UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

RONALD D. WEIR, JR.,

Defendant.

CR: 17-50022

FACTUAL BASIS STATEMENT

Ronald D. Weir, Jr., the Defendant in the above-entitled matter, states that the following facts are true and correct and the parties agree that they establish a factual basis for the Defendant's plea of guilty to the offense charged, pursuant to Rule 11(b)(3) of the Federal Rules of Criminal Procedure and is incorporated by reference into the plea agreement entered into between the Defendant and the United States of America. This statement is a summary made for the purpose of providing the Court with a factual basis for the Defendant's guilty plea and therefore does not include all the facts known to the Defendant concerning criminal activity in which he and/or others engaged.

Ronald D. Weir, Jr.

In about 2005, Weir became an employee of Robert "Larry" Lytle, who owned, operated, directed, and controlled a number business entities based responsible for

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the manufacturing, designing, processing, marketing, packing, labeling, holding, selling, and interstate distribution of a collection of medical devices known as the "QLaser System." While employed by Lytle, Weir was responsible for selling QLaser devices to consumers throughout the United States through Lytle's various business entities based in Rapid City, South Dakota. On or about December 24, 2007, Weir created and became president of Laser Wellness, Inc. ("Laser Wellness"), to market, sell, and distribute Lytle's QLaser devices to consumers throughout the United States using support, tools, training, and resources provided by Lytle. Weir, through Laser Wellness, continued to market, sell, and distribute QLasers in interstate commerce through at least August 2015.

The QLaser System

The QLaser System is a collection of instruments, machines, and apparatuses that are intended for use in the cure, mitigation, treatment, and prevention of disease in man and other animals. QLasers are also intended to affect the structure and functions of the body of man and other animals. These devices do not achieve their primary intended purposes through chemical action within or on the body and are not dependent upon being metabolized for the achievement of their primary intended purposes. Accordingly, they are "devices" as defined by 21 U.S.C. § 321(h).

The QLaser devices were sold under various model numbers including: Q10, Q1000, Q1000NG, 660 FlashProbe, 660 Enhancer Probe, 808 FlashProbe, 808 Enhancer Probe, *etc.* Weir, Lytle, and other QLaser distributors marketed the QLasers for home use as a safe and effective treatment for over 200 medical

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conditions. Purchasers of the device, the vast majority of whom were elderly and/or suffering from chronic illnesses, normally spent between $4,000 and $13,000 for QLaser devices from Weir.

Conspiracy to Distribute Misbranded Devices with the Intent to Defraud and Mislead Consumers

Beginning around 2005 and continuing through August 2015, Weir voluntarily and intentionally entered into an agreement with Lytle and others to introduce medical devices into interstate commerce, which were misbranded because their labeling was false and misleading, with the intent to defraud and mislead consumers about the devices' safety and efficacy.

As part of this conspiracy, Weir, Lytle, and others employed a strategy to market QLaser devices to consumers as a safe and effective treatment for more than 200 medical conditions, including such serious diseases as diabetes, Lou Gehrig's disease, dementia, and even cancer. The QLaser's labeling falsely claimed that there was virtually no disorder or disease that the QLaser could not potentially improve or cure. These claims were false and were intended to defraud and mislead consumers. In fact, the Defendant is unaware of any published clinical studies that demonstrate that the QLaser devices can safely or effectively treat any these conditions.

Weir and his co-conspirators intended for this material to create the false impression in the minds of consumers that the QLaser device could safely and effectively treat virtually any malady. For example, as part of the conspiracy, Weir published and distributed QLaser advertisements on the internet and print publications that falsely claimed that QLasers could "help almost every health

problem ever experienced by a human being." As another example, Weir and his co-conspirators distributed a book with the QLaser device—authored by Lytle—that provided specific, step-by-step instructions on how to use QLaser devices to treat over 200 different medical conditions. Potential purchasers would frequently ask whether the QLaser device could treat their particular malady; no matter what the disease or disorder was, Weir and his employees would advise the consumer that the QLaser could safely and effectively treat it. Weir and his co-conspirators made these and similarly false statements to induce the consumer to purchase the device.

Not only did the printed and written material that Weir distributed with regard to the QLaser falsely claim that the device was effective, it also falsely conveyed the impression that the QLaser device was categorically safe. In fact, under certain conditions, use of a QLaser could result in damage to skin and eyes, including temporary or permanent blindness.

Weir Continued to Participate in the Conspiracy Even After Being Enjoined

On or about January 21, 2015, Weir received a copy of the January 14, 2015, preliminary injunction issued by the U.S. District Court for the District of South Dakota, which prohibited Lytle and anyone acting in concert or participation with him from continuing to sell the QLaser, in part because of the devices' false and misleading labeling. Because Weir owed Lytle hundreds of thousands of dollars stemming from wholesale QLaser purchases, they decided together that Weir would continue to participate in the conspiracy to sell misbranded QLasers—in spite of the injunction—in order to settle the debt. Indeed, on several occasions during the first

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half of 2015, Weir paid Lytle tens of thousands of dollars using the proceeds from his continued QLaser sales.

On or about February 3, 2015, in the furtherance of the conspiracy, Lytle sent an email to several QLaser distributors which informed them that despite the preliminary injunction, they could purchase QLaser devices from Weir at a discount. Weir responded by asking Lytle to advise the distributors to call Weir's office telephone rather than his home.

On or about March 14, 2015, in the furtherance of the conspiracy, Weir directed a Laser Wellness representative to conduct a QLaser sales presentation at the Embassy Suites Hotel in Bloomington, Minnesota. About a dozen consumers attended to hear Weir's representative falsely tout the QLaser's ability to treat scores of serious diseases and disorders. At Weir's direction, the Laser Wellness representative distributed false and misleading QLaser labeling to the attendees, most of whom were elderly.

In the furtherance of the conspiracy, between the date that Weir received the preliminary injunction from Lytle—January 21, 2015—and when FDA conducted an inspection of Laser Wellness on August 14, 2015, Weir sold and distributed approximately 258 misbranded QLaser devices to consumers throughout the United States. Weir's sales of QLaser devices during this seven-month period generated approximately $810,244 in revenue.

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RANDOLPH J. SEILER
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Dated this 25th day of January, 2017

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Dated this 26 day of January, 2017

RONALD D. WEIR, JR.
Defendant

Dated this 26 day of January, 2017

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