UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

FEDERAL TRADE COMMISSION, Plaintiff, v. NEUROMETRIX, INC., a corporation, and SHAI GOZANI, individually and as an officer of NEUROMETRIX, INC., Defendants.	**Case No. _____** **COMPLAINT FOR PERMANENT INJUNCTION AND OTHER EQUITABLE RELIEF**

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 wearable transcutaneous electrical nerve stimulation devices under the brand names "Quell" and "Quell 2.0" (hereinafter "Quell") that purportedly relieve chronic or severe pain throughout the body from a fixed site of application below the knee.

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 NeuroMetrix, Inc. ("NeuroMetrix") is a Delaware corporation with its principal place of business at 1000 Winter Street, Waltham, Massachusetts, 02446. NeuroMetrix 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, NeuroMetrix has advertised, marketed, distributed, or sold Quell to consumers throughout the United States.

7. Defendant Shai Gozani is the founder, Chairman, President, and Chief Executive Officer of NeuroMetrix. 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 of NeuroMetrix, including the acts and practices set forth in this Complaint. Defendant Gozani has managed day-to-day operations of the business in connection with Quell, including business strategy, product development and research, creation and approval of advertising and marketing materials, evaluation of scientific support for marketing claims, and regulatory compliance. Among other things, Defendant Gozani: (1) directed NeuroMetrix's research into the efficacy of Quell; (2) actively participated in the creation of, reviewed, edited, and approved advertising concepts and ad copy for Quell, including materials containing advertising claims that form the basis of this Complaint; (3) directed NeuroMetrix's efforts to obtain regulatory clearance from the Food and Drug Administration ("FDA") to sell Quell commercially in the United States, and participated in preparing submissions to, and communications with, that agency; (4) personally made challenged claims about the health benefits of Quell to the public; and (5) responded to inquiries from the media, potential investors, and others about scientific support for the herein challenged advertising claims.

8. Furthermore, Defendant Gozani disregarded multiple warnings that the support Defendants proffered as substantiation for Quell's claimed efficacy was not competent and reliable scientific evidence. He also mischaracterized a marketing survey conducted to generate advertising claims as a clinical study showing Quell's efficacy. Defendant Gozani resides in this district and, in connection with the matters alleged herein, transacts or has transacted business in this district and throughout the United States.

COMMERCE

9. 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.

TENS DEVICES

10. Transcutaneous electrical nerve stimulation ("TENS") devices deliver low-voltage electrical currents across the skin's surface, via hydrogel pads or "electrodes" placed at the site of pain, which purportedly stimulate the underlying peripheral nerves. TENS technology has been used for decades to relieve pain locally, as opposed to beyond the site of application.

DEFENDANTS' BUSINESS ACTIVITIES

11. Quell is an over-the-counter wearable TENS device consisting of a flexible band that houses an electrical stimulator and four electrodes. Consumers wear the device around the upper calf, below the knee. From this fixed application site, Quell purportedly relieves various types of severe and chronic pain throughout the body, including pain experienced in more than one location as well as in locations distant from the site of application. Based on what Defendants claim is typical use, consumers must replace the electrodes every two weeks. Quell also includes an optional mobile app called the "Quell Relief App," which, *inter alia*, allows users to start, stop, and adjust the strength of the electrical stimulation delivered. The Quell Relief App also collects anonymized data relating to product use.

12. Quell typically costs $249 for the original version and $299 for a second-generation version called Quell 2.0, which is 50% smaller. The initial cost of the device is

roughly ten times that of other TENS devices. Replacement electrodes typically cost $29.95, $84.95, and $99.95, respectively, for a one-month, three-month, and four-month supply.

13. Since 2015, Defendants have labeled, advertised, marketed, distributed, and sold Quell to the public, directly and through healthcare professionals and various retailers, including Amazon, Best Buy, CVS, Hammacher Schlemmer, Target, Walgreens, and Walmart. Defendants have advertised and promoted Quell to the public through a national television campaign, the Internet, including the website quellrelief.com, paid search ads, banner ads, Facebook, and the crowd-funding platform Indiegogo, and at trade conferences such as the Consumer Electronics Show ("CES"). The core advertising messages are that, by activating areas of the brain responsible for the central inhibition of pain, Quell produces widespread relief of chronic and severe pain throughout the body from a fixed site of application below the knee, that it is clinically proven to do so, and that it is cleared by FDA for this specific use.

14. To induce consumers to purchase Quell, Defendants have disseminated, or caused to be disseminated, ads and promotional materials for Quell, including, but not limited to, the television ads attached as Exhibits A through D. Many of Defendants' television advertisements combine statements, as set forth in Subparagraphs A – D below, with depictions of how Quell affects the central nervous system and of users achieving relief from pain in different parts of the body. These and other ads and promotional materials contain the following statements and depictions, among others:

A. Excerpts from Quell TV ad (Exhibit A (video), airing until at least February 2019)

* * *

ON SCREEN: Reclaim Your Life From Chronic Pain –

[*Video depicts a man grabbing his lower back in pain after loading tools into a truck*].

ANNOUNCER: Reclaim your life from chronic pain . . .

ON SCREEN: Quell 2.0 Wearable Pain Relief Technology

[*Video depicts Quell device and packaging*].

ANNOUNCER: with Quell 2.0.

ON SCREEN: 100% Drug-Free
FDA Cleared

Quell 2.0 BUYQUELL.COM

[*Video depicts a woman in athletic attire attaching Quell 2.0 to her lower left leg, below the knee, and then getting up to go outside*].

ANNOUNCER: Quell is 100% drug free and FDA cleared.

ON SCREEN: Designed for People with a Wide Range of Chronic Pain Conditions

Quell 2.0 BUYQUELL.COM

ANNOUNCER: It's designed for people with a wide range of chronic pain conditions.

ON SCREEN: [*Animation depicts a Quell 2.0 wrapping around a woman's right lower leg, below the knee, then sending electrical pulses up the leg and into the central nervous system*].

Dramatization of Quell mode of action. * * * [small print, bottom of screen].

ANNOUNCER: Worn just below the knee, the Quell technology accesses the central nervous system.

ON SCREEN: Blocks Chronic Pain

[*Animation depicts a woman's body, from the back, with pain-flare ups in her lower back, lower legs, and feet that disappear after a Quell 2.0 worn on her right leg, below the knee, sends electrical pulses to the brain via the spinal column, releasing "natural pain blockers" throughout her body]*.

Dramatization of Quell mode of action. * * * [small print, bottom of screen].

ANNOUNCER: It sends neural pulses to the brain triggering a natural response that blocks pain signals in the body,

ON SCREEN: In a Published Study, 4 out of 5 users Reported Improvement in Chronic Pain* —

*Journal of Pain Research 2016; (9); 469-479. Based on 60 days of product use. Results may vary. [small print, bottom of screen].

[*Video depicts a smiling and laughing woman wearing a Quell device on her lower right leg, below the knee, carrying a salad outside and serving it to three other persons seated at a picnic table*].

ANNOUNCER: And Quell delivers proven results. In a published study, four out of five users reported an improvement in their chronic pain --

ON SCREEN: In a Published Study, 2 out of 3 Reported a Reduction in Pain Medication Use* –

*Journal of Pain Research 2016; (9); 469-479. Based on 60 days of product use. Results may vary. [small print, bottom of screen]

[*Video depicts same man from earlier experiencing back pain after loading tools into truck, now getting out of truck smiling*].

ANNOUNCER: And two out of three reported a reduction in their chronic pain medications. … .

* * *

ON SCREEN: FDA Cleared for Day/Night Use*

*Quell is FDA Cleared for use while sleeping. Quell is not a sleep aid. [small print, bottom of screen].

[*Video depicts a man sleeping peacefully*].

ANNOUNCER: Quell can be used day and night, even while you sleep.

ON SCREEN: [*Animation depicts a Quell 2.0 wrapping around a woman's lower right leg, below the knee, then sending electrical pulses up the leg and into the central nervous system*].

ANNOUNCER: You do not need to wear Quell on the area where you are experiencing pain –

ON SCREEN: [*Animation depicts a man's body, from the back, with pain-flare ups in his lower back, lower legs, and feet that disappear after a Quell 2.0 worn on his right leg, below the knee, sends electrical pulses to the brain via the spinal column, releasing "natural pain blockers" throughout his body]*.

Dramatization of Quell mode of action. * * * [small print, bottom of screen].

ANNOUNCER: Nerve stimulation can produce a widespread response that blocks pain signals beyond where you wear it.

* * *

B. Excerpts from Quell TV ad (Exhibit B (video), airing until at least October 2018)

ON SCREEN: When You Suffer from Chronic Pain –

[*Video depicts a man rubbing his knee in pain*].

ANNOUNCER: When you suffer from chronic pain, you can't –

ON SCREEN: CAN'T

[*Video depicts a seated woman turning to look at her kitchen, a woman in a dark room staring outside a window, and a man grabbing his lower back in pain after loading tools into a truck*].

ANNOUNCER: -- do the things you enjoy, like being active. Even doing everyday jobs can be painful.

* * *

ON SCREEN: CAN'T * * *

CAN

[*Video depicts a woman grabbing her shoulder in pain, and then the same woman wearing Quell 2.0 on her lower leg as she pushes two children on a swing*].

ANNOUNCER: For chronic pain sufferers, it's time to turn can't into can.

ON SCREEN: Quell 2.0 Wearable Pain Relief Technology

ANNOUNCER: Introducing Quell 2.0 –

ON SCREEN: 100% Drug-Free

ANNOUNCER: – 100 percent drug-free, wearable technology –

ON SCREEN: Relieves Chronic Pain

* * *

ANNOUNCER: – that's designed for people with a wide range of chronic pain conditions.

ON SCREEN:

[*Animation depicts a Quell 2.0 wrapping around a woman's leg, below the knee, and then sending electrical signals up the leg into the central nervous system*].

Dramatization of Quell mode of action. * * * [small print, bottom of screen].

ANNOUNCER: From this comfortable stimulation point below the knee, the Quell technology gently accesses the central nervous system.

ON SCREEN: Clinically Proven Technology

FDA Cleared

[*Animation depicts a woman's body, from the back, with pain flare-ups in her lower back, lower legs, and feet that disappear after a Quell 2.0 worn on her right leg, below the knee, sends electrical pulses to her brain via the spinal column, releasing "natural pain blockers" throughout her body*].

Dramatization of Quell mode of action. * * * [small print, bottom of screen].

ANNOUNCER: It sends neural pulses to the brain that trigger your body's own natural pain blockers.

* * *

ANNOUNCER: So you can activate the power inside you to relieve chronic pain, turning can't moments into can.

ON SCREEN: CAN'T * * *

CAN

[*Video depicts a man grabbing his lower back in pain, and then the same man stretching forward on a ladder to install a ceiling fan]*.

ANNOUNCER: Now, with Quell, you can get back to doing the things you enjoy and living life again.

* * *

ON SCREEN: CAN –

In a published study, 4 out of 5 users Reported Improvement in Chronic Pain.* –

*Journal of Pain Research 2016 (9):469-479. Based on 60 days of product use. Results may vary. Quell is not a sleep aid. [small print, bottom of screen].

ANNOUNCER: In a published study, four out of five users who tried Quell reported improvement in their chronic pain.

C. Excerpts from Quell TV ad (Exhibit C (video), aired between approximately July 2017 and September 2018)

ON SCREEN: [*Video depicts a seated man rubbing his knee in pain*].

UNIDENTIFIED MALE: Arthritis.

ON SCREEN: [*Video depicts a man stretching backward with his arm behind his back*].

UNIDENTIFIED MALE: My back pain.

ON SCREEN: [*Video depicts a woman curled up on a coach, under a blanket*].

UNIDENTIFIED FEMALE: It hurts all over.

ON SCREEN: * * *

[*Animation depicts a Quell wrapping around a woman's right lower leg, below the knee, then sending electrical pulses up the leg and into the central nervous system*].

ANNOUNCER: Wherever you feel pain, it can be managed from here with Quell. From this optimal point, the revolutionary Quell technology accesses the central nervous system.

ON SCREEN: Designed for Back Pain, Arthritic Pain, Nerve Pain, Leg and Foot Pain.

* * *

[*Animation depicts a woman's body, from the back, with pain flare-ups in her lower back, shoulders, elbows, lower legs, and feet that disappear after a Quell worn on her right leg, below the knee, sends electrical pulses to her brain via the spinal column, releasing "natural pain blockers" throughout her body*].

ANNOUNCER: It sends precise neuro-pulses to the brain that trigger your body's own natural pain blockers.

ON SCREEN: 100% Drug Free. FDA Cleared.

* * *

Quell relieves chronic pain only while using the device. * * * [small print, bottom of screen].

ANNOUNCER: Quell is 100 percent drug-free, FDA-cleared, and easy to use.

ON SCREEN: 4 out of 5 people experience relief. –

* * *

Results were based on 60 days of product use. Results may vary. [small print, bottom of screen].

[*Video depicts the man who earlier complained of back pain wearing a Quell on his leg and carrying a golf bag full of clubs*].

ANNOUNCER: And for four out of five people, it works. Reclaim your life from chronic pain with Quell.

D. Excerpts from Quell TV ad (Exhibits D (video), aired between approximately July 2017 and September 2018)

ON SCREEN: Brian. Actual Quell User.

BRIAN: From my back pocket to my foot was like a lava flow down that sciatic nerve.

*** * ***

ON SCREEN: [*Video depicts a woman in a medical coat discussing Quell with another woman*].

ANNOUNCER: Quell is 100 percent drug free, FDA-cleared, and doctor-recommended.

* * *

ON SCREEN: 4 out of 5 people experience relief. –

* * *

Results were based on 60 days of product use. Results may vary. [small print, bottom of screen].

ANNOUNCER: Best of all, for four out of five people, it works.

* * *

BRIAN: I'm doing things that I used to do, and I'm a happier, healthier guy. My whole life's turned around.

ON SCREEN: 2 out of 3 people reported reduction.

* * *

You should not change your pain medication before consulting your doctor. Results were based on 60 days of product use. Results may vary. [small print, bottom of screen].

ANNOUNCER: And two out of three people reported a reduction in their pain medications with Quell.

UNIDENTIFIED MALE: And she said, you know, haven't refilled your prescriptions in a while, because I have one of these.

* * *

ANNOUNCER: * * * Quell is easy to use and up to ten times more powerful than ordinary TENS devices. It's strong enough to deliver widespread relief just by wearing it here, so it doesn't restrict you and you can get back to living your life. * * * Quell's pain-relieving effects build over time. * * * Reclaim your life from chronic pain with Quell.

E. Excerpts from quellrelief.com website and video to which the website links (available until at least July 2019)

[Home>News: Page that displays if click "News" link on quellrelief.com home page]

Featured News

*** * ***

*** * ***

[Video that plays if click "Common Ground: QUELL for Pain" contains the statements and depictions below, among others]

NEWS REPORTER: Eighteen months ago the Natomas resident could barely move.

INTERVIEWED MALE: I couldn't walk a mile with my kids to go someplace.

* * *

NEWS REPORTER: High doses of pain killers robbed [Natomas resident] of the joys of family life.

INTERVIEWED MALE: At one point, the doctor said this is the maximum pain medication we can give you.

ON SCREEN: [*Video depicts interviewed male running after his two children at an outdoor playground]*.

NEWS REPORTER: But today he can play with two sons and even take long walks, something that was unthinkable before.

* * *

NEWS REPORTER: So what's changed? After researching medication-free pain treatments, he came across Quell.

INTERVIEWED MALE: I was looking for something that I could replace my pain medications with.

*** * ***

NEWS REPORTER: Quell is a wearable pain relief device that delivers electrical stimulation to sensory nerve cells, providing pain relief throughout the body.

*** * ***

ON SCREEN: [*Video depicts Dr. Shai Gozani holding a Quell electrical stimulator*].

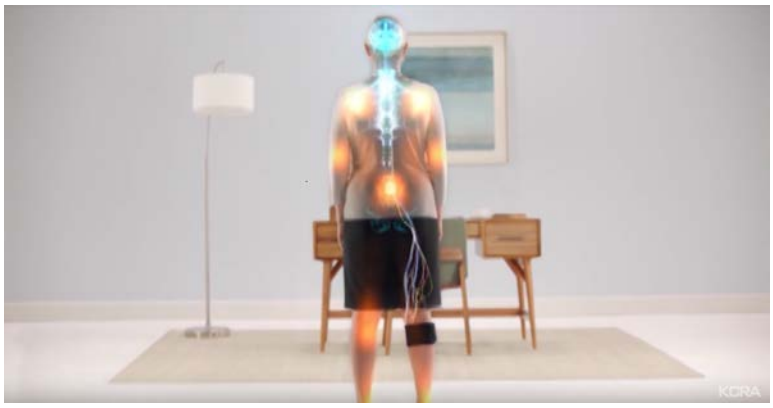
DR. SHAI GOZANI: This is the Quell stimulator, so this has the battery and the technology to – stimulate your nerves.

The high frequency with the high intensity will trigger your brain to release your own endogenous opioids, your sort of your own safe opioids, and those will block your pain.

ON SCREEN: [*Video depicts interviewed male placing Quell below his knee, on one of his legs*].

NEWS REPORTER: The stimulator is strapped around your leg. On the strap are a series of water-based gel packets that contain tiny silver electrodes.

ON SCREEN:



[*Animation depicts a woman's body, from the back, with pain flare-ups in her lower back, shoulders, elbows, lower legs, and feet that disappear after a Quell worn on her right leg, below the knee, sends messages to her brain via the spinal column, releasing pain relievers throughout her body*].

NEWS REPORTER: Together the unit sends high-frequency messages to the brain. Relief is delivered to wherever pain exists in the body.

*** * ***

DR. SHAI GOZANI: This is the only device, umm, that is available that has FDA clearance to be used while you're sleeping.

NEWS REPORTER: Dr. Shai Gozani designed Quell and actually uses one to control his own chronic back pain.

DR. SHAI GOZANI: I didn't design Quell for my own problems but once I, once we designed it and we saw the results people were getting for lower back pain, I started using it for my own purposes and found it to be very beneficial.

*** * ***

F. Excerpts from printable Quell 2.0 brochure available on quellrelief.com website (available until at least June 2019)

Quell® 2.0 Wearable Pain Relief Technology™

* * *

How Quell Works
Nerve stimulation, such as by Quell, can have widespread effects that provide pain relief beyond the site of stimulation. Quell (1) activates sensory nerves which (2) sends neural pulses to the brain, (3) triggering a natural pain relief response in the central nervous system.

+ Designed for multiple types and sources of chronic pain

* * *

+ In a published study, 81% of users reported improvement in chronic pain*

* * *

*Journal of Pain Research 2016;(9): 469-479.

[second page]

Quell has been shown in multiple clinical studies to relieve chronic pain.

+ **World Congress of the World Institute of Pain, May 2018 -** *Efficacy of High-Frequency Transcutaneous Electrical Nerve Stimulation for Chronic Lower Back Pain: Does Hypersensitivity Matter?*
+ **Journal of Pain Research, April 2018 -** *Effectiveness of fixed-site high-frequency transcutaneous electrical nerve stimulation in chronic pain: a large-scale observational study*
+ **American Academy of Pain Medicine Annual Meeting, April 2018 -** *Levels and Predictors of Activity in Users of Wearable Neurostimulators with Chronic Pain*

* * *

G. Excerpts from quellrelief.com website (captured November 15, 2018; substantially similar statements and depictions on website until at least March 2019)

[**Home**>]

Reclaim your Life from Chronic Pain

New Quell 2.0 Wearable Pain Relief Technology™ is a revolutionary, 100% drug free system, which uses prescription strength nerve stimulation to block chronic pain. * * *

How it Works [hyperlink]*** * ***

In a published study, 4 out 5 people reported an improvement in chronic pain.[2] The more you use Quell, the better the chance of pain relief.[3]

A New Treatment for Your Chronic Pain

* * *

Powerful Neurotechnology Relieves Pain Without Holding You Back

Worn just below the knee, Quell is designed for multiple types and sources of chronic pain.

*** * ***

2 Gozani SN. Fixed-site high-frequency transcutaneous electrical nerve stimulation for treatment of chronic low back and lower extremity pain. J of Pain Research 2016 (9):469-479.

[7.5 point font, at bottom of webpage]

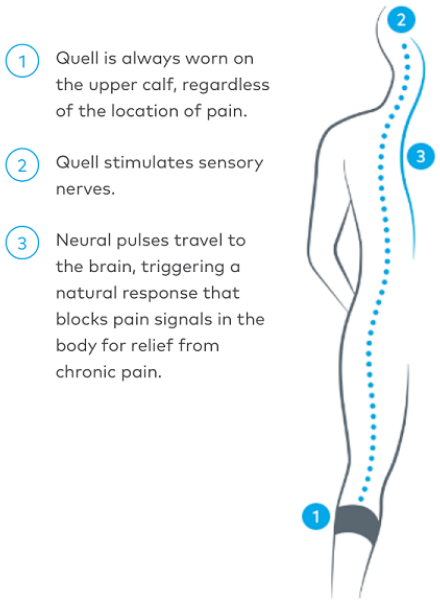
* * *

[**Home>How it Works**: Page that displays if click "How it Works" link on home page]

Powerful neurotechnology activates the power inside you to block chronic pain

Quell's 100% drug free, clinically proven technology stimulates the sensory nerves in your calf sending neural pulses to your brain that trigger your body's natural pain blockers.

How Quell works to treat chronic pain:



* * *

Designed for multiple types and sources of chronic pain.

Quell's prescription strength neurotechnology designed for multiple types and sources of chronic pain. * * * What's more, it's proven to work.

* * *

Learn More About the Science Behind Quell [hyperlink]

[**Home>How it Works>The Science Behind Quell**: Page that displays if click "Learn More About the Science Behind Quell" link on How it Works page]

Backed by over 20 years of Neurotechnology Research

* * *

Clinically Proven Technology

But don't just take our word for it, browse through the growing number of published studies, white papers and abstracts which are foundational to efficacy of Quell technology:

H. Excerpts from quellrelief.com website (captured July 27, 2018)

[**Home**>]

Reclaim what chronic pain has taken from you.

100% drug free wearable technology for relief from chronic pain.

How it works [hyperlink]

Powerful enough to tap into your body's natural pain relief response.

Quell's 100% drug free, clinically proven technology automatically adjusts therapy to optimize pain relief.

Learn More [hyperlink]

In a clinical study,
4 out 5 people reported
improvement in their
chronic pain.[1]

81% reported improvement in their chronic pain.

67% reported reduction in their pain medication.

[Text that displays if mouse-over "Clinically Proven Technology" badge above]

* * *

Chronic pain is more than just pain.

One in three Americans suffers from chronic pain. Chronic pain is defined as pain lasting more than three months, and it can interfere with your daily activities,

impact your mood, and prevent you from sleeping soundly. Quell can provide widespread relief from chronic pain, and may be right for you.

Click below to learn how Quell can help with different types of chronic pain.

[*Image of Quell*]

Nerve Pain>Arthritic & Joint Pain>Leg & Foot Pain>Widespread Pain>Lower Back Pain [hyperlinks]

* * *

"I suffer from fibromyalgia, which unlike other pain conditions doesn't respond well to pain medication. . . I take at least half the OT pain medicine, have more energy, sleep much better, ache less. . ., and feel happier than in a long time."

[**Home>How it Works**: Page that displays if click "How it Works" link on home page]

* * *

Quell's 100% drug free, clinically proven technology automatically adjusts therapy to optimize pain relief.

* * *

Quell: A better option for widespread relief from chronic pain.

* * *

Quell is always worn on the upper calf and stimulates sensory nerves.

It taps into your body's natural pain relief response.

Sensory nerves carry neural pulses to your brain.

Neural pulses trigger a natural response that blocks pain signals, leading to widespread pain relief.

* * *

[**Home>Managing Chronic Pain>Nerve Pain**: Page that displays if click "Nerve Pain" link on home page]

"Now that I'm using Quell, my pain is greatly reduced and I'm also sleeping much better throughout the night."

Jesse

[*Video testimonial of Jesse, who speaks of pain due to neuropathy*].

Fast facts about nerve pain:

- Nerve pain can be associated with an underlying condition such as diabetes, sciatica, and shingles, but is often not associated with a particular disease.

- Nerve pain can result from drugs used to treat conditions such as cancer.

- It can be hard to figure out what to do for nerve pain.

What nerve pain may feel like:

- Burning, pinpricks, or sudden shocks of electricity.

How Quell can help

Studies have shown that high frequency intensive nerve stimulation is an effective option for treating various types of chronic pain.

Quell is wearable technology that uses intensive nerve stimulation to provide widespread pain relief. It is designed to be worn on the calf, regardless of where you are experiencing pain, and simulates your nerves in a way that is powerful enough to trigger the release of your body's natural pain blockers. Pain is blocked at the spinal cord, which helps you feel widespread relief from your pain, not just relief in a specific part of your body.

* * *

Read more about the experiences with Quell of people with a specific type of nerve pain, diabetic neuropathy.

* * *

Near Miraculous for Me

"I had been suffering from extreme neuropathic pain… Since using Quell, I have had absolutely no significant discomfort nor pain… This is a fantastic product that is destined to change the lives of millions who suffer from chronic pain."

* * *

[**Home>Managing Chronic Pain>Arthritic & Joint Pain**: Page that displays if click "Arthritic & Joint Pain" link on home page]

* * *

[*Video testimonial of David, who speaks of general pain from his hips to his toes*].

* * *

Fast facts about arthritic and joint pain:

- The two most common types of arthritis are osteoarthritis and rheumatoid arthritis, affecting 27M and 1.5M people in the U.S., respectively, and more women than men.

- Symptomatic knee osteoarthritis occurs in 10% of men and 13% of women aged 60 years or older.

- Rheumatoid arthritis is an autoimmune disease and can cause inflammation not only in the joints but also in the internal organs.

What arthritic and joint pain may feel like:

- People with osteoarthritis may experience joint pain and progressive stiffness, often in their hands, knees, hips, or spine.

- People with rheumatoid arthritis can experience pain, swelling, stiffness, and loss of function in joints including wrists and fingers, often upon awakening.

How Quell can help

[Same statements that appear on the Nerve Pain page, as set forth above above]

* * *

[**Home>Managing Chronic Pain>Leg & Foot Pain**: Page that displays if click "Leg and Foot Pain" link on home page]

"I was taking anti-inflammatories daily. Now, using the Quell device, I don't have to take any more anti-inflammatories."

Valerie

[*Video testimonial of Valerie, who speaks of pain in her right knee after multiple surgeries*].

Fast facts about leg & foot pain:

- Leg pain may have various causes, including neurological and musculoskeletal.
- Neurological causes of leg pain include neuropathy, sciatic nerve pain, and restless legs [sic] syndrome, among others.
- Arthritis, which affects joints including hips, knees, and ankles, is an example of a musculoskeletal cause of leg and foot pain.

What leg and foot pain may feel like:

- Leg and foot pain could include pain from the hip area down through the leg, knees, and ankles to the feet.

How Quell can help

[Same statements that appear on the Nerve Pain page, as set forth above]

* * *

[**Home>Managing Chronic Pain>Widespread Pain**: Page that displays if click "Widespread Pain" link on home page]

* * *

[*Video testimonial of Sarah, who speaks of pain due to temporomandibular, jawbone-related, joint disorder*].

Fast facts about widespread pain:

- People with chronic pain may suffer from multiple conditions and experience pain in multiple parts of their bodies or throughout the body.

- An estimated 10M people in the US are affected by the condition known as fibromyalgia, which is associated with widespread pain, fatigue, poor sleep quality, and difficulty thinking clearly.

- Multisite musculoskeletal pain is a common type of widespread pain as well.

What widespread pain may feel like:

- All-over or widespread pain may be described as deep, aching, radiating, shooting, or tender pain.

How Quell can help

[Same statements that appear on the Nerve Pain page, as set forth above]

* * *

[Home>Managing Chronic Pain>Lower Back Pain: Page that displays if click "Lower Back Pain" link on home page]

"I was very skeptical. Previously, I had two spinal surgeries and could only control pain with strong prescription meds. Since Quell came with a 60-day trial, I figured it was worth trying. I've only had it a week, but it has substantially reduced the amount of pain meds I need. Sometimes I use it and am entirely pain-free, but other times it reduces my pain level 60-70%. I'm very impressed."

R. P.

I. Excerpts from quellrelief.com website and video to which the website links (captured July 27, 2018)

[Home>News: Page that displays if click "ALL NEWS" or "News" link on quellrelief.com home page]

Featured News

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[Video that plays if click "FDA Approves Device to Treat Chronic Pain Without Pills" contains the statements below, among others]

ON SCREEN: Pill-Free Pain Relief

[*Image of the caduceus*].

NEWS ANCHOR: There's a new way to treat chronic pain without taking any pills. KPIX 5's Michelle Griego shows us the revolutionary wearable technology that can provide relief from all kinds of conditions.

ON SCREEN: [*Video depicts Frank McGillin with his suit pant-leg up and a Quell on his lower leg*].

FRANK MCGILLIN: With automation you can wear it all day and basically forget about it and it's helping you relieve pain.

ON SCREEN: [*Video zooms in on a Quell in front of a Quell package*].

MICHELLE GRIEGO: This contraption is called Quell. It was recently approved by the FDA.

ON SCREEN: Frank McGillin, NEUOROMETRIX, INC., WALTHAM

FRANK MCGILLIN: It basically stimulates sensory nerves in your legs, which triggers the release of endogenous opioids and those are the body's natural pain relievers. They block pain throughout the body.

ON SCREEN: [*Animation depicts the brain and neural network*].

MICHELLE GRIEGO: The technology uses the body's central nervous system instead of drugs to relieve pain.

FRANK MCGILLIN: People are using it for all kinds of conditions, arthritis, nerve pain, painful diabetic neuropathy, fibromyalgia.

ON SCREEN: [*Video depicts a woman bending over, as a doctor in a medical coat attends to her*].

FRANK MCGILLIN: Sciatica, lower back pain.

ON SCREEN: [*Video depicts a man who flexes his shoulders while on an examination table in a doctor's office, and then a man who grabs his lower back while at work*].

FRANK MCGILLIN: Chronic pain, it's really an epidemic. 100 million Americans are suffering from some sort of chronic pain.

ON SCREEN: [*Video depicts pills spilling out of a bottle, and then, two men on a squash court*].

MICHELLE GRIEGO: People like Dave Anderson who had to take up to 12 ibuprofen pills a day just to keep playing squash.

DAVE ANDERSON: My physician told me to stop taking the ibuprofen and I said I have got to start doing something else.

ON SCREEN: [*Video depicts Dave Anderson strapping a Quell around his leg*].

MICHELLE GRIEGO: So he strapped on a sports band with a therapy pod and hasn't looked back.

DAVE ANDERSON: I'm not taking any more ibuprofen. It's completely controlled the daily pain that I was having and it has allowed me a much faster recovery after physical exercise.

* * *

J. Excerpts from the quellrelief.com website (captured June 8, 2017)

He Simply Lost Hope Until Quell

For two years, my husband was in severe pain due to nerve damage from shingles. His pain was excruciating … Within one hour of starting Quell, his pain went from an 8 to a very mild 1. He is happy and slowly returning to the person his family loves!

K. Excerpts from Hammacher Schlemmer retail web page that sells Quell (captured May 21, 2018)

The All Night Chronic Pain Reliever

This is the device that relieves pain throughout the body to promote a good night's sleep. The pain reliever is worn around the calf and sends harmless high-frequency electrical pulses that stimulate nerves and block pain signals throughout the body. The device can relieve pain from diabetic neuropathy, sciatica, fibromyalgia, and osteoarthritis in as little as 15 minutes without the need for costly prescription drugs.

L. Excerpts from an Indiegogo crowd-funding campaign for Quell (on or around March 2, 2015 until April 20, 2015)

Quell is the only FDA cleared, doctor recommended, 100% drug free device clinically proven to relieve chronic pain at the touch of a button.

* * *

Quell is a doctor recommended, 100% drug-free solution for alleviating chronic pain, including conditions such as painful diabetic neuropathy and other neuropathic pain, fibromyalgia, sciatica, and osteoarthritis among others.

* * *

Will Quell work for my chronic pain?

* * * Quell has been cleared by the FDA for relief from chronic pain. There is a strong body of evidence supporting the use of nerve stimulation for relief of many types of chronic pain, including from conditions such as diabetes, low back pain, fibromyalgia, and osteoarthritis. * * *

* * *

How does Quell work?

Worn just below the knee, Quell utilizes NeuroMetrix's patented wearable intensive nerve (WINS) technology that is customized for every user, determining the ideal therapeutic intensity of electrical nerve stimulation to provide optimal pain relief.

Quell triggers a central inhibition effect that "turns down the volume" of pain signals, by stimulating the sensory nerves, which cause the brain to release chemicals (endogenous opioids) that ultimately reduce pain signal transmission (through the delta opioid receptor).

PURPORTED SUBSTANTIATION FOR DEFENDANTS' ADVERTISING CLAIMS

15. To substantiate the above advertising claims of widespread relief from chronic and severe pain from a fixed application site below the knee, including pain that is distant from the application site or due to conditions such as osteoarthritis, nerve damage, sciatica, shingles, and fibromyalgia, would require randomized, placebo-controlled, prospective, human clinical trials ("RCTs") demonstrating non-localized analgesia in persons with chronic pain, or for the specific conditions claimed. However, neither RCTs on Quell (or on any substantially similar device with comparable dosing and placement), nor the entire body of relevant scientific evidence, demonstrate that Quell is effective in relieving chronic and severe pain beyond the site of application.

16. The only two RCTS conducted on Quell have substantial flaws. One such study, conducted by Brigham and Women's Hospital in 2017-2018, explored Quell's feasibility as a treatment for chronic low back pain (hereinafter "Brigham and Women's Hospital Study"). This pilot study used usual treatment alone as its control, comparing pain levels between a group of persons who used Quell and a second group who used only usual treatment. As a result, the study did not blind the subjects or investigators to the treatment received, which meant that any pain reduction that it detected could be due to placebo effects (as opposed to the device). Additional limitations of this study included its small size, insufficient duration, and its failure to adequately control for other treatments that subjects might have received (*e.g.*, medications or physical therapy) or other environmental factors influencing their pain. Thus, the Brigham and Women's Study was not sufficient to determine Quell's effects on chronic lower back pain; placebo-controlled studies of larger size and longer duration would be necessary to do so.

17. The second RCT was a sham-controlled pilot on Quell and cancer-related pain that Scripps Translational Science Institute conducted in 2017-2018 (hereinafter "Scripps Study"). Although this pilot study had a sham control group and therefore controlled for placebo effects, it also was inadequate to determine whether Quell was efficacious in relieving chronic pain, including because of its small size, its low retention rate of subjects, and its limited duration. Furthermore, as set forth in a report provided to Defendants, the authors found no statistically significant difference between the decreased pain scores and opioid use in the Quell and sham groups. The authors further stated, "The results of this study showed a strong placebo effect." Thus, neither the Scripps Study nor the Brigham and Women's Hospital Study demonstrates that Quell is efficacious.

18. Various ads and promotional materials for Quell, including Exhibits A through D and ads described in Subparagraphs 14.F, G, and H above, feature a study purported to show Quell's efficacy; however, the study cited is not clinical testing of the device's efficacy in humans. Instead, the cited study is a marketing survey conducted by a market research firm that NeuroMetrix hired to generate potential advertising claims.

19. Based on partial responses to this marketing survey, Defendant Gozani wrote a paper characterizing it as a clinical study showing Quell's efficacy, which he then published in an online open access journal. Defendants proceeded to feature this paper in ads and promotional materials for Quell, and otherwise tout it as clinical data on Quell to the public.

FDA 510(K) CLEARANCE OF QUELL FOR COMMERCIAL SALE

20. Various ads and promotional materials for Quell, including Exhibits A through D and ads described in Subparagraphs 14.I and L above, tout Quell as "FDA Cleared" or approved.

Under the 1976 Amendments to the Federal Food, Drug, and Cosmetic Act, 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). Lower-risk devices, such as TENS devices, undergo a less stringent regulatory review, known as the 510(k) regulatory pathway, that does not require clinical data demonstrating efficacy or safety. 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/deviceregulationandguidance/howtomarketyourdevice/premarketsubmissions/premarketnotification510k/default.htm [hereinafter, *FDA Advice on Premarket Notification 510(k)*] (last modified Sept. 27, 2018); 21 C.F.R. § 882.5890 (2018) (classifying TENS as a Class II device).

21. Pursuant to the 510(k) regulatory pathway, to receive "clearance" from FDA to distribute a new TENS device commercially, a marketer need only demonstrate that it is "substantially equivalent" to an existing device (the "predicate device") that is already legally marketed in the United States. *FDA Advice on Premarket Notification 510(k)*. An FDA finding of substantial equivalence means that the new device has the same intended use as the predicate

device and has either the same technological characteristics or different technological characteristics that do not raise different questions of safety and effectiveness. *Id.*; 21 U.S.C. § 360c(i)(1)(A). Thus, receiving FDA clearance to a sell a new TENS device for the same intended use as the predicate device does not require clinical testing demonstrating its safety or efficacy.

22. FDA has cleared Quell for use as a TENS device to relieve pain based on its substantial equivalence to predicate devices cleared for localized pain relief. FDA has not cleared Quell for use providing widespread relief of chronic or severe pain that is experienced beyond the site of application or that is due to specific health conditions, such as osteoarthritis, nerve damage, sciatica, shingles, and fibromyalgia.

23. 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 four years, continued their unlawful acts or practices despite knowledge of complaints that advertising claims for Quell were not substantiated and went beyond claims the FDA allowed for similar devices, and continued such deceptive advertising unabated until FTC staff notified them it would recommend law enforcement action.

VIOLATIONS OF THE FTC ACT

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

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

26. 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, Quell 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 QUELL

27. Through the means described in Paragraph 14, Defendants have represented, directly or indirectly, expressly or by implication, that:

A. Quell provides widespread relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site below the knee, such as in the lower back, shoulder, and opposite leg;

B. Quell achieves this widespread relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site below the knee, by activating areas of the brain responsible for the central inhibition of pain;

C. Quell relieves chronic or severe pain throughout the body due to a wide range of conditions, including osteoarthritis, nerve damage, sciatica, shingles, and fibromyalgia;

D. Four out of five persons achieve significant pain relief with Quell;

E. Eighty-one percent of persons achieve significant pain relief with Quell;

F. Two out of three persons significantly reduce their pain medication with Quell; and

G. Sixty-seven percent of persons significantly reduce their pain medication with Quell.

28. The representations set forth in Paragraph 27 are false or misleading or were not substantiated at the time the representations were made.

29. Therefore, the making of the representations as set forth in Paragraph 27 of this Complaint 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 II

FALSE PROOF CLAIMS FOR QUELL

30. Through the means described in Paragraph 14, Defendants have represented, directly or indirectly, expressly or by implication, that clinical studies prove that:

A. Quell provides widespread relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site below the knee, such as pain in the lower back, the shoulder, and the opposite leg;

B. Quell achieves this widespread relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site below the knee, by activating areas of the brain responsible for the central inhibition of pain;

C. Quell relieves chronic or severe pain throughout the body due to a wide range of conditions, including osteoarthritis, nerve damage, sciatica, shingles, and fibromyalgia;

D. Four out of five persons achieve significant pain relief with Quell;

E. Eighty-one percent of persons achieve significant pain relief with Quell;

F. Two out of three persons significantly reduce their pain medication with Quell; and

G. Sixty-seven percent of persons significantly reduce their pain medication with Quell.

31. The representations set forth in Paragraph 30 are false.

32. Therefore, the making of the representations as set forth in Paragraph 30 of this Complaint 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 III

FALSE CLAIMS ABOUT THE USE FOR WHICH FDA CLEARED QUELL

33. Through the means described in Paragraph 14, Defendants have represented, directly or indirectly, expressly or by implication, that FDA cleared Quell for use as a TENS device that:

A. Provides widespread relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site below the knee, such as pain in the lower back, shoulder, and opposite leg;

B. Achieves this widespread relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site below the knee, by activating areas of the brain responsible for the central inhibition of pain; and

C. Relieves chronic or severe pain throughout the body due to a wide range of conditions, including osteoarthritis, nerve damage, sciatica, shingles, and fibromyalgia.

34. The representations set forth in Paragraph 33 are false.

35. Therefore, the making of the representations as set forth in Paragraph 33 of this Complaint 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.

CONSUMER INJURY

36. 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

37. 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 but not limited to, 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: March 3, 2020

/s/ Laura M. Sullivan
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