

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF SOUTH DAKOTA
WESTERN DIVISION

UNITED STATES OF AMERICA,

CR17-50020

Plaintiff,

vs.

ROBERT LARRY LYTLE,

**FACTUAL BASIS
STATEMENT**

(a/k/a Larry Lytle);

Defendant.

Robert Larry Lytle, the Defendant in the above-entitled matter, states that the following facts are true and correct; the parties agree that they establish a factual basis for the Defendant's plea of guilty to the offenses charged, pursuant to Rule 11(b)(3) of the Federal Rules of Criminal Procedure; and that this Statement 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.

As to Count I in the superseding information, conspiracy to introduce misbranded medical devices into interstate commerce with the intent to

defraud, the Defendant admits that he designed the QLaser, a device designed for treating the human body which was a medical device under 21 U.S.C. § 321(h).

The Defendant labeled the QLaser as a “veterinary device,” however the Defendant, along with others, agreed to market and distribute the QLaser device through interstate commerce intending that the QLaser device would be purchased to be used on humans. The Defendant admits that beginning in 2005, and running through 2015, multiple QLaser devices were shipped in interstate commerce to customers. The Defendant further admits that he ordered hundreds of QLaser devices from Tri Tec Manufacturing with the intent to distribute the QLaser devices to other independent distributors who then intended to distribute the QLaser devices to customers for human use. One of the purposes of having the veterinary label on the QLaser was to evade review by the Food and Drug Administration (FDA).

As part of this conspiracy, the Defendant and his co-conspirators employed a strategy to market QLaser devices to consumers as a safe and effective treatment for more than 200 medical conditions. To support these claims, Defendant and his co-conspirators created and distributed labeling for the QLasers that was intended to create the false impression that the safety and efficacy of the QLaser to treat these conditions was supported by a large

body of scientific evidence gleaned from reliable, well-designed, well-conducted research relating to the QLaser device. In fact, there are no published, peer-reviewed clinical studies regarding the QLaser device.

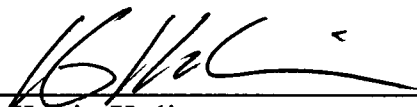
As to Count 2, criminal contempt, the Defendant admits that he was served with a true and correct copy of the Preliminary Injunction shortly after it was issued by the United States District Court for the District of South Dakota, on January 14, 2015 (ECF No. 48 in the matter entitled *United States v. 2035 Inc. et al.*, Civ. No. 14-5075-JLV). The Defendant admits that the Preliminary Injunction instructed him to permit representatives of the FDA to take, examine, and copy records relating to the QLaser device. The Defendant admits that, on or about April 3, 2015, he violated the Preliminary Injunction when he refused to allow agents of the FDA to conduct an investigation related to records concerning the QLaser device. The Defendant further admits that, directly or indirectly, he continued distributing QLaser devices after he received the Preliminary Injunction.

FOR THE UNITED STATES OF AMERICA:

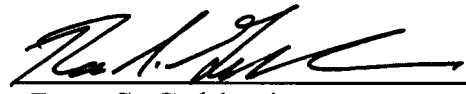
Dated this 26th day of January, 2018:

RONALD A. PARSONS, Jr.
United States Attorney

CHAD A. READLER
Acting Assistant Attorney
General, Civil Division



Kevin Koler
Assistant United States Attorney
P.O. Box 2638
Sioux Falls, SD 57104
Email:
Kevin.Koler@usdoj.gov



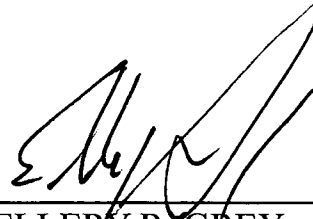
Ross S. Goldstein
Trial Attorney
Consumer Protection Branch
United States Department of
Justice
P.O. Box 386
Washington, DC 20044
Email:
Ross.Goldstein@usdoj.gov

FOR THE DEFENDANT, ROBERT LARRY LYTLE:

Dated this 26th day of January, 2018:



ROBERT LARRY LYTLE
Defendant



ELLERY R. GREY
Attorney for the Defendant
Grey & Eisenbraun Prof. LLC
909 St. Joseph Street, #555
Rapid City, SD 57701
Tel: 605-791-5454