UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES	)	
v.	)	**Criminal No. 15-10076-ADB**
WILLIAM FACTEAU, PATRICK FABIAN	)	
Defendants.	)	

JURY INSTRUCTIONS

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DUTY OF THE JURY TO FIND FACTS AND FOLLOW THE LAW

It is your duty as jurors to find the facts from the evidence admitted in this case. You will then apply the law as I give it to you to the facts as you find them. You must follow the law as I explain it to you whether you agree with that law or not. Regardless of any opinion you may have as to what the law should be, it would violate your sworn duty as a juror in this case to base a verdict on any view of the law other than that given in my instructions. You must decide the case solely on the evidence before you and according to the law.

Counsel and witnesses may have quite properly referred to some of the applicable rules of law in the course of trial. There has been evidence as to what witnesses and other persons communicated about the law and its requirements. If, however, any difference appears to you between the law as stated by counsel or witnesses or otherwise reflected in the exhibits and the law as stated by the Court, you are to be governed by the instructions given to you by the Court.

In following my instructions, you must follow all of them, and not single out some and ignore others. They are all important.

You must not interpret these instructions, or anything I may have said or done, as a suggestion by me as to what verdict you should return—that is a matter entirely for you to decide.

PRESUMPTION OF INNOCENCE; PROOF BEYOND A REASONABLE DOUBT

Every person accused of a crime is presumed to be innocent unless and until his guilt is proved beyond a reasonable doubt. The presumption is not a mere formality. It is a fundamental principle of our system of justice.

The presumption of innocence means that the burden of proof is always on the government to prove that a defendant is guilty of the crimes with which he is charged beyond a reasonable doubt.

This burden never shifts to the defendant. It is always the government's burden to prove each of the elements of the crimes charged beyond a reasonable doubt. A defendant does not have to prove that he is innocent, or even present any evidence.

The presumption of innocence alone may be sufficient to raise a reasonable doubt and to require the acquittal of the defendant. You may not convict a defendant of any crime charged against him if the government fails, or is unable to prove every element of that crime beyond a reasonable doubt.

A reasonable doubt is a doubt that a reasonable person has after carefully weighing all the evidence. It is a doubt that would cause a reasonable person to hesitate to act in a matter of importance in his or her personal life. Proof beyond a reasonable doubt must, therefore, be proof of a convincing character that a reasonable person would not hesitate to rely upon in making an important decision. A reasonable doubt may arise not only from the evidence produced, but also from a lack of evidence. Reasonable doubt exists when, after weighing and considering all the evidence, using reason and common sense, jurors cannot say that they have a settled conviction of the truth of the charge.

You may not convict a defendant based on speculation or conjecture.

You may not convict a defendant if you decide that it is equally likely that he is guilty or not guilty. If you decide that the evidence would reasonably permit either of two conclusions—either that he is guilty as charged, or that he is not guilty—you must find the defendant not guilty.

You may not convict a defendant if you decide that it is only probable, or even strongly probable, that he is guilty. A mere probability of guilt is not guilt beyond a reasonable doubt.

The law does not require that the government prove guilt beyond all possible doubt; proof beyond a reasonable doubt is sufficient to convict. There are very few things in this world that we know with absolute certainty, and in criminal cases the law does not require proof that overcomes every possible doubt.

Again, a defendant is presumed to be innocent, and the government bears the burden of proving him guilty beyond a reasonable doubt. If, after fair and impartial consideration of all the evidence, you have a reasonable doubt as to a defendant's guilt, it is your duty to acquit him. On the other hand, if after fair and impartial consideration of all the evidence, you are satisfied beyond a reasonable doubt as to his guilt, you should vote to convict him.

DEFENDANT'S CONSTITUTIONAL RIGHT NOT TO TESTIFY

Like all defendants, the Defendants in this case have a constitutional right not to testify. No inference of guilt, or of anything else, may be drawn from the fact that a Defendant did not testify, nor may the fact that he did not testify be discussed or considered by you in any way in arriving at your verdict.

VERDICT BASED SOLELY ON THE EVIDENCE; IMPROPER CONSIDERATIONS

Your verdict must be based solely upon the evidence. It would be improper for you to base your verdict on anything that is not evidence.

You may not base your verdict on any personal feelings, prejudices, or sympathies you may have about either Defendant or about the nature of the crimes with which they are charged.

You may not consider or be influenced by any possible punishment that may be imposed on a defendant.

Again, your verdict must be based solely on the evidence and according to the law.

THE EVIDENCE

The evidence in this case consists of the sworn testimony of witnesses, both on direct and cross-examination; the exhibits that have been received into evidence; and any facts to which the parties have agreed or stipulated. You should consider all of the evidence, no matter what form it takes, and no matter which party introduced it.

Whether the government has sustained its burden of proof does not depend upon the number of witnesses it has called, or upon the number of exhibits it has offered, but instead upon the nature and quality of the evidence presented.

WHAT IS NOT EVIDENCE

Certain things are not evidence.

(1) Arguments and statements by lawyers are not evidence. The lawyers are not witnesses. What they said in their opening statements, or what they will say in their closing arguments, and at other times is intended to help you interpret the evidence, but it is not evidence. If the facts as you remember them from the evidence differ from the way the lawyers have stated them, your memory of the facts should control.

(2) Questions by lawyers, standing alone, are not evidence. Again, the lawyers are not witnesses. The question and the answer taken together are the evidence.

(3) Objections by lawyers are not evidence. Lawyers have a duty to their clients to object when they believe a question or an exhibit is improper under the rules of evidence. You should not be influenced by any objection or by my ruling on it, and you should not speculate or guess about what the answer might have been or what an exhibit might have said.

(4) Anything that I have struck or instructed you to disregard is not evidence.

(5) The indictment is not evidence.

(6) Anything you may have seen or heard when the court was not in session is not evidence. You must decide the case solely on the evidence received at trial.

KINDS OF EVIDENCE—DIRECT AND CIRCUMSTANTIAL

Evidence may take the form of either "direct evidence" or "circumstantial evidence." "Direct evidence" is direct proof of a fact, such as testimony from an eyewitness that the witness saw something. "Circumstantial evidence" is indirect evidence; that is, proof of a fact (or facts) from which you could draw a reasonable inference that another fact exists, even though it has not been proved directly.

You are entitled to consider both direct and circumstantial evidence. The law permits you to give equal weight to both. It is for you to decide how much weight to give to any particular piece of evidence, whether direct or circumstantial.

INFERENCES

Although you may consider only the evidence presented in the case, you are not limited to the plain statements made by witnesses or contained in the documents. In other words, you are not limited solely to what you saw and heard as the witnesses testified.

You are permitted to draw reasonable inferences from the facts, if you believe those inferences are justified in light of common sense and personal experience. An inference is simply a deduction or conclusion that may be drawn from the facts that have been established. Any inferences you draw must be reasonable, and based on the facts as you find them. Inferences may not be based on speculation or conjecture.

CAUTIONARY AND LIMITING INSTRUCTIONS

A particular item of evidence was sometimes received for a limited purpose only. That is, it can be used by you only for one particular purpose, and not for any other purpose. I have told you when that occurred, and instructed you on the purposes for which the item can and cannot be used.

CREDIBILITY OF WITNESSES

You do not have to accept the testimony of any witness if you find that the witness is not credible. You must decide which witnesses to believe, considering all of the evidence and drawing upon your common sense and personal experience. You may believe all of the testimony of a witness, or some of it, or none of it. You alone are the judges of the witnesses' credibility.

In deciding whether to believe testimony of the witnesses, you may want to take into consideration such factors as their conduct and demeanor while testifying; any apparent fairness or unfairness they may have displayed; any interest they may have in the outcome of the case; any prejudice or bias they may have shown; their opportunities for seeing and knowing the things about which they have testified; the reasonableness or unreasonableness of the events that they have related to you in their testimony; and any other evidence that tends to support or contradict their versions of the events.

PRIOR INCONSISTENT STATEMENTS

The testimony of a witness may be discredited or impeached by showing that he or she previously made statements that are inconsistent with his or her present testimony. If a witness made inconsistent statements about any significant matter, you have a right to distrust the testimony of that witness in other respects. You may reject all of the testimony of that witness or give it such credibility as you may think it deserves.

Sometimes, of course, people make innocent mistakes, particularly as to unimportant details; not every contradiction or inconsistency is necessarily important. Again, you alone are the judges of the witnesses' credibility.

IMMUNIZED WITNESS

You have heard the testimony of witnesses who testified under grants of immunity, and you have seen their immunity agreements.

"Immunity" means that a witness's testimony may not be used against him or her in any later criminal proceeding. However, if the witness testifies untruthfully, he or she could be prosecuted for perjury or making a false statement, even though he or she was testifying under a grant of immunity.

Some people in this position are entirely truthful when testifying. Still, you should consider the testimony of immunized witnesses with particular care and caution. They may have had reason to make up stories or exaggerate what others did because they wanted to help themselves. You must determine whether the testimony of such a witness has been affected by any interest in the outcome of this case, any prejudice for or against the Defendants, or by any of the benefits he or she has received from the government as a result of being immunized from prosecution.

As with any witness, it is for you to decide whether to accept the testimony of any witness, and what weight, if any, to give to that testimony.

NOTE-TAKING

As I indicated at the beginning of the trial, you have been permitted to take notes, but some cautions apply. You should bear in mind that not everything that is written down is necessarily what was said. When you return to the jury room to discuss the case, do not assume simply because something appears in somebody's notes that it necessarily took place in court. Notes are an aid to recollection, nothing more; the fact that something is written down does not mean that it is necessarily accurate.

EXHIBIT NUMBERS

The numbers assigned to the exhibits are for convenience and in order to ensure an orderly procedure. You should draw no inference from the fact that a particular exhibit was assigned a particular number, or that there may be gaps in the number sequence.

THE INDICTMENT

This case, like most criminal cases, began with an indictment. The indictment is not evidence or proof of guilt. The indictment is simply an accusation—it is the means by which defendants are charged with crimes and brought before this court.

An indictment may allege more than one charge against more than one defendant. When it does, the different charges are stated separately in what we call counts. The indictment in this case has fourteen Counts.

The defendants are not on trial for any act or any conduct not specifically charged in the indictment.

CONSIDER EACH COUNT AND EACH DEFENDANT SEPARATELY

There are two Defendants on trial before you. You must, as a matter of law, consider each count of the indictment and each Defendant's involvement in that count separately, and you must return a separate verdict on each Defendant for each count in which he is charged.

In reaching your verdict, bear in mind that guilt is personal and individual. Your verdict of guilty or not guilty must be based solely upon the evidence about each Defendant. The case against each Defendant, on each count, stands or falls upon the proof or lack of proof against that Defendant alone, and your verdict as to any Defendant on any count should not control your decision as to the other Defendant.

Similarly, the Defendants are charged in multiple counts of the indictment. You must consider each count separately, and you must return a separate verdict as to each count. Your verdict as to each count must be determined solely on the evidence, or lack of evidence, presented against each defendant on that count.

UNANIMOUS VERDICT

Your verdict must be unanimous in order to convict either defendant as to any count. In other words, all of you must agree that a defendant is guilty as to a particular count in order to convict that Defendant as to that count.

DESCRIPTION OF THE INDICTMENT IN THIS CASE

Now I turn to the indictment in this case and the statutes on which it is based. First, I remind you that an indictment is not evidence of any kind against the Defendants. The indictment is just an accusation, filed in writing, with the Court to bring a criminal charge against a defendant.

As I said, the indictment in this case has fourteen Counts.

- Count 1 charges both Defendants with conspiring to commit violations of the Federal Food, Drug and Cosmetic Act, which makes it unlawful to introduce or cause the introduction of adulterated and/or misbranded medical devices in interstate commerce.

- Counts 5-7 charge both Defendants with wire fraud—that is—participating in a fraudulent scheme to distribute the Stratus for an intended use not cleared or approved by the FDA, and concealing the conduct, all to increase the valuation and revenues of Acclarent and using specific emails or wire transmissions in furtherance of the scheme.

- Counts 9-18 charge both Defendants with substantive violations of the Federal Food, Drug and Cosmetic Act based on the allegation that they introduced or caused the introduction of a misbranded and/or adulterated device into interstate commerce, and that they did so with the intent to defraud or mislead.

As we discussed at the outset, there are gaps in the numerical sequence. If I did not mention a count, that is because there is no count with that number in this case. Missing counts are not relevant to your deliberations and you should draw no conclusions from the numbering.

Both Defendants deny that they are guilty of these charged offenses and are presumed to be innocent. Again, for you to find a defendant guilty, the government must prove each element of a charged offense beyond a reasonable doubt.

THE FEDERAL FOOD, DRUG & COSMETIC ACT

I am now going to talk to you about provisions of the Federal Food, Drug, and Cosmetic Act, also referred to as the FDCA, that will be relevant to your consideration of the charges in this case. The FDCA requires that most new medical devices, unless exempted, be approved or cleared by the Food and Drug Administration, or FDA, before they can be introduced in interstate commerce. The FDCA also prohibits the introduction into interstate commerce of misbranded and adulterated medical devices.

Classification

The FDCA classifies medical devices according to the risks associated with their use. There are three classes that can be assigned to a device—Class I, Class II or Class III. Each class is subject to different regulatory controls, with Class I devices getting the least scrutiny and Class III devices getting the most. Device classification depends on the technology and the intended use of a device. Thus, a single device can be assigned to different classes based on different intended uses, and similarly, two devices that are otherwise the same can be assigned to different classes based on different intended uses.

Any device that was not distributed before May 28, 1976, is automatically classified as a Class III device unless that device has otherwise been classified by the FDA as a Class I or II device. The government and the Defendants have stipulated, that is agreed, that the Stratus was not introduced into interstate commerce prior to May, 1976.

Class III Devices/PMA Approval

A device classified as a Class III device must be approved by the FDA before it can be distributed in interstate commerce. This is generally accomplished through the Premarket Approval, also called the PMA, process, which involves the manufacturer of the device

submitting a premarket approval application to the FDA. Once a manufacturer of a Class III device has submitted a premarket approval application to the FDA, the FDA will approve the PMA for the device only if the information in the PMA provides the FDA with reasonable assurance that the device is safe and effective under the conditions of use recommended in the device's proposed labeling.

Section 510(k) Process/Substantial Equivalence

A device can be removed from the automatic Class III designation, bypass the PMA process, and be assigned to either Class I or Class II if the manufacturer obtains a Section 510(k) determination or order of "substantial equivalence" from the FDA for the device's intended use. "Substantial equivalence" means that the device has the same intended use as the predicate device and the FDA has found that the device has the same intended use as an already cleared Class I or Class II "predicate" device, and, in addition, that (1) it has the same technological characteristics as the predicate device, or, (2) if the technological characteristics are different, that the device is at least as safe and effective as the predicate device and does not raise different questions of either safety or effectiveness than the predicate device.

A manufacturer seeking to obtain a determination of substantial equivalence for a new device must submit a premarket notification, also referred to as a "510(k) submission," to the FDA at least ninety days before the manufacturer intends to start commercially distributing the device.

"Intended use" is a defined term under the FDCA and its regulations, meaning that it doesn't necessarily have what you might think of as its usual, every day meaning. During the 510(k) review process, the FDA's determination of whether a new device's intended use is the same as the predicate device's intended use is based solely on the manufacturer's proposed

labeling for the new device, which must be part of the 510(k) submission. A manufacturer's submission of labeling and its statement of intended use in the 510(k) notification means that that is the intended use for which the manufacturer seeks clearance under section 510(k). The manufacturer is not required to submit all possible or contemplated uses of the device in its 510(k) notification.

When determining that a device is substantially equivalent to a legally marketed device, the FDA may require a statement in the labeling that provides appropriate information regarding a use of the device not identified in the proposed labeling if the FDA determines and states in writing (1) that there is a reasonable likelihood that the device will be used for an intended use not identified in the proposed labeling for the device; and (2) that such use could cause harm.

If the FDA issues a "substantial equivalence" order for a device, the manufacturer may then market the device for the intended use described in the 510(k) submission.

Off-Label Uses of Medical Devices

A device that is cleared by the FDA may be legally used by physicians for uses other than the use for which it is cleared or approved. This is referred to as off-label use. Physicians are legally permitted to use a cleared or approved device for any purpose, including an off-label purpose. Off-label use is common. A device cleared under the 510(k) process is not adulterated or misbranded merely because a physician uses the device for an off-label purpose.

Although the FDA and FDCA regulate the marketing of medical devices, they do not regulate the practice of medicine or how physicians use medical devices, nor do they limit the authority of doctors to use medical devices that have been approved or cleared for one use for a different, unapproved, or uncleared use. The FDA does, however, regulate manufacturers in

their distribution of medical devices by prohibiting them from distributing medical devices for any intended use that has not been FDA-cleared or approved.

Merely distributing a device with knowledge that it will be used for a use other than the use cleared or approved by the FDA is not fraudulent or illegal. That being said, if a manufacturer has received 510(k) clearance to distribute a device for one intended use, it may not distribute the device for a significantly different intended use unless it obtains a new 510(k) clearance or a PMA approval for the device with that new intended use. I will explain what is meant by "intended use" in the distribution context a bit later in these instructions.

Off-Label Promotion of Medical Devices

Off-label promotion refers to promoting a device for an off-label use, meaning an intended use that has not been FDA-cleared or approved. It is not illegal in and of itself for a device manufacturer to provide truthful, not misleading information about an off-label use. The FDCA does not prohibit or criminalize truthful, not misleading off-label promotion. You may not convict a Defendant of a crime based solely on truthful, non-misleading statements promoting an FDA-cleared or approved device, even if the use being promoted is not a cleared or approved use. Over the course of this trial, you have heard evidence about a number of statements, marketing claims, and other communications about the Stratus. It is up to you to decide whether a statement is truthful and non-misleading, or whether it is false or misleading.

The indictment in this case does not charge any defendant with the crime of promoting a device off-label, because that is not itself a crime. Rather, the FDCA crimes charged are conspiring to introduce, and causing the introduction of, devices into interstate commerce that were adulterated or misbranded. Although you may not convict a Defendant of a crime based solely on truthful, non-misleading statements regarding off-label use, even truthful statements

about an off-label use can be considered as evidence. To put it another way, to convict, there must be a criminal act. Truthful, non-misleading speech cannot be a criminal act in and of itself, but it can be evidence and therefore used by you to determine whether the government has proved each element of each offense beyond a reasonable doubt, including the element of intent.

Intended Use

As I have mentioned, "intended use" is a defined legal term. I previously have instructed you on the meaning of "intended use" during the FDA's 510(k) clearance process. I now will instruct you on the meaning of "intended use" as it applies outside the clearance process.

The term "intended use" refers to the objective intent of the manufacturer or seller of the device. The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the device. This objective intent may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives. It may be shown by the circumstances that the device is, with the knowledge of such persons or their representatives, offered and used for a purpose for which it is neither labeled nor advertised. A device can have more than one intended use.

Mere knowledge that doctors are using a device for purposes other than its labeled use does not give rise to a new intended use. Off-label promotional statements can constitute evidence of an intended use, although truthful, non-misleading speech alone cannot be the basis for a criminal conviction. Neither the First Amendment nor any other law, however, protects false or misleading speech.

In addition, it is permissible to respond to unsolicited requests for information about FDA-regulated medical products by providing truthful, balanced, non-misleading, and non-promotional scientific or medical information that is responsive to the specific request, even if

responding to the request requires a manufacturer to provide information on unapproved or uncleared indications or conditions of use. Under these circumstances, such responses may not be considered as evidence of a new or different "intended use."

Label and Labeling

The terms "label" and "labeling" have specific meanings under the FDCA.

"Label" means any written, printed, or graphic matter upon the immediate container of a product. All words, statements, and other information required to be on the label must also appear on the outside container or wrapper.

"Labeling" is broader than the term "label." "Labeling" means all labels as well as any other written, printed, or graphic matter on or accompanying the product in interstate commerce. Labeling may include promotional material or literature, including package inserts, pamphlets, mailing pieces, fax bulletins, reprints of press releases, information posted on internet websites selling the product, and all other literature from the manufacturer that supplements or explains the product in connection with its sale.

ELEMENTS OF THE OFFENSES - INTRODUCTION

I am now going to give you some more specific instructions on the crimes charged in the indictment and the elements of the offenses that the government must prove beyond a reasonable doubt.

I will explain each of the charges alleged in the 14 Counts, although I am not going to do it in numerical order. Having just discussed the Food, Drug and Cosmetic Act, I am going to begin with the adulteration and misbranding charges (Counts 9-18) and then move on to Count 1 which alleges a conspiracy to violate the FDCA, and finally, the wire fraud (Counts 5-7).

ADULTERATION AND MISBRANDING – (COUNTS 9 - 18)

Counts 9 through 18 charge the Defendants with violations of the Federal Food, Drug, and Cosmetic Act, which I have been referring to as the FDCA.

Counts 9 through 13 of the indictment charge the Defendants with introducing or causing the introduction of an adulterated medical device into interstate commerce, and Counts 14 through 18 of the indictment charge the Defendants with introducing or causing the introduction of a misbranded medical device into interstate commerce. Each of these charges requires the government to prove three elements beyond a reasonable doubt. For misbranding and adulteration, the first two elements are the same, although the third is different for the two charges. I am going to begin by instructing you on the two elements that are common to both adulteration and misbranding and finally instruct on the third element that the government must prove beyond a reasonable doubt, first for adulteration and then misbranding.

DEFINITION OF DEVICE

The first element that the government must prove beyond a reasonable doubt for both misbranding and adulteration is that the Stratus was a "device" regulated under the FDCA. For purposes of your deliberations, the parties have stipulated that the Stratus is a prescription medical device as those terms are defined in the FDCA.

INTERSTATE COMMERCE

The second element that the government must prove beyond a reasonable doubt for both adulteration and misbranding is that the defendant caused the Stratus to be delivered or introduced into interstate commerce. "Interstate commerce" means commerce between any state and any place outside of that state, including other states, or a foreign country.

With regards to Counts 9 through 13, the indictment alleges the following:

Count 9 concerns a Stratus shipped to Hospital 1 in S. Weymouth on approximately 10/21/09

Count 10 concerns a Stratus shipped to Hospital 2 in Plymouth on approximately 11/06/09

Count 11 concerns a Stratus shipped to Hospital 3 in Lowell on approximately 11/17/09

Count 12 concerns a Stratus shipped to Hospital 4 in Hyannis on approximately 8/11/10

Count 13 concerns a Stratus shipped to Hospital 5 in Worcester on approximately 2/25/11

With regards to Counts 14 through 18, the indictment alleges the following:

Count 14 concerns a Stratus shipped to Hospital 4 in Hyannis on approximately 12/15/09

Count 15 concerns a Stratus shipped to Hospital 1 in S. Weymouth on approximately 1/19/10

Count 16 concerns a Stratus shipped to Hospital 2 in Plymouth on approximately 1/10/10

Count 17 concerns a Stratus shipped to Hospital 1 in S. Weymouth on approximately 10/13/10

Count 18 concerns a Stratus shipped to Hospital 5 in Worcester on approximately 5/27/11.

The government and the Defendants have stipulated that the Stratus shipments identified in Counts 1 and 9-18 were introduced into and traveled in interstate commerce, but you will still need to determine whether a defendant caused that to happen.

ADULTERATION ELEMENTS

For the crime of introducing or causing the introduction of adulterated devices into interstate commerce, charged in Counts 9-13 of the indictment, the third element that the government must prove beyond a reasonable doubt is that the Stratus was adulterated.

A medical device is adulterated if it is a Class III device that is required to have, but does not have, an FDA approved premarket approval or "PMA" application for a particular intended use and is not otherwise exempt from such approval. If a device has been classified by the FDA as a Class I or Class II device under a 510(k) clearance, then it is not a Class III device for the intended use for which it has been cleared, although it would be a Class III device for any uncleared or unapproved intended use that is significantly different from the use for which it was cleared unless it is Class I exempt. The fact that a physician buys a Class I device in order to use it for an off-label purpose does not change the classification of the device.

In sum, for you to find a defendant guilty of these counts, the government must prove each of the following elements beyond a reasonable doubt:

One: That the Stratus products listed in Counts 9-13 were "devices;"

Two: That the defendant caused those products to be introduced into interstate commerce; and

Three: That those products were adulterated.

MISBRANDING ELEMENTS

Counts 14 through 18 of the indictment charge the defendants with introducing or causing the introduction of a misbranded device into interstate commerce. In order to find a defendant guilty of any of these charges, you must find that the government has proved the following elements beyond a reasonable doubt:

One: That the Stratus products listed in Counts 14 through 18 were "devices";

Two: That the defendant caused those products to be introduced into interstate commerce" and;

Three: That those products were "misbranded."

I defined the terms "device" and "interstate commerce" earlier in these instructions and they have the same meaning here.

Counts 14 through 18 allege that the Stratus devices were misbranded in three specific ways, which I will discuss in a minute. To find either defendant guilty of introducing or causing the introduction of misbranded devices into interstate commerce, you must find beyond a reasonable doubt that the Stratus devices were misbranded in at least one of these three ways. You do not need to find that the devices were misbranded in more than one way, but you must be unanimous as to which type of misbranding, if any, that the government has proven beyond a reasonable doubt.

FALSE AND MISLEADING LABELING

First, a device is misbranded if its labeling is materially false or misleading in any particular. I instructed you earlier on the definition of "labeling" and you should use that same definition throughout.

In determining whether a device's labeling is misleading, you may take into account (among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling fails to reveal facts material in the light of such representations or with respect to consequences which may result from the use of the device under the conditions of use prescribed in the labeling or under such conditions of use as are customary or usual. Half truths or incomplete statements that omit material information can make a label false and misleading if the omitted information is necessary to avoid making the statement misleading.

A fact is "material" if it has a natural tendency to influence or is capable of influencing the decision of the decision-maker to whom it was addressed.

MISBRANDING BY FAILURE TO FILE PREMARKET NOTIFICATION

Second, a medical device is also misbranded if the manufacturer introduces the device into interstate commerce for an intended use that is significantly different from the use covered by its 510(k) clearance and without submitting a new premarket notification to the FDA regarding the different intended use.

MISBRANDING – LACK OF ADEQUATE DIRECTIONS FOR USE

Finally, a device is misbranded if its labeling does not bear adequate directions for its intended use.

"Adequate directions for use" for a prescription device like the Stratus means that any labeling that furnishes or purports to furnish information for the use of the device must bear adequate information for such use, including indications, effects, routes, methods, and frequency and duration of administration, and any relevant hazards, contraindications, side effects, and precautions under which practitioners licensed by law to use the device can use it safely and for the purpose for which it is intended, including all purposes for which it is advertised or represented. This information may be omitted from the package from which the device is to be dispensed, if, but only if, the directions, hazards, warnings, and other information are commonly known by practitioners licensed by law to use the device and there is no labeling on or within the package from which the device is to be dispensed that furnishes or purports to furnish any information for use of the device.

CORPORATE OFFICIAL'S LIABILITY FOR VIOLATIONS OF FDCA

With regard to Counts 9 through 18, you must first determine whether the government has proved beyond a reasonable doubt that a defendant caused the introduction into interstate commerce of adulterated or misbranded devices. If you find that a defendant caused the introduction into interstate commerce of adulterated or misbranded devices, you should then consider whether the defendant held a "position of responsibility" within Acclarent and the authority to prevent or to correct the adulteration or misbranding violations charged in the indictment. If you find beyond a reasonable doubt that the defendant held such a "position of responsibility" with respect to the adulteration or misbranding counts charged in the indictment but failed to prevent or correct the violations, you may find the defendant guilty of causing the introduction of adulterated or misbranded devices into interstate commerce, even if he did not intend the devices to become adulterated or misbranded and did not personally know about the specific circumstances that caused the devices to become adulterated or misbranded.

A defendant cannot be convicted solely based on his position in the company or if you find it was impossible for him to prevent or correct the adulteration or misbranding charged in the indictment. Rather, the government must prove beyond a reasonable doubt that the defendant had the authority to prevent or correct the specific adulteration or misbranding charged here and that preventing the introduction of misbranded or adulterated devices into interstate commerce was not impossible.

Good faith, which I will discuss in more detail shortly, is not a defense because the law does not require a defendant to know about or to have actively engaged in wrongdoing in order to be held responsible for his company's distribution of adulterated or misbranded devices. All that the law requires is that the defendant held such a position of responsibility within the

company and that he had sufficient authority to prevent or correct the violation and that the violation nonetheless occurred or was not corrected

INTENT TO DEFRAUD OR MISLEAD

Again with regard to Counts 9 through 18, if for a particular count and Defendant, you do not find beyond a reasonable doubt that the Defendant caused the introduction of adulterated or misbranded devices as charged in that count, you should acquit that Defendant on that count and move on to the next. If, however, you do find beyond a reasonable doubt that a defendant caused the introduction of adulterated and/or misbranded devices into interstate commerce as charged in each of Counts 9 through 18, you must then go on to determine whether the government has also proved beyond a reasonable doubt that the Defendant committed the adulteration or misbranding violations with the intent to defraud or mislead. There will be two separate questions that you will have to answer - first, consistent with my other instructions, did the Defendant cause the introduction into interstate commerce of adulterated and/or misbranded devices? If no, move onto the next count. But if yes, you must then decide if he did so with the intent to defraud or mislead.

A defendant acts with intent to defraud or mislead under the FDCA if the defendant acts with the specific intent to defraud or mislead either the government or individuals.

To act with the intent to defraud or mislead the government means to act with the specific intent to interfere with or obstruct a lawful government function by deceit, craft, trickery, or dishonesty, ordinarily for the purpose of either causing some financial loss to another or bringing about some financial gain to the defendant or another. The government must prove beyond a reasonable doubt that there was an intent to defraud or mislead an identifiable regulatory agency rather than just a general intent to defraud or mislead. An intent to defraud or mislead the government can be demonstrated through evidence that a defendant took steps, in connection with the distribution of products, to conceal material facts from the FDA or that a defendant

acted with an intent to materially deceive the FDA and thereby hinder the FDA in carrying out its regulatory responsibilities.

An intent to defraud or mislead individuals can be proven by showing that a defendant knowingly made or caused materially false statements or representations to be made or that he intentionally concealed material facts for the purpose of misleading. It is not necessary for you to find that anyone was actually misled or defrauded, so long as you find beyond a reasonable doubt that the defendant acted with the intent to mislead or defraud.

In order to prove beyond a reasonable doubt that each Defendant distributed an adulterated or misbranded device with the specific intent to defraud or mislead, the government must prove, beyond a reasonable doubt, that each Defendant knew that the conduct was unlawful, and nevertheless engaged in the conduct with the specific intent to disobey or disregard the known legal duties.

The intent to defraud or mislead must be connected to the alleged adulteration or misbranding violation – that is, the government must prove beyond a reasonable doubt that the Defendant you are considering caused the introduction of misbranded or adulterated devices into interstate commerce with the intent to defraud or mislead.

To prove intent to defraud or to mislead, the government must prove, beyond a reasonable doubt, that a Defendant did not act in good faith, but instead acted with the specific intent to defraud or mislead. As I will discuss next, good faith is a complete defense because it is inconsistent with the intent to defraud or mislead.

If you find a Defendant did not have an intent to defraud or mislead, or if you have reasonable doubt as to whether a Defendant had intent to defraud or mislead or whether he acted

in good faith, you must find that the government has failed to prove that the defendant acted with the intent to defraud or mislead.

It can be difficult to prove a defendant's state of mind directly, but a defendant's state of mind can be proved indirectly from the surrounding circumstances. This includes things such as what the defendant said or did, how the defendant acted, and any other facts or circumstances in evidence that bear on the defendant's intent.

GOOD FAITH

A Defendant's good faith is a complete defense to the portions of the adulteration and misbranding charges that require you to find an intent to defraud or mislead. This is the second question relating to misbranding and adulteration. Good faith is not relevant to the first question where you must determine whether a Defendant caused the introduction of adulterated or misbranded devices into interstate commerce. Good faith is also a complete defense to any other charge that requires the government to prove that a defendant acted knowingly and willfully or with an intent to defraud or mislead. This is because if a Defendant acted in good faith, then the Defendant necessarily lacked the knowledge and willfulness, or specific intent to defraud or mislead that the government must prove beyond a reasonable doubt in order to convict a defendant of a count that requires proof of such a state of mind. Again, not all counts charged in this case require proof of such a state of mind and this instruction applies only to those that do.

A defendant did not act in "good faith" if, even though he honestly held a certain opinion or belief, he also knowingly made false or fraudulent statements, representations or promises to others.

If a person acts either on a belief or an opinion honestly held that his actions were not criminal, that person's actions are not criminal simply because the belief or opinion turns out to be incorrect, inaccurate, or wrong.

A defendant does not bear the burden of proving good faith. Rather, it is the government's burden to prove, beyond a reasonable doubt, that a Defendant did not act in good faith, but instead acted with the specific intent to defraud or mislead with regard to those counts that require proof of the specific intent to defraud or mislead.

If you find a Defendant did not have intent to defraud or mislead, or if you have reasonable doubt as to whether a Defendant had intent to defraud or mislead or whether he acted in good faith, you must find the Defendant not guilty of any charge that requires proof of such intent, including wire fraud, which I will discuss shortly.

CONSPIRACY – ELEMENTS – (COUNT 1)

Now for Count 1. Counts 9 through 18 charge substantive violations of the FDCA, by which I mean actual violations of the FDCA. Count 1, the conspiracy count, by contrast, charges the Defendants with conspiring to violate the FDCA. The crime is the agreement to commit the FDCA offenses rather than the actual commission of the offense. To find a defendant guilty of Count 1, you must unanimously find that the government has proved the following three elements beyond a reasonable doubt:

First, that at least two people agreed to violate the Federal Food, Drug, and Cosmetic Act ("FDCA"), in the ways alleged in Count 1;

Second, that the defendant willfully joined the agreement, intending that the charged crime or crimes be committed; and

Third, that at least one conspirator committed at least one overt act during the period of the conspiracy in an effort to further the purpose of the conspiracy.

A conspiracy is an agreement, spoken or unspoken. The conspiracy does not have to be a formal agreement or plan in which everyone involved sat down together and worked out all the details.

But the government must prove beyond a reasonable doubt that those who were involved shared a general understanding about the crime. Mere similarity of conduct among various people, or the fact that they may have associated with each other or discussed common aims and interests does not necessarily establish proof of the existence of a conspiracy, but you may consider such factors.

To act "willfully" means to act voluntarily and intelligently and with the specific intent that the underlying crime be committed—that is to say, with bad purpose, either to disobey or

disregard the law—not to act by ignorance, accident or mistake. The government must prove two types of intent beyond a reasonable doubt to establish that a defendant willfully joined the conspiracy: One, an intent to agree, and two, an intent, whether reasonable or not, that the underlying crime be committed. In considering whether either Defendant had the specific intent to commit the underlying FDCA offenses, you should apply the instructions on intent that I previously gave you for each of the underlying offenses. Good faith is a defense to the charge of conspiracy. Mere presence at the scene of a crime is not alone enough, but you may consider it among other factors. Intent may be inferred from the surrounding circumstances.

Proof that a defendant willfully joined in the agreement must be based upon evidence of his own words and actions. You need not find that a defendant agreed specifically to or knew about all the details of the crime, or knew every other co-conspirator, or that he participated in each act of the agreement, or played a major role, but the government must prove beyond a reasonable doubt that he knew the essential features and general aims of the criminal venture. Even if a defendant was not part of the agreement at the very start, he can be found guilty of conspiracy if the government proves that he willfully joined the agreement later. On the other hand, a person who has no knowledge of a conspiracy, but simply happens to act in a way that furthers some object or purpose of the conspiracy, does not thereby become a conspirator.

An overt act is any act knowingly committed by one or more of the conspirators in an effort to accomplish some purpose of the conspiracy. Only one overt act has to be proven. The government is not required to prove that one of these two Defendants personally committed or knew about the overt act. It is sufficient if one conspirator committed one overt act at some time during the period of the conspiracy.

The government does not have to prove that the conspiracy succeeded or was achieved. The crime of conspiracy is complete upon the agreement to commit the underlying crime and the commission of one overt act by at least one coconspirator.

INDIVIDUALS NOT ON TRIAL

Some of the people who may have been involved in these events are not on trial. There is no requirement that all members of a conspiracy be charged and prosecuted, or tried together in one proceeding. Your task is limited to considering the charges contained in the indictment and only as to the Defendants before you.

WIRE FRAUD – ELEMENTS – (COUNTS 5 - 7)

Finally, the Defendants are charged in Counts 5 through 7 with wire fraud. These counts generally allege that the Defendants participated in a fraudulent scheme to sell the Stratus for an intended use that was not FDA-cleared or approved and to hide that conduct from the FDA and actual and potential investors and purchasers of Acclarent, in order to increase Acclarent's revenues and valuation. To find a defendant guilty of wire fraud, you must find that the government has proved each of the following four elements beyond a reasonable doubt:

One: That there was a scheme, substantially as charged in the indictment, to defraud or to obtain money or property by means of false or fraudulent pretenses;

Two: That the scheme to defraud involved the misrepresentation or concealment of a material fact or matter or the scheme to obtain money or property by means of false or fraudulent pretenses involved a false statement, assertion, half-truth or knowing concealment concerning a material fact or matter;

Three: That the defendant knowingly and willfully participated in this scheme with the intent to defraud; and

Four: That for the purpose of executing the scheme or in furtherance of the scheme, the defendant either caused an interstate wire communication, in this case, the emails charged in the indictment, or it was reasonably foreseeable that for the purpose of executing the scheme or in furtherance of the scheme, the interstate emails would be sent, on or about the dates alleged.

WIRE FRAUD

A scheme includes any plan, pattern or course of action. The government does not need to prove all of the details alleged in the indictment concerning the precise nature and purpose of the scheme. The government also does not have to prove that the alleged scheme actually succeeded in defrauding or misleading anyone. What must be proven beyond a reasonable doubt is that a defendant knowingly participated in a scheme to defraud that was substantially as charged in the indictment.

The term "defraud" means to deceive another by misrepresenting or concealing a material fact in order to obtain money or property. To defraud, the deceit must cause someone to do that which they would otherwise not do which results in a deprivation of money or property or causes another to obtain money or property as a result of the fraud. A regulatory clearance does not qualify as money or property for purposes of the wire fraud statute.

The term "false or fraudulent pretenses, representations, or promises" means any false statements or assertions (1) that concern a material aspect of the matter in question, (2) that were either known to be untrue when made or made with reckless indifference to their truth, and (3) that were made with the intent to defraud.

A false representation can take several forms and can include the following:

1. A knowingly false statement about a material matter that is intended to deceive;
2. A "half truth"—meaning a statement about a material matter that is literally true but is intentionally made deceptive by leaving out important additional information; and
3. An intentional failure to disclose material information that one has a duty to disclose for the purpose of deceiving.

With regards to number 3, generally a failure to disclose alone is not sufficient to establish fraud. A person or business has a duty to disclose information only if the law imposes such a duty. I instruct you that a person who submits a written request to FDA for an order of substantial equivalence, also known as a 510(k) submission, has a duty to disclose in the submission all facts material to the determination of substantial equivalency.

A "material" fact or matter is one that has a natural tendency to influence or is capable of influencing the decision of the decision-maker to whom it was addressed.

To act "knowingly" means to act voluntarily and intentionally and not because of ignorance, mistake or accident.

An act or failure to act is "willful" if done voluntarily and intentionally, and with the specific intent to do something the law forbids, or with the specific intent to fail to do something the law requires to be done; that is to say, with bad purpose either to disobey or to disregard the law. Thus, if a defendant acted in good faith, he cannot be guilty of the crime of wire fraud. The burden to prove intent, as with all other elements of the crime, rests with the government.

Again, intent or knowledge may not ordinarily be proven directly because there is no way of directly scrutinizing the workings of the human mind. In determining what a defendant knew or intended at a particular time, you may consider any statements made or acts done or omitted by him and all other facts and circumstances received in evidence that may aid in your determination of his knowledge or intent. You may infer, but you certainly are not required to infer, that a person intends the natural and probable consequences of acts knowingly done or knowingly omitted. It is entirely up to you, however, to decide what facts are proven by the evidence received during this trial.

An "interstate wire communication" includes an e-mail transmission or other internet communication. The indictment alleges three specific emails – one for each of Counts 5, 6 and 7.

Count 5 alleges an email sent on November 13, 2009 from Sales Rep A, Barbara Logan, to Clinic B in Boston. Count 6 alleges an email sent on November 16, 2009 from Sales Rep A, Barbara Logan, to Dr. C in Boston. And Count 7 alleges an email sent on November 19, 2009 from Mr. Fabian to Training Team in Massachusetts.

The wire communication does not itself have to be essential to the scheme, but it must have been made for the purpose of carrying it out. There is no requirement that either Defendant was personally responsible for the wire communication, that the wire communication itself was fraudulent, or that the use of wire communications facilities in interstate commerce was intended as the specific or exclusive means of accomplishing the alleged fraud. But the government must prove beyond a reasonable doubt that each defendant knew, or could reasonably have foreseen, that the use of a wire communication, in furtherance of or for the purpose of executing the scheme, would follow in the course of the scheme.

The government and the Defendants have stipulated that the emails and other wires identified in Counts 1 and 5-7 were interstate wire communications and traveled in interstate commerce.

AIDING AND ABETTING

In Counts 5-7 and Counts 9-18, each Defendant has been charged both as a principal and an aider or abettor. I have already instructed you on the elements of the offenses that need to be proven beyond a reasonable doubt for you to find either Defendant guilty as a principal.

A person may also be found guilty of each of those counts if he aided or abetted another in committing the charged offense. To "aid and abet" means intentionally to help someone else commit the charged crime. To establish aiding and abetting, the government must prove beyond a reasonable doubt:

First, that the charged crime was actually committed by someone. This person is called the "principal.";

Second, that the Defendant took an affirmative act to help or cause the commission of the charged offense; and

Third, that the Defendant intended to help or cause the commission of the charged offense.

The second element, the "affirmative act" element, can be satisfied without proof that the Defendant participated in each and every element of the charged offense. It is enough if the Defendant assisted in the commission of the charged offense or caused the charged offense to be committed.

The third element, the "intent" element, is satisfied if a Defendant had advance knowledge of the facts that make the principal's conduct criminal. "Advance knowledge" means knowledge at a time the defendant can opt to walk away.

A general suspicion that an unlawful act may occur or that something criminal is happening is not enough. Mere presence at the scene of the charged offense and knowledge that

the charged offense is being committed are also not sufficient to constitute aiding and abetting. But you may consider these things among other factors in determining whether the government has met its burden.

DELIBERATIONS

It is now time for you to start your deliberations. Let me say a few words about those deliberations.

Each of you must decide the case for yourself, but you should do so only after considering all of the evidence and listening to the views of your fellow jurors. You should not hesitate to reconsider your views from time to time and to change them if you are persuaded that this is appropriate. But do not come to a decision simply because other jurors insist that it is right, and do not surrender an honest belief about the weight and effect of the evidence just to reach a verdict.

Your verdict must be unanimous as to each of the questions I am going to ask you to answer on the verdict form.

I am going to ask juror number **1** to serve as foreperson. The foreperson will have the same voice and the same vote as the other deliberating jurors. The fact that one of you is foreperson does not give that person special status in your deliberations. You are all equal. The foreperson will act, to the extent helpful, as the moderator of the discussion and will serve as the jury's spokesperson. The foreperson's most important obligation is to insure that any juror who wishes to be heard on any material issue has a full and fair opportunity to be heard by his or her fellow jurors.

If you as a group decide to take a recess during your deliberations, you should stop discussing the case until the recess is over. Do not discuss the case during a recess when not all jurors are present.

If it becomes necessary during your deliberations to communicate with me, you may do so by sending a note through the court officer. No member of the jury should ever attempt to

communicate with me, except by such a signed writing. If you do communicate with me, do not tell me in the note how you stand numerically or otherwise, on any issue before you, until after you have reached a verdict. You are not to communicate with anyone but me about the case outside the jury room, and then only in writing. In turn, I will only communicate with you only in writing or orally here in open court, on anything concerning the case. On matters touching simply on the arrangements for your meals, schedule, and convenience, you are free to communicate with the court officer or Karen, my courtroom clerk, orally rather than in writing.

When you have reached your verdict, your answers will be recorded by your foreperson on what is called the verdict slip or the verdict form. This is simply the written notice of the decision you reach in this case.

[Explain verdict form].

After you have reached unanimous agreement on the verdict, your foreperson will fill in the verdict form, sign and date it, and advise the court officer outside your door that you are ready to the return to the courtroom. After you return to the courtroom, your foreperson will deliver the completed verdict form as directed in open court.