UNITED STATES DISTRICT COURT
DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

CR: 17-50020-01

UNITED STATES OF AMERICA,

Plaintiff,

vs.

ROBERT LARRY LYTLE
(a.k.a. Larry Lytle),

Defendant.

REDACTED SUPERSEDING INFORMATION

CONSPIRACY
18 U.S.C. § 371

CRIMINAL CONTEMPT
18 U.S.C. § 401(3)

FORFEITURE ALLEGATION
21 U.S.C. § 334; 21 U.S.C. 853(p);
28 U.S.C. § 2461

THE UNITED STATES ATTORNEY CHARGES:

At all times material to this Superseding Information, unless otherwise alleged:

BACKGROUND AND GENERAL ALLEGATIONS

The Defendant

1. Defendant ROBERT LARRY LYTLE (also known as Larry Lytle), a resident of South Dakota, owned, operated, and controlled a number of business entities based in Rapid City, South Dakota, that were involved in the designing, manufacturing, packing, labeling, holding, marketing, selling and distributing of medical devices known as "QLasers" or the "QLaser System," a collection of various apparatuses marketed as low level laser therapy devices for consumers' home use. At various times, these entities included the following:

- 2035 Inc.
- 2035 PMA
- 2035 PMA Trust
- 2035, Inc.
- Dewot Limited Partnership
- Energy for Life Limited Partnership
- Go-Jo Limited Partnership
- Health and Wellness, Inc.
- Lasers, Inc.
- Low Level Lasers, Inc.
- Old Cap Trust
- Old Cap, Inc.
- Overshot Limited Partnership
- QLaser Healing Light Limited Partnership
- QLasers PMA
- Subtle Energy Limited Partnership
- Windor Limited Partnership
- Windy Knob Limited Partnership
- Wowapi, Inc

The QLaser Medical Device System

2. Beginning at least as early as about 2001, LYTLE marketed and distributed the QLaser devices to consumers throughout the United States by falsely claiming that the QLaser devices safely and effectively treated a panoply of medical

conditions at home, including *e.g.,* cancer, heart attacks, paralysis, HIV/AIDS, and diabetes.

3. In addition to selling QLasers directly to consumers, LYTLE also sold QLasers to a network of distributors, including Ronald D. Weir, Jr. and Irina Kossovskaia, who then marketed and re-sold the devices to consumers, using support, tools, training, and resources provided by LYTLE.

4. LYTLE, Kossovskaia, Weir, along with other QLaser distributors, sold the devices alone and in combination packages mostly to elderly consumers for prices that ranged from approximately $4,000 to $13,000 or more.

The Prior Injunctions

5. Pursuant to the Federal Food, Drug, and Cosmetic Act, 21 U.S.C. § 301 *et seq.* ("FDCA"), the United States Food and Drug Administration ("FDA") was the federal agency charged with protecting the health of the American public by ensuring that medical devices marketed in the United States were safe and effective for their intended uses, and by preventing those that were unsafe or ineffective from finding their way into the hands of American consumers.

6. QLasers were devices within the meaning of the FDCA because they were 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 did not achieve their primary intended purposes through chemical action within or on the body of

man or other animals and which were not dependent upon being metabolized or achievement of their primary intended purposes. 21 U.S.C. § 321(h).

7. 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.

8. Under 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 or marketing material as well as any directions or instructions circulated as part of a distribution program for the device.

9. Under federal law, unless explicitly exempted by law or regulation, all medical devices were required to be evaluated by FDA for safety and effectiveness for each of the devices' intended use(s) before being distributed in interstate commerce.

10. Despite receiving numerous warnings from the FDA since 2002 that selling QLaser devices in the United States for uses that FDA had not cleared or approved was unlawful under the FDCA, LYTLE and several of his distributors, including Weir and Kossovskaia, continued to distribute the QLaser devices in interstate commerce through about 2016.

11. On or about October 21, 2014, the United States filed a civil complaint in this Court against LYTLE and his businesses seeking to permanently enjoin him from continuing to violate the FDCA by distributing misbranded and adulterated medical devices in interstate commerce. Along with the complaint in that action, the government moved for the entry of a preliminary injunction to enjoin Lytle and those operating in concert and participation with him from further violating the FDCA. *See generally* Compl. for Inj., *United States v. 2035 INC. et al.*, No. 14-cv-5075-JLV (D.S.D. Oct. 21, 2014), ECF No. 1 & Mot. for Prelim. Inj., (Oct. 21, 2014), ECF No. 4.

12. On or about January 14, 2015, this Court issued an Order of Preliminary Injunction against LYTLE and his businesses. 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., *2035 INC.* (Jan. 14, 2015), ECF No. 48. In addition, the Preliminary Injunction ordered LYTLE to permit FDA to inspect his operations, including his business records.

13. On or about October 6, 2015, this Court entered an Order of Permanent Injunction in the civil enforcement action. Perm. Inj., *2035 INC.* (Oct. 6, 2015), ECF No. 138. That Order was amended with only grammatical and non-substantive

revisions on or about October 13, 2015. Amend. Perm. Inj., *2035 INC.* (Oct. 13, 2015), ECF No. 139 (hereinafter collectively referred to as the "Permanent Injunction"). As with the Preliminary Injunction that preceded it, the Permanent Injunction prohibited LYTLE and all persons acting in concert or participation with him from manufacturing, storing, and distributing QLaser devices.

14. As part of the Permanent Injunction, this Court ordered LYTLE to make restitution of the full amount paid to anyone who, since June 30, 2001, purchased QLaser devices from LYTLE or one of his distributors. *See* Permanent Injunction ¶19. The Court further ordered LYTLE to provide certain records, documents, and reports to the United States and prohibited him and all persons in active concert or participation with him, from interfering with restitution by disposing of or transferring assets or records. *See id.*

COUNT ONE

CONSPIRACY — 18 U.S.C. § 371

Object of the Conspiracy

15. It was the object of the conspiracy that the Defendant and his co-conspirators, known and unknown, with the intent to defraud and mislead consumers, would generate revenue through the marketing, sale, and distribution of medical devices bearing false and misleading labeling.

Manner and Means of the Conspiracy

16. 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.

17. It was further part of the conspiracy that LYTLE and others placed advertisements in newspapers and periodicals offering to send consumers more information about the QLaser's purported ability to "help almost every health problem ever experienced by a human being."

18. It was further part of the conspiracy that LYTLE and others operated various internet websites that contained false representations about the QLaser device's safety and effectiveness.

19. It was further part of the conspiracy that beginning in or about 2011, LYTLE authored the *Low Level Laser Application Guide*, which LYTLE, Kossovskaia, Weir, and other QLaser distributors disseminated to consumers both together with, and independent of, QLaser devices.

20. It was further part of the conspiracy that the *Low Level Laser Application Guide* directed consumers how to use the QLaser devices to treat over 200 different

diseases and disorders, such as cancer, diabetes, HIV/AIDS, hypertension, mental disturbances, and Lou Gehrig's disease (amyotrophic lateral sclerosis).

21. It was further part of the conspiracy that LYTLE, Kossovskaia, Weir, and others distributed material to consumers to create the false impression that QLaser devices had been scientifically proven to safely and effectively treat scores of human diseases and medical disorders, including those described in the *Low Level Application Guide*. This material included, for example:

a. A promotional brochure that listed scores of diseases and proclaimed in a lift-out banner that "Every Ailment on This list has A Clinical Study Dictating the Benefits of Low Level Laser Therapy [sic];"

b. Another brochure's page was entitled "Research Proves Efficacy" and told potential QLaser purchasers that: "From simple 'N-of-One' studies … to full clinical research studies, QLaser has also been shown to be effective for a wide range of health issues;" and

c. An internet webpage maintained by LYTLE entitled "Research" that stated that the QLaser device is "the result of decades of research" and that "more than 100 positive-double-blind studies, conducted throughout the world, attest to the fact that this laser light stimulates healing."

The fact is, however, that there has never been even a single published, peer-reviewed clinical study that demonstrated that QLaser devices are able to safely and effectively treat any of the more than 200 indications listed in the QLasers' promotional material.

22. It was further part of the conspiracy that LYTLE, Kossovskaia, Weir, and others distributed material to consumers falsely stating that using QLaser devices was categorically safe.

23. It was further part of the conspiracy that LYTLE, Kossovskaia, Weir, and others described LYTLE in promotional material as a retired dentist and regularly referred to him as "Doctor" or "Dr. Larry Lytle, D.D.S., Ph.D." in order to create the false impression that LYTLE was especially knowledgeable, scientifically competent, credible, and authoritative, while omitting both that his "Ph.D." was not a legitimate academic degree and also that his license to practice dentistry had been permanently revoked by the State of South Dakota for previously engaging in fraud and material deception.

24. It was further part of the conspiracy for LYTLE, Kossovskaia, Weir, and others to identify QLasers as being sold "for veterinary use only" in order to disguise the devices' true intended use from the FDA, while representing to consumers that the device was nevertheless safe and effective for human use.

25. It was further part of the conspiracy that LYTLE would make false statements to the FDA and this Court, create false and fraudulent documents, and obstruct and impair agency proceedings, in order to prevent and forestall governmental action which would prevent him from continuing to generate revenue from unlawful QLaser sales, including making false statements regarding the whereabouts and disposition of hundreds of QLaser devices that were in LYTLE's inventory at the time the Court issued the Preliminary Injunction.

26. It was further part of the conspiracy that, after entry of the Permanent Injunction, LYTLE directed a collection agency to send debt collection notices to consumers falsely claiming that the consumers owed LYTLE and his businesses money from their QLaser purchases, while in fact, it was the other way around—LYTLE owed consumers restitution payments pursuant to this Court's orders, which LYTLE had failed and refused to make.

27. As a result of the conspiracy, LYTLE obtained at least $16,669,015 in revenue from the sale of misbranded QLasers and related accessories.

Overt Acts

28. In furtherance of the conspiracy, and to effect the purpose of the conspiracy, LYTLE, Kossovskaia, 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:

a. In or about 2011, LYTLE and his co-conspirators began to distribute the first edition of LYTLE's *Low Level Laser Application Guide* to consumers, which contained false and misleading information about the QLaser's safety and effectiveness;

b. In about December 2012, LYTLE unlawfully refused to permit FDA to inspect his QLaser operation;

c. In or about 2013, LYTLE and his co-conspirators began to distribute the second edition of LYTLE's *Low Level Laser Application Guide* to consumers, which contained false and misleading information about the QLaser's safety and effectiveness;

d. On or about October 1, 2013, LYTLE caused a shipment of QLaser devices to be sent via U.S. Mail from Rapid City, South Dakota to Wellington, Florida.

e. On or about July 10, 2014, LYTLE caused a QLaser advertisement to be published in the MINNEAPOLIS STAR TRIBUNE to induce consumers to purchase the QLaser device which stated that "The problem of trying to explain the healing powers of low-level laser therapy is it works so well on so many different problems, it seems like it couldn't possibly be true! But it *is* true!" (emphasis in original);

f. On or about November 21, 2014, LYTLE caused a shipment of QLaser devices to be sent from Rapid City, South Dakota via commercial interstate carrier to Kossovskaia in Niagara Falls, New York.

g. On or about January 14, 2015, LYTLE falsely represented to the FDA and the Court in a letter that he was no longer distributing QLasers to consumers, while working with Kossovskaia, Weir, and others to sell QLasers to consumers and receiving a portion of the proceeds obtained from such sales.

h. In about April or May of 2015, while the preliminary injunction was in effect, LYTLE, Kossovskaia, and others caused approximately 547 QLaser devices to be transported surreptitiously from the home of one of Lytle's employees in Rapid City, South Dakota to a storage location in New York that Kossovskaia controlled. Kossovskaia then continued to sell and distribute these devices in interstate commerce through January 2017, and conveyed a portion of the proceeds from these sales to LYTLE.

i. On or about April 3, 2015, LYTLE knowingly made false, fraudulent and misleading statements, knowingly used false writings and documents, and knowingly withheld, concealed, altered and destroyed

material documents and other information that was sought by FDA during an inspection of LYTLE's business operations;

j. Between about August 11, 2015 and August 13, 2015, during another FDA inspection of LYTLE's business operations, LYTLE knowingly made false, fraudulent and misleading statements, and knowingly withheld, concealed, altered and destroyed material documents and other information that was sought by FDA;

k. On or about September 8, 2016, LYTLE caused a debt collection agency in Rapid City, South Dakota to send collection dunning letters to several consumers across the United States.

l. Between about November 5, 2015, and August 4, 2016, Kossovskaia and another co-conspirator transferred proceeds from QLaser sales to LYTLE via ten interstate wire transfers to LYTLE totaling $281,303.

m. On or about May 20, 2016, Kossovskaia sold one of the QLaser devices described in subparagraph (h.) above to an undercover United States Postal Inspector who had responded to one of her online advertisements. Kossovskaia caused the device to be shipped via U.S. Mail from Lewiston, New York to Council Bluffs, Iowa.

29. The United States Attorney re-alleges and incorporates by reference paragraphs 1–28 of this Superseding Information and further charges that:

30. Beginning in or about 2002, and continuing thereafter until at least June 2016, in the District of South Dakota and elsewhere, the Defendant,

ROBERT LARRY LYTLE

knowingly and willfully conspired, combined, with individuals and entities both known and unknown to the United States Attorney, including Kossovskaia and Weir, 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 and Sections 331 and 333(a)(2) of Title 21, of the United States Code.

COUNT TWO

CRIMINAL CONTEMPT — 18 U.S.C. § 401(3)

31. The United States Attorney re-alleges and incorporates by reference paragraphs 1–30 of this Superseding Information and further charges that:

32. Beginning in or about January 2015, and continuing thereafter until the date of this Superseding Information, in the District of South Dakota and elsewhere, the Defendant,

ROBERT LARRY LYTLE,

did willfully and knowingly disobey and resist lawful writs, processes, orders, rules, decrees, and commands by a Court of the United States, namely: the Preliminary Injunction issued by the United States District Court for the District of South Dakota, entered on January 14, 2015, as Electronic Case Filing ("ECF") No. 48 in the matter entitled *United States v. 2035 Inc. et al.*, Civ. No. 14-5075-JLV; and the Permanent Injunction issued on October 6, 2015, in the same matter as ECF No. 138, and as amended by the Amended Order of Permanent Injunction issued on October 13, 2015, in the same matter as ECF No. 139, by:

a. Directly and indirectly processing, packing, labeling, holding, and distributing for sale and otherwise, articles of device;

b. Failing and refusing to comply with the provisions contained therein relating to FDA inspections;

c. Failing and refusing to comply with the provisions contained therein relating to the payment of restitution, including the disposal and transferring of assets and records.

in violation of said Injunctions.

All in violation of Section 401(3) of Title 18 of the United States Code.

FORFEITURE ALLEGATIONS

33. The allegations contained in Paragraphs 1 through 32 of this Information are hereby re-alleged and incorporated by reference for the purpose of alleging forfeitures.

34. Upon conviction of the offense in violation of Section 371 of Title 18, United States Code, as set forth in Count One of this Superseding Information, the Defendant,

ROBERT LARRY LYTLE

shall forfeit to the United States of America, pursuant to Title 21, United States Code, Section 334, any misbranded QLaser devices and accessories.

35. If any of the property described above, as a result of any act or omission of the Defendants:

- cannot be located upon the exercise of due diligence;
- has been transferred or sold to, or deposited with a third party;
- has been placed beyond the jurisdiction of the Court;
- has been substantially diminished in value; or

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

it is the intent of the United States of America, pursuant to 21 U.S.C. § 853(p), as incorporated by 28 U.S.C. § 2461(c), to seek forfeiture of substitute assets from the defendant, up to $16,669,015, that is the value of the property subject to forfeiture, including the following:

a. **MONEY JUDGMENT**: A sum of money equal to at least $16,669,015 representing the value of the property subject to forfeiture;

b. One (1) white 2015 Ram 1500 Longhorn pickup truck, Vehicle Identification Number 1C6RR7PMOFS505300;

c. One (1) brown 2014 Ram 3500 ST diesel pickup truck, Vehicle Identification Number 3C63RRGL2EG165789;

d. Two thousand, three hundred twenty-five (2,325) "Battle of the Coral Sea" ½-ounce silver bullion coins;

e. Sixty-one (61) "Battle of the Coral Sea" $^{1}/_{10}$-ounce gold bullion coins;

f. The contents of a bank account held at BankWest, account number [redacted]0419, available on August 16, 2016, then containing $33,672.41;

g. The contents of a bank account held at BankWest, account number [redacted]4711, available on August 4, 2016, then containing $34,441.81;

h. The contents of a bank account held at BankWest, account number [redacted]8635, available on August 16, 2016, then containing $28,795.26.

i. The contents of a bank account held at First Interstate Bank, account number [redacted]0598, available on February 29, 2016, then containing $16,474.33;

j. The contents of a bank account held at Security First Bank, account number [redacted]0130, available on August 31, 2016, then containing $85,468.00; and

k. The contents of a bank account held at Pioneer Bank and Trust, account number [redacted]1877, available on July 28, 2016, then containing $40,859.84.

All pursuant to Title 21, United States Code, Sections 334 and 853, and Title 28, United States Code, Section 2461(c).

Dated this 26th day of January, 2018.

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