UNITED STATES DISTRICT COURT EASTERN DISTRICT OF MICHIGAN

FEDERAL TRADE COMMISSION,CasePlaintiff,COv.PEIv.ANPHYSICIAN'S TECHNOLOGY, LLC, aREOrporation,VILLOW LABS, LLC, a corporation,WILLOW LABS, LLC, a corporation,DAVID SUTTON, individually and as an
officer of PHYSICIAN'S
TECHNOLOGY, LLC, andRONALD SHAPIRO, individually and as
an officer of PHYSICIAN'S
TECHNOLOGY, LLC, and WILLOW
LABS, LLC.Row

Case No. <u>2:20-cv-11694</u>

COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF

Defendants.

Plaintiff, the Federal Trade Commission ("FTC"), for its Complaint alleges:

1. The FTC brings this action under Section 13(b) of the Federal Trade

Commission Act ("FTC Act"), 15 U.S.C. § 53(b), to obtain permanent injunctive

relief, rescission or reformation of contracts, restitution, the refund of monies paid,

disgorgement of ill-gotten monies, and other equitable relief for Defendants' acts

or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a)

and 52, in connection with the manufacturing, labeling, advertising, marketing, distribution, and sale of low-level light devices under the brand name "Willow Curve" (herein referred to as "Willow Curve").

JURISDICTION AND VENUE

2. This Court has subject matter jurisdiction pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345.

3. Venue is proper in this District under 28 U.S.C. §§ 1391(b)(1), (b)(2),
(b)(3), (c)(1), (c)(2), and (d), and 15 U.S.C. § 53(b).

PLAINTIFF

4. The FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), which prohibits unfair or deceptive acts or practices in or affecting commerce. The FTC also enforces Section 12 of the FTC Act, 15 U.S.C. § 52, which prohibits false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce.

5. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the FTC Act and to secure such equitable relief as may be appropriate in each case, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies. 15 U.S.C. § 53(b).

DEFENDANTS

6. Defendant Physician's Technology, LLC ("Physician's Technology") is a Michigan corporation with its principal place of business at 23 East Front Street, Suite 200, Monroe, Michigan 48161. Physician's Technology transacts or has transacted business in this District and throughout the United States. At all times material to this Complaint, acting alone or in concert with others, Physician's Technology has advertised, marketed, distributed, or sold Willow Curve to consumers throughout the United States.

7. Defendant Willow Labs, LLC ("Willow Labs") is a Michigan corporation with its principal place of business at 747 South Monroe Street, Monroe, Michigan 48161. Willow Labs transacts or has transacted business in this District and throughout the United States. Since 2017, acting alone or in concert with others, Willow Labs has advertised, marketed, distributed, or sold Willow Curve to consumers throughout the United States.

8. Defendant Ronald Shapiro is the Medical Director of Physician's Technology and a managing member of both that company and Willow Labs. At all times material to this Complaint, acting alone or in concert with others, he has formulated, directed, controlled, had the authority to control, or participated in the acts and practices set forth in this Complaint. As co-founder and -owner of Physician's Technology and Willow Labs and co-inventor of Willow Curve,

among other things, Defendant Shapiro: (1) developed, managed, and controlled business and marketing strategy for Willow Curve; (2) was in charge of evaluating the scientific support for Willow Curve's advertising claims; (3) actively participated in the creation, review, and approval of advertising concepts and ad copy for Willow Curve, including materials containing advertising claims that form the basis of this complaint; (4) personally made deceptive claims about the health benefits of Willow Curve to the public; (5) responded to inquiries from the media, potential investors, and others about scientific support for Willow Curve's advertising claims and its compliance with regulations promulgated by the Food and Drug Administration; and (6) actively participated in and controlled decisionmaking with respect to whether and when to pay refunds to purchasers of Willow Curve.

9. Defendant David Sutton is the Chief Executive Officer of Physician's Technology and a managing member of both that company and Willow Labs. At all times material to this Complaint, acting alone or in concert with others, he has formulated, directed, controlled, had the authority to control, or participated in the acts and practices set forth in this Complaint. As co-founder and -owner of Physician's Technology and Willow Labs and co-inventor of Willow Curve, among other things, Defendant Sutton: (1) developed, managed, and controlled business and marketing strategy for Willow Curve; (2) actively participated in the

creation, review, and approval of advertising concepts and ad copy for Willow Curve, including materials containing advertising claims that form the basis of this complaint; (3) was responsible for developing and implementing refund policies for Willow Curve; (4) personally made deceptive claims about the health benefits of Willow Curve to the public; (5) responded to inquiries from the media, potential investors, and others about scientific support for Willow Curve's advertising claims and its compliance with regulations promulgated by the Food and Drug Administration; and (6) actively participated in and controlled decision-making with respect to whether and when to pay refunds to purchasers of Willow Curve.

COMMON ENTERPRISE

10. Defendants Physician's Technology and Willow Labs (collectively, "Corporate Defendants") have operated as a common enterprise while engaging in the deceptive acts and practices alleged below. Corporate Defendants have conducted the business practices described below through interrelated companies that have common ownership, officers, managers, business functions, employees, and office locations, and that commingled funds relating to the marketing and sale of Willow Curve. Because these Corporate Defendants have operated as a common enterprise, each of them is jointly and severally liable for the acts and practices alleged below. Defendants Shapiro and Sutton formulated, directed, controlled, had the authority to control, or participated in the acts and practices of the Corporate Defendants that constitute the common enterprise.

COMMERCE

11. At all times material to this Complaint, Defendants have maintained a substantial course of trade in or affecting commerce, as "commerce" is defined in Section 4 of the FTC Act, 15 U.S.C. § 44.

DEFENDANTS' BUSINESS ACTIVITIES

12. Willow Curve is a curved plastic device that applies low-level light and mild heat to the site of pain, via light-emitting diodes ("LEDs") and heat resistors. To start a 24-minute "treatment" session, consumers select from among five different settings, which differ with respect to the parameters of the light emitted, such as angle, frequency, and sweep pattern. Willow Curve also includes sensors on its curved underside that purportedly measure skin-surface temperature.

13. Since approximately 2014, Willow Curve typically cost \$599 and, as of approximately January 2018, cost \$799, plus an additional non-refundable charge for shipping and handling.

DECEPTIVE ADVERTISING OF WILLOW CURVE TO CONSUMERS

14. Since at least 2014, Defendants have labeled, advertised, marketed, distributed, and sold Willow Curve to the public, directly and through retailers and healthcare professionals, including Amazon and Active Recovery Essentials.

Defendants have advertised and promoted Willow Curve to the public through national television campaigns, satellite radio, the Internet, including the websites willowcurve.com, trywillowcurve.com, and willomd.com, paid search ads, Facebook, in-bound telemarketing, and email and other correspondence. The core advertising messages are that Willow Curve relieves chronic and severe pain and reduces inflammation associated with such pain, is clinically proven to do so, and diagnoses and responds to individual consumers' pain conditions.

15. To induce consumers to purchase Willow Curve, Defendants have disseminated, or caused to be disseminated, ads and promotional materials for Willow Curve, including, but not limited to, the television ads attached as Exhibits A through D. These and other ads and promotional materials contain the following statements and depictions, among others:

A. Excerpts from Willow Curve TV ad (Exhibit A (video) aired between approximately July 2017 and November 2017; posted to Facebook on February 14, 2019)



ANNOUNCER: If you or someone you know takes opioids or other pain medications, please pay close attention.

ANNOUNCER: Introducing the Willow Curve -



ANNOUNCER: – an innovative drug-free medical device that is FDA registered and –

ANNOUNCER: - proven to relieve pain and stiffness in minutes -

ANNOUNCER: without harmful side effects or recovery time.

ON SCREEN:

* * * [Video depicts a person receiving treatment in a medical office]

ANNOUNCER: Pain clinics across the country use therapeutic laser technology to treat pain and stiffness.

ANNOUNCER: But, now, you can use Willow Curve's smart technology conveniently at home or on the go for a fraction of the price.

ANNOUNCER: The Willow Curve uses digital anti-inflammatory technology to provide –

ANNOUNCER: – real, lasting, proven pain relief, without the costs, risks or inconvenience associated with elective surgery, prescription drugs or office visits.

* * *



ANNOUNCER: – to experience the soothing, deep healing pain relief –

ON SCREEN: World's #1 Digital Pain Relief Device

* * *

ANNOUNCER: – you can only get from the world's number one digital pain relief device.

ON SCREEN: Joe Wittenberg Willow Curve Owner

> * * * [Video of Mr. Wittenberg speaking]

JOE WITTENBERG: I have rheumatoid arthritis primarily in my hands. The morning after I played golf, I could not open my hands. Frankly, I thought I was going to have to give golf up.

JOE WITTENBERG: I started using the Willow Curve before I played golf and used it after I got home from golf. The next morning, my hands were fine.

– The relief is, I think, nothing short of a miracle.

ON SCREEN:



[Animation depicting a red, inflamed knee joint that returns to a normal color after receiving treatment from the Willow Curve]

ANNOUNCER: When applied, the Curve's diagnostic sensors gather information that's used to adjust the kinetic energy that stimulates your body's own natural pain-relieving pathways.

ON SCREEN:



ANNOUNCER: It delivers a tailored digital prescription that can



ON SCREEN:

ANNOUNCER: - increase circulation and reduce inflammation -

* * *

ON SCREEN:



ANNOUNCER: Call or log on now to try your very own Willow Curve risk-free for 60 days –

* * *

Get the proven high-tech pain relief you deserve with the Willow Curve.

* * *

B. Excerpts from Willow Curve TV ad (Exhibit B (video), aired between approximately February 2016 and May 2016)

* * *

ON SCREEN: Chuck Woolery Television Personality Willow Spokesperson

CHUCK WOOLERY: – while [by] now you've seen me talking about the Willow Curve, the pain relief device that temporarily reduces joint pain, all without medication.



CHUCK WOOLERY: Still people ask, does the Willow Curve really work?

Well, the all-digital Willow Curve is so effective that it's now used in doctors' offices and, of course, by tens of thousands of people just like you.

ON SCREEN: Tom U. Actual Willow Curve User

Not a Paid Actor

TOM U.: I could actually feel the meniscus tear –

– My wife had heard about the Willow Curve. She got one. Within two or three days, just the pain relief was phenomenal. It really helped [me in] getting around and I was just amazed at how quickly I saw the change in my pain level. I couldn't recommend it higher.

* * *

ON SCREEN:



CHUCK WOOLERY: – there's no need to wonder about the Willow Curve any longer. * * *

ON SCREEN:



ANNOUNCER: Order your Willow Curve today with a risk-free money-back guarantee by phone or online at TryWillowCurve.com.

C. Excerpts from Willow Curve TV ad (aired between approximately November 2015 and March 2016)

* * *

CHUCK WOOLERY: The Curve is a non-invasive, drug-free digital pain relief device and it's proven to help relieve pain and stiffness. * * *

* * *

ON SCREEN: Rob L. Actual Willow Curve User

Not a Paid Actor

[Video of Rob speaking]

ROB L.: I can walk a mile now where [sic] I never used to be able to walk that far.

* * *

ON SCREEN:



ANNOUNCER: Experience the same relief from pain and inflammation with the Willow Curve. ***

* * *

CHUCK WOOLERY: People often ask how it works. On the Curve, there are diagnostic sensors that evaluate –

ON SCREEN:



CHUCK WOOLERY: – and respond to your body's pain. This is amazing. The Curve's smart onboard computer adjusts the protocol to your needs. It helps increase circulation with thermal energies and provides temporary, but effective, pain relief.

* * *

CHUCK WOOLERY: If you have knee pain, shoulder pain, wrist pain, arthritis, even leg pain, and you feel that other treatment options are not living up to their promises, it's time to ask yourself if you have the courage to try a different kind of pain reliever.

ON SCREEN: Kris Y. Actual Willow Curve User

Not A Paid Actor

[Video of Kris speaking]

KRIS Y.: Burning, tingling, if you don't have diabetes, you really don't know what it's like.

ON SCREEN:



KRIS Y.: After the Willow Curve finished its cycle, my foot felt better than it's felt in over a year. It was just odd. I never realized how little I felt until I used the Willow Curve.

ON SCREEN:



ANNOUNCER: Order your Willow Curve today with a risk-free money-back guarantee by phone or online at YourWillowCurve.com.

D. Excerpts from Willow Curve TV ad (Exhibit C (video), aired between approximately October 2015 and December 2015)

* * *

CHUCK WOOLERY: If I had said 20 years ago that one day we'd have computers in our pockets or driverless cars or you could wear a device that gets rid of your pain, you'd say I was crazy. Yet, all of those things are here, even the pain relief device. It's called the Willow Curve.

ON SCREEN:



CHUCK WOOLERY: The Willow Curve is a non-prescription, drugfree, digital anti-inflammatory device. It's proven to relieve pain, swelling, and stiffness in minutes. * * *

CHUCK WOOLERY: * * * The Willow Curve uses digital antiinflammatory technology to provide real lasting pain relief without the risks or pain of surgery and without the side effects of drugs.

* * *

CHUCK WOOLERY: Just put the Curve on the painful area, push a button, and let the device relieve your pain.

* * *

ON SCREEN: Denise H. Rheumatoid Arthritis Patient Willow Curve User

Not A Paid Endorsement

[Video of Denise speaking]

DENISE H: I was diagnosed with severe RA two and a half years ago. –

– So for the last two and a half years, I've been trying everything out there to get relief. My right hand was in a flaring state, so I tried the Willow Curve. After only 24 minutes of treatment –

– I could not only move my finger and joint area, but the inflammation was down tremendously.

ANNOUNCER: * * * When applied, the Curve's diagnostic sensors gather information from your skin. Then the smart device adjusts the photonic and thermal kinetic energies, stimulating the body's natural pain-relieving and anti-inflammatory responses. It's not science fiction. It's a trusted, effective breakthrough in pain relief technology.

* * *

E. Excerpts from Willow Curve TV ad (Exhibit D (video), aired between approximately January 2015 and March 2015)

* * *

CHUCK WOOLERY: Are you considering shoulder or knee surgery? Please pay close attention because this device, the Willow Curve –

– has helped saved people from invasive surgery, like knee replacement.

ON SCREEN:



CHUCK WOOLERY: The Curve is a non-prescription, non-invasive, drug-free device that is proven to relieve pain, swelling, and stiffness in minutes.

* * *

CHUCK WOOLERY: Surgery is not guaranteed and it's risky and it may not be your only option.

ON SCREEN:



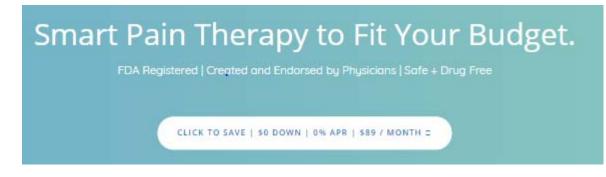
CHUCK WOOLERY: One Pro Football Hall of Famer found out for himself. He actually canceled his own knee replacement after using the Curve. Now, he's off pain meds, too, thanks to this incredible device.

* * *

F. Excerpts from willowcurve.com website (captured May 1, 2019)

Smart Pain Therapy to Fit Your Budget

FDA Registered | Created and Endorsed by Physicians | Safe + Drug Free



[Series of video testimonials in a tile design]

* * *

The commitment to help reduce the escalating cost of joint pain therapy. In some cases, for the cost of a single pain injection you could get a Willow Curve.

Today, certain injections for pain can cost over \$4,000 with an annual cost of nearly \$40,000. The Cleveland Clinic recently reported on certain pain injection therapies that can cost up to \$1,800 per injection. * * * Digital technology like the Willow Curve can bring various efficiencies to certain aspects of health care costs.

* * * The Willow Curve is an FDA registered, software controlled, handheld device for joint pain relief. It combines the documented benefits of safe laser, infrared, and LEDs in one device that produces GET YOUR WILLOW CURVE

safe medical grade pain relief at a fraction of the cost. READ MORE

Clinical Support

The Willow Curve combines safe laser, infrared, and diode in one safe software controlled device.

Low Level Laser Therapy (LLLT) is well researched and documented * * *. Now, safe advanced PT technology comes home. According to the National Institute of Health (NIH) there have been 400 randomized, double-blind, placebo-controlled trials published with over 4,000 basic science research and clinical studies of Low Level Laser Therapy (LLLT). Much of the landmark research was done by the National Aeronautics and Space Administration (NASA), providing the springboard for many additional studies. LEARN MORE.

* * *

Dr. Deb S., DC, RN

"* * *. From a professional standpoint, it effectively reduces soft tissue inflammation, facilitates adjustments and provides a realistic way to help maintain the favorable result of office treatments beyond adjustments alone."

[left side of screen]

Dr. Tiziano Marovino, DPT, MPH, RMSK, DAAPM Diplomat American Academy of Pain Management Key Opinion Leader

"Patients using the Willow Curve are 2x more likely to reduce their pain by 3-10 pain scale numbers with a single treatment."

[center of screen]

Dr. Eric P., MD, FACEP Emergency Medicine

"I had a chance to try the Willow Curve and the results were absolutely incredible. I went from a limited 45 degree painful knee flexion before treatment to over a 90 degree pain free flexion after treatment. I've been able to walk with-out pain."

[right side of screen]

Real People. MedTech Hanna

[image of MedTech Hanna in softball uniform]

I have had six major joint injuries and multiple sports accidents. I didn't want to depend on pain medications, and physical therapy only gave me minimal relief. After 2-3 treatments in my injured areas with the Willow Curve, I received significant relief of pain and inflammation [sic]. I continue to use the Curve which has become an important treatment in my life to remain pain free and get back to my activities * * *

Real People. Fireman Lt. Eric

"Now, the pain is gone and my range of motion has improved over-[sic] thirty five degrees and my heel lifts have returned to near normal. My skin and scar have dramatically improved. It's amazing.

* * *

[willowcurve.com>pages>how-to-select-the-right-product-foryour-joint-pain: Page that displays if visitor clicks "What's right for you?" on home page]

How to select the right product for your joint pain.

The Willow Curve is a smart laser device, designed by physicians to relieve joint and arthritis pain. It is used effectively in clinics, at

home, or gym.

* * *

How is the Willow Curve a More Advanced Laser for Pain?

• **Bigger is Better** - * * *. This allows you to easily administer relief to joints and arthritis.

• **Safer** - * * *. Much safer than pain meds.

• **Smart Artificial Intelligence** - Patented smart laser technology optimizes pain therapy and results. Willow Curve is the smart laser for joint pain.

* * *

• **Multi-Application** - One advanced device treats 10 physical applications and 30 pain conditions.

• **Effective** - Pain relief can start in as little as 12 minutes. Tens of thousands in use in (private and clinical).

• Accreditations - FDA registered; ISO 13485; Arthritis Foundation. Ease of Use Commendation; American Medical Association assigned CPT code 0552T; patented; GSA Federal contract V797D-70038.

[willowcurve.com>pages>frequently-asked-questions: Page that displays if visitor clicks "Frequently Asked Questions" link on home page

* * *

WHAT DOES THE WILLOW CURVE DO?

The Willow Curve Smart Laser produces dynamic multi-band alternating pulse therapy (ATP) the body tissues absorb to:

- Enhance central pain management systems function,
- Spark the body's opioid receptor,

• Reduce inflammatory pain response and accelerate tissue healing.

• Suppress sensory fatigue (adaptation), improving extended pain relief momentum and recovery.

• The Willow Curve is not a conventional therapeutic laser; however, the resulting physio-biological changes in the treated area mimic what happens when therapeutic lasers are used.

* * *

HOW IS THIS UNIT BETTER THAN ANY OTHER UNIT ON THE MARKET?

* * *

• Physicians and patients report over a 90% favorable response rate when used as suggested.

* * *

HOW DOES THE CURVE WORK?

• Sports, other trauma, and joint disease can create joint inflammation and pain.

• Published medical research reveals how inflammation can attack tissue structures and leave behind floating cellular debris that wear on delicate joint tissue and delay healing.

* * *

• The Willow Curve is a 100% drug free medical device designed to temporarily relieve pain and increase circulation, reduce stiffness, and help your body do what it does naturally to ease the pain and promote natural healing.

"IS THE WILLOW CURVE JUST A FANCY HEATING PAD?"

* * *

• While we cannot comment specifically on a heating pad, the Willow Curve is a digital smart low level laser therapy device (LLLT) that combines both patented bio-sensory and bio-therapeutic features. *** [Willow Curve] reduces pain, swelling, increasing mobility while enhancing the healing process. Many of our patients comment on how the results of using a heating pad pale in comparison to the Willow Curve.

• The Willow Curve produces a unique customized digital prescription. It utilizes a wide spectrum of energies, frequencies and delivery parameters that change thousands of times /sec. are adjusted in real time to your condition.

• The Willow Curve joint scanning technology collects information from at and below your skin surface. Then the Curve calculates and digitally delivers multiple energy beams that change thousands of times/second * * *.

* * *

IS THE CURVE FDA APPROVED?

• The Willow Curve® is FDA registered and has been determined to be a low risk device, and is registered for marketing in the United States.

[willowcurve.com>Zero Down>30-Day Risk Free Plan>Installment Payments]: Page that displays if visitor clicks "Get Your Willow Curve" link on home page]

Willow Curve | Zero Down | 30-Day Risk Free Plan | Installment Payments

30-DAY RETURN GUARANTEE

We stand behind the Willow Curve. If you are not satisfied with your Willow Curve, you can return it for a replacement or refund. We must

receive your Willow Curve within 35 days after purchase. If you plan to return it call us at (800) 943-2802 for a Return Authorization Number. When returned it should be in "like new" condition free of damage along with all the accessories and in the original packaging. We do not pay return shipping charges. It is a good idea to keep the tracking number. Thank you.

* * *

Willow's guarantee does not cover ordinary wear and tear or damage caused by improper use or accidents.

* * *

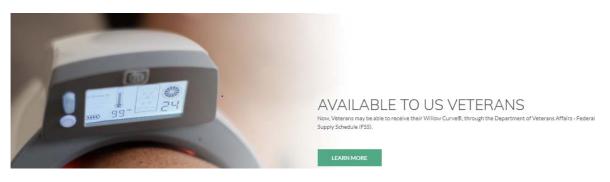
G. Excerpts from willowcurve.com website (captured February 12, 2019)

[willowcurve.com: home page]

[First of three rotating statements]



[Third of three rotating statements]



FEATURES & BENEFITS [left side of screen]

The Willow Curve delivers treatment specific to your condition, digitally activating many processes within the body that provide relief, detoxify the joint and promote healing.

Drug-Free Pain Relief

* * *

The Willow Curve is a registered medical device with the FDA who has determined it to be 510-K exempt.

PHYSICIAN-ENDORSED [right side of screen]

Often, doctors are seeking alternatives to prescription medications for their patients. Now, they turn to the Willow Curve as a drug-free option for pain management

* * *

CAN THE WILLOW CURVE HELP WITH YOUR PAIN?

THE NEXT EVOLUTION IN PAIN RELIEF — WITH NONE OF THE SIDE EFFECTS

The Willow Curve has been clinically proven to temporarily relieve pain caused by various common conditions. Check out the full list to see if the Willow Curve would work for you.

TREATABLE CONDITIONS [hyperlink]

REAL PEOPLE. REAL STORIES.

DENISE'S STORY

"I can't believe the difference. I've got myself back

again. I'm able to move; I'm able to get out and function like a normal person again. * * *"

After being diagnosed with rheumatoid arthritis, Denise felt that life was over as she knew it. Multiple ineffective treatment options left her hopeless – until she found the Willow Curve, and everything changed.

CLICK HERE TO WATCH HER STORY PLUS OTHER REAL SUCCESS STORIES

[willowcurve.com>conditions: Page that displays if visitor clicks "Treatable Conditions" link on home page]

WILLOW CURVE® TREATABLE CONDITIONS

* * *

The Willow Curve has been used successfully to treat a number of conditions in thousands of hospitals and clinics nationwide, as well by the Navy SEALS and in professional sports training facilities.

Some users experience relief and better range of motion from the very first use, while others require a few treatments before feeling a reduction in pain and inflammation. * * *

THE WILLOW CURVE MAY BE ABLE TO HELP YOUR CONDITION

CLICK BELOW TO LEARN MORE ABOUT THESE PAIN AREAS:

[conditions listed include: Osteoarthritis, Rheumatoid Arthritis, Psoriatic Arthritis, Fibromyalgia, Plica Syndrome, Osgood-Schlatter, Patellofemoral Syndrome, Gout, Lupus, Plantar Fasciitis, Carpal Tunnel, Occipital Myospastic Headaches, Tension Headaches, and Muscular Headaches]

* * *

[willowcurve.com>stories: Page that displays if visitor clicks "Real Stories" or Click Here to Watch Her Story Plus Other Real Success Stories" links on home page]

REAL PEOPLE. REAL STORIES.

* * *

[Video testimonial of Eva B.]

CASE STUDY: Eva B.

CONDITION: Ankle Pain

Eva broke her ankle and used the Willow Curve nightly to reduce pain and inflammation. Her medication upset her stomach, and the Curve offered her an effective alternative for relief.

"I went ahead and used it faithfully, every single day, for the next couple of weeks, and the swelling went down. So that inflammation, when it went down, it reduced the pain."

[Video testimonial of Alvin F.]

CASE STUDY: Alvin F.

CONDITION: Ankle Pain

Alvin injured his ankle over 20 years ago, and weight gain as he aged aggravated the pain. The Willow Curve has helped relieve that pain and increased his mobility.

"I've been using it every other day, and I've been relieved of pain. It's been amazing, and I have greatly improved my quality of life."

[Video testimonial of Kristine Y.]

CASE STUDY: Kristine Y.

CONDITION: Nerve Pain

Kris suffers from diabetic neuropathy in her feet, causing burning, numbness and tingling. Over-the-counter medications provided no relief, but the Willow Curve has greatly improved sensation and function in her foot.

* * *

TESTIMONIALS

"* * The pain relief is amazing and it works every time! We struggle with arthritis and fibromyalgia pain, and it is such a blessing, helps every time! I had Bicep Tendonitis in my arm for years, and now I only have pain if I sleep with my arm in the wrong position. It seems to be healed! * * *."

* * *

"When I bought the Curve, I had trigger finger in my right thumb. Very painful. I used the Curve and after several treatments, my finger finally eased then went away. Also my knees have given me periodic pain, with the Curve it helps the inflammation. I dance and the Curve allows me to dance without pain. * * *."

* * *

"I have had 4 knee surgeries. I am a retired postal worker. I have had numerous shots, injections 3 sessions long with ultra sound, and lived on Motrin 800 for years hoping to deal with arthritis pain in knees. * * *. I use it on both knees morning and night and by the 3rd day felt tremendous relief! * * *. A lot of time kinda [sic] but pain is liveable [sic] now without shots and meds."

* * *

[**willowcurve.com>stories**: Page that displays if visitor clicks "How It Works" link on home page]

THE DEVICE

The Willow Curve is a portable, low-level laser designed to help temporarily reduce pain without the use of potentially harmful medications or invasive surgeries. * * *

- Pain Relief Without Medication
- No Harmful Side Effects
- Diagnostic Sensors Regulate Treatments

* * *

• Promotes and Accelerates Healing

* * *

WHAT'S AILING YOU?

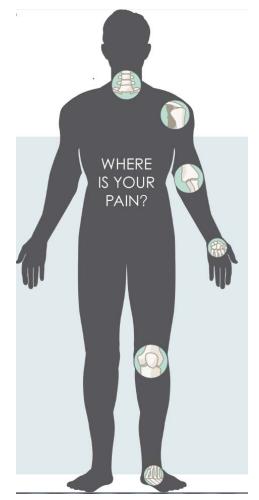
The Willow Curve can help you treat pain from a variety of ailments, virtually anywhere on your body.

* * *

* * *. While the Willow Curve is useful in relieving pain from damaged joints, it also is beneficial for many other conditions. This includes the various forms of arthritis, as well as the pain and numbness often caused by diabetes.

Click below for a full list of treatable conditions. * * *.

FULL LIST OF TREATABLE CONDITIONS



THE SCIENCE

Because the Willow Curve is a smart computer, at the beginning of each treatment it assesses the condition of your joint and delivers a targeted, customized "digital prescription" based on the assessment.

* * *

• Diagnostic sensors gather information from the surface of your skin. Your body's responses help determine the appropriate algorithm of treatment that the Willow Curve is about to deliver.

• Photonic and thermal kinetic energies stimulate 15 biophysiological processes for treating the joint and surrounding tissues.

* * *

• Increased lymphatic flow and immune system response aids detoxification and reduces swelling. The production of new inflammatory cells is also reduced with treatment.

- Nerve response time is slowed, reducing the perception of pain.
- Endorphins are released, also reducing the perception of pain.
- Toxic debris in the joint, a cause of inflammation and pain, is cleared away with increased circulation.
- Specific pain receptors are blocked, which promotes pain relief.

* * *

[willowcurve.com>clincials: Page that displays if visitor clicks "Clinicals" link on home page]

WILLOW CURVE CLINICAL TRIALS

Yes, the Willow Curve has been tested in double-blind studies. And, yes, it has been proven effective. Although we continue to test our science to increase its effectiveness, various studies have been conducted over the years to prove (and improve) the effectiveness of

the Willow Curve.

* * *

H. Excerpts from printable document available on willowcurve.com website (captured February 12, 2019) and Willow Curve Facebook page

[willowcurve.com>purchase>Veterans]



Dear Veteran,

* * *

Many of our Veterans are plagued with joint and muscle pain. Some rely on pain medications to keep moving.

The Willow Curve® is a precision digital pain relief device. * * *

Now, Veterans may be able to receive their Willow Curve[®], through the Department of Veterans Affairs - Federal Supply Schedule (FSS).

Steps:

Step 1: Print the next page and take it to your VA physician.

* * *

[next page]



Dear VA Physician,

Your patient is suffering from a painful joint and muscle condition limiting their functional ability and their quality of life. As Medical Director of Physician's Technology, LLC, a medical device company dedicated to developing and advancing safe, effective and noninvasive digital technology for joint and muscle pain, I am writing to apprise you of the technology. This unique FDA registered, patented medical device is marketed as the Willow Curve®.

The Willow Curve® is a three-module computer with sensory, CPU, and digital therapeutic modules that evaluates the condition of the tissue, calculate [sic] a customized digital prescription, and delivers it to the skin surface and deeper tissues. Double blinded controlled studies, physicians, and patients (over 50 thousand) have validated the consistent and favorable Willow Curve® results.

* * * Regards, Ronald S. Shapiro, MD, PhD, FACP Medical Director

I. Excerpts from willowcurve.com website (captured December 26, 2017)

[willowcurve.com: home page]

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Try your Willow Curve at home or office for 60 days. If you're not satisfied, call us to return it.

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MONEY-BACK GUARANTEE

With the Willow Curve's satisfaction guarantee, you never need to ask yourself if it is worth the investment. Try the Willow Curve in your home, risk-free, for **60-DAYS**.

Return it for a refund if you're not completely satisfied. Click here for details.

* * *

J. Excerpts from Willow Curve Facebook page (captured May 1, 2019)

[Posted February 20, 2019]



[Posted February 1, 2019]



Our latest story is from Deborah. She had countless surgeries on her neck. Deborah even lost a kidney due to the use of pain medication. Read how the Willow Curve enabled Deb to ditch the pain pills and helped get her life back!

"I wouldn't sell it for any amount of money."



sid my husband the Willow Curve would be sut for his knee to keep him from having anter knee replacement,

If it was the last one you ever made i wouldn't, sell it for any amount of money, it has given memy life back. There had four neck surgeries starting in 1985, with the last one being 2013 and lost one of my kicheys-endod 1985 due to many Advits that the doctors prescribed. All of the borns have heade but my doctor threads either the wire from the first surgery might be injeing or a nerve or that C=4 is now Causing the nerve pain. Thus been living with a pulk level of 6 to mostly 10 for most of this time; that is 11 light for "Curve". I couldn't believe after one use my pain week, from the level 10 to 4.0 bit had have to scheduled appointment with my doctor to have an Edebuled appointment with my doctor to

[Posted November 27, 2017]



Fibromyalgia causes widespread pain that can lead to fatigue, sleep problems, and memory issues. The digital anti-inflammatory benefits of the Willow Curve can help temporarily alleviate the chronic pain and stiffness from many issues that affect joints and smaller muscle groups, including #fibromyalgia. Learn more: https://goo.gl/bGCsWH #pain #painrelief



K. Excerpt from an instruction manual for Willow Curve, titled "The Willow Curve Pain Management Treatment Plan"

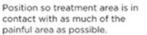
How to Treat Shingles (Herpes Zoster) of the Body

- 1. Identify lesions, tender or abnormal feeling areas. In order to treat these areas, they must fit under the Curve so the treatment surface touches the skin.
- 2. Position yourself in a recliner chair, bed, or couch.
- Choose the most bothersome area to treat. Areas that fit well and that are frequently affected might be the forehead, neck, shoulder, arms, thigh, and legs.
- 4. Drape the Curve over the area or rest the affected area in the Curve.
- 5. Padding under an area often helps in a better fit and comfort.
- 6. You can lie on your back or side to get the most comfortable fit and most surface area contact.
- 7. Treat with Mode 5.
- 8. If symptoms persist, treat immediately with Mode 5.
- 9. Reposition the Curve to treat additional affected areas.
- 10. Approximately 10-12 hours later, repeat treatment sequence.



Curve treatment of elevated leg.







L. Excerpts from an online magazine article (Exhibit E) promoting the Willow Curve, titled "Understanding the Gender Gap in Sports Injuries and Treatment"



TLM ONLINE



^{* * *}

* * * the Willow Curve, a low-level smart laser that treats joint pain.

Often joint injuries are treated with what health professionals refer to as RICE (rest, ice, compression, elevation), which can help ease pain and reduce swelling.

Many people also use over-the-counter medication, and if the pain persists they might turn to a doctor for prescription medication and in some cases surgery. More recently, technology is emerging as an alternative option for temporarily relieving pain.

Shapiro has been involved in that research and, as a leader in the growing field of technaceuticals, co-invented with David B. Sutton

the Willow Curve, which is one example of how technology designed for the home can work to temporarily ease chronic pain. Because it's also a smart computer, the device assesses the condition of the joint and delivers a targeted digital treatment.

"Digital-therapeutic technology holds great opportunity to improve the quality of life for weekend warriors, both women and men, who have put their bodies to the test," Shapiro says, "and also for anyone with chronic joint pain."

16. Defendants also have disseminated ads purporting to be independent news stories written by impartial journalists, discussing the health benefits of Willow Curve, including Exhibit E. Instead, a marketing company that Defendants hired wrote these articles, whose purpose was to promote the health benefits of Willow Curve and position Dr. Shapiro as an expert on pain relief, and facilitated such articles' publication in various magazines and newspapers. These articles closely resemble the non-advertising content surrounding them, and are not identifiable as commercial advertising. The articles also are not identifiable as ads if consumers post or share them on social media or email. For example, posting Exhibit E on Facebook produces the following auto-generated message:



DEFENDANTS' MARKETING OF WILLOW CURVE THROUGH DISTRIBUTORS AND RESELLERS

17. Defendants also sell Willow Curve through a network of distributors and resellers. They have supplied these companies with advertising, packaging, clinical studies, and other promotional materials about Willow Curve's purported health benefits. These distributors and resellers have incorporated Defendants' health benefit claims into their advertising and promotional materials for Willow Curve. For example, one medical supplies company, on its website and Amazon store page for Willow Curve, published Exhibit A and various statements and depictions described in Subparagraph 15.G. Another medical supplies seller to health care professionals published on its website various statements and depictions described in Subparagraph 15.K.

DEFENDANTS' ADVERTISED RISK-FREE AND MONEY-BACK REFUND GUARANTEE

18. As demonstrated in Paragraph 15, including Exhibits A through B and ads described in Subparagraphs 15.C, F, I, and J, to further induce consumers to purchase Willow Curve, Defendants also have advertised a "risk-free" and "money-back" guarantee that purportedly allows consumers who are "not completely satisfied" to obtain a refund if they return Willow Curve within a specified time period, typically within between 30 to 180 days of delivery.

19. Shipping and handling, and return shipping, costs for Willow Curve were not refundable. In many instances, Defendants also required that consumers pay fees and other costs, and undertake burdensome tasks, including completing a regimen of 92 "treatments" over a 180-day period, to obtain a refund. Defendants hid such conditions and limitations on their offer of a money-back guarantee behind links on the willowcurve.com website and at the bottom of a purchase invoice shipped with Willow Curve. In many instances, consumers learned of these conditions and limitations only after purchasing Willow Curve or attempting to obtain a refund.

20. Return rates for Willow Curve during the relevant time-period were high, with more than one in four and as many as one in three purchasers returning the device. In numerous instances, Defendants have represented to consumers that they issue refunds within seven to ten business days of return.

21. In numerous instances, however, even when unsatisfied consumers returned Willow Curve in accordance with Defendants' policies, Defendants failed to issue refunds or did not honor such requests for a year or more, only issuing refunds, in many cases, after consumers complained to a State Attorney General's Office or the Better Business Bureau.

22. Individual Defendants were aware of consumer complaints regarding not receiving promised refunds. Individual defendants also were aware of

Corporate Defendants' failing to respond to consumer emails or phone calls seeking information about refund requests.

FDA'S PURPORTED REVIEW OF WILLOW CURVE PRIOR TO ITS COMMERCIAL SALE

23. Various ads and promotional materials for the Willow Curve, including Exhibit A and ads described in Subparagraphs 15.F through H, tout Willow Curve as "FDA Registered," certified, or approved. Under the 1976 Amendments to the Federal Food, Drug, and Cosmetic Act, the Food and Drug Administration ("FDA") regulates the bringing of new medical devices to market. 21 U.S.C. § 360c. FDA classifies devices into one of three categories based on the risk they pose to the public. § 360c(f); see also 21 C.F.R. § 860.3 (2018). Under FDA regulations, marketers cannot sell higher-risk products without premarket approval from FDA, a regulatory pathway that includes a rigorous review of safety and efficacy data. FDA, Device Advice: Comprehensive Regulatory Assistance: *Overview of Medical Device Regulation: How to Study and Market Your Device:* Premarket Submissions: Premarket Approval (PMA), available at https://www.fda.gov/medicaldevices/deviceregulationandguidance/ /howtomarketyourdevice/premarketsubmissions/premarketapprovalpma/ (last modified Sept. 27, 2018).

24. Lower-risk devices undergo a less stringent regulatory review, known as the 510(k) regulatory pathway, that does not require clinical data demonstrating

efficacy or safety, only a showing that a new device is "substantially equivalent" to an existing device already legally marketed in the United States. FDA, *Device Advice: Comprehensive Regulatory Assistance: How to Study and Market Your Device: Premarket Submissions: Premarket Notification 510(k), available at* https://www.fda.gov/medicaldevices/deviceregulationand

guidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510 k/default.htm (last modified Sept. 27, 2018). In addition, FDA has exempted some lower-risk devices, such as heating pads and topical heating devices that emit infrared light, such as Willow Curve, from even this less stringent 510(k) regulatory pathway. *Id.*; *see also* 21 C.F.R. § 890.5550 (2018) (exempting infrared lamps from 510(k) premarket notification requirement); 21 C.F.R. § 890.5950 (2018) (exempting powered heating units from 510(k) premarket notification requirement). These 510(k)-exempt devices therefore undergo no FDA regulatory review before companies bring them to market.

25. FDA separately requires that manufacturers and distributors of medical devices in the United States register annually and submit a device list, a process known as "establishment registration." 21 C.F.R. § 807 (2018); FDA, *Device Advice: Comprehensive Regulatory Assistance: How to Study and Market Your Device: Device Registration and Listing, available at https://www.fda.gov/medical-devices/how-study-and-market-your-device/device-*

registration-and-listing [hereinafter, FDA Advice on Device Registration and Listing] (last modified Sept. 27, 2018). The purpose of this registration requirement is to inform FDA where medical devices are made, in the event of a public health emergency to which the agency must respond. FDA Advice on Device Registration and Listing. Defendants are not registered as a medical device manufacturer or distributor, and have not submitted listing information for Willow Curve to the FDA.

26. Based on the facts and violations of law alleged in this Complaint, the FTC has reason to believe that Defendants are violating or are about to violate laws enforced by the Commission because, among other things, Defendants engaged in their unlawful acts and practices repeatedly over a period of more than five years, continued their unlawful acts or practices despite knowledge of complaints that advertising claims for Willow Curve were not substantiated and were inconsistent with claims for which FDA cleared it, and continued advertising a risk-free, money-back guarantee for Willow Curve with knowledge that they could not honor such promises, and continued such deceptive advertising after they learned that the FTC was investigating them in August 2017 until at least June 2019.

VIOLATIONS OF THE FTC ACT

27. Section 5(a) of the FTC Act, 15 U.S.C. § 45(a), prohibits "unfair or deceptive acts or practices in or affecting commerce."

28. Misrepresentations or deceptive omissions of material fact constitute deceptive acts or practices prohibited by Section 5(a) of the FTC Act.

29. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, Willow Curve is a "device" as defined in Section 15(d) of the FTC Act, 15 U.S.C. § 55(d).

Count I

FALSE OR UNSUBSTANTIATED EFFICACY CLAIMS FOR WILLOW CURVE

30. Through the means described in Paragraph 15, Defendants have represented, directly or indirectly, expressly or by implication, that:

- A. Willow Curve treats or relieves severe or chronic pain due to a range of conditions, including rheumatoid arthritis, diabetic neuropathy, nerve damage, fibromyalgia, shingles, lupus, torn tendons, and broken bones;
- B. Willow Curve treats or reduces inflammation associated with severe or chronic pain;
- C. Willow Curve provides pain relief comparable to that from drugs or surgery;

- Willow Curve restores mobility and joint function to consumers with severely restricted movement of their hands, knees, legs, and other body parts;
- E. Willow Curve reduces pain by three to ten points on numerical pain scales after a single use;
- F. Ninety-percent of persons achieve significant pain relief with Willow Curve; and
- G. Willow Curve evaluates, diagnoses, and treats the cause of individual consumers' severe or chronic pain, thereby relieving such pain and reducing associated inflammation.

31. The representations set forth in Paragraph 30 are false or misleading or were not substantiated at the time the representations were made.

32. Therefore, the making of the representations as set forth in Paragraph 30 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

Count II

FALSE PROOF CLAIMS FOR WILLOW CURVE

33. Through the means described in Paragraph 15, Defendants have represented, directly or indirectly, expressly or by implication, that clinical studies

prove that:

- A. Willow Curve treats or relieves severe or chronic pain due to a range of conditions, including rheumatoid arthritis, diabetic neuropathy, nerve damage, fibromyalgia, shingles, lupus, torn tendons, and broken bones;
- B. Willow Curve treats or reduces inflammation associated with chronic or severe pain;
- C. Willow Curve provides pain relief comparable to that from drugs or surgery;
- Willow Curve restores mobility and joint function to consumers with severely restricted movement of their hands, knees, legs, and other body parts;
- E. Willow Curve reduces pain by three to ten points on numerical pain scales after a single use;
- F. Ninety-percent of persons achieve significant pain relief with Willow Curve; and
- G. Willow Curve evaluates, diagnoses and treats the cause of individual consumers' severe or chronic pain, thereby relieving such pain and reducing associated inflammation.
- 34. The representations set forth in Paragraph 33 are false.

35. Therefore, the making of the representations as set forth in Paragraph 33 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

Count III

FALSE CLAIMS ABOUT FDA'S REVIEW OF WILLOW CURVE

36. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Willow Curve, Defendants have represented, directly or indirectly, expressly or by implication, that FDA reviewed, registered, accredited, certified, approved, or cleared Willow Curve for:

- A. Treating or relieving severe or chronic pain due to a range of conditions, including rheumatoid arthritis, diabetic neuropathy, nerve damage, fibromyalgia, shingles, lupus, torn tendons, and broken bones;
- B. Treating or reducing inflammation associated with severe or chronic pain; and
- C. Evaluating, diagnosing, and treating the cause of individual consumers' severe or chronic pain, and thereby relieving such pain and reducing associated inflammation.
- 37. The representations set forth in Paragraph 36 are false.

38. Therefore the making of the representations as set forth in Paragraph 36 constitutes a deceptive act or practice and the making of false advertisements, in or affecting commerce, in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Count IV

DECEPTIVELY FORMATTED ADVERTISEMENTS

39. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Willow Curve, including Exhibit E and through the means described in Paragraph 16, Defendants have represented, directly or indirectly, expressly or by implication, that articles discussing Willow Curve for pain relief were independent statements and opinions of impartial publications regarding Willow Curve.

40. In truth and in fact, these articles were not independent statements and opinions of impartial publications regarding Willow Curve; they were commercial advertising.

41. Therefore, the making of the representation as set forth in Paragraph39 constitutes a deceptive act or practice in violation of Section 5(a) of the FTCAct, 15 U.S.C.

§ 45(a).

Count V

DEFENDANTS' PROVISION OF MEANS AND INSTRUMENTALITIES OF DECEPTION

42. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Willow Curve, including through the means described in Paragraph 17, Defendants have provided third-party distributors and resellers with advertising, marketing, and substantiation materials that contain false or misleading or unsubstantiated representations as set forth in Paragraphs 30, 33, and 36.

43. By furnishing third-party distributors and resellers with the materials described in Paragraph 42, Defendants have provided the means and instrumentalities for the commission of deceptive acts and practices, in violation of Sections 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count VI

FALSE REFUND AND RISK-FREE CLAIMS

44. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Willow Curve, Defendants have represented, directly or indirectly, expressly or by implication, that Willow Curve comes with a risk-free, money-back guarantee.

45. In truth and in fact, Defendants have required consumers to pay the cost of shipping and handling and other fees, and to take onerous steps to obtain a

refund. In many cases, Defendants have failed to provide refunds to consumers who complied with their return policy or did not honor such refund requests for a year or more.

46. Therefore, the making of the representation set forth in Paragraphs 44 constitutes a deceptive act or practice, in or affecting commerce, in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

CONSUMER INJURY

47. Consumers are suffering, have suffered, and will continue to suffer substantial injury as a result of Defendants' violations of the FTC Act. In addition, Defendants have been unjustly enriched as a result of their unlawful acts or practices. Absent injunctive relief by this Court, Defendants are likely to continue to injure consumers, reap unjust enrichment, and harm the public interest.

THIS COURT'S POWER TO GRANT RELIEF

48. Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), empowers this Court to grant injunctive and such other relief as the Court may deem appropriate to halt and redress violations of any provision of law enforced by the FTC. The Court, in the exercise of its equitable jurisdiction, may award ancillary relief, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies, to prevent and remedy any violation of any provision of law enforced by the FTC.

PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15

U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

A. Enter a permanent injunction to prevent future violations of the FTC Act;

B. Award such relief as the Court finds necessary to redress injury to consumers resulting from Defendants' violations of the FTC Act, including rescission or reformation of contracts, restitution, the refund of monies paid, and the disgorgement of ill-gotten monies; and

C. Award Plaintiff the costs of bringing this action, as well as such other and additional relief as the Court may determine to be just and proper.

Respectfully submitted,

ALDEN F. ABBOTT General Counsel

Dated: June 25, 2020

LOCAL COUNSEL

MATTHEW SCHNEIDER United States Attorney

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