UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

CR: 17-50022

UNITED STATES OF AMERICA,

Plaintiff,

vs.

RONALD D. WEIR, JR.,

Defendant.

INFORMATION

Conspiracy
18 U.S.C. § 371

THE UNITED STATES ATTORNEY CHARGES:

At all times material to this Information:

BACKGROUND AND GENERAL ALLEGATIONS

1. Defendant RONALD D. WEIR, JR., owned, operated, directed, and controlled a number of business entities with their principal place of business in Rapid City, South Dakota, that marketed, sold, and distributed various medical devices known as the QLaser, which were marketed as low level laser therapy devices for home use.

2. A co-conspirator, ROBERT "LARRY" LYTLE, owned, operated, directed, and controlled a number of business entities with their principal place of business in Rapid City, South Dakota that were involved in the manufacturing, designing, processing, packing, labeling, holding, selling, and interstate distribution of QLasers.

3. Beginning in or about 2005 and continuing until sometime in 2015, Defendant WEIR, in active concert and participation with LYTLE and others, caused QLaser devices to be

marketed, sold, and distributed to consumers throughout the United States as a treatment for over 200 different diseases and medical disorders including cancer, cardiac arrest, diabetes, HIV/AIDS, sickle cell anemia, and Alzheimer's disease for prices that ranged from approximately $4,000 to $13,000 or more.

4. In addition to selling QLaser devices to consumers, LYTLE also sold them to distributors, including WEIR, who then marketed and re-sold the devices to consumers, using support, tools, training, and resources provided by LYTLE.

5. Defendant WEIR obtained the QLaser devices and much of their labeling from LYTLE and business entities LYTLE owned, operated, directed, and controlled.

6. Congress enacted the Federal Food, Drug, and Cosmetic Act ("FDCA"), set forth at 21 U.S.C. § 301 *et seq.*, to protect the health of the American public by ensuring that medical devices that are marketed in the United States are safe and effective for their intended uses and that their labeling is not false or misleading.

7. QLasers are devices within the meaning of the FDCA because they are intended for use (a) in the cure, mitigation, treatment, or prevention of disease, and (b) to affect the structure or any function of the body of man, and do not achieve their primary intended purposes through chemical action within or on the body of man or other animals and which are not dependent upon being metabolized for achievement of their primary intended purposes. 21 U.S.C. § 321(h).

8. Sections 331(a) and 333(a)(2) of Title 21 of the United States Code prohibited the introduction or causing the introduction into interstate commerce of any device that was misbranded with the intent to defraud or mislead.

9. Under Section 352(a) of Title 21 of the United States Code, a device was deemed to be misbranded if, among other things, the device's labeling was false or misleading.

10. Pursuant to Section 321(m) of Title 21 of the United States Code, the labeling of a device included any written, printed, or graphic matter that appeared upon the device or its containers or wrappers, and any written, printed or graphic matter that accompanied the device. Under the FDCA, the labeling of a device included items such as promotional and marketing material as well as any directions or instructions circulated as part of a distribution program for the device.

11. On or about January 14, 2015, this Court issued an Order of Preliminary Injunction against LYTLE and his businesses pursuant to Section 332 of Title 21 of the United States Code. That Order prohibited LYTLE and all persons in active concert or participation with him who received notice of the injunction from, *inter alia*, "directly or indirectly manufacturing, designing, processing, packing, labeling, holding or distributing for sale or otherwise any article of device, including but not limited to [QLaser model numbers]." Prelim. Inj., *United States v. 2035 INC. et al.*, No. 14-cv-5075-JLV (D.S.D. Jan. 14, 2015).

OBJECT OF THE CONSPIRACY

12. It was the object of the conspiracy that WEIR, LYTLE, and their co-conspirators, known and unknown, would generate revenue through the marketing, sale, and distribution of medical devices bearing false and misleading labeling.

MANNER AND MEANS OF THE CONSPIRACY

13. It was part of the conspiracy that beginning at a time unknown to the United States Attorney, but no later than about 2002, LYTLE, with others known and unknown, developed a strategy to market QLaser devices as a means for consumers to treat more than 200 medical conditions at home, including cancer, HIV/AIDS, diabetes, and many more, by falsely claiming that the QLaser could improve or cure virtually any medical problem.

14. It was further part of the conspiracy that in about 2005, WEIR began to sell QLaser devices to consumers on behalf of, and as an employee of LYTLE and his various business entities.

15. It was further part of the conspiracy that on or about December 24, 2007, WEIR founded and became the president of Laser Wellness, Inc., a company he created to sell and distribute QLasers in concert and active participation with LYTLE as a QLaser distributor.

16. It was further part of the conspiracy that LYTLE, WEIR, and other co-conspirators would create and publish written and graphic advertisements for the QLaser device on the internet and in newspapers that falsely claimed that the device could "help almost every health problem ever experienced by a human being."

17. It was further part of the conspiracy that, WEIR, LYTLE, and other co-conspirators would distribute false and misleading labeling for QLasers to consumers that was intended to create the false impression that the QLaser device could safely and effectively treat scores of serious medical conditions and diseases. Among this labeling was a book entitled *Low Level Laser Application Guide*, which instructed consumers on how to use the QLaser device to treat over 200 different diseases and disorders, such as cancer, diabetes, mental disturbances, and Lou Gehrig's disease (amyotrophic lateral sclerosis).

18. It was further part of the conspiracy that WEIR, LYTLE, and other co-conspirators would distribute labeling for the QLaser device to consumers that intentionally conveyed the false impression that use of the QLaser device was categorically safe. In fact, under certain conditions use of the devices could result in damage to skin and eyes, including temporary or permanent blindness.

19. WEIR and his co-conspirators intended these and similarly false statements to induce consumers to purchase the QLaser device.

20. It was part of the conspiracy that notwithstanding the Court's entry of the Preliminary Injunction on or about January 14, 2015, that WEIR, LYTLE, and others known and unknown to the United States Attorney, continued to sell, market, and distribute QLasers to consumers with false and misleading labeling.

OVERT ACTS

21. In furtherance of the conspiracy, and to effect the objects of the conspiracy, WEIR and other co-conspirators known and unknown to the United States Attorney, committed and caused the following overt acts to be committed in the District of South Dakota and elsewhere:

22. On or about February 3, 2015, after the Court had issued the Preliminary Injunction, LYTLE sent an email to QLaser distributors from LYTLE which stated that distributors could continue to buy QLaser devices at a discount from WEIR. WEIR responded to LYTLE by requesting that QLaser distributors to call WEIR's office number, rather than the home number contained in LYTLE's email when ordering QLasers.

23. On or about March 14, 2015, at WEIR's direction, an employee of WEIR conducted a QLaser sales presentation in Bloomington, Minnesota, on behalf of WEIR's company, Laser Wellness PMA. At this event attended by more than a dozen consumers, most of whom were elderly, WEIR's employee touted the QLaser's purported ability treat a multitude of diseases and disorders and distributed false and misleading labeling for the QLaser.

24. On or about March 9, 2015, WEIR caused Laser Wellness to issue a check in the amount of $32,945.58 to one of LYTLE's QLaser businesses.

25. On or about June 1, 2015, WEIR caused Laser Wellness to issue a check in the amount of $8,692.98 to one of LYTLE's QLaser businesses.

26. Between about January 14, 2015 and about August 11, 2015, WEIR, through his company Laser Wellness PMA, sold approximately 258 QLaser devices and associated products to consumers throughout the United States, for approximately $810,244.

COUNT ONE

CONSPIRACY
18 U.S.C. § 371

27. Paragraphs 1 through 26 are incorporated herein by reference.

28. Beginning on or about January 14, 2015, and continuing thereafter until about October 2015, in the District of South Dakota and elsewhere, the Defendant,

RONALD D. WEIR, JR.,

knowingly and willfully conspired, combined, and agreed with individuals both known and unknown to the United States Attorney, to commit an offense against the United States by, with the intent to defraud and mislead, introducing and delivering for introduction into interstate commerce, and causing the introduction and delivery for introduction into interstate commerce of, articles of device, to wit QLasers, that were misbranded under Section 352(a) of Title 21 of the United States Code, in that their labeling was false and misleading, in violation of Sections 331(a) and 333(a)(2) of Title 21 of the United States Code.

All in violation of Section 371 of Title 18 of the United States Code.

Dated this 30th day of January, 2017.

RANDOLPH J. SEILER
United States Attorney

By: _____
TED L. MCBRIDE
Assistant United States Attorney
515 9th Street #201
Rapid City, SD 57701
605-342-7822
605-342-1108 (fax)
ted.mcbride@usdoj.gov

JOYCE R. BRANDA
Acting Assistant Attorney General,
Civil Division

By: _____
ROSS S. GOLDSTEIN
Trial Attorney
United States Department of Justice
Consumer Protection Branch
P.O. Box 386
Washington, DC 20044
202-353-4218
202-514-8742 (fax)
ross.goldstein@usdoj.gov