclarent and its management abandoned plans for an IPO at that time but continued to work on selling Acclarent.

84. In the summer and fall of 2009, Acclarent's management, including FACTEAU, engaged in discussions with Ethicon, a corporation headquartered in New Jersey, about merging Acclarent into Ethicon.

85. During the fall and winter of 2009, FACTEAU, FABIAN and others at Acclarent made presentations and representations about Acclarent, its products, its revenues and value, including from Stratus, to Ethicon and others in connection with trying to sell Acclarent.

86. During these negotiations, FACTEAU, FABIAN and others at Acclarent knew but did not disclose to Ethicon and others that Acclarent and its sales force, at their direction, had been regularly promoting the Stratus for uses not cleared by the FDA, including specifically for steroid delivery.

87. The fact that Acclarent, at the direction of FACTEAU, FABIAN and others, had been regularly promoting the use of the Stratus for uses other than those approved by the FDA, was material to the negotiations with and decisions by the investment bankers, Ethicon and others as to the sale or merger of Acclarent and purchase and acquisition of Acclarent stock by Ethicon and its shareholders.

88. In December 2009, Ethicon announced that it was merging Acclarent into Ethicon for a sales price to Acclarent stockholders of approximately $785 million (the "merger").

89. In the merger agreement between Acclarent and Ethicon (the "Merger Agreement"), FACTEAU, signing on behalf of Acclarent and the shareholders, falsely represented that Acclarent was in compliance with all legal and regulatory requirements and that it had all necessary regulatory clearances from the FDA for its products on the market.

90. In Section 3.9 of the Merger Agreement, FACTEAU falsely represented:

> Neither the Company nor any of its Subsidiaries is or has been in any material respect in conflict with, or in default or in violation of, any Legal Requirement applicable to the Company or any of its Subsidiaries . . . The Company and its Subsidiaries hold, to the extent required under any Legal Requirement, all permits, authorizations, . . . clearances, . . and approvals ("Permits") from Governmental Entities, including the U.S. Food and Drug Administration ("FDA") that are material to the operation of the Company Business and for it to own, lease or operate its properties and assets . . . The Company and its subsidiaries are and at all times have been in compliance in all material respects with the terms of the Company Permits.

91. In Section 3.17 of the Merger Agreement, FACTEAU falsely represented:

> The operation of the Company Business, including the . . . labeling, . . . marketing, and distribution of all Company Products is and at all times has been in material compliance with all applicable Legal Requirements, Company Permits, Governmental Entities and orders administered by the FDA for Company Products sold in the United States

92. These representations in the Merger Agreement were material to Ethicon.

93. The Merger Agreement also provided that approximately $109 million of the purchase price would be held in escrow for one to two years (the "escrow") to indemnify Ethicon for any breach of the agreement or false representations made in the agreement, including the representations of regulatory compliance.

94. As part of the Merger Agreement implementation, FACTEAU, FABIAN and others at Acclarent agreed to be paid out for their stock and options, including by a portion of the

escrow, if it was not utilized, over the two years following the merger.

95. Over the two-year period following the merger of Acclarent into Ethicon, Ethicon agreed to release the escrow and this amount was paid out to shareholders of Acclarent nationwide, including FACTEAU and FABIAN.

96. In connection with the negotiation and implementation of the sale and transfer of Acclarent's stock to Ethicon and the payment of the full purchase price, FACTEAU and FABIAN made and caused to be made false and fraudulent statements and material omissions to Ethicon and others about the design, purpose and intended use of the Stratus, as well as about the past and ongoing promotion of the Stratus, so as to make Acclarent look more desirable as a target company and increase the payments received from Ethicon in various forms and ensure payment of the full price and bonuses pursuant to the merger and exchange of Acclarent stock.

97. In connection with the sale and transfer of Acclarent's stock to Ethicon, FACTEAU falsely represented to Ethicon that Acclarent had complied with the law and promoted and distributed the Stratus for its cleared FDA intended use, when FACTEAU and FABIAN and others knew that they and others at Acclarent had been selling the Stratus for uses not approved by the FDA, including steroid delivery, and not for its cleared FDA intended use.

Ethicon Instructs FACTEAU and FABIAN to Cease All Stratus Promotion and Report Off-Label of Stratus to FDA

98. In or around early 2010, Ethicon management expressed concern about continuing to sell and promote the Stratus in light of the significant amount of off-label use.

99. FACTEAU advocated for continued distribution and promotion of the Stratus, despite Ethicon's determination that Acclarent was not permitted to continue to promote the Stratus and that such conduct would expose Ethicon to unacceptable risk of a government enforcement action.

100. Despite FACTEAU's repeated objections, in March of 2010, Ethicon prohibited Acclarent from promoting the Stratus at all and required that the Stratus be made available as a "catalog only" product. This meant that there was to be no promotion of the Stratus and that all sales force bonus compensation attributable to projected Stratus sales was to be removed from the sales representatives' compensation package.

101. At Ethicon's insistence, on or about March 26, 2010, FACTEAU announced to Acclarent, including FABIAN, that Acclarent would no longer promote the Stratus at all and it would no longer be part of sales compensation because of the legal risks from continuing to actively promote it.

102. Ethicon also instructed Acclarent to notify an FDA Office of Compliance about the extensive off-label use. FACTEAU wrote in protest: "I remain very concerned with the approach of including OC [Office of Compliance] at FDA. I believe it adds considerable risk to J&J [Johnson & Johnson], Acclarent employees, and our former shareholders."

103. Nonetheless, at Ethicon's insistence, and with FACTEAU's knowledge, in or about March and April 2010, Acclarent's Regulatory Vice-President did contact the Office of Device Evaluation at FDA and acknowledge that Acclarent was aware that "our physician customers predominantly choose" to use the Stratus with a drug rather than saline, but also represented that Acclarent was no longer promoting the Stratus for any use and that Acclarent's previous promotion of the Stratus had been consistent with its labeling.

FACTEAU and FABIAN Directs the Sales Force to Continue Promoting Stratus in Violation of Ethicon's Orders in Order to Achieve Revenue and Bonus Targets

104. Despite the instructions from Ethicon's CEO to no longer promote the Stratus, despite FACTEAU's announcement to Acclarent employees that there would be no such promotion due to the legal and enforcement risks, and despite Acclarent's representations to the

FDA that it was no longer promoting the Stratus at all, FACTEAU and FABIAN sent a different message to the sales force.

105. In or around June and July 2010, FABIAN wrote to the sales managers, and then to the entire sales force, each with a copy to FACTEAU, instructing the sales force to continue to sell Stratus and that all on-label discussions were ok, despite Ethicon's instruction that there was to be no promotion at all of the Stratus. In that email, FABIAN explained: "declining Stratus business (ignoring stratus business) has shown a strong correlation to declining core business."

106. In or around June 2010, FABIAN wrote to the five top sales representatives asking how they were driving their business in the first half of 2010. One wrote back "STRATUS, STRATUS, STRATUS" and made clear that he continued to promote Stratus for the unapproved use of drug delivery as part of his selling pitch.

107. FABIAN responded to this email by thanking the sales representative for his hard work. That representative received special stock options for being a high performer the following year.

108. At a meeting in about July 2010, FABIAN and FACTEAU again communicated to the sales representatives that they should continue to push sales of the Stratus. In FACTEAU's presence, FABIAN explained that one of the things that top sales representatives were continuing to do to push their sales was to sell Stratus and that this was something all sales representatives should be doing.

109. FACTEAU and FABIAN directed the sales force to continue to promote Stratus despite the no-promotion direction from Ethicon at least in part to try to achieve the Acclarent revenue targets necessary for FACTEAU and FABIAN to earn maximum bonuses.

110. In implementing the sale of Acclarent's stock to Ethicon and causing payment of the $109 million of the escrowed sales price, FACTEAU and FABIAN and others engaged in a

scheme to deceive and mislead both the FDA and Ethicon by purporting to follow Ethicon's directives to no longer actively market or promote the Stratus for any use, and by falsely reporting to the FDA that Acclarent (a) had not promoted the Stratus for an off-label use and had only promoted and distributed it for its cleared FDA use, and (b) was no longer promoting the Stratus at all, when in fact Defendants were instructing the sales force to continue to sell the Stratus in order to increase revenues, and thereby Defendants' bonuses.

FACTEAU and FABIAN's Compensation and Responsibilities

111. FABIAN made approximately $4 million from his stock options and other compensation in connection with the merger.

112. FACTEAU made approximately $30 million from his stock and options and other compensation in connection with the merger.

113. Defendants FACTEAU and FABIAN were each responsible corporate persons and persons in a responsible relationship with respect to Acclarent's regulatory, sales and marketing activities, including specifically with respect to the Stratus.

114. Defendants FACTEAU and FABIAN were responsible corporate persons with respect to the Stratus, under 21 U.S.C. §§ 331(a), 333(a)(1), 351(f)(1)(B), 352(a) and 352(f)(1) and 352(o), when Acclarent introduced and caused the introduction into interstate commerce of Stratus devices that were adulterated and misbranded.

COUNT ONE
18 U.S.C. § 371 (Conspiracy)

115. The Grand Jury re-alleges and incorporates by reference paragraphs 1-114 of this Indictment and further charges that:

116. From a date unknown in or about 2006, and continuing through in or about 2011, in the District of Massachusetts and elsewhere, Defendants,

(1) WILLIAM FACTEAU and
(2) PATRICK FABIAN,

knowingly conspired with individuals and entities both known and unknown to the Grand Jury,

(A) to commit offenses against the United States in violation of 21 U.S.C. §§ 331(a), 333(a)(1)-(2), 351 and 352, by, with the intent to defraud and mislead, causing the introduction and delivery for introduction into interstate commerce of the Stratus, which was (1) an adulterated device within the meaning of 21 U.S.C. § 351(f)(1)(B) in that it was a Class III device that lacked an FDA-approved pre-market approval and was not properly exempt from such approval; and (2) a misbranded device in that its labeling was false and misleading in violation of 21 U.S.C. § 352(a), and lacked adequate directions for use and did not qualify for an exemption to this requirement, in violation of 21 U.S.C. § 352(f)(1), and in that no pre-market notification was provided for the device as required by section 510(k) [codified at 21 U.S.C. § 360(k)], in violation of 21 U.S.C. § 352(o); and

(B) to commit securities fraud (15 U.S.C. § 78j(b) and 78ff): that is, willfully, by the use of means and instrumentalities of interstate commerce and the mails, directly and indirectly to use and employ manipulative and deceptive devices and contrivances in connection with the purchase and sale of a security, to wit, stock of Acclarent, in contravention of Rule 10b-5 (17 C.F.R. § 240.10b-5) of the Rules and Regulations promulgated by the SEC, by (a) employing any device, scheme and artifice to defraud; (b) making any untrue statement of material fact and omitting to state any material fact necessary in order to make the statement made, in light of the circumstances under which it was made, not misleading; and (c) engaging in any act, practice and course of business which would and did operate as a fraud and deceit, in connection with the purchase and sale of securities, in violation of 15 U.S.C. §§ 78j(b) & 78ff(a), and 17 C.F.R. § 240.10b-5, and 18 U.S.C. § 2.

Objectives of the Conspiracy

117. The object of the conspiracy was to make money by selling the Stratus as a steroid delivery device, an intended use not cleared or approved by the FDA, and hiding that conduct

from the FDA, all in order to increase the revenues of Acclarent, the value of the company and Defendants and their co-conspirators' stock options and compensation.

Manner and Means of the Conspiracy

118. In order to deceive the FDA, and to avoid FDA scrutiny into its product and its marketing, as well as to defraud others, Defendants and others known and unknown to the Grand Jury knowingly made and caused to be made a series of false and misleading statements to the FDA and others on behalf of Acclarent, including false and misleading statements about the intended use of the Stratus and the justification for certain design elements and modifications.

119. These false statements included but are not limited to the following:

a. The original 510(k), in or about August 2006, stated that the intended use of the Stratus was to maintain an opening in the sinus and had instructions for use that called for the injection of saline;

b. The 510(k) in or about October 2007 to expand use of Stratus to all sinuses stated that the intended use of the Stratus was to maintain an opening in the sinus and had instructions for use that called for the injection of saline, as well as false reasons for the requested modifications to 28 days' implantation time and a larger hole size;

c. The 510(k) in or about December 2008 for a Stratus focused on the frontal sinuses stated that the intended use of the Stratus was to maintain an opening in the sinus and had instructions for use that called for the injection of saline;

d. Other filings with the FDA from in and around 2007 through in and around 2011 falsely stated that the intended use of the Stratus was to maintain an opening to the sinus and set forth instructions for its use with saline; and

e. Representations about the Stratus made to the FDA from in and around 2007 through in and around 2011, including in meetings FACTEAU attended, that the intended use of the device was to hold open a space and the impetus for use with a drug was originally initiated by physicians using the device, and failing to disclose that the product was specifically designed to elute Kenalog-40 and did not work to elute saline over time.

120. On various dates from in or about early 2007 until in or about December 2011, Defendants and others known and unknown to the Grand Jury agreed to and did cause the

introduction and delivery for introduction into interstate commerce of an adulterated and misbranded medical device, Stratus, when that device and access system lacked FDA marketing authorization or premarket approval for its intended use, had false and misleading labeling, and lacked adequate directions for its intended use, including by:

a. distributing Stratus to physicians nationwide for the intended use as a steroid delivery device with Kenalog-40, a use for which the device had not been shown to be safe or effective and was not cleared or approved by the FDA;

b. creating and communicating false, misleading and fraudulent messages both orally and in writing about (1) the efficacy of Stratus to deliver saline in a sustained release fashion, and (2) the basis and nature of the FDA's clearance of the device, including specifically failing to disclose that Acclarent had received clearance from the FDA only by falsely claiming that the intended use of the product was as a spacer for use with saline, and that the FDA had specifically refused to clear it for therapeutic use with drugs generally and had raised specific safety concerns about Kenalog-40, including about potentially causing optical injury and blindness;

c. making false, misleading and unsupported claims about the safety and efficacy of the Stratus to physicians, including claims that it worked well with Kenalog-40 and could be used with Kenalog-40 to treat chronic sinusitis and polyps and was safe and effective for these uses;

d. failing to provide adequate instructions, warnings and safety information as to how to use the Stratus for its intended uses;

e. distributing Stratus for the intended use of being implanted for longer than 14 days when the FDA clearance was for just 14 days and without providing adequate warnings and safety information, including about the fact that on occasion the device's retention wings had broken off from and gotten stuck in the patients and at times the device had migrated within the patients;

f. training physicians to use Stratus with Kenalog-40 and demonstrating Stratus to physicians using a milky substance, often creamer, that looked like Kenalog-40 rather than saline;

g. delivering Stratus to physicians and attending and supporting surgeries in which they knew Stratus was going to be used as a steroid delivery device to deliver Kenalog-40 to the sinuses without providing appropriate warnings and safety information;

h. preparing misleading marketing materials and messages that falsely conveyed the message that Stratus could provide extended bathing of the sinuses with saline, when they knew the saline ran right out of the device;

i. preparing misleading marketing materials that did not mention Stratus' sole cleared intended use of mechanically maintaining an opening to the sinus;

j. preparing and distributing promotional materials and sales training scripts that evidenced Acclarent's and Defendants' intent that the Stratus be distributed and used for the purpose of delivering Kenalog-40 and implantation longer than 14 days, among other unapproved and uncleared uses;

k. training employees to use for promotional purposes a videotape of a surgery where the Stratus was implanted and then inflated with the milky white Kenalog-40; and

l. training its employees to promote the Stratus to physicians for use as a steroid delivery device by using probing questions to lead the physician to a discussion of the use of the device for drug delivery.

121. Defendants and others at Acclarent also concealed from the FDA and others, including payors, potential and actual investors, buyers, Acclarent's own investment bankers and Ethicon, both before and after the merger, the fact that FACTEAU, FABIAN and others at Acclarent had been and were extensively promoting the Stratus for uses not cleared by the FDA and causing the distribution of Stratus for intended uses not cleared or approved by the FDA.

OVERT ACTS

In furtherance of the conspiracy, Defendants FACTEAU and FABIAN and other co-conspirators known and unknown to the Grand Jury, committed and caused the following overt acts to be committed in the District of Massachusetts and elsewhere:

122. In or about the winter and spring of 2008, Acclarent employees delivered the Stratus to physicians with the intent that the physicians use the Stratus for the purpose of delivering Kenalog-40 to the sinuses.

123. In or about the spring and summer of 2008, Defendants FACTEAU and FABIAN and other known and unknown to the Grand Jury caused to be prepared, and approved,

marketing materials and labeling for the Stratus to promote the use of the Stratus for unapproved uses, including steroid delivery.

124. In or about July 2008, Defendants FACTEAU and FABIAN and other known and unknown to the Grand Jury participated in organizing, on behalf of Acclarent, a meeting known as the Sinus Forum at which physicians were paid to attend and speak, and others were taught, among other things, how to use the Stratus for drug delivery.

125. On or about August 15, 2008, FACTEAU wrote to a group of physicians, including one in Massachusetts, and explained that the best way to think about the Stratus was "as another tool in your armamentarium to manage your surgical patients where you think they may benefit from a local dose of steroid to reduce inflammation . . ." In this email, FACTEAU also stated:

> There has been a tremendous amount of interest from the physician community to use this as a mechanism to deliver drugs locally. . . . [T]he device being discussed in the presentations is specifically developed for the ethmoid sinuses and has only been studied with Kenalog-40, . . . the efficacy and indications have not yet been determined . . .

126. On or about September 3, 2008, FACTEAU sent a set of slides to the physicians on Acclarent's Scientific Advisory Board, including one member in Massachusetts, as well as to others at Acclarent, regarding the positioning of the Stratus. The slides stated:

> Stratus is simply a way to obtain sustained drug delivery to a targeted sinus or sinus complex . . . The goal of Stratus is to address the need expressed by most if not all ENT physicians -- to find a way to get sustained local delivery of a drug to the sinus of interest.

127. On or about September 16, 2008, FACTEAU and FABIAN held two mandatory teleconference calls with the Acclarent sales and marketing teams in which FACTEAU instructed the sales force to position Stratus in the market to provide a benefit as a local drug delivery device.

128. In or about July 2009, Defendants FACTEAU and FABIAN and other known and unknown to the Grand Jury participated in organizing, on behalf of Acclarent, a meeting known as the Sinus Forum at which physicians were paid to attend and speak, and others were taught, among other things, how to use the Stratus for drug delivery.

129. On or about August 14, 2009, FABIAN emailed a sales representative encouraging him to sell Stratus as a method of medical management, and stated: "Leverage the minimalistic approach most ENT surgeons claim to embrace to sell maxillary and Stratus, Stratus is just an extension of medical management."

130. In or about October 2009, FACTEAU and FABIAN and others at Acclarent made a presentation to Ethicon, including about the Stratus and its sales, without disclosing that those sales were being obtained illegally.

131. In or about December 2009, FACTEAU signed the Merger Agreement, which he knew contained false representations to Ethicon.

132. On or about July 11, 2010, FABIAN thanked one of Acclarent's representatives for his hard work in response to that representative's explanation as to how he sold so much of Acclarent's product by selling the Stratus for drug delivery as follows:

> STRATUS, STRATUS, STRATUS . . . . My docs . . . are now . . . only taking down the tissue that needs to be removed and allowing the new drug therapy tool to handle the rest . . .

133. Acclarent shipped Stratus to medical providers, including as set forth in the factual allegations in Counts Nine to Eighteen below.

134. Defendants and other co-conspirators sent and caused to be sent the wires set forth in Counts Five to Eight below.

All in violation of 18 U.S.C. § 371.

COUNTS TWO-FOUR
15 U.S.C. §§ 78j(b) & 78ff(a), 17 C.F.R. § 240.10b-5
(Fraud in Connection with Purchase and Sale of Securities)

135. The Grand Jury re-alleges and incorporates by reference paragraphs 1-114 and 117-134 of this Indictment, and further charges that:

136. On the dates set forth below, in the District of Massachusetts and elsewhere, Defendants,

(1) WILLIAM FACTEAU and
(2) PATRICK FABIAN,

knowingly and willfully, by the use of means and instrumentalities of interstate commerce and the mails, did directly and indirectly use and employ manipulative and deceptive devices and contrivances in connection with the purchase and sale of a security, to wit, Acclarent stock, in contravention of Rule 10b-5 (17 C.F.R. § 240.10b-5) of the Rules and Regulations promulgated by the SEC, by (a) employing any device, scheme and artifice to defraud; (b) making any untrue statement of material fact and omitting to state any material fact necessary in order to make the statement made, in light of the circumstances under it was made, not misleading; and (c) engaging in any act, practice and course of business which would and did operate as a fraud and deceit, in connection with the following payments in connection with the purchase and sale of securities:

Count	Date (On or About)	Description
2	1/20/2010	First Payments for Acclarent Stock and Options
3	1/20/2011	Payments of First Installment of Escrow of Price for Acclarent Stock and Options
4	1/20/2012	Payments of Second Installment of Escrow of Price for Acclarent Stock and Options

All in violation of 15 U.S.C. §§ 78j(b) & 78ff(a), 17 C.F.R. § 240.10b-5, and 18 U.S.C. § 2.

COUNTS FIVE-SEVEN
18 U.S.C. §§ 1343, 1349 (Wire Fraud and Attempted Wire Fraud)

137. The Grand Jury re-alleges and incorporates by reference paragraphs 1-114 and 117-133 of this Indictment, and further charges that:

138. On or about the following dates, in the District of Massachusetts and elsewhere, Defendants,

(1) WILLIAM FACTEAU and
(2) PATRICK FABIAN,

having devised and intending to devise a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations and promises concerning material facts and matters, to wit, to sell Stratus as a steroid delivery device, an intended use not cleared or approved by the FDA, and hiding that conduct from the FDA and actual and potential investors and purchasers of Acclarent, all in order to increase the revenues and valuation of Acclarent, and their own stock options and compensation, transmitted and caused to be transmitted, and attempted to transmit and cause to be transmitted, in interstate commerce by means of wire and radio communication, writings, signs, signals, pictures, and sounds, for the purpose of executing that scheme and artifice, as follows:

Count	Date	From	To	Item
5	11/13/2009	Sales Rep. A	Clinic B, Boston	Email re: "Stratus . . . allows for direct bathing with a solution to the infected sinuses [and] . . . for patient not to have to take oral steroids"
6	11/16/2009	Sales Rep. A	Dr. C, MA	Email re: Stratus "helps eliminate inflammation and melts away the polyps by directing bathing the tissue."
7	11/19/2009	FABIAN	Training Team, MA	Email noting very productive course and "solid [Return on Investment]. . . re: Stratus training"

All in violation of 18 U.S.C. §§ 1343, 1349 and 2.

COUNT EIGHT
18 U.S.C. §§ 1343, 1349 (Wire Fraud and Attempted Wire Fraud)

139. The Grand Jury re-alleges and incorporates by reference paragraphs 1-114 and 117-133 of this Indictment, and further charges that:

140. On or about the date set forth below, in the District of Massachusetts and elsewhere, Defendants,

(1) WILLIAM FACTEAU and
(2) PATRICK FABIAN,

having devised and intending to devise, a scheme and artifice to defraud and to obtain money and property by means of false and fraudulent pretenses, representations and promises concerning material facts and matters, to wit, to sell Stratus as a steroid delivery device, an intended use not cleared or approved by the FDA, and hiding that conduct from the FDA and Ethicon and contrary to Ethicon's direction and their representations to Ethicon, all in order to receive and increase the revenues of Acclarent, and their own compensation and bonuses, transmitted and caused to be transmitted, and attempted to transmit and cause to be transmitted, in interstate commerce by means of wire and radio communication, writings, signs, signals, pictures, and sounds, for the purpose of executing that scheme and artifice, as follows:

Count	Date	From	To	Item
8	07/08/2010	FABIAN	All ENT Sales, cc: FACTEAU	Email instructing sales force to continue to sell Stratus and train on Stratus

All in violation of 18 U.S.C. §§ 1343, 1349 and 2.

COUNTS NINE-THIRTEEN
21 U.S.C. §§ 331(a), 333(a) (1)-(2), 351(f)(1)(B) (Distribution of Adulterated Device)

141. The Grand Jury re-alleges and incorporates by reference paragraphs 1-114 and 117-132 of this Indictment and further charges that:

142. On or about the dates listed below, in the District of Massachusetts and elsewhere, Defendants

(1) WILLIAM FACTEAU and
(2) PATRICK FABIAN,

with the intent to defraud and mislead, caused the introduction and delivery for introduction into interstate commerce of the Stratus, which was an adulterated device within the meaning of 21 U.S.C. § 351(f)(1)(B) in that it was a Class III device that lacked an FDA-approved pre-market approval and was not properly exempt from such approval, as set out in each count below:

Count	Stratus Shipped To	Approximate Shipment Date
9	Hospital 1, S. Weymouth	10/21/2009
10	Hospital 2, Plymouth	11/06/2009
11	Hospital 3, Lowell	11/17/2009
12	Hospital 4, Hyannis	08/11/2010
13	Hospital 5, Worcester	02/25/2011

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1)-(2), 351(f)(1)(B) and 18 U.S.C. § 2.

COUNTS FOURTEEN-EIGHTEEN
21 U.S.C. §§ 331(a), 333(a) (1)-(2), 352(a), 352(f), 352(o)
(Misbranded/Lack of Adequate Directions for Use/
Pre-Market Notification and False and Misleading Labeling)

143. The Grand Jury re-alleges and incorporates by reference paragraphs 1-114 and 117-132 of this Indictment, and further charges that:

144. On or about the dates listed below, in the District of Massachusetts and elsewhere, Defendants

(1) WILLIAM FACTEAU and
(2) PATRICK FABIAN,

with the intent to defraud and mislead, introduced, and delivered for introduction into interstate commerce, and caused the introduction and delivery for introduction into interstate commerce, the below-listed device, namely the Stratus, which was misbranded in that its labeling was false and misleading in violation of 21 U.S.C. § 352(a), and lacked adequate directions for use and did not qualify for an exemption to this requirement, in violation of 21 U.S.C. § 352(f)(1), and in that no pre-market notification was provided for the device as required by section 510(k) [codified at 21 U.S.C. § 360(k)], in violation of 21 U.S.C. § 352(o), as set out in each count below:

Count	Stratus Shipped To	Approximate Shipment Date
14	Hospital 4, Hyannis	12/15/2009
15	Hospital 1, S. Weymouth	01/19/2010
16	Hospital 2, Plymouth	01/10/2010
17	Hospital 1, S. Weymouth	10/13/2010
18	Hospital 5, Worcester	05/27/2011

All in violation of 21 U.S.C. §§ 331(a), 333(a)(1)-(2), 352(a), 352(f), 352(o) and 18 U.S.C. § 2.

FORFEITURE ALLEGATIONS
(18 U.S.C. §§ 981(a)(1)(C), 982(a)(7), and 28 U.S.C. § 2461(c))

145. The Grand Jury further charges that: upon conviction of one or more of the offenses charged in Counts One through Eighteen of this Indictment, Defendants

(1) WILLIAM FACTEAU and
(2) PATRICK FABIAN,

jointly and severally, shall forfeit to the United States, pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7), and Title 28, United States Code, Section 2461(c), any property, real or personal, that constitutes, or is derived from, proceeds traceable to the commission of the offenses.

146. If any of the property described in paragraph 145 hereof as being forfeitable pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7), and Title 28, United States Code, Section 2461(c), as a result of any act or omission of the defendants:

a. cannot be located upon the exercise of due diligence;

b. has been transferred to, sold to, or deposited with a third party;

c. has been placed beyond the jurisdiction of the Court;

d. has been substantially diminished in value; or

e. has been commingled with other property which cannot be divided without difficulty,

it is the intention of the United States, pursuant to Title 28, United States Code Section 2461(c), and Title 18, United States Code, Section 982(b), incorporating Title 21, United States Code Section 853(p), to seek forfeiture of any other property of the defendants up to the value of the property described in paragraph 145 above.

All pursuant to Title 18, United States Code, Sections 981(a)(1)(C) and 982(a)(7), and Title 28, United States Code, Section 2461(c).

A TRUE BILL:

Elizabeth L Taylor

FOREPERSON

SARA MIRON BLOOM
PATRICK M. CALLAHAN
Assistant United States Attorneys

Thomas F. Quinn
Deputy Clerk
4/8/2015 @ 11:50am