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. 20cv10428-FDS

STIPULATED ORDER FOR PERMANENT INJUNCTION AND MONETARY JUDGMENT

Plaintiff, the Federal Trade Commission ("Commission" or "FTC"), filed its Complaint for Permanent Injunction and Other Equitable Relief ("Complaint"), for a permanent injunction and other equitable relief in this matter, pursuant to Section 13(b) of the Federal Trade Commission Act ("FTC Act"), 15 U.S.C. § 53(b). The Commission and Defendants stipulate to the entry of this Stipulated Order for Permanent Injunction and Monetary Judgment ("Order") to resolve all matters in dispute in this action between them.

THEREFORE, IT IS ORDERED as follows:

FINDINGS

1. This Court has jurisdiction over this matter.

2. The Complaint charges that Defendants participated in deceptive acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52, in the manufacturing, labeling, advertising, marketing, distribution, and sale of Quell and Quell 2.0, wearable transcutaneous electrical nerve stimulation Devices.

3. Defendants neither admit nor deny any of the allegations in the Complaint, except as specifically stated in this Order. Only for purposes of this action, Defendants admit the facts necessary to establish jurisdiction.

4. Defendants waive any claim that they may have under the Equal Access to Justice Act, 28 U.S.C. § 2412, concerning the prosecution of this action through the date of this Order, and agree to bear their own costs and attorney fees.

5. Defendants and the Commission waive all rights to appeal or otherwise challenge or contest the validity of this Order.

DEFINITIONS

For the purpose of this Order, the following definitions apply:

A. "**Defendants**" means the Individual Defendant and the Corporate Defendant, individually, collectively, or in any combination.

1. "**Corporate Defendant**" means NeuroMetrix, Inc., a corporation, and its successors and assigns.

2. "**Individual Defendant**" means Shai Gozani.

B. "**Device**" means an instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, which is: (1) recognized in the official National Formulary, or the United States Pharmacopeia, or any supplement to them; (2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in humans or other animals; or (3) intended to affect the structure or any function of the body of humans or other animals; and which does not achieve any of its principal intended purposes through chemical action within or

on the body of humans or other animals and which is not dependent upon being metabolized for the achievement of any of its principal intended purposes.

ORDER

I.
PROHIBITED REPRESENTATIONS: HEALTH-RELATED CLAIMS REQUIRING HUMAN CLINICAL TESTING FOR SUBSTANTIATION

IT IS ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation that such Device:

A. Provides widespread relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site;

B. Relieves chronic or severe pain throughout the body due to osteoarthritis, nerve damage, sciatica, shingles, fibromyalgia, or other specific health conditions; or

C. Relieves pain for a certain percentage of users or causes them to stop or reduce their use of medication to relieve pain

unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence substantiating that the representation is true.

For purposes of this Section, competent and reliable scientific evidence shall consist of human clinical testing of the Device that is sufficient in quality and quantity, based on standards

generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true. Such testing shall be (1) randomized, double blind, and sham-controlled; and (2) conducted by researchers qualified by training and experience to conduct such testing. In addition, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as described in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission.

II.
PROHIBITED REPRESENTATIONS: OTHER HEALTH-RELATED CLAIMS

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device, are permanently restrained and enjoined from making, or assisting others in making, expressly or by implication, including through the use of a product name, endorsement, depiction, or illustration, any representation, other than representations covered under the Section entitled Prohibited Representations: Regarding Health-Related Claims Requiring Human Clinical Testing For Substantiation, about the health benefits, performance, efficacy, safety, or side effects of any Device, unless the representation is non-misleading, and, at the time of making such representation, they possess and rely upon competent and reliable scientific evidence that is sufficient in quality and quantity based on standards generally accepted by experts in the relevant disease, condition, or function to which the representation relates, when

considered in light of the entire body of relevant and reliable scientific evidence, to substantiate that the representation is true.

For purposes of this Section, competent and reliable scientific evidence means tests, analyses, research, or studies (1) that have been conducted and evaluated in an objective manner by experts in the disease, condition, or function to which the representation relates; (2) that are generally accepted by such experts to yield accurate and reliable results; and (3) that are randomized, double-blind, and sham-controlled human clinical testing of the Device, when such experts would generally require such human clinical testing to substantiate that the representation is true. In addition, when such tests or studies are human clinical tests or studies, all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of such testing as set forth in the Section entitled Preservation of Records Relating to Competent and Reliable Human Clinical Tests or Studies must be available for inspection and production to the Commission.

III.
PROHIBITED REPRESENTATIONS: TESTS, STUDIES, OR OTHER RESEARCH

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device are permanently restrained and enjoined from misrepresenting, in any manner, expressly or by implication, including through the use of any product name, endorsement, depiction, or illustration:

A. That any Device is clinically proven to:

1. Provide widespread relief from chronic or severe pain, including pain experienced in areas of the body distant from the application site;
2. Activate areas of the brain responsible for the central inhibition of pain, and thereby relieve chronic or severe pain in the body beyond the application site;
3. Relieve chronic or severe pain throughout the body due to a wide range of conditions, including osteoarthritis, nerve damage, sciatica, shingles, and fibromyalgia; or
4. Relieve pain for a certain percentage of users or cause them to stop or reduce their use of medication to relieve pain;

B. That the performance or benefits of any Device are scientifically or clinically proven or otherwise established; or

C. The existence, contents, validity, results, conclusions, or interpretations of any test, study, or other research.

IV.
PROHIBITED REPRESENTATIONS: FDA CLEARANCE OF DEVICES FOR COMMERCIAL SALE

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, whether acting directly or indirectly, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device, are permanently restrained and enjoined from misrepresenting, or assisting others in misrepresenting, in any manner, expressly or by implication, including through the use of any product name, endorsement, depiction, or illustration, the existence, scope, or findings of any

premarket clearance or approval of such Device by the Food and Drug Administration, including that the Food and Drug Administration cleared or approved such Device for use as a Device that:

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

B. Activates areas of the brain responsible for the central inhibition of pain, and thereby relieves chronic pain in the body beyond the application site; or

C. Provides relief from chronic or severe pain throughout the body due to conditions such as osteoarthritis, nerve damage, sciatica, shingles, and fibromyalgia.

V.
PRESERVATION OF RECORDS RELATING TO COMPETENT AND RELIABLE HUMAN CLINICAL TESTS OR STUDIES

IT IS FURTHER ORDERED that, with regard to any human clinical test or study ("test") upon which Defendants rely to substantiate any claim covered by this Order, Defendants shall secure and preserve all underlying or supporting data and documents generally accepted by experts in the field as relevant to an assessment of the test, including:

A. All protocols and protocol amendments, reports, articles, write-ups, or other accounts of the results of the test, and drafts of such documents reviewed by the test sponsor or any other person not employed by the research entity;

B. All documents referring or relating to recruitment; randomization; instructions, including oral instructions, to participants; and participant compliance;

C. Documents sufficient to identify all test participants, including any participants who did not complete the test, and all communications with any participants relating to the test; all raw data collected from participants enrolled in the test, including any participants who did

not complete the test; source documents for such data; any data dictionaries; and any case report forms;

D. All documents referring or relating to any statistical analysis of any test data, including any pretest analysis, intent-to-treat analysis, or between-group analysis performed on any test data; and

E. All documents referring or relating to the sponsorship of the test, including all communications and contracts between any sponsor and the test's researchers.

Provided, however, the preceding preservation requirement does not apply to a reliably reported test, unless the test was conducted, controlled, or sponsored, in whole or in part by: (1) any Defendant; (2) any Defendant's officers, agents, representatives, or employees; (3) any other person or entity in active concert or participation with any Defendant; (4) any person or entity affiliated with or acting on behalf of any Defendant; or (5) the supplier or manufacturer of the Device at issue.

For purposes of this Section, "reliably reported test" means a report of the test has been published in a peer-reviewed journal, and such published report provides sufficient information about the test for experts in the relevant field to assess the reliability of the results.

For any test conducted, controlled, or sponsored, in whole or in part, by Defendants, Defendants must establish and maintain reasonable procedures to protect the confidentiality, security, and integrity of any personal information collected from or about participants. These procedures must be documented in writing and must contain administrative, technical, and physical safeguards appropriate to Corporate Defendant's size and complexity, the nature and scope of Defendants' activities, and the sensitivity of the personal information collected from or about the participants.

VI.
MONETARY JUDGMENT

IT IS FURTHER ORDERED that:

A. Defendants are ordered to pay to the Commission Four Million Dollars ($4,000,000), which, as Defendants stipulate, their undersigned counsel will hold in escrow for no purpose other than payment to the Commission. Such payment must be made within 30 days of entry of this Order by electronic fund transfer in accordance with instructions previously provided by a representative of the Commission. If the full payment is not made within 30 days, it becomes immediately due, less any payment previously made, plus interest computed from the date of entry of this Order.

B. Corporate Defendant NeuroMetrix is ordered to turn over to the Commission all commercial milestone payments received under Paragraph 3(viii)-(x) of Amendment No. 1 to the Development and Services Agreement between Corporate Defendant NeuroMetrix and GlaxoSmithKline plc ("GSK") dated December 6, 2018, and any amendment or supplement thereto. Defendants immediately shall remit the full amount of such payments received from GSK to the Commission or its designated agent by electronic fund transfer in accordance with instructions previously provided by a representative of the Commission. Defendants represent that there is no restriction on the transfer of such funds to the Commission.

VII.
ADDITIONAL MONETARY PROVISIONS

IT IS FURTHER ORDERED that:

A. Defendants relinquish dominion and all legal and equitable right, title, and interest in all assets transferred pursuant to this Order and may not seek the return of any assets.

B. The facts alleged in the Complaint will be taken as true, without further proof, in any subsequent civil litigation by or on behalf of the Commission, including in a proceeding to enforce its rights to any payment or monetary judgment pursuant to this Order, such as a nondischargeability complaint in any bankruptcy case.

C. The facts alleged in the Complaint establish all elements necessary to sustain an action by the Commission pursuant to Section 523(a)(2)(A) of the Bankruptcy Code, 11 U.S.C. § 523(a)(2)(A), and this Order will have collateral estoppel effect for such purposes.

D. Defendants acknowledge that their Taxpayer Identification Numbers (Social Security Numbers or Employer Identification Numbers), which Defendants must submit to the Commission, may be used for collecting and reporting on any delinquent amount arising out of this Order, in accordance with 31 U.S.C. §7701.

E. All money paid to the Commission pursuant to this Order may be deposited into a fund administered by the Commission or its designee to be used for equitable relief, including consumer redress and any attendant expenses for the administration of any redress fund. If a representative of the Commission decides that direct redress to consumers is, wholly or partially, impracticable or money remains after redress is completed, the Commission may apply any remaining money for such other equitable relief (including consumer information remedies) as it determines to be reasonably related to Defendants' practices alleged in the Complaint. Any money not used for such equitable relief is to be deposited to the U.S. Treasury as disgorgement. Defendants have no right to challenge any actions the Commission or its representatives may take pursuant to this Subsection.

VIII.
CUSTOMER INFORMATION

IT IS FURTHER ORDERED that Defendants, Defendants' officers, agents, employees, and attorneys, and all other persons in active concert or participation with any of them, who receive actual notice of this Order, are permanently restrained and enjoined from directly or indirectly failing to provide sufficient customer information to enable the Commission to efficiently administer consumer redress. If a representative of the Commission requests in writing any information related to redress, Defendants must provide it, in the form prescribed by the Commission, within 14 days.

IX.
ORDER ACKNOWLEDGMENTS

IT IS FURTHER ORDERED that Defendants obtain acknowledgments of receipt of this Order:

A. Each Defendant, within 7 days of entry of this Order, must submit to the Commission an acknowledgment of receipt of this Order sworn under penalty of perjury.

B. For 5 years after entry of this Order, Individual Defendant for any business that such Defendant, individually or collectively with any other Defendant, is the majority owner or controls directly or indirectly, and Corporate Defendant must deliver a copy of this Order to: (1) all principals, officers, directors, and LLC managers and members; (2) all employees having managerial responsibilities for conduct related to the subject matter of the Order and all agents and representatives who participate in conduct related to the subject matter of the Order; and (3) any business entity resulting from any change in structure as set forth in the Section titled Compliance Reporting. Delivery must occur within 7 days of entry of this Order for current personnel. For all others, delivery must occur before they assume their responsibilities.

C. From each individual or entity to which a Defendant delivered a copy of this Order, that Defendant must obtain, within 30 days, a signed and dated acknowledgment of receipt of this Order.

X.
COMPLIANCE REPORTING

IT IS FURTHER ORDERED that Defendants make timely submissions to the Commission:

A. Sixty days after entry of this Order, each Defendant must submit a compliance report, sworn under penalty of perjury:

1. Each Defendant must: (a) identify the primary physical, postal, and email address and telephone number, as designated points of contact, which representatives of the Commission may use to communicate with Defendant; (b) identify all of that Defendant's businesses by all of their names, telephone numbers, and physical, postal, email, and Internet addresses; (c) describe the activities of each business, including the goods and services offered, the means of advertising, marketing, and sales, and the involvement of any other Defendant (which Individual Defendant must describe if he knows or should know due to his own involvement); (d) describe in detail whether and how that Defendant is in compliance with each Section of this Order; and (e) provide a copy of each Order Acknowledgment obtained pursuant to this Order, unless previously submitted to the Commission.

2. Additionally, Individual Defendant must: (a) identify all telephone numbers and all physical, postal, email, and Internet addresses, including all residences; (b) identify all business activities, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest; and (c) describe in detail such Defendant's involvement in each such

business, including title, role, responsibilities, participation, authority, control, and any ownership.

B. For 10 years after entry of this Order, each Defendant must submit a compliance notice, sworn under penalty of perjury, within 14 days of any change in the following:

1. Each Defendant must report any change in: (a) any designated point of contact; or (b) the structure of Corporate Defendant or any entity that Defendant has any ownership interest in or controls directly or indirectly that may affect compliance obligations arising under this Order, including: creation, merger, sale, or dissolution of the entity or any subsidiary, parent, or affiliate that engages in any acts or practices subject to this Order.

2. Additionally, Individual Defendant must report any change in: (a) name, including aliases or fictitious name, or residence address; or (b) title or role in any business activity, including any business for which such Defendant performs services whether as an employee or otherwise and any entity in which such Defendant has any ownership interest, and identify the name, physical address, and any Internet address of the business or entity.

C. Each Defendant must submit to the Commission notice of the filing of any bankruptcy petition, insolvency proceeding, or similar proceeding by or against such Defendant within 14 days of its filing.

D. Any submission to the Commission required by this Order to be sworn under penalty of perjury must be true and accurate and comply with 28 U.S.C. § 1746, such as by concluding: "I declare under penalty of perjury under the laws of the United States of America that the foregoing is true and correct. Executed on: _____" and supplying the date, signatory's full name, title (if applicable), and signature.

E. Unless otherwise directed by a Commission representative in writing, all submissions to the Commission pursuant to this Order must be emailed to DEbrief@ftc.gov or sent by overnight courier (not the U.S. Postal Service) to: Associate Director for Enforcement, Bureau of Consumer Protection, Federal Trade Commission, 600 Pennsylvania Avenue NW, Washington, DC 20580. The subject line must begin: *FTC v. NeuroMetrix, Inc.*, FTC No. X_____.

XI.
RECORDKEEPING

IT IS FURTHER ORDERED that Defendants must create certain records for 10 years after entry of the Order, and retain each such record for 5 years. Specifically, Corporate Defendant, in connection with the manufacturing, labeling, advertising, promotion, offering for sale, sale, or distribution of any Device, and Individual Defendant for any business that such Defendant, individually or collectively with any other Defendant, is a majority owner or controls directly or indirectly, must create and retain the following records:

A. Accounting records showing the revenues from all goods or services sold;

B. Personnel records showing, for each person providing services, whether as an employee or otherwise, that person's: name; addresses; telephone numbers; job title or position; dates of service; and (if applicable) the reason for termination;

C. Records of all consumer complaints and refund requests, whether received directly or indirectly, such as through a third party, and any response;

D. All records necessary to demonstrate full compliance with each provision of this Order, including all submissions to the Commission; and

E. A copy of each unique advertisement or other marketing material for any Device.

XII.
COMPLIANCE MONITORING

IT IS FURTHER ORDERED that, for the purpose of monitoring Defendants' compliance with this Order, including any failure to transfer any assets as required by this Order:

A. Within 14 days of receipt of a written request from a representative of the Commission, each Defendant must: submit additional compliance reports or other requested information, which must be sworn under penalty of perjury; appear for depositions; and produce documents for inspection and copying. The Commission is also authorized to obtain discovery, without further leave of court, using any of the procedures prescribed by Federal Rules of Civil Procedure 29, 30 (including telephonic depositions), 31, 33, 34, 36, 45, and 69.

B. For matters concerning this Order, the Commission is authorized to communicate directly with each Defendant. Defendant must permit representatives of the Commission to interview any employee or other person affiliated with any Defendant who has agreed to such an interview. The person interviewed may have counsel present.

C. The Commission may use all other lawful means, including posing through its representatives as consumers, suppliers, or other individuals or entities, to Defendants or any individual or entity affiliated with Defendants, without the necessity of identification or prior notice. Nothing in this Order limits the Commission's lawful use of compulsory process, pursuant to Sections 9 and 20 of the FTC Act, 15 U.S.C. §§ 49, 57b-1.

D. Upon written request from a representative of the Commission, any consumer reporting agency must furnish consumer reports concerning Individual Defendant, pursuant to Section 604(1) of the Fair Credit Reporting Act, 15 U.S.C. §1681b(a)(1).

XIII.
RETENTION OF JURISDICTION

IT IS FURTHER ORDERED that this Court retains jurisdiction of this matter for purposes of construction, modification, and enforcement of this Order.

SO ORDERED this 4th day of March, 2020.

UNITED STATES DISTRICT JUDGE

SO STIPULATED AND AGREED:

FOR PLAINTIFF FEDERAL TRADE COMMISSION

/s/ Laura M. Sullivan

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Date: 1/16/20

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DEFENDANTS NEUROMETRIX, INC. AND SHAI GOZANI

Date: JAN. 16, 2020

Shai Gozani, individually and
as an officer of NeuroMetrix, Inc.