

**IN THE UNITED STATES DISTRICT COURT
FOR THE NORTHERN DISTRICT OF ILLINOIS
EASTERN DIVISION**

FEDERAL TRADE COMMISSION,)	
)	
Plaintiff,)	Case No. 03 C 3578
)	
v.)	Magistrate Judge Morton Denlow
)	
QT, INC., Q-RAY COMPANY,)	
BIO-METAL, INC., QUE TE PARK,)	
a.k.a. ANDREW Q. PARK, and)	
JUNG JOO PARK,)	
)	
Defendants.)	

MEMORANDUM OPINION AND ORDER

**“The pain just went away.”
“Within seconds the pain was gone.”
“You don’t have to live with pain.”**

The Q-Ray® Ionized Bracelet® (“Q-Ray bracelet”) achieved tremendous commercial success through a series of 30-minute infomercials. The Federal Trade Commission (“FTC”) brings this action claiming Defendants marketed the Q-Ray bracelet in a deceptive and misleading manner by representing that the bracelet provides immediate, significant or complete pain relief and scientific tests prove their pain-relief claims. Defendants deny their advertising was false or misleading. They contend adequate substantiation exists for the advertising claims made in connection with the promotion and sale of the Q-Ray bracelet.

The Court conducted a seven-day bench trial between June 6 and July 11, 2006. The Court has carefully considered the testimony of the witnesses who testified in person and by deposition, the Joint Stipulations of Fact for Trial, the exhibits introduced into evidence, the written submissions of the parties, and the oral arguments of counsel. The counsel on both sides presented the case in a highly professional manner.

The following constitutes the Court's findings of fact and conclusions of law pursuant to Rule 52(a) of the Federal Rules of Civil Procedure. To the extent certain findings may be deemed conclusions of law, they shall be considered conclusions. Similarly, to the extent matters contained in the conclusions of law may be deemed findings of fact, they also shall be considered findings.

I. NATURE OF THE ACTION.

The FTC brings this action under § 13(b) of the Federal Trade Commission Act (“the Act”) seeking monetary and injunctive relief for alleged violations of §§ 5 and 12 of the Act. 15 U.S.C. §§ 45(a), 52 and 53(b). The FTC's complaint alleges three violations of the Act by Defendants.

In Count I, the FTC alleges Defendants represented that the Q-Ray bracelet “provides immediate significant or complete relief from various types of pain, including, but not limited to, musculoskeletal pain, sciatic pain, persistent headaches, sinus problems, tendonitis, or injuries.” (Comp. ¶ 19). In Count II, the FTC alleges Defendants represented that “tests prove that the [Q-Ray bracelet] relieves pain.” (Comp. ¶ 21). The FTC claims these representations were false or Defendants lacked a reasonable basis for these representations

in violation of the Act. In Count III, the FTC alleges Defendants falsely represented that QT's 30-day satisfaction guarantee permits "consumers to readily obtain a full refund of the purchase price if they return the [Q-Ray bracelet] within 30 days." (Comp. ¶ 24). The Defendants deny these allegations.

II. ISSUES PRESENTED.

The following issues are presented:

1. Whether the FTC has met its burden of proving that QT, Inc.'s advertising was likely to mislead a reasonable consumer in violation of the Act. Yes.
2. Whether the FTC has met its burden of proving that QT, Inc.'s advertising represented, without a sufficient basis, that tests prove that the Q-Ray bracelet relieves pain in violation of the Act. Yes.
3. Whether the FTC has met its burden of proving that the Q-Ray bracelet is a device within the meaning of § 12 of the Act. Yes.
4. Whether the FTC has met its burden of proving that QT's refund policy did not permit consumers to readily obtain a refund of the purchase price. Yes.
5. Whether Que Te Park is personally liable for the violations of the Act. Yes.
6. Whether Jung Joo Park is personally liable for the violations of the Act. No.
7. Whether the Court should order equitable relief in the form of consumer redress, disgorgement and restitution. Yes.
8. Whether the FTC has established a basis for permanent injunctive relief. Yes.

III. PROCEDURAL BACKGROUND.

On May 27, 2003, the FTC filed a Complaint for Injunctive and Other Equitable Relief ("Complaint") in this action, naming as defendants QT, Inc., Q-Ray Company, Bio-

Metal, Inc., Que Te Park, a.k.a. Andrew Q. Park, and Jung JooPark. *Stipulated*.¹

On May 29, 2003, the Court granted the FTC's motion for an *ex parte* temporary restraining order and asset freeze. *Stipulated*; Dkt. 2.

On June 11, 2003, the Court entered a stipulated preliminary injunction with asset transfer restrictions and other equitable relief. *Stipulated*; Dkt. 34; PX 3.

IV. FINDINGS OF FACT.

A. THE PARTIES.

1. Plaintiff Federal Trade Commission.

The FTC is an independent agency of the United States Government created by statute. 15 U.S.C. §§ 41-58. The FTC enforces Sections 5(a) and 12 of the Act, 15 U.S.C. §§ 45(a) and 52, which prohibit, respectively, unfair or deceptive acts or practices, and false advertisements for food, drugs, devices, services, or cosmetics in or affecting commerce. The FTC is authorized to initiate federal district court proceedings, by its own attorneys, to enjoin violations of the Act and secure such equitable relief as may be appropriate in each case, including consumer redress. 15 U.S.C. § 53(b).

2. Defendant QT, Inc.

Defendant QT, Inc. ("QT") is an Illinois corporation with its principal place of business at 500 W. Algonquin Road, Mt. Prospect, Illinois. It transacts or has transacted business in the Northern District of Illinois and throughout the United States. Since at least

¹*Stipulated* refers to facts stipulated to by the parties. T.____ refers to the trial transcript. PX____ refers to the FTC's trial exhibits and DX____ refers to Defendants' trial exhibits. Dkt.____ refers to a docket entry in the Court's docket. The Court has cited to certain stipulations, transcript pages and exhibits, but relies upon the entire record in support of this decision.

1996, QT has advertised, marketed, and sold the Q-Ray bracelet via U.S. media outlets and identical Internet sites, www.gray.com, www.q-ray.com, and www.bio-ray.com. *Stipulated.*

3. Defendant Q-Ray Company.

Defendant Q-Ray Company (“QRC”) is an Illinois corporation with its principal place of business at 500 W. Algonquin Road, Mt. Prospect, Illinois. It transacts or has transacted business in the Northern District of Illinois and throughout the United States through the distribution of the Q-Ray bracelet. *Stipulated.*

QRC has performed the fulfillment operations of QT, including shipping the Q-Ray bracelet to consumers and receiving returned products from consumers since mid-2002. *Stipulated.*

4. Defendant Bio-Metal, Inc.

Defendant Bio-Metal, Inc. (“Bio-Metal”), which was formerly known as Bio-Ray International, Inc., is an Illinois corporation with its principal place of business at 500 W. Algonquin Road, Mt. Prospect, Illinois. *Stipulated.*

5. Defendant Que Te Park.

At all relevant times, defendant Que Te Park, also known as Andrew Q. Park (“Que Te Park”), was and is the President of QT, QRC, and Bio-Metal. He resides and/or transacts business in the Northern District of Illinois. *Stipulated.* He testified at the trial and certain of his deposition excerpts were also introduced as evidence. PX 19.

Que Te Park has been the Chief Executive Officer of QT and QRC since at least 2001. Que Te Park is the sole shareholder of QT and QRC. *Stipulated.*

6. Defendant Jung Joo Park.

Defendant Jung Joo Park is Que Te Park's wife. She resides in the Northern District of Illinois. *Stipulated.* She testified by means of a deposition. PX 311.

From at least 1987 through June 2003, Jung Joo Park was Secretary of QT. She was listed as Secretary of QT in the company's annual reports to the State of Illinois for the years 1999 through 2002. Jung Joo Park was listed as a Secretary of QT until at least June 2005. From at least 2000 through June 2003, Jung Joo Park was Secretary of QRC. She was listed as Secretary of QRC in the company's annual reports to the State of Illinois for the years 1999 through 2002. Jung Joo Park, as Secretary of those entities, had signatory authority for eight of the ten QT and QRC corporate bank accounts. *Stipulated.*

Jung Joo Park worked full-time at QT from 2001 through at least August of 2004. She has worked for QT for a total of 15 years. *Stipulated.* For her \$98,000 salary, Jung Joo Park looks after the office when Que Te Park is out of the country. She also helps any place around the office that needs a hand and has no set position. T. 606-07. Jung Joo Park assists QT in areas that are short-staffed, and sometimes, for example, goes to the factory to help with assembly and shipping and handling. *Stipulated.*

Jung Joo Park assists with employee relations at QT, and she consults with Korean-speaking employees regarding internal conflicts among those employees. *Stipulated.*

Jung Joo Park was not involved in the marketing of the Q-Ray bracelet. She was not involved in the creation, review, media placement, or production of any of the Q-Ray bracelet infomercials. She had no authority over the customer service department policies. PX 311 at 21-4.

B. FACT WITNESSES.

1. Charles Park.

Que Te Park's and Jung Joo Park's son, Charles Park, has been employed by QT since approximately 2002 and has served as an executive vice-president since May or June of 2003. He oversees the activities of the vice-presidents of operations, finance, marketing, and sales. He currently reports to Que Te Park. Before that, he was vice-president in charge of information technology and some administrative areas, including some parts of operations and some parts of finances. *Stipulated.* Charles Park testified at the trial.

2. Crystal Holloway.

Crystal Holloway ("Holloway") has been employed by QT as a senior customer service manager since February, 2003. She testified by means of a deposition. PX 312.

3. Elizabeth Ann Ciprian.

Elizabeth Ann Ciprian ("Ciprian") was employed at QT from 1990 to 2003. From 1999 to 2003, she was the sales and marketing manager. T. 190-91, 202. She testified at the trial.

4. DeAnn Trapp.

DeAnn Trapp ("Trapp") was a graduate student at Northern Illinois University in 2001 and 2002 when she performed two studies involving the Q-Ray bracelet. Her married name is now DeAnn Petitgout. She testified at the trial.

5. Dr. Robert Bratton.

Dr. Robert Bratton (“Dr. Bratton”) is employed by the Mayo Clinic in the Department of Family Medicine and as an Associate Professor at the Mayo College of Medicine in Jacksonville, Florida. He conducted a clinical trial of the Q-Ray bracelet, which resulted in a published study. PX 280. He testified by means of two depositions. DX 42-3.

6. Linda Hall.

Linda Hall (“Hall”) is employed at the Mayo Clinic in Jacksonville, Florida. She was a clinical research coordinator who assisted Dr. Bratton in the Q-Ray bracelet study. She testified by means of a deposition. DX 44.

C. EXPERT WITNESSES.

Six expert witnesses testified at the trial:

1. Dr. Marc C. Hochberg - FTC Expert.

Dr. Marc C. Hochberg (“Dr. Hochberg”) is a Professor of Medicine, Professor of Epidemiology & Preventive Medicine, and Head of the Division of Rheumatology & Clinical Immunology at the University of Maryland School of Medicine. *Stipulated*; PX 293 (Dr. Hochberg’s CV). Dr. Hochberg testified as an expert in the fields of: (a) rheumatic diseases, including arthritis and other musculoskeletal disorders; (b) clinical testing related to prevention and treatment of rheumatic diseases; and (c) pain due to rheumatic disease. *Stipulated.*

2. John P. Wikswo, Jr., Ph.D. - FTC Expert.

Dr. John P. Wikswo, Jr. (“Dr. Wikswo”) is a Professor of Biomedical Engineering, Professor of Molecular Physiology and Biophysics, Professor of Physics, and Director of the Vanderbilt Institute for Integrative Biosystems Research and Education at Vanderbilt University. Dr. Wikswo testified as an expert in biological physics, biomedical engineering, and electromagnetism. *Stipulated*; PX 294 (Dr. Wikswo’s CV).

3. Michael Feldstein, Ph.D. - Defendants’ Expert.

Dr. Michael Feldstein (“Dr. Feldstein”) has a Ph.D. in statistics from the State University of New York at Buffalo and is the Vice-President for Clinical Services at Medical Device Consultants, Inc. His responsibilities as Vice-President include running the department of clinical services, which seeks to design, conduct, and manage clinical trials for clients. DX 19 (Dr. Feldstein’s CV). He testified as an expert in the area of statistics and biostatistics and the conduct of clinical trials. T. 673-79.

4. William A. Tiller, Ph.D. - Defendants’ Expert.

Dr. William A. Tiller (“Dr. Tiller”) is Professor Emeritus from Stanford University in the fields of applied science and materials science. DX 20 (Dr. Tiller’s CV). Dr. Tiller testified as an expert in materials science.

5. Dr. Brian Olshansky - Defendants’ Expert.

Dr. Brian Olshansky (“Dr. Olshansky”) is a Professor of Medicine and the director of Cardiac Electrophysiology at the University of Iowa Hospitals. DX 18 (Dr. Olshansky’s

CV). He testified as an expert in the fields of electrophysiology, complementary and alternative medicine, and the placebo effect.

6. Frank Yurasek, Ph.D. - Defendants' Expert.

Dr. Frank Yurasek ("Dr. Yurasek") holds a Masters degree and Ph.D. in Oriental Medicine. DX 21 (Dr. Yurasek's CV). He testified as an expert in the area of eastern Asian and Traditional Chinese Medicine. T. 919, 922-23.

D. OTHER PARK-RELATED FAMILY MEMBERS AND BUSINESSES.

1. James Park.

Que Te Park's and Jung Joo Park's son, James Park, has worked full-time at QT in creative design since 2000 or 2001 and was listed as a Director of QT, Inc. on the company's 2002 annual report to the State of Illinois. *Stipulated.*

2. Ion-Ray.

Ion-Ray is a Canadian corporation that distributes the Q-Ray bracelet in Canada. Charles Park is an officer, director, and shareholder of Ion-Ray. The other shareholders of Ion-Ray are James Park and Nina Park, Jung Joo Park's children. Ion-Ray received at least \$4 million in start-up funding from QT, Inc. *Stipulated.*

E. THE Q-RAY BRACELET.

The Q-Ray bracelet is a C-shaped bracelet with screw caps that is manufactured in Spain by Bio-Ray S.A. PX 55 (brochure); T. 346. The bracelet comes in four sizes: x-small, small, medium and large. PX 55. The bracelet is made in six styles at different price points:

Natural Titan Finish, Standard Silver Plated, Standard Gold Plated, Deluxe Silver Finish, Deluxe Combo and Deluxe Gold Plated. PX 55.

Que Te Park first saw the bracelet in the Barcelona, Spain airport in 1994. It was being sold by Bio-Ray, S.A. as the Bio-Ray bracelet. He purchased the bracelet and he believes it helped relieve his lower back pain. He also purchased one for his wife to relieve her migraines. T. 353-54.

Beginning in 1996, QT began selling the bracelet on a mostly wholesale basis in the United States under the Q-Ray name. QT began selling directly to consumers by means of infomercials in 2000. T. 327.

None of the experts analyzed the composition of the Q-Ray bracelet. Que Te Park represented to the Mayo Clinic that the bracelet is 85% copper and 15% zinc. T. 364-65; PX 180. Although the bracelet is composed of more than 50% copper, Que Te Park acknowledged that the infomercials say the Q-Ray bracelet is not copper. T. 368-69. Que Te Park testified that all of the different compositions of the bracelet and different metal plating used in the various styles do not affect the performance of the Q-Ray bracelet in any way. Each bracelet works the same through ionization. PX 19 at 251:7-252:2.

According to Que Te Park, the Q-Ray bracelet is unique because of the ionization. He testified in his deposition that when he uses the term “ionizing” with respect to the Q-Ray Bracelet’s ionizing process, he is referring to a high-voltage process that changes metal

conductivity. PX 19 at 252:10-253:1. He testified that it makes the metal more conductive, with less resistance. PX 19 at 253:3-8.

Que Te Park does not know how much electric charge is delivered to the Q-Ray bracelet. Although he has seen a figure of 150,000 volts put out on a technical information sheet by the factory, he does not believe that figure because if it were a secret, the factory would not disclose it. PX 19 at 263:4-264:7; 255:25-257:7.

Que Te Park testified during the trial, however, that he picked the term ‘ionized’ because “ionized is very simple, very easy to remember.” T. 355. Moreover, despite trademarking the term “ionized,” he has no definition for the term and now claims he did not intend to convey to consumers the notion that the Q-Ray bracelet is electrically charged. T. 358-59. He selected the name ionized because the Polaroid Company prevented him from using the name “polarized.” T. 360. Que Te Park then testified that the manufacturer called the process that is applied to the bracelets “polarization,” meaning that the bracelets are electrically charged and that he uses the term “ionization” to mean “polarization.” T. 359-60.

Que Te Park has no idea what the polarization process is supposed to do to the bracelet. Polarization, however, is a shorthand Que Te Park uses to say the bracelet is electrically charged. T. 360. Que Te Park testified that he needs more studies and cannot say that the Q-Ray bracelet affects ions within the body. PX 19 at 246:16-22.

QT does not confirm through independent testing that each bracelet it receives from Bio-Ray S.A., the manufacturer in Spain, is actually ionized. PX 7 at No. 283; PX 8 at No. 360.

QT does not have any tests or studies to prove that the Q-Ray bracelet actually discharges ions. T. 379.

Que Te Park testified that “ionization” has no scientific meaning. He has no idea what the phrase “ionization performance,” which appears in his consumer brochures, means. T. 371-72. His testimony on ionization was contradictory and full of obfuscation. He was lacking in credibility. He is a clever marketer but a poor witness.

Que Te Park made up the theory that the bracelet works like acupuncture or Eastern medicine. He has *no* testing or studies to support his theory. T. 379. He testified that anyone can find the theory on Google. T. 376-79.

There was no scientific evidence presented that the Q-Ray bracelet actually receives, retains, or emits an electrical charge or has any properties different from any other bracelet made from the same metals. The Q-Ray bracelet was marketed as an “ionized bracelet” as part of a scheme devised by Que Te Park and the corporate defendants (hereafter collectively referred to as “Defendants”) to defraud consumers out of millions of dollars by preying on their desire to find a simple solution to alleviate their physical pain.

F. ADVERTISING AND SALE OF THE Q-RAY BRACELET.

1. Advertising Scope.

Since at least September 2000, QT, QRC, and/or Bio-Metal advertised, promoted, offered for sale, sold, and distributed the Q-Ray bracelet to the public nationally, using advertisements in print media, the Internet, and on cable television stations such as the Golf Channel, the Learning Channel, USA Network, and the Discovery Channel. T. 327-29; PX

4 at ¶ 12.; PX 7 at No. 27; PX 8 at No. 29. *Stipulated as to QT, Inc. only.*

QT also has dealers, which are mostly stores, and Internet distributors. The company does not give its dealers advertisements, but asks them to refer to QT's website. QT monitors its distributors' claims. PX 19 at 59:12-61:6.

To induce consumers to purchase Q-Ray bracelets, QT, QRC, and/or Bio-Metal have disseminated or caused to be disseminated at least four different television infomercials, Internet advertisements on www.qray.com, www.q-ray.com and www.bio-ray.com, and a product brochure. The advertisements disseminated include Exhibits A, C, and D to the Complaint. PX 4 ¶ 13; PX 7 at Nos. 58, 61. *Stipulated as to QT, Inc. only.*

Infomercials for the Q-Ray bracelet aired 42,213 times between April 14, 2001 and June 29, 2003. Short spot television advertisements for the Q-Ray bracelet aired approximately 10,147 times between March 11, 2002 and September 8, 2003. *Stipulated.*

The first infomercial ("Prime Time infomercial") ran from August 2000 through May 2001. The second infomercial ("Onyx infomercial") ran from June 2001 through October 2001. The third infomercial ("Warren infomercial") ran from November 2001 through April 2002. The fourth infomercial, which is Exhibit A to the Plaintiff's complaint ("Complaint infomercial"), aired from May 2002 through June 2003. *Stipulated.*

2. Development of the Advertising.

QT employed Ciprian between October 1990 and July 2003 and she served as QT's sales and marketing manager from at least 1999 to July 2003. *Stipulated.* As sales and marketing manager, it was part of Ciprian's job to help create advertisements for the Q-Ray

bracelet and market the product. She reported to Que Te Park for approval of the advertisements. T. 201.

Prior to filming the infomercials, the production companies prepared scripts for only the infomercial hosts and voiceovers. Except for the script for the first infomercial, QT reviewed those scripts prior to filming. *Stipulated.* Ciprian was responsible for verifying the accuracy of the testimonials. T. 221.

QT hired Prime Time Sports to create the Prime Time infomercial in approximately January or February 2000. The first production of the infomercial was tested in August 2000. QT, including Ciprian and Que Te Park, gave Prime Time Sports basic product information that was included in the infomercial. Que Te Park was present during portions of the filming of the Prime Time infomercial. He watched the interview between the host, Mitch Laurence, and Dr. Jeremy Cole. *Stipulated.*

A lawsuit was filed against QT in approximately December of 2000, about three months after the first infomercial started airing. Because of this lawsuit in California, the Onyx infomercial was created as a re-edited version of the Prime Time infomercial. *Stipulated.*

After the first infomercial, QT's VP of Marketing or VP for Television Media was generally responsible for creating television advertisements. Loren Skagen and Gene Semmelhack held that position. T. 397-98. Skagen worked together with the infomercial producers to write the scripts for the Warren and Complaint infomercials. PX 19 at 61:21-63:10, 83:7-17, and 86:9-19.

Starting at least with the Warren infomercial, Que Te Park received a report from the vice-president of marketing regarding the creation of the infomercials. Before the film was shot, Que Te Park looked at scripts and corrected things, required that certain language not be used, or required the use of more disclaimers. He also sometimes reviewed semi-finished versions of the infomercial before they were sent to legal counsel. *Stipulated.*

QT was involved with creating a website for the Q-Ray bracelet. QT believed that television infomercials would increase website sales. Prior to infomercials, QT had modest revenues from its website sales. Those sales increased in September 2000 after the first infomercial began airing. *Stipulated.*

QT was involved with creating brochures and print advertisements for the Q-Ray bracelet. Plaintiff's Exhibit 55 is a true and correct copy of the brochure that advertised the Q-Ray bracelet. *Stipulated.*

QT registered the phrase, "NATURAL PAIN RELIEF" as a trademark. QT filed for the trademark on or about March 25, 1999, and the trademark was registered on or about June 18, 2002. *Stipulated.* QT also trademarked the term "ionized bracelet." T. 335.

Que Te Park exercised final approval authority over QT's television, print, and radio advertisements and brochures before these advertisements and brochures were disseminated.

He also had final approval of advertising copy on the website for the Q-Ray bracelet. PX 8 at Nos. 44-46; T. 337, 385-86.

G. DEFENDANTS' ADVERTISING FOR THE Q-RAY BRACELET CONVEYED THE CLAIM TO THE CONSUMER THAT THE Q-RAY BRACELET PROVIDES IMMEDIATE, SIGNIFICANT OR COMPLETE PAIN RELIEF.

Defendants' four infomercials that aired between 2000 and 2003 convey, expressly or by implication, the net impression that the Q-Ray bracelet provides immediate, significant or complete relief from various types of pain, including but not limited to, musculoskeletal pain, sciatic pain, persistent headaches, sinus problems, tendinitis, or injuries. PX 39 and PX 40 (Complaint); PX 46 and PX 47 (Primetime); PX 48 and PX 49 (Onyx); PX 50 and PX 51 (Warren Group)². These claims are material, false, and were relied upon by consumers in making their purchases of the Q-Ray bracelet.

1. Complaint infomercial (PX 39 and PX 40).

The Complaint infomercial presents apparently satisfied users of the Q-Ray bracelet in order to convey the message that the Q-Ray bracelet provides immediate, significant or complete relief from pain. The Complaint infomercial begins with an unidentified female stating, "I got tingly all over and the pain is gone." PX. 40 at 3:17-18.³ Then, following a narrator's introduction of the Q-Ray bracelet, an unidentified female states that "And I felt this tingly throughout my body and all of a sudden – I didn't feel the pain anymore." PX 40

²PX 39, 46, 48, and 50 are the videotapes of the infomercials. PX 40, 47, 49, and 51 are the written transcripts of those infomercials.

³This testimonial also appears in a previous version of the infomercial (Warren Group). See PX 50; PX 51 at 3:10-11.

at 5:4-8.⁴ This testimonial is accompanied by the onscreen, written statement “I didn’t feel the pain anymore.” PX 40 at 5:6. This is immediately followed by Howard Wyckoff stating “I came up here, put [the Q-Ray bracelet] on my wrist, and immediately my shoulder – I have movement . . . the pain really just went away.” PX 40 at 5:12-19.⁵ This testimonial is accompanied by the onscreen, written statement “the pain just went away.” PX 40 at 5:17.

The message that the Q-Ray bracelet provides immediate relief from pain is repeatedly reinforced by the infomercial. The announcer then states that the Q-Ray bracelet is “designed to help the body restore its normal equilibrium the natural way, to reduce pain . . .” PX 40 at 6:16-18. This is immediately followed by an unidentified male who confirms the narrator’s assertion by saying, “My back has been bothering me probably for the last – I’d say for about the last four or five years. . . . And when he put this [the Q-Ray bracelet] on me, it was almost – within 10 or 15 seconds, the pain was gone.” PX 40 at 6:25 - 7:6. This is further reinforced by the onscreen, written statement, “within seconds the pain was gone.” The Complaint infomercial explicitly conveys the message that the Q-Ray bracelet provides immediate relief from back pain.

⁴This testimonial also appears in a previous version of the infomercial. See PX 51 at 28:12-14.

⁵This testimonial also appears in previous versions of the infomercial. See PX 46 (Prime Time), PX 47 at 12:19-22, PX 48 (Onyx), and PX 49 at 11:18-21.

The immediacy of the pain relief provided by the Q-Ray bracelet is continually reaffirmed. Thus, testimonialist Sheila Thompson states that she “wore it last night and in 24 hours all my pains disappeared from my arm, my hip and my shoulder.” PX 40 at 9:12-14.⁶ Immediately thereafter, Allen Brown states that “[i]t was amazing to me that it worked that quickly.” PX 40 at 9:15-16. This was further reinforced by Sandra Kohler’s statement that “[i]t’s just been over an hour and I don’t have any pain,” which is trailed by the following colloquy between unidentified female and male testimonialists: “The pain is gone.” “The pain is gone?” “Yes.” “Right away?” “Yeah, immediately.” “Yeah.” “It is better.” “Better right away.” PX 40 at 9:19 - 10:3. These statements clearly communicate and reinforce the immediacy of the pain relief provided by the Q-Ray bracelet.

The infomercial further promotes the efficacy of the Q-Ray bracelet at relieving pain when testimonialist Ken Bruhn relates his observation of various satisfied users:

What I’m amazed at is person after person in line has reported, you know, my pain is gone, my pain is gone. I’ve never heard anybody and watching this for an hour, I’ve never seen anybody say, gee, that doesn’t help me at all. There’s not been one negative response. I don’t know how you could beat that.

PX 40 at 10:25 - 11:5. The types of pain the Q-Ray bracelet relieves are then expressly stated by the host, John Early (“Early”):

Time and time again people are telling us their Q-Ray bracelet works wonders to relieve the aches and pains they live with every day. Not just from persistent headaches, but joint stiffness, injuries, even back pain.

PX 40 at 11:8-12.

⁶Similar testimonials by Sheila Thompson are featured in previous versions of the infomercial. See PX 47 at 11:24 - 12:5, 24:17 - 25:15; PX 49 at 12:25 - 13:6 and 28:4-25.

The infomercial further reinforces the message of significant or complete pain relief of all types when Early states that “[p]eople who wear a Q-Ray ionized bracelet tell us it’s so effective because Q-Ray delivers lasting relief for their pain and discomfort throughout their entire body.” PX 40 at 12:19-22. Moreover, the immediate nature of this relief is then reaffirmed when a testimonialist, Noel Bishop states, “Actually, the first night I put it on, I woke up the next morning, I was – felt great. I’ve loved it ever since.” PX 40 at 13:4-6.

The infomercial repeatedly drives home the same message of immediate, significant or complete relief from pain. Audra Wallace’s testimonial states:

The worst thing is the pain in my legs, the soreness, it feels like needles going through my body. He put the bracelet on me and right away I felt the – like almost a clear sensation in my stomach and then it went to my knees and then it just worked its way up my body.

PX 40 at 13:12-17.⁷ While Audra Wallace was speaking, the following message appears on the screen: “You don’t have to live with pain.” PX 40 at 13:22. Thereafter, Early sums up this message: “If you’re fed up living with pain and discomfort every day, if you’ve become convinced you’ll live with pain the rest of you’re life, don’t believe it.” PX 40 at 13:23 - 14:1.

The message of immediate, significant or complete pain relief from wearing the Q-Ray bracelet is continually reinforced through user testimonials and statements by the announcer. Thus, the following testimonials were used: Allen Brown, who states, “He put this [Q-Ray bracelet] on me. It was almost within 10 or 15 seconds the pain was gone”; an

⁷This statement was also in the Onyx Infomercial. PX 49 at 10:4-8.

unidentified male, who states, “I put the bracelet on and the pain went away, almost entirely. It just feels so much better”; and Lonnie Everett, who says, “The pain’s not there, the stiffness is not there, I have more movement. It’s really surprising. It’s just been a matter of 15 minutes.”⁸ PX 40 at 14:9-20.

A male announcer then reinforces the message of significant pain relief following the purchase of the Q-Ray bracelet:

If you are one of millions of people suffering from back pain, sciatic pain, persistent headaches, sinus problems, tendinitis, joint dysfunction or injuries, if you’ve become convinced you will live with pain and discomfort for the rest of your life, don’t believe it Introducing Q-Ray, the original ionized bracelet, made with an exclusive proprietary ionization process that we believe helps restore your body to its – normal equilibrium the natural way, to reduce pain and increase energy.

PX 40 at 15:7 to 16:5. Again, the vast array of pain is represented to be significantly reduced by the Q-Ray bracelet. This soliloquy is accompanied by the onscreen, written statements, “Reduce Pain” and “People who wear a Q-Ray ionized bracelet tell us they are free from aches and pains!” PX 40 at 15:25, 16:4-5. These representations are followed by directions on how to order the Q-Ray bracelet.

During the 30-minute infomercial, the Q-Ray bracelet’s purported significant and immediate efficacy for pain relief is constantly repeated. Thus, testimonialist Bill Wheeler relates how “[h]e cornered me and put a [Q-Ray] bracelet on me for my lower back pain. It’s gone.” Sandra Wheeler follows up by saying, “It’s unbelievable. I have [my Q-Ray

⁸This testimonial also appears in previous versions of the infomercial. See PX 47 at 7:4-15; PX 49 at 7:24 - 8:10.

bracelet] too, because we both have been back pain sufferers for a long time and I've carried this [pain] in my lower back and it's just a part of my life." Mr. Wheeler then asks about this long time back pain, "Gone?" Mrs. Wheeler replies, "It's gone." PX 40 at 23:18-23. Again, these statements represent that the Q-Ray bracelet will provide immediate, significant or complete pain relief.

Still other testimonialists help convey the same claim. Bill Kleiman states that "[a]s soon as I put the bracelet on, the pain throughout my entire body disappeared." He further informs the viewer that "ever since I put that bracelet on, it's been two years now, I have not had that pain return." PX 40 at 25:7-8, 18-20.⁹ The latter statement is bolstered by the onscreen, written statement, "After wearing a Q-Ray ionized Bracelet - 'I haven't had the pain return in 2 years.'" PX 40 at 25:16-17.

Similarly, the infomercial presents testimonialist Jeff Brodsky saying that "I put it on and I walked around this show and I came back to the booth an hour later to tell these people that I was pain-free," and an unidentified female states, "My back, I walked in here with pain in my back. I walked in here with pain in my back. It's gone." PX 40 at 26:10-16.

Thereafter, the host, Early, asserts that "[i]f someone close to you is suffering from

⁹A previous version of the infomercial features a testimonial from Bill Kleiman stating, "I was initially very skeptical of this whole thing. But when I first put that bracelet on and it took the pain away, the skepticism went away with the pain." PX 51 at 12:12-15. He further praises the Q-Ray stating, "...As soon as I put the bracelet on, the pain throughout my entire body dissipated. It was gone. And I was amazed. I couldn't believe that that really worked. So, I asked them to take it off and let me wait and see if my pain returned. Within a few minutes, the pain returned. We put the bracelet back on again and once again it was eliminated. And ever since I put that bracelet on, it's been two years now, I have not had that pain return." PX 51 at 18:10-19.

pain and discomfort day after day, give them a Q-Ray bracelet of their own. They'll absolutely love you for it." Then, the off-screen announcer, as he introduces the ordering procedures, states, "If you or someone you know still suffers from neck aches, back pain, soreness in arms, wrist, knees or feet – . . . call the number on your screen right now to order your personal Q-Ray ionized bracelet." PX 40 at 28:16-18, 29:1-2. The infomercial then offers yet more testimonials, with an unidentified male stating that "[s]ince I've put it on five minutes ago, I don't have any problem. The pain is gone. It's amazing." This statement is accompanied by the onscreen, written statement, "The pain is gone." PX 40 at 34:22 to 35:2.

Next, the infomercial presents additional testimonials and a brief discourse from Early. First, an unidentified female states that "this is the first time I haven't had pain in my elbow for three months and I'm able to move my wrist and my arm without any pain at all," which is accompanied by the onscreen, written statement, "I haven't had pain for 3 months." Then, Robert Stock says, "We put the Q-Ray on and I went like this (the video depicts him rotating his head and neck to the right), there was no pain, it was amazing. The bracelet had to do it." Ed Willis then says, "I mean, it worked immediately. It went away. Just put it on, just try it. You've got nothing to lose but pain."¹⁰ Testimonialist Bill Kleiman returns to say, "I was initially very skeptical of this whole thing. But when I first put that bracelet on, it took the pain away and skepticism went away with the pain." PX 40 at 37:6-16, 38:10-17. The host, Early, then interjects and provides yet another opportunity for the viewer to order

¹⁰The testimonial from Ed Willis also appears in a previous version of the infomercial. See PX 48 and PX 49 at 20:4-6.

the Q-Ray bracelet:

Nobody wants to live with pain and discomfort for the rest of their life. Please don't let skepticism keep you from taking this opportunity right now to dramatically improve the way your body feels. Try your Q-Ray ionized bracelet and experience how much better you can feel starting the very first day, the very first minute you try it on, absolutely risk-free.

PX. 40 at 38:21 to 39:7. Again, these testimonials and assertions from the announcer and host reinforce the claim that the Q-Ray bracelet provides immediate, significant or complete pain relief.

As the infomercial plays to completion, more testimonials and host claims appear. Thus, Bud Kling, after discussing his history of wrist pain, says, "When I put this [Q-Ray] bracelet on and I tried to use it, I could force my wrist in every direction possible and I've experienced no pain whatsoever. PX 40 at 41:6-11.¹¹

Then another testimonialist, Paul Seery, states:

I've had total knee replacements in both of my knees. I had a total of seven major operations. I was experiencing a great deal of difficulty walking. I was on a cane all of the time. I put the [Q-Ray] bracelet on and everything changed. It was as though a miracle of sorts happened. The pain went away. I wear it all the time and it works for me.

His statement was reinforced by the onscreen, written statement, "The pain went away - It works for me." PX 40 at 42:4-14.¹² The infomercial host, Early, then elaborates about the

¹¹Bud Kling's testimonial also appears in previous versions of the infomercial. See PX 47 at 12:8-14; PX 49 at 13:9-15.

¹²Similar testimonials by Paul Seery also appear in previous versions of the infomercial. For example, Mr. Seery states, "I have no pain in my knees. I have no pain at all. . . Before I put the bracelet on, I had to have a cane and I wasn't playing any golf. I put the bracelet on and everything changed. It was as though a miracle of sort happened. The pain went away. I wear it

bracelet's purported efficacy:

Imagine what it must feel like to be able to throw away your cane forever. Folks, if you're suffering from nagging pain or maybe your body just doesn't work the way it used to, pick up the phone, right now, and start wearing the Q-Ray ionized bracelet for 30 days absolutely risk-free.

PX 40 at 42:16-21. These statements reinforce the clear message that the Q-Ray bracelet immediately provides significant or complete pain relief; indeed, pain relief so significant it allowed an individual with double knee replacements to "throw away [his] cane forever."

The host, Early, also states, near the end of the infomercial, that "if you're someone who suffers from persistent pain in your back, sinuses, headaches, even tendinitis, you need to pick up the phone and order your Q-Ray right now and experience for yourself the amazing improvements that Q-Ray ionized bracelet can make in your life." PX 40 at 45:14-19.

The infomercial continues with more consumer testimonials and one last sales pitch from the host. Testimonialist Howard Wyckoff states that "I'm almost speechless. I mean, it really – the pain really just went away. I got complete movement in my shoulder and it's not in any pain." PX 40 at 46:22-25.¹³ An unidentified female then says, "I've had tendinitis in my elbow and bursitis in my shoulder for about three years. Playing golf is a struggle and

all the time and it works for me." PX 51 at 16:17 - 17:3. He is also quoted as saying, "The first day I was here. . . I could barely walk. . . Today [after wearing the Q-Ray bracelet]. . . I have walked the length of this building up and down two-and-a-half times and I am comfortable." PX 49 at 30:3-18.

¹³Similar testimonials from Howard Wyckoff also appear in previous versions of the infomercial. See PX 47 at 11:15-21; PX 49 at 16-22.

I wear a brace on my arm. And it's gone. It really works." PX 40 at 43:14-17. Early then reappears to conclude, "If you don't begin to feel relief from your aches and pains immediately and if you don't continue to improve, to feel healthier and stronger with each new day, just send your Q-Ray back to us for a full refund of your purchase price." PX 40 at 47:11-15. The combination of the testimonials describing complete pain relief achieved with the Q-Ray bracelet and the host's assertions of immediate pain relief adds to the clear message that the Q-Ray bracelet provides immediate, significant or complete pain relief.

The infomercial concludes with additional consumer testimonials from Bill Kleiman stating that "when you put [the Q-Ray bracelet] on and you realize the benefit of this bracelet, I don't think there's enough money in the world to talk about when it comes to relieving the pain in your body," and an unidentified male who states, "You just put it on, just try it. You've got nothing to lose but pain." PX 40 at 48:4-7, 49:9-10.¹⁴ These testimonials give the viewer one last reinforcement of the message that the Q-Ray bracelet provides immediate, significant or complete relief from various types of pain.¹⁵

Defendants QT, QRC, Bio-Ray, and Que Te Park admit that Exhibit 40, through the use of consumer testimonials, makes the claim that the Q-Ray bracelet reduces pain. PX 7 at No. 78; PX 8 at No. 95. Defendants' sprinkling of several inconspicuous disclaimers in

¹⁴Bill Kleiman's testimonial also appears in a previous version of the infomercial. *See* PX 47 at 34:22 - 35:3.

¹⁵Defendants' inconspicuous small-font statement appearing just six times during the 30-minute infomercial that "this product is not intended to diagnose, treat, cure or prevent disease" is wholly inadequate to change the net impression of the pain relief claims made in the infomercial.

small print for a couple of seconds stating, “Individual results may vary,” does not alter the strong net impression conveyed by the prolific use of consumer testimonials and the sales pitch by the host. *See* PX 40.

2. Prime Time infomercial (PX 46 and PX 47).

The Prime Time infomercial conveys the message that the Q-Ray bracelet immediately relieves pain. Many of the testimonials above appeared in Defendants’ previous versions of the infomercials, either word-for-word or in similar testimonials. *See, e.g.*, nn. 2-14, *supra*. In some instances in those earlier infomercials, additional strong claims and testimonials about relief from severe pain were also presented. For example, a testimonial from Audra Wallza, a woman suffering from ovarian cancer and undergoing painful chemotherapy treatments, was prominently featured in the first infomercial for the Q-Ray bracelet. Her tearful testimonial also appears in previous versions of the Q-Ray infomercial and convey the claim of relief from severe pain. She states, “I’m suffering from ovarian cancer. I’ve had one ovary removed and I’m currently going through chemotherapy. I’ve had my fifth treatment and, I can deal with the nausea, but the worst thing is the pain in my legs, the soreness, it feels like needles going through my body. . . . there’s just some mornings I just can’t even get out of bed.” PX 47 at 8:20 - 9:14 and 3:9-14.¹⁶ Driving home the message of Q-Ray’s purported efficacy in relieving severe pain, she further states, “I didn’t think it was going to be this powerful and I – it kind of just brought tears to my eyes

¹⁶An edited version of this testimonial also appears in PX 49 at 3:17-21.

because I'm just amazed and in disbelief. I'm just excited that, you know, my life is normal again." PX 47 at 25:19-23.

Setting the stage about the impact of pain, the statements "Over 100 million Americans suffer from pain every year," and "Over 93 million work days are missed each year due to pain" appear on screen while a man identified as a pharmacist, Steve Hospodavis, states, "Chronic pain, the impact that it would have on a person's life can be devastating. They can go from taking merely aspirin or Tylenol all the way up to morphines and codeines – and a variety of stronger products." PX 47 at 3:15-4:7.

The host of this version of the infomercial, Mitch Laurence ("Laurence"), immediately follows the pharmacist and informs viewers, "If you or someone you know is one of over 100 million Americans that suffer with pain, this may be one of the most important programs you'll ever watch. . . What you're going to see and hear are people who have been trying to cope with that pain and how an amazing new non-medical device called the Q-Ray Ionized Bracelet has changed their lives." PX 47 at 4:10-22.

Throughout the infomercial, an off-screen announcer tells viewers, “If you or someone you know is one of over 100 million Americans who suffer from pain. . .you’re not alone. . . . Now, an incredible non-medical device called the Q-Ray Ionized Bracelet is changing the lives of people all over the world. The Q-Ray Ionized Bracelet is a non-medical device designed to allow excess positive ions to leave our bodies, thereby helping the body return to its normal electrical balance naturally, resulting in decreased pain. . .” PX 47 at 9:18 - 10:10.

A variety of testimonials are given throughout the program in order to convey the message that the Q-Ray bracelet produces immediate pain relief. For example, Kerin Holder-Krohn states, “I have been having chronic sinus pressure for about – problems for the last three or four years, and really bad over the last year. Constant pain, constant pressure in my face. And back pain that I didn’t mention. And so, it wasn’t very long after I put this on that I felt an immediate change in the facial pressure, in the pain in my face. It’s amazing.” PX 47 at 26:21-27:3.

Que Te Park, identified onscreen as “Andrew Park, President/Founder, Q-Ray,” also appears in the first version of the infomercial to praise the Q-Ray bracelet’s purported efficacy and quick relief. He states, “It’s natural forces, natural power, natural energy. At the same time, when your body is balanced naturally, your pain also removed at the same time, almost technically in a second because we are talking body electricity. . . the speed of electricity. Very quick.” PX 47 at 26:7-18.

Defendants QT, QRC, Bio-Ray, and Que Te Park admit that Exhibit 47, through the

use of consumer testimonials, makes the claim that the Q-Ray bracelet reduces pain. PX 7 at No. 66; PX 8 at No. 83. Moreover, Defendants did not attempt to disclaim the overall impression of these testimonials. This infomercial is devoid of any disclaimer such as, “Results not typical.” See PX 46.

3. Onyx infomercial (PX 48 and PX 49).

The Onyx infomercial conveys the message that the Q-Ray bracelet provides immediate pain relief. In the Onyx version of the infomercial, a male announcer states, “The Q-Ray Ionized Bracelet is designed to restore the body to its normal electrical balance naturally, thereby reducing pain and increasing energy.” PX 49 at 24:23-25:1.

The Onyx infomercial host states, “Over 3,000 years ago, people began to study the effects of electrical current within our body and develop treatments like acupuncture, tai chi, chi gong and others to help relieve pain and restore energy. These ancient insights have led to a greater understanding of how electricity works in the body and have inspired one very innovative product. The Q-Ray Ionized Bracelet is designed to restore the body to its normal electrical balance the natural way, thereby reducing pain and increasing energy.” *Stipulated.*

The host introduces Dr. Jeremy Cole, who states that “approximately a year ago, a good friend of mine approached me and showed me his Q-Ray bracelet. He had some back pain. He put the bracelet on, the back pain went away immediately. So, I ordered a bracelet for myself. When the bracelet arrived, I put it on and within a few moments my back pain was quite better. In fact, it disappeared. . . . I used it selectively on some patients who had chronic bursitis, some tendinitis. There were some patients that I used it on who had some

low back pain and arthritis, and I was absolutely amazed at the response.” This discussion is accompanied by the onscreen, written statement, “Natural Pain Relief; www.Qray.com.” *Id.* at 16:15-16.

The Onyx infomercial includes the following testimonial from LPGA Touring Professional Colleen Walker: “I suffered from tendinitis for one solid year in both my elbows. . . . A friend introduced the Q-Ray bracelet to me and said, try this, it will help you. . . . I have been without my pain for three years now.” The Onyx infomercial host further states, “When you’ve tried everything to reduce your pain and nothing works, a new, all-natural alternative with literally thousands of success stories is a very exciting discovery.” *Stipulated.*

Defendants QT, QRC, Bio-Ray, and Que Te Park admit that Exhibit 49, through the use of consumer testimonials, makes the claim that the Q-Ray bracelet reduces pain. PX 7 at No. 70; PX 8 at No. 87. Moreover, Defendants did not disclaim the overall impression of these testimonials. This infomercial is devoid of any disclaimer such as, “Results not typical.” *See* PX 46.

4. Warren infomercial (PX 50 and PX 51).

The Warren infomercial communicates the message that the Q-Ray bracelet provides immediate pain relief. The infomercial emphasizes the great impact a Q-Ray bracelet can have on daily living. For instance, Linda Meredith states, “I have six [horses], and it’s a very time-consuming passionate hobby. I woke up one morning and there was like this catch in my hip and . . . I’m limping – I mean, just really limping, and it was to the point where I

couldn't even pull myself into the saddle because it was my left hip and that's the foot that you put in the stirrup. . . I can't imagine not being able to ride them. . . I was just really, really getting depressed about it and I saw the Q-Ray commercial and so I thought, oh, what the heck, I'll send for the thing. I put it on, click, there I was on my feet." PX 51 at 8:15-9:4.

The infomercial host further stresses the pain relief benefits from wearing the Q-Ray bracelet stating "Linda is living life to its fullest, something she says she was unable to do before receiving her Q-Ray Ionized Bracelet. Imagine doing what you love for so many years and then having to quit due to pain and suffering. Don't let pain beat you. If you suffer from daily life pain, you need to try the Q-Ray Ionized Bracelet." PX 51 at 10:9-15.

The claim of fast-acting pain relief is reiterated throughout the infomercial. An off-screen announcer states, "Millions of people suffer daily life pain often preventing a full and meaningful life. . . Not anymore," while onscreen, the text, "Daily Life Pain? Q-Ray," appears. The announcer continues, "Introducing Q-Ray, the world's original ionized bracelet. People around the globe, young and old, have felt the immediate impact, including . . . reduction in their daily life pain." PX 51 at 12:12-25, 21:5-8, and 25:25 - 26:5. Later, the off-screen announcer states, "If you'd like to have your life back, free of daily life pain. . . then you need to do what millions of people around the globe do, try Q-Ray." PX 51 at 13:21-24, 21:15-18, and 26:14-17. The host states that "the Q-Ray Ionized Bracelet makes an instant impact, but has lasting results." PX 51 at 17:6-7. Leland Ferris, identified as having been in a car accident, states, "They told me I'd never – most likely I'd never walk again. Though I started using a cane, it just hurt real bad. I didn't do much. . . I just was in

so much pain all the time, it hurt to move. . . as soon as I got the bracelet on . . . I started feeling better and it just got better and better. It's given me a lot more sense of freedom, you know, when you go from staying in your house for almost 24 hours a day and not wanting to do anything and then going and wanting to get out and do everything, just to see what you could do without pain." PX 51 at 23:10-22.

Defendants QT, QRC, Bio-Ray, and Que Te Park admit that Exhibit 51, through the use of consumer testimonials, makes the claim that the Q-Ray bracelet reduces pain. PX 7 at No. 74 and PX 8 at No. 91. Moreover, Defendants did not disclaim the overall impression of these testimonials. This infomercial is devoid of any disclaimer such as, "Results not typical." *See* PX 46.

None of the four infomercials contain elements that contradict or eliminate this pain-relief claim. The onscreen statement, "Individual results may vary," shown in conjunction with some of the testimonials in the Complaint infomercial (PX 39 and PX 40) is inconspicuous and thus insufficient to negate the impression that consumers can achieve similar pain relief. Notably, none of the earlier infomercials even display this purported disclaimer. PX 46-51.

Each of the four versions of the infomercial for the Q-Ray bracelet that aired between 2000 and June 2003 conveys the clear message that the Q-Ray bracelet provides fast relief from significant, severe, and/or chronic pain from a variety of conditions. The infomercials reinforce this message by means of testimonials, statements by the announcer, onscreen messages and the failure to provide any meaningful disclaimers. These infomercials are

designed to sell the Q-Ray bracelet on the basis of its claimed ability to provide immediate, significant or complete pain relief.

5. Websites.

On or around November 7, 2002, QT's website contained the following statements: "Natural Relief™: Q-Ray is the original Ionized Bracelet® which we believe helps balance your body's Ying-Yang (Negative and Positive Ions). When your body is balanced, (Chi) (bio-energy) is generated facilitating Natural Pain Relief®." *Stipulated. See also PX 322-23.*

On or around May 19, 2003, QT's website featured the text, "Imagine a life without pain. . ." and "Don't live with pain and discomfort another day!" Que Te Park confirmed that the above claims appeared on the company's website. *Stipulated. See also PX 322-23.*

The corporate Defendants admit disseminating the claims "Imagine a life without pain" and "Don't live with pain and discomfort another day!" on QT's website. PX 4 at ¶ 13. *Stipulated as to QT, Inc. only.*

On or around May 19, 2003, QT's website contained the following text: "How long will it work? Individual results vary. Once the positive benefits that you enjoy while wearing the Q-Ray Ionized Bracelet begin to fade or disappear it is time for a new Q-Ray as the ionized power in your bracelet has been exhausted, and cannot be restored." *Stipulated.*

On or around May 19, 2003, QT's website contained the following statements: "Discover its Power; Q-Ray is the original Ionized Bracelet which we believe helps balance your body's Yin-Yang (Negative and Positive Ions). Q-Ray applies an exclusive cutting edge Technology for 24 hours of non-stop performance." *Stipulated.*

6. Brochures.

From 2001 through at least June 2003, Defendants disseminated a brochure for the Q-Ray bracelet that included the following statements:

- a) Q-Ray applies cutting-edge exclusive ionization technology in each Q-Ray for 24 hours of non-stop performance.
- b) Improve your health and well-being with a high-performance Q-Ray Ionized Bracelet.
- c) It is believed that the Q-Ray Ionized Bracelet works under the same principles as the ancient Chinese practice of acupuncture.
- d) Q-Ray is an exclusive Ionized Bracelet which we believe helps balance your body's Yin-Yang (Negative & Positive Ions). When your body is balanced, (Chi (qi)) (the vital life energy) is generated, facilitating natural relief.

PX 4 at ¶ 13 and PX 55. *Stipulated as to QT, Inc. only.*

From at least 2000 through 2001, QT disseminated a brochure for the Q-Ray bracelet that included the following statements:

- a) The bracelet is based on Chi, the Yin-Yang balancing power. So fast and effective, not slowly or locally like other products.
- b) Natural Pain Relief; Yin-Yang Therapy.
- c) Our bodies run on electrical energy. It is this electrical current that moves through our nervous system and controls every aspect of our body. As long as this flow of energy remains unimpeded, it is believed that we remain physically and mentally balanced and therefore, in good health. . . When injury or chronic conditions impede this flow, the body can begin to generate an overabundance of positive (yang) ions which offsets the balance of our body's electrical system. The Ionized Technology designed to discharge positive (Yang) ions which flow through the body and restore the Yin Yang balance.
- d) Do not lend the bracelet to another person, for each bracelet develops a memory cycle specific to each individual wearer.
- e) Q-Ray has one to two year average ionized life span.

Stipulated.

QT has no studies or tests to support the claim of a one to two-year average ionized life span. T. 360.

7. Packaging.

From at least 2000 through at least 2002, QT disseminated packaging for the Q-Ray bracelet that featured the following statements:

- a) It's not a bracelet, it's ionized!
- b) Natural Pain Relief.
- c) How long will it last? Individual results vary. Once the positive benefits that you enjoy while wearing the Q-Ray Ionized Bracelet begin to fade or disappear it is time for a new Q-Ray as the ionized power in your bracelet has been exhausted, and cannot be restored.
- d) (in the 'Sizing and How To Wear' section) If you do not notice any difference after 24 hours switch the bracelet to the left wrist, but the terminals must be worn down (underside) position on the wrist.

- e) Invented by Dr. Manuel Polo, a specialist in pain disorders of the nervous system, it is the world's only ionized Natural Power Bracelet. Like Chinese acupuncture, it is intended to help harmonize the body's bio-energy frequency and balance its yin (negative ions) and yang (positive ions). When these ions become unbalanced, the body's functions can be altered, often with debilitating results.

Stipulated.

- f) The Q-Ray® Ionized Bracelet® is a non-medical device which we believe affects the body's bio-electrical balance of positive and negative ions (yin-yang) so as to achieve 'chi', the vital life energy present in all living organisms.

PX 57.

H. DEFENDANTS' ADVERTISING FOR THE Q-RAY BRACELET CONVEYED THE CLAIM THAT TESTS PROVED THAT THE Q-RAY BRACELET RELIEVES PAIN.

Defendants' infomercials and other advertising convey, expressly or by implication, that tests proved that the Q-Ray bracelet relieves pain.

1. Complaint infomercial (PX 39 and PX 40).

The host, Early, introduces a segment of the infomercial featuring Dr. James Christiansen ("Dr. Christiansen") by stating, "Recently, doctors put a Q-Ray to the test to try to determine what effect the Q-Ray ionized bracelet has on the human body." PX 40 at 20:17-19. Simultaneous with the introduction, there is an onscreen, written statement introducing "Dr. James Christiansen Ph.D, F.A.B.C.T., D.A.A.P.M. This test was performed by licensed medical professionals." *Stipulated.* Dr. Christiansen then introduces Mr. Oaks, the patient, and the scientific equipment, called an "infrared imager," to be used in his test. Dr. Christiansen explains that the infrared imager is used to view surface body temperatures.

The body temperatures depicted in the visual image are from the patient. The image is described as including areas of pink and red, which colors Dr. Christiansen explains are related to elevated temperatures. PX 40 at 20:24 - 22:4. The onscreen writing states, “Computer monitor showing back and areas of pain. Before wearing Q-Ray Ionized Bracelet.” PX 40 at 21:3-5.

In the infomercial, Dr. Christiansen makes clear that the colors displayed by the infrared imager are indicators of pain; of the pink and red colors he says that “[t]hose are increased temperature, indicating increased blood flow. The increased blood flow typically is associated with inflammation and pain. In the case of Mr. Oaks, these areas are precisely where he described feeling pain when he first came in.” PX 40 at 21:6-11. Then Dr. Christiansen puts a Q-Ray bracelet on the patient “to see if there’s any change in the thermal profile that goes along with the application of the bracelet. After five minutes with the Q-Ray bracelet on his wrist, you can see that the temperature has declined dramatically – apparently much less inflammation, and that decrease in temperature correlates very well with Mr. Oaks’ indication that he feels much less pain in that area.” The Q-Ray bracelet’s success in significantly reducing Mr. Oaks’ pain over the course of five minutes is reinforced onscreen, “Patient reports much less pain.” PX 40 at 21:16 - 22:4. Thereafter, the success of this test is echoed by Mr. Oaks, who states, “After I put the Q-Ray bracelet on, it just seemed to – the pain seemed to dissipate dramatically It seems like the pain is almost negligible.” Again, the success of the test is emphasized in the onscreen writing, “After wearing Q-Ray patient reports pain was reduced dramatically.” PX 40 at 22:6-14.

Finally, the scientific nature of this infrared imager testing is made specific. An

unidentified male asks, “Doctor, are these infrared imaging machines reliable?” Dr. Christiansen replies, “Very true, very accurate, very reliable.” Concurrent with this dialogue, Dr. Christiansen’s scientific credentials appear onscreen: “Dr. James Christiansen Ph.D., F.A.D.C.T., D.A.A.P.M. This test was performed by licensed medical professionals.” PX 40 at 22:21 - 23:3. The totality of the discussion creates the net impression that tests prove the Q-Ray bracelet relieves pain.

Defendants QT, QRC, Bio-Metal, and Que Te Park admit that this infomercial claimed that tests prove the Q-Ray bracelet reduces pain. PX 7 at No. 77; PX 8 at No. 99. Moreover, the disclaimer, “Q-Ray makes no claim that there is a scientific consensus regarding this product,” which appeared only four times in tiny print during the entire 30-minute infomercial, did not take away from the net impression that tests prove the Q-Ray bracelet reduces pain. *See* PX 40.

2. Prime Time infomercial (PX 46 and PX 47).

Previous versions of the Q-Ray infomercial featured a segment with Dr. Jeremy Cole, who is identified by the host, Mitch Laurence, as a specialist in internal medicine and pulmonary disease. The text, “Jeremy Cole, M.D., Specialist, Internal Medicine,” appears onscreen as the host introduces Dr. Cole. *Stipulated.* After being asked how he “got involved with the Q-Ray bracelet,” Dr. Cole replies, “A good friend of mine. . . showed me his Q-Ray bracelet. He had some back pain. He put the bracelet on, the back pain went away immediately. So, I ordered a bracelet for myself. When it arrived, I put it on and within a few moments my back pain was quite better. In fact, it disappeared.” PX 47 at

14:2-10. Dr. Cole continues, “I became very interested in [the Q-Ray bracelet] and did a little bit more research on it and then I decided to give the bracelet a try on some of my patients. I used it selectively on some patients who had chronic bursitis, some tendinitis. There were some patients that I used it on who had some low back pain and arthritis, and I was absolutely amazed at the response.” *Stipulated.*

To drive home the message that the Q-Ray bracelet is a medically accepted form of treatment, Dr. Cole describes the Q-Ray bracelet as a “systemic form of treatment,” saying that “when [the Q-Ray bracelet] is applied, [it] discharges the positive ions throughout the body. . .” PX 47 at 15:15-17. Distinguishing the Q-Ray bracelet from other competitor or look-alike products, Dr. Cole continues, “The Q-Ray bracelet, being an ionizing bracelet, works almost immediately and, again, it works for a large variety of conditions, not only just arthritis.” PX 47 at 16:4-6. The net impression of the conversation between the infomercial host and Dr. Cole is that the Q-Ray bracelet is considered to be a scientifically-based treatment for chronic and severe pain by medical professionals.

3. Warren infomercial (PX 50 and PX 51).

The infomercials for the Q-Ray bracelet also convey the net impression that the method of action for the product is scientifically proven. For example, in the Warren infomercial, the host refers again to Dr. Jeremy Cole to discuss how the Q-Ray bracelet works: “You may remember Dr. Jeremy Cole from our first program. Dr. Cole is an internist and he explained what makes the Q-Ray Ionized Bracelet so unique.” PX 51 at 5:14-16. Dr. Cole explains, “The way the Q-Ray bracelet works is that it discharges the

positive ions from the body, thus restoring the electrical balance of the body in order to relieve pain.” PX 51 at 5:17-20. Next, to further support the impression that the Q-Ray bracelet is based on scientific principles, an off-screen announcer states, “[I]t’s this ionization process that sets Q-Ray apart. From the time of Plato and Aristotle, people have believed that an electric charge or current could be used for medical purposes and to reduce pain.” PX 51 at 5:23-6:1. The off-screen announcer makes the express claim that the Q-Ray bracelet’s efficacy is proven stating, “Q-Ray has proven effective in various studies around the world.” PX 51 at 6:12-13. QT, QRC, Bio-Metal, and Que Te Park admit that the Warren infomercial claimed that the Q-Ray bracelet had been proven effective in various studies around the world. PX 7 at No. 77; PX 8 at No. 94.

4. The infomercials imply efficacy proven by scientific principles.

The infomercials convey the message that the Q-Ray bracelet is analogous to acupuncture and other eastern medicine theories as proof that it is a scientifically proven remedy. For example, in the Warren infomercial, the off-screen announcer states that “the effect of the Q-Ray is often related to the well-known alternative therapy . . . acupuncture.” PX 51 at 6:10-12. In the Onyx infomercial, the text “We believe Q-Ray works in a manner similar to acupuncture. . .” appears onscreen. PX 49 at 4:14-15.

The host of the Onyx infomercial, Mitch Laurence, further emphasizes a connection between the Q-Ray bracelet and alternative treatments such as acupuncture. He states, “Over 3,000 years ago, people began to study the effects of electrical current within our body and develop treatments like acupuncture, tai chi, chi gong and others to help relieve pain and

restore energy. These ancient insights have led to a greater understanding of how electricity works in the body and have inspired one very innovative product. The Q-Ray Ionized Bracelet is designed to restore the body to its normal electrical balance the natural way, thereby reducing pain. . .” PX 49 at 6:23-7:7. The association between alternative medicine treatments and the Q-Ray bracelet is repeated again towards the end of the program. PX 49 at 24:15-25.

The message that the Q-Ray bracelet works and its efficacy is based on scientific principles is also present in the Complaint infomercial. For example, host John Early states, “The science behind [the Q-Ray] bracelet is not new.” PX 40 at 5:22-23. Onscreen, an animation of the human body is featured to illustrate Early’s description of the principles behind the Q-Ray bracelet. He elaborates further, “[O]ver 3,000 years ago, people began to study the positive and negative electrical energy within our body, and they discovered by using natural treatments like acupuncture, they could tap into the human body’s natural energy to relieve pain. . . The people at Q-Ray put this knowledge to work to help create their ionized bracelet.” PX 40 at 6:2-6:9.

5. Brochures and packaging.

Defendants disseminated a brochure for the Q-Ray bracelet, which conveys the claim that tests prove the Q-Ray relieves pain. The brochure includes the following statements from Dr. Christiansen: “Thermographic Technology; This thermographic image of a male lower back shows the before and after effect of wearing the Q-Ray® Ionized Bracelet®. ‘I was surprised and pleased at the results obtained with Mr. Oaks. His “hot” lumbar area correlating with his pain, and the dissipation of the heat and pain almost instantaneously upon wearing the Q-Ray Bracelet was a convincing piece of evidence for it’s [sic] effectiveness.’ Dr. James Christiansen, Ph. D.” PX 55.

QT used a brochure for the Q-Ray bracelet that included the following statements: “Only Q-Ray has Passed the Critical Yin-Yang Test; No other bracelets can pass these Natural Power tests.” *Stipulated.*

QT employed packaging for the Q-Ray bracelet that featured the following statements: “The Q-Ray® Ionized Bracelet® is a non-medical device, which we believe affects the body’s bio-electrical balance of positive and negative ions (yin-yang) so as to achieve ‘chi,’ the vital life energy present in all living organisms. Introduced to America by the man known as Dr. Bracelet, it is believed that the Q-Ray works under the same principles as the ancient Chinese practices that originated over three thousand years ago and is based on the belief that health and the body’s overall well-being are determined by a balanced flow of ‘chi.’” *Stipulated.*

I. DEFENDANTS’ PURPORTED SUBSTANTIATION.

Que Te Park and Ciprian were responsible for generating, collecting, reviewing, or evaluating substantiation for claims regarding the Q-Ray Bracelet. PX 6 at No. 6; T. 224-25, 452-53. Ciprian was responsible for collecting studies about the Q-Ray bracelet and identifying researchers to conduct studies on the Q-Ray bracelet. She reported to Que Te Park regarding proposed studies and consulted him for approval of the proposed studies. T. 224-25. Ciprian's job did not include evaluation of whether claims in the Q-Ray Bracelet's advertising were scientifically supported. PX 7 at No. 144 and PX 8 at No. 180.

Que Te Park has no formal education in science, medicine, or clinical research. *Stipulated.* Que Te Park never consulted with any independent scientists about the studies he had collected prior to running his infomercials. T. 409-11. QT has never employed any scientists on its staff. *Stipulated.*

At one time, Que Te Park believed the following studies supported the claims for the Q-Ray Bracelet: the Italian study by Cesare Tossani, a Korean study, a Chinese study, a study by a Dr. Niwa in Japan, two studies by Trapp, and a study by Dr. Michael Manginelli. *Stipulated.*

In 2000, QT had in its possession the Italian study (DX 5) and the Korean study (DX 9) for the claims that the Q-Ray Bracelet would relieve pain. T. 409-10, 430. Que Te Park received copies of the Korean study from his distributor and the Italian study from Bio-Ray S.A., the manufacturer in Spain. T. 409, 436.

1. Korean Study - DX 9.

The Korean study was conducted by a Korean distributor of QT. QT only received

the final report of the Korean study, but not any underlying data. T. 428-29. The 1994 study tested the Bio-Ray bracelet against a fake bracelet among 50 patients. DX 9. There is no indication that a Q-Ray bracelet was used in the study. DX 9.

2. Italian Study - DX 5.

QT had no involvement in the Italian study, which was conducted in the early 1990's. Que Te Park did not receive any underlying data from the study. T. 413-14. The Italian study compared three treatments: a biomagnetic technique (the Bio-Ray bracelet), transcutaneous electric nervous stimulation (“Tens”), and a placebo. DX 5. The study of the Bio-Ray bracelet began with 120 patients. There is no indication that a Q-Ray bracelet was used in the study. DX 5.

3. Chinese Study - DX 8.

QT provided Q-Ray bracelets for the Chinese study titled “Beijing Municipal Institute of Labor Protection ‘Field Intensity Test Report.’” *Stipulated*. The study refers to Group B (two persons) wearing the “beetling accoutrement.” Que Te Park does not know what a beetling accoutrement is and his company did not provide beetling accoutrements for the study. *Stipulated*. The study conducted in May 1999 involved three people who wore a biomagnetic bracelet and two who wore the beetling accouterment. DX 8; T. 440. The Chinese study researchers did not share their underlying data with Que Te Park or QT. T. 437.

4. Japanese Study - DX 10.

QT and Que Te Park relied on a two-paragraph letter dated March 17, 1998 from Dr. Masayuki Niwa describing his study results. DX 10. Neither QT nor Que Te Park requested

copies of the underlying data for Dr. Niwa's study. PX 7 at No. 226; PX 8 at Nos. 280-281. The study dealt only with muscle strength and flexibility, not pain relief. DX 10; T. 424-25. QT did not supply Dr. Niwa with any placebo bracelets; it only sent him active bracelets. *Stipulated.* Que Te Park testified he has no idea whether Dr. Niwa tested any placebo bracelets. *Stipulated.*

5. Market Facts Consumer Survey - DX 11.

QT and Que Te Park relied on the document, "Market Facts, Pain Prevention Bracelet – April 2001," to substantiate their claims that the Q-Ray Bracelet relieves pain and that tests prove that the Q-Ray Bracelet relieves pain. DX 11; PX 7 at Nos. 227-228; PX 8 at Nos. 282-285. QT paid Market Facts to conduct a survey reported in "Market Facts, Pain Prevention Bracelet – April 2001." *Stipulated.* The Market Facts survey showed, at best, a 50/50 split in consumer satisfaction with the Q-Ray bracelet for relieving pain. DX 11.

6. First Deann Trapp Study - DX 6.

QT and Que Te Park relied on "An Investigation to Determine the Effectiveness of Q-Ray Bracelets as Strength and Flexibility Enhancers" ("First Trapp Study") by Deann Trapp ("Trapp") to substantiate its advertising claims. DX 6; PX 7 at No. 179; PX 8 at Nos. 217-218. The study is dated August, 2001. DX6.

It was part of Ciprian's job to locate researchers who might be interested in conducting studies concerning the Q-Ray bracelet. This job included providing the researchers with the necessary active and placebo bracelets. *Stipulated.* Ciprian initiated contact with Trapp through a trainer she knew and asked Trapp to do a study of the Q-Ray

bracelet. Ciprian did not know exactly what Trapp's background was, except that she was a certified trainer. At the time Trapp conducted her first study, she was a graduate student at Northern Illinois University pursuing a Masters of Science in Education degree. *Stipulated.* Trapp had no prior experience in conducting clinical studies. T. 484.

Trapp completed a second study in 2002 titled "An Investigation to Determine the Effectiveness of Q-Ray Ionized Bracelets as Pain Reducers" ("Second Trapp Study"). DX 7. Ciprian's job responsibilities at QT included communicating with Trapp about the progress of the First and Second Trapp Studies and about the results of the First and Second Trapp Studies. QT provided ionized and placebo bracelets for both Trapp studies on the Q-Ray bracelet. *Stipulated.*

The First Trapp Study was conducted in or before August 2001. *Stipulated.* Ciprian received an email from Trapp on or about July 9, 2001, which contained an excerpt from the results of her study. The excerpt reported that the Q-Ray group experienced no significant change in pain. It also noted that there was a placebo group that experienced significant decreases in pain. PX 111, 132; T. 254, 491-93.

Ciprian received a copy of the research report from Trapp, entitled, "An Investigation to Determine the Effectiveness of Q-Ray Bracelets as Strength and Flexibility Enhancers" by email on or about July 16, 2001. PX 133; T. 255-56. The report explicitly discussed the results of a placebo group. PX 133 at 7. The research report stated that subjects' pain levels were measured in the study, *id.* at 4, and the Q-Ray group experienced no statistically significant change in pain but the placebo group did experience a statistically significant

reduction in pain levels. *Id.* at 5. Ciprian shared a copy of the draft report of the First Trapp Study with Que Te Park. T. 259.

Ciprian sent an email to Trapp on or before August 1, 2001 asking for specific data from the study, including measurements taken. She further asked Trapp, “What is it you would write up? I think it is fine with us as long as it is positive data you will inform them. Let me know.” PX 111.

Trapp came to Chicago on or about August 11, 2001, to be filmed in a QT infomercial. PX 112; PX 113; PX 134. While in Chicago, Trapp personally gave Que Te Park a copy of her Masters’ Thesis, which contained a full discussion of all the research she did for her study, including the pain and placebo data. PX 134; PX 268; T. 501.

On August 20, 2001, Ciprian asked whether Trapp was going to publish the study. Ciprian further stated, “We obviously would like you to as long as you are only showing the positive aspects to the Q-RAY Bracelet and how it will help your body. Let me know.” PX 134; T. 260-61. Ciprian asked Trapp to remove the discussion of the pain and placebo data from her first study. T. 504-505; PX 135; PX 136; PX 144; *see* PX 111; PX 134. As of at least October 8, 2001, Trapp complied with Ciprian’s request and removed the placebo and pain data from a report of her first study she then gave to QT. T. 507-508; PX 111; PX 114; PX 135; PX 136; PX 138; PX 144; DX 6. Trapp did not remove any of this information and data from the thesis she submitted for her Masters of Science in Education degree. PX 268; T. 526.

Ciprian received a final report from Trapp in October 2001. PX 114; T. 261-63. She

shared a copy of the final report of the First Trapp Study with Que Te Park. T. 265. The final report that Trapp sent to Ciprian did not include pain data or placebo data, pursuant to Ciprian's request. T. 507-508.

When Que Te Park was asked why the First Trapp Study in QT's files differed from Trapp's thesis, PX 268, he stated, "All I want was good study and good results and that's all I want to hear. I do not want to read every detail. I am president of company. I have a lot of things to do." T. 476.

On or about November 30, 2001, after receiving the First Trapp Study, Ciprian sent an email to a distributor who sold Q-Ray bracelets on the web, asking him to make certain changes to his website. She stated in the email, "We are not allowed to make any claims that we don't have proof for and right now we have various pending studies, therefore, stay away from making any claims or even using the word pain." PX 104; T. 217-18.

As of November 30, 2001, the company's pending studies were the Mayo Clinic Study and the Second Trapp Study. PX 149; PX 114.

On or about December 26, 2001, Ciprian sent an email to the same distributor, telling him to take out a testimonial and also the phrase "relieves pain" from the title on the front page of his website, and further stating, "This claim is a bit too much to use." PX 105; T. 219-20.

7. Second Trapp Study - DX 7.

In September 2001, QT asked Trapp to conduct a double-blind study on the Q-Ray Bracelet and pain. *Stipulated.* Trapp was paid approximately \$1,000 for the pain study on

the Q-Ray bracelet. T. 526.

Ciprian sent an email on or before September 19, 2001, asking Trapp whether she could do a double-blind study on pain instead of muscle flexibility and strength. She stated, “We are looking to find someone to do something on pain asap, let me know your thoughts.” PX 141. Ciprian sent an email to Trapp on or before September 26, 2001, explaining what she would like Trapp to do. Ciprian stated, “We will be using placebo bracelets again. You can base the study on chronic or acute pain, either is fine and areas all over the body. We would like you to do a study with 25 placebos and 25 actual or a total of 50 patients.” PX 142.

Ciprian dictated the design of the study, including the study parameters, timing of the measurements, and the types of measurements to be taken. T. 528-529. Trapp sent Ciprian numerous emails seeking additional guidance on how to design and conduct this second study. PX 116-120; PX 139; PX 142-144.

Trapp completed her second study, titled “An Investigation to Determine the Effectiveness of Q-Ray Ionized Bracelets as Pain Reducers,” some time after February 12, 2002. *Stipulated.* QT and Que Te Park relied on the Second Trapp Study to substantiate claims that the Q-Ray bracelet relieves pain. PX 7 at No. 183; PX 8 at Nos. 226-227. Trapp recognized that the results of the Second Trapp Study had some of the same shortcomings as the First Trapp Study regarding the pain findings. T. 527-28.

8. Manginelli Study - DX 4.

QT and Que Te Park relied on the study by Michael Manginelli (“Manginelli”), “The

Q-Ray Ionized Bracelet Relieves Pain, Increases Strength and Improves Flexibility,” DX 4, to substantiate its advertising claims that the Q-Ray Bracelet relieves pain and that tests prove that the Q-Ray Bracelet relieves pain. PX 7 at Nos. 252-254; PX 8 at Nos. 319-324. The study by Manginelli is dated “Draft - 5/1/02.” *Stipulated*. No final version was ever prepared.

QT provided ionized and placebo bracelets for Manginelli’s study; the bracelets were the same style as the ones that were sent to the Mayo Clinic. *Stipulated*. No one at QT ever asked for the actual data from Manginelli’s study. Que Te Park understood that this was a single-blinded study, meaning the tester was not blinded. T. 534. QT arranged for one of its outside service providers, Peter Allen, to assist Manginelli in writing the report. T. 548-49.

Que Te Park knew Manginelli for years. He consulted for QT in the past. DX 4. Manginelli was a testimonialist prior to the study and he and Que Te Park had planned to go into business together prior to him conducting the study. T. 547-48. Manginelli provided a post-study testimonial in an infomercial for the Q-Ray bracelet. T. 563. *See* PX 39-40.

9. Anecdotal Evidence.

Que Te Park also relied on anecdotal evidence to substantiate his claims that the Q-Ray bracelet provides pain relief. He based his view on personally meeting 8,100 consumers. T. 441. This represents, however, only about *one percent* of all Q-Ray bracelet purchasers. T. 442.

Charles Park testified that the company relied on feedback from warranty cards,

consumer letters, and sports stars as substantiation for its claims that the Q-Ray bracelet reduces pain. T. 1016, 1026, 1029, 1037-38; DX 14, 16.

Many of the warranty cards that Defendants relied upon as support for their claim that the Q-Ray bracelet relieves pain gave consumers an incentive to provide testimonials to QT. The warranty cards notified consumers that they would receive a 20% discount on their next purchase of a Q-Ray bracelet if they submitted a testimonial. PX 320.

Both Que Te Park and Charles Park acknowledged that QT had at least a 25% refund request rate from dissatisfied purchasers. T. 599; 1063. Between January 1, 2000, and June 30, 2003, \$27,132,249 was refunded to consumers. *Stipulated*. This represents well over 100,000 consumers who were not satisfied with the bracelet and did not experience the benefits claimed in QT's advertising.

J. MAYO STUDY - PX 280.

QT signed a Clinical Research agreement with the Mayo Clinic on or about September 24, 1999. *Stipulated*. QT cooperated in the Mayo study of the Q-Ray bracelet. T. 568. The study was initiated by Dr. Robert Bratton ("Dr. Bratton"). T. 568.

In May 1999, Que Te Park wrote a letter to Dr. Bratton confirming that QT would provide the Mayo Clinic of Jacksonville 305 activated Q-Ray Bracelets and 305 placebo bracelets. PX 149. In July 1999, Que Te Park also wrote a letter to Dr. Bratton stating that the components of the Silver Flash (Brass) Q-Ray Bracelet was 85% copper and 15% zinc. PX 180; T. 364-66. Que Te Park told Dr. Bratton that he could not describe the ionization process because it was a trade secret. T. 569. Ciprian was QT's administrative contact to the Mayo Clinic. She communicated directly with the Mayo Clinic about the progress of the

study. *Stipulated.*

QT ordered ionized and placebo bracelets from Bio-Ray S.A. for the Mayo study. PX 7 at No. 271; PX 8 at No. 345. The placebo bracelets provided by the manufacturer in Spain were non-active bracelets. T. 236.

When she sent bracelets to the Mayo Clinic, Ciprian followed Dr. Bratton's instruction and did not disclose which bracelets were active and which bracelets were placebos. T. 240. *See* PX 153 (emails dated October 3, 2000) and PX 154 (emails dated October 4, 2000). QT provided a sealed envelope with the blinding code to the Mayo Clinic. *Stipulated.*

The Mayo study reported the following results: "Analysis of the data showed significant improvements in pain scores in both groups, but no differences were observed between the group wearing the placebo bracelet and the group wearing the ionized bracelet." PX 280. The Mayo study came to the following conclusion: "The finding that subjective improvement in pain scores was equivalent with ionized and placebo bracelet use questions the benefit of using an ionized bracelet. New treatments in alternative medical therapy must be shown to be effective through vigorous, unbiased, objective testing before physicians acknowledge potential benefits or recommend these treatments to patients." *Id.*

K. DEFENDANTS' ACTIONS SUBSEQUENT TO PUBLICATION OF THE MAYO STUDY.

QT and Que Te Park learned about the published results of the Mayo study in or about November or early December, 2002. PX 7 at No. 88; PX 8 at No. 106; T. 564-67. Que Te

Park viewed the results as very good because approximately 80 percent of the people who used the Q-Ray bracelet showed pain relief. T. 569. Approximately seventy-five percent who wore the placebo bracelet also experienced pain relief. PX 7, 8.

After learning of the results of the Mayo study, QT's lawyers advised QT to change its marketing material. T. 576-78.

After reviewing the study results, Ciprian sent an email to Dr. Bratton stating, "We were a bit surprised at these results especially the positive results from the placebo bracelets. In further discussion we feel that there may have been a mix up with the samples (placebo and real ionized bracelets) and hence would like to have further investigation before anything is released or even another study conducted to clarify some issues." *Stipulated.*

QT continued airing its ongoing Complaint infomercial for the Q-Ray bracelet, PX 39, for at least six months after it learned of the results of the Mayo study. PX 7 at No. 91; PX 8 at No. 111. QT did not revise or discontinue the Complaint infomercial, PX 39, after it learned of the results of the Mayo study. PX 7 at No. 90; PX 8 at No. 109-12; T. 576-77.

In February 2003, QT and QRC began working with counsel and outside experts to design, develop, and contract for a double-blind, placebo-controlled, clinical study with over 600 subjects. T. 579-82, 872-73. The purpose of the proposed study was to avoid the purported errors of the Mayo study and produce more reliable results. T. 805-06. The proposed clinical study was being designed by Defendants' expert witness, Dr. Michael Feldstein, and his company, but it was never conducted. T. 582; PX 19 at 232:3-19.

In February 2003, investigators from the Food and Drug Administration (FDA) inspected QT. T. 599. Que Te Park was aware that the FDA was concerned that the Q-Ray

bracelet was intended for the treatment of medical conditions such as arthritis and musculoskeletal pain. T. 602-03.

In or about March 2003, Que Te Park ordered QT to spend less money on television advertising for the Q-Ray bracelet and to reduce the amount of television advertising for the Q-Ray bracelet. *Stipulated.* In March 2003, Que Te Park told Loren Skagen, the vice-president of marketing, to “fly[] under the antenna scope.” By that, he meant to reduce the amount of money spent on television ads and reduce the amount of TV ads they were showing to reduce their exposure. T. 579. At the time, they had 5-6 class actions pending due to the Mayo study. T. 576-79; PX 101. As of March 14, 2003, QT was still advertising the Q-Ray bracelet through the Complaint infomercial and the website without change until the FTC filed suit at the end of May 2003. T. 576-77.

L. THE Q-RAY BRACELET ADVERTISING CLAIMS WERE FALSE AND UNSUBSTANTIATED.

Six experts testified at trial. Two experts, Dr. Hochberg and Dr. Feldstein, testified regarding clinical testing and the statistical significance of the various studies. Two other experts, Dr. Wikswo and Dr. Tiller, testified regarding the theory behind the claimed ionization of the Q-Ray bracelet. Dr. Olshansky testified regarding complementary and alternative medicine and the placebo effect. Finally, Dr. Yurasik testified regarding eastern Asian or Traditional Chinese medicine. The Court makes the following findings based on an evaluation of the testimony of the experts:

1. There is inadequate scientific substantiation for the claim that the Q-Ray bracelet provides immediate, significant or complete pain relief.

2. QT's claim that scientific or medical clinical tests prove the Q-Ray bracelet relieves pain is false.
 3. There is no scientific evidence that the Q-Ray bracelet emits any electrical charge.
 4. The Q-Ray bracelet does not reduce one's perception of pain any more than a placebo bracelet.
 5. The concept of "ionization" is not a part of Traditional Chinese or eastern medicine.
- 1. Clinical Trial and Statistical Experts - Dr. Hochberg and Dr. Feldstein.**

Dr. Hochberg is a Professor of Medicine, Professor of Epidemiology & Preventive Medicine, and Head of the Division of Rheumatology & Clinical Immunology at the University of Maryland School of Medicine in Baltimore, Maryland. *Stipulated*; PX 293.

Dr. Hochberg was called by the FTC as an expert in the fields of: (a) rheumatic diseases, including arthritis and other musculoskeletal disorders; (b) clinical testing related to prevention and treatment of rheumatic diseases; and (c) pain due to rheumatic disease.

Stipulated.

Dr. Feldstein has a Ph.D. in statistics from the State University of New York at Buffalo and is the Vice-President for Clinical Services at Medical Device Consultants, Inc. His responsibilities as Vice-President include running the department of clinical services, which seeks to design, conduct, and manage clinical trials for clients. He was called by Defendants as an expert in the area of statistics and biostatistics and the conduct of clinical trials. T. 673-79; DX 19. He has over ten years of experience in the design and conduct of clinical trials for devices seeking FDA approval. T. 673-74.

a. Requirements of an appropriate substantiating study.

According to Dr. Hochberg, to support a claim that a product relieves or treats musculoskeletal pain, qualified experts in the field would require that such a claim be supported by at least one well-conducted, placebo-controlled, randomized, double-blind or sham-controlled clinical trial. T. 54. Such a trial must (a) include patients who fulfill criteria for the type of pain to be treated; (b) be randomized so that each individual has the same probability of being in either the treatment or the placebo group; (c) be a double-blind study so that neither the investigator conducting the study nor the participants know who is receiving the placebo; (d) utilize a pain rating instrument that has been demonstrated to be valid, reliable, and responsive for that disease and population; (e) subject its data to appropriate statistical analysis; and (f) show a statistically significant and clinically significant improvement in the treatment group, when compared to the control group, at the end of the trial. T. 56-65. *See* Kaye, DH & Freedman, DA, Reference Guide on Statistics, Reference Manual on Scientific Evidence, Federal Judicial Center (2d Ed. 2000) at 92-93 (“Reference Guide on Statistics”) (well-designed study is randomized with treatment and control groups). This view is shared by the bulk of the relevant scientific community. T. 54-5.

Dr. Feldstein agrees that a double-blind, placebo-controlled, randomized trial is the “gold standard” in the scientific community and that depending on which claims you wish to make, you should attempt a double-blind, placebo-controlled, randomized test to support the claims. T. 688, 869-70.

In a randomized, placebo-controlled, clinical study, the appropriate statistical analysis

is one that statistically compares the change observed in the treatment group to the change in the same measure observed in the placebo group. This is known as a “between group” analysis. T. 63, 866, 1126.

In a randomized, placebo-controlled, clinical study, it is not scientifically appropriate to rely on a “within group” statistical analysis; that is, an analysis of only the change in a measured parameter in the treatment group from the beginning to the end of the study, because the result may be due to other factors such as regression to the mean or the placebo effect. T. 63-65, 866.

For a randomized, double-blind, placebo-controlled, clinical study to conclude that a treatment is effective, the change in the treatment group must be statistically significantly greater compared to the change in the placebo group. Statistical significance is achieved if the statistical analysis shows that there is a 0.05 or less likelihood that the difference measured is due to chance ($p \leq 0.05$). T. 62-63, 779-81, 861-62; *see* Reference Guide on Statistics at 123-24. If statistical significance is not achieved, the treatment cannot be said to have had an effect. T. 100-03, 779-80.

Pain can be measured in a scientifically objective manner. T. 54. Dr. Hochberg has been part of a scientific study in which changes in pain levels were measured objectively. *Id.* The concept of a clinical trial is to enroll patients who meet certain inclusion as well as possible exclusion criteria. T. 56. In a pain study, the inclusion criteria includes persons having pain and then following them over a pre-set determined period of time in order to assess changes in their pain level in response to an intervention. T. 56.

In order to allocate study participants, the preferred method is randomization. T. 56. Randomization is a statistical technique which provides each individual with the same probability of being either in the group receiving the experimental treatment or in the group receiving the placebo or sham treatment. T. 56-7.

In order to minimize bias entering the study, a double-blind clinical trial is used to ensure that the investigator who conducts the study, the individuals who administer the study, and the study participants do not know who is using the device under investigation and who is using the placebo. This minimizes bias. T. 57-8.

Another element is the placebo control or a controlled clinical trial. This compares the experimental device to a placebo device in order to control for two phenomena: regression to the mean and the placebo effect. T. 58-9.

Regression to the mean refers to a phenomenon whereby people who enter a study are oftentimes experiencing an increase in their level of symptoms. Because of the waxing and waning nature of pain in musculoskeletal disorders, it is typical that the level of pain will improve over the course of a study. This is referred to as regression to the mean. A comparison group is necessary to control for that possibility. T. 59, 747-49.

The placebo effect can be defined as an inert or innocuous treatment that works not because of the therapy itself, but because of its suggestive effect. T. 1141-42.

A randomized, double-blind, placebo controlled study of the Q-Ray bracelet could have been conducted to determine if the bracelet had an effect on pain relief. T. 66, 779, 1128. QT should have obtained a randomized, double-blind, placebo controlled study to

support its pain relief claim for the Q-Ray bracelet because that is the recognized standard necessary to support such a claim. Q-Ray had the financial resources necessary to finance such a study.

According to Dr. Hochberg, to qualify as a well-designed study likely to produce reliable results, a clinical study should specify the inclusion and exclusion criteria for subjects, measure baseline and final (and any intermediate) data for the relevant characteristics of the subjects (*e.g.*, pain levels), specify how subjects' compliance with the required treatment regimens will be measured, specify how subject drop-outs will be handled, specify the precise procedures by which the clinical data will be collected from subjects, and measure end points that are most related to a determination of whether the treatment had an effect on the condition being studied. T. 94-99.

Dr. Hochberg explained that anecdotal evidence, that is, reports of positive results in individual patients or in a group of patients, is not sufficient to demonstrate the efficacy of a product to treat pain. T. 66-69; *accord* Feldstein at 781.

b. Defendants' purported substantiation is inadequate to support the Q-Ray bracelet's pain-relief claim.

Dr. Hochberg testified that none of the studies conducted on the Q-Ray bracelet he reviewed provided reliable scientific evidence that the Q-Ray bracelet significantly relieves musculoskeletal pain. T. 111-14. Dr. Feldstein agrees that some of the studies that Defendants relied upon, namely, the Chinese, Korean, Italian, Manginelli, and both Trapp studies, are "sadly lacking" from a statistical point and they do not conform to the standard of randomized prospectively designed controlled studies. PX 272; T. 781-96. The Court

agrees, and it will analyze each of the studies for their purported substantiation.

Manginelli Study

Dr. Hochberg testified that the Manginelli study, DX 4, does not provide reliable scientific evidence that the Q-Ray Bracelet relieves pain. The Manginelli study included a between group comparison that shows a greater proportion of patients who received active bracelets experienced pain relief as compared to those who received the placebo bracelet. T. 94. Dr. Hochberg testified that this study is significantly flawed in its design and in the reporting of its results because it was single-blinded (only participants were blinded as to whether they were receiving active or sham bracelets) and lacks specificity regarding the study's patient population and the measurements taken, as well as the raw data necessary to replicate or verify the study's findings. T. 72, 93-99.

Dr. Feldstein also found a number of problems with the Manginelli study. First, it was written with a built-in bias. Second, the write-up contains insufficient information to let one assess and evaluate what actually took place in the study. Third, the study does not explain how many subjects were actually included in the active and placebo groups. Fourth, the study fails to explain what happened to the dropouts. Fifth, the study was flawed by the lack of analytical information. Finally, the study is flawed because it does not explain how it measures pain relief. As a result, Dr. Feldstein concluded that the Manginelli study should be left out of any argument that the Q-Ray bracelet has been scientifically shown to relieve pain. T. 787-90; PX 272.

Trapp Studies

Dr. Hochberg testified that neither of the Trapp studies provides reliable scientific support for the Q-Ray bracelet pain-relief claim. T. 72, 85-93.

Dr. Hochberg testified that the reliability of the First Trapp Study, DX 6, designed as a single-blind, placebo-controlled trial to measure the effects of the Q-Ray bracelet on strength and flexibility over six weeks, is undermined by several significant flaws in the study design and the report of its results. First, no selection or screening criteria were presented in the study report, and the narrow patient population – college students, some of whom were athletes – might not be applicable to the likely population of Q-Ray bracelet consumers. T. 85-7.

Second, the study was not properly blinded. Although the study was designed to be single-blinded, there was a noticeable difference between the active and placebo bracelets given to the participants. The ionized bracelets had an imprinted logo while the placebo bracelets did not. Thus, participants could possibly detect their group assignments, which would allow for the introduction of bias into the trial, and render the study non-blinded. T. 87-89.

Third, the First Trapp Study did not present any data about the placebo group results. Adequate and accurate statistical analysis requires that results from the treatment group must be compared with results from the placebo or control group. The treatment may be concluded to have had an effect only if the treatment group results are statistically significantly different from the placebo group results. T. 87-8.

Fourth, DX 6 is also unreliable because it is an incomplete report of the research done during the First Trapp Study. The full report of the First Trapp Study is contained in PX 268.

PX 268 demonstrates that the First Trapp Study included a placebo group and measured changes in pain levels of both the Q-Ray bracelet and placebo groups. The full report of the First Trapp Study includes a within group analysis that shows no change in pain levels reported by the Q-Ray group but a significant reduction in pain in the placebo group. T. 257-58, 500-03; PX 133; PX 268 at 16-17. In creating DX 6, the data for pain levels and all the data for the placebo group were removed at Defendants' request. T. 504-05. Thus, Defendants manipulated the data from the First Trapp Study to make it appear to be more supportive of the efficacy of the Q-Ray bracelet than the study demonstrated.

Finally, the First Trapp Study is also incapable of providing reliable scientific evidence to support any pain relief claim for the Q-Ray bracelet because it does not report any data relating to pain. T. 85-6.

Dr. Feldstein also found the First Trapp Study to be seriously flawed because: 1) it contained a placebo group that provided no statistical analysis of the results of the active group compared to the placebo group; 2) it may have been totally unblinded because the placebo bracelet was markedly different from the active bracelet; 3) there was no medical condition being reported by the participants; and 4) it did not measure pain. T. 790-97; PX 272.

Dr. Hochberg testified that the Second Trapp Study, DX 7, designed to evaluate the effectiveness of the Q-Ray bracelet in relieving pain, is inadequate to support pain relief claims for the Q-Ray bracelet and does not provide reliable scientific evidence that the Q-Ray bracelet relieves pain. T. 72, 91-93.

There are several significant flaws in the design of the Second Trapp Study and in the reporting of its results. For example, the patient population is too small and inadequately described. T. 790-94. There is not enough information about the measurements used to evaluate pain, how pain was scored, or the basis of the pain measurement (for example, whether it was measured from baseline, the most painful site, or overall pain level). T. 792. Dr. Hochberg testified that the report also lacks a comparison of the results from both groups and that, although Trapp reported results of greater pain relief in the active group than in the placebo group, without a comparison of the results from both groups, the significance of such a difference cannot be determined. T. 91-93.

The Second Trapp Study is also flawed because it is only a single-blind study that does not state whether the investigator knew who received active or placebo bracelets. T. 91-92.

Dr. Feldstein agrees that the Second Trapp Study was a weak and not well-controlled study because: 1) it was not well-controlled in terms of blinding; 2) the study population was very young and included a substantial number of athletes, and therefore raises generalization problems to a larger population; 3) it used only one pain scale to determine changes in pain; 4) its entry criteria were overbroad; and 5) the men and women were not evenly divided between the two groups. T. 790-94; PX 272. According to Dr. Feldstein, the Second Trapp Study was a “rather weak study with weak findings.” T. 272.

Italian Study

DX 5, a study titled “Experiences of ‘Bio Ray RBM’ on Pain of Diverse Origine”

(“Italian study”), provides no support for QT’s pain relief claims because there is no evidence that the study was conducted on the Q-Ray bracelet. Instead, the study on its face indicates that it tested a magnetic bracelet called the Bio-Ray, whereas the Q-Ray bracelet is purported to work on non-magnetic principles. Thus, there is no evidence to support an inference that the Italian study actually tested the Q-Ray bracelet, and, accordingly, its results cannot be applied to the Q-Ray bracelet. T. 72, 79-83. Defendants produced no evidence that the Bio-Ray and Q-Ray bracelet are identical and they have no underlying documentation from the study. T. 413-18.

According to Dr. Hochberg, the Italian study, which is reported to be a double-blind, randomized trial comparing the efficacy of the Bio-Ray Bracelet, transcutaneous electrical stimulation therapy (“TENS”), and a placebo in the treatment of pain, does not provide any reliable scientific evidence that the Q-Ray Bracelet relieves pain. T. 72-9.

Dr. Hochberg observed several major flaws in the Italian study, including the absence of a description of the subject population enrolled in the study, no description of the selection criteria used, and uncertainty regarding whether the subjects of the Italian study were properly randomized into groups for the second phase of the trial. T. 79-80. Another major shortcoming is that the study does not appear to be blinded or adequately placebo-controlled. No placebo bracelet is identified and Dr. Hochberg testified that without the use of an appropriately designed placebo, neither the study participants nor the researcher can be properly blinded. Without the use of an appropriate placebo control group, it cannot be reliably determined whether any resulting effects are properly attributed to the Bio-Ray Bracelet tested. T. 79-81. In addition, the measurements and analysis of the Italian study results are inadequate. T. 81-82.

Dr. Feldstein also concluded that the Italian study was vague and incomplete with a number of serious flaws. It was difficult to read and critique. The study's use of a composite and point makes it virtually impossible to compare its results with the results of any of the other Q-Ray studies. The study failed to analyze the data the way the study was designed to do it. In addition, the study fails to explain what happened to the non-completers and it was not blinded. T. 783-86; PX 272.

Chinese Study

Dr. Hochberg testified that the "Field Intensity Test Report" from the Beijing Municipal Institute of Labor Protection ("Chinese Study"), DX 8, which apparently tested the efficacy of a bio-magnetic bracelet as compared to a "beetling accouterment," provides too little data to provide any reliable evidence for the Q-Ray Bracelet pain-relief claims. This study fails to meet the basic standard of scientific evidence: there were only five participants in the study, it does not appear to have been blinded in any way, and it was not placebo-controlled. Dr. Hochberg further testified that, at best, this study can be considered anecdotal evidence, which is insufficient to support pain-relief claims. T. 72-5.

This study, like the Italian study, does not appear to have been conducted on the Q-Ray bracelet, but rather on a magnetic bracelet of some kind. *See* DX 8. Defendants, who have the burden of producing their purported substantiation, provided no evidence, other than Que Te Park's undocumented assertion, that they were in fact the same. Accordingly, the results of this study cannot be applied to the Q-Ray bracelet.

According to Dr. Feldstein, the Chinese study "is purely anecdotal with a tiny number

of cases - I see nothing useful here.” PX 292; T. 781-82.

Korean Study

The Korean study, DX 9, provides no reliable scientific evidence supporting the Q-Ray bracelet's purported ability to relieve pain. It does not appear to be blinded and it fails to conduct a statistical analysis between the subjects wearing the Bio-Ray bracelet and those wearing the "Fake" bracelet. Dr. Feldstein found that this study provided no "credible" evidence. T. 782-83; PX 272. The study gives no detail about how pain was measured, how often it was measured, or how a percentage of improvement was calculated. The study does not claim to be double-blinded, there is no statistical analysis or P-value reported and it is not clear if the study was randomized. T. 782-83; PX 272 (referred to in this exhibit as the Jeonjn Chinese Medical Hospital of Wonkang University study).

Japanese Study

According to Dr. Hochberg, the Japanese study, DX 10, provides no scientific support for pain-relief claims for the Q-Ray bracelet. T. 52. It consists of nothing more than a two-paragraph letter. DX 10. Most significantly, it contains no data or information regarding the potential impact of the Q-Ray bracelet on pain. The two paragraphs also fail to provide any information regarding how any study on the Q-Ray bracelet might have been conducted. T. 52. Dr. Feldstein agrees that this document contains no data or information regarding the Q-Ray bracelet's potential impact on pain. T. 798.

c. The Mayo study fails to substantiate the Q-Ray bracelet's pain-relief claims.

Dr. Feldstein conducted a more thorough review of the Mayo study than Dr. Hochberg. Defendants obtained the underlying data from the Mayo study. Dr. Feldstein

received all of the documents he requested. T. 695. On the other hand, Dr. Hochberg rendered his opinion based on the Mayo study report, PX 280, without reviewing any of the underlying documents. T. 163.

Based upon his review of the Mayo study and the underlying documents, Dr. Feldstein concluded that the conclusions are not supported by the data and the study had numerous flaws. T. 695-777. If Dr. Feldstein is correct and the Mayo study is fatally flawed, it is fatally flawed for all of the study conclusions, and cannot, therefore, support an argument that the Q-Ray bracelet is effective in relieving pain. Dr. Feldstein offers no opinion as to whether the Q-Ray Bracelet relieves pain and has no basis to offer an expert opinion as to whether the Q-Ray bracelet is an effective treatment for pain. T. 52.

Dr. Hochberg testified that, based upon his experience in the conduct of clinical trials and the review of clinical trial data, he was of the opinion that the Mayo study, PX 280, provides a valid evaluation of the Q-Ray bracelet and demonstrates that the Q-Ray bracelet does not completely relieve pain. Dr. Hochberg testified that the study is a well-designed, randomized, controlled, clinical trial on a large number of patients. T. 102.

Dr. Hochberg based his conclusion that the Mayo study was a good study on the five pages of the published study and nothing more. T. 163. He did not see the protocol, even though it would have been helpful. T. 171. He was not aware of problems in the Mayo study in rendering his opinion. T. 173-78.

Dr. Hochberg testified that the data from the Mayo study indicates that a substantial number of subjects in both the treatment and placebo groups reported improvement in pain levels, but there was no statistically significant difference between the two groups. Thus, the Mayo study shows that the Q-Ray bracelet is no better than a placebo bracelet at relieving pain. Dr. Hochberg testified that the pain relief experienced by the patients in the study is likely due to the placebo effect. Dr. Hochberg testified that it therefore was his opinion that the Mayo data show that there is nothing specific to the Q-Ray bracelet that causes pain relief, and that based on this data, the Q-Ray bracelet itself cannot be said to be effective in relieving musculoskeletal pain. Rather, the improvement in both groups was due to the placebo effect. T. 102-03, 111.

The fact that the Mayo study established that the Q-Ray bracelet had no statistically significantly greater effect on pain relief than did the placebo bracelet means that the study was unable to detect a difference between the active bracelet and the placebo bracelet. T. 59-63, 102-03, 111, 780, 866. The Mayo study was the most thorough study performed. While it has its problems, its conclusion that the Q-Ray bracelet is no more effective than a placebo bracelet means that there are no “gold standard” clinical trials to support Q-Ray’s claims.

2. Dr. Wikswo and Dr. Tiller.

The FTC introduced the testimony of Dr. Wikswo to establish that the purported mode of action of the Q-Ray bracelet was scientifically untenable. Dr. Wikswo has engaged in scholarly research and writing related to biological physics, biomedical engineering, and electromagnetism, among other subjects. He has authored or co-authored over 100 articles

that have been published in peer-reviewed journals, as well as numerous book chapters, comments, brief reports, and invited review articles. Dr. Wikswo has presented papers at over 300 conferences in various fields such as biological physics, biomedical engineering, cardiac and cellular electrophysiology, electromagnetism, and SQUID magnetometry. *Stipulated.*

Based upon his education, training, and experience, Dr. Wikswo is an expert in biological physics, biomedical engineering, and electromagnetism. *Stipulated.* Biological physics is science conducted at the interface between physics and biology. T. 269. Biomedical engineering is the application of engineering to the understanding of biology, medicine, and biomedical systems. T. 270. Electromagnetism is the physics of electric fields, magnetic fields, and electromagnetic fields. T. 270.

Dr. Tiller was offered by Defendants as an expert in materials science. T. 903. Materials science is the science of wood, plastics, metals, water, and “peripherally some biomaterials.” T. 898. Dr. Tiller was not qualified by the Court as an expert in biophysics, electromagnetism, electrophysiology, or in any branch of science related specifically to electricity. Dr. Tiller is not an expert in biological sciences. T. 916. He offered no opinion on the effect of the Q-Ray bracelet on humans.

Dr. Wikswo testified that there is no scientifically plausible means – other than through means involving the use of radioactive particles or vacuums – of maintaining a charge on a metal bracelet for more than a few minutes, regardless of the type of metal from which the bracelet is made. T. 269. Furthermore, there is no scientifically plausible means

by which a charged metal bracelet could cause health benefits in a human body. T. 288.

Dr. Wikswo testified that an ion is an atom that has had one or more electrons removed or added, such that it is no longer electrically neutral. T. 272. An atom that does not have the same number of protons and electrons is considered to have a “net electrical charge.” T. 272, 284-85. Under Coulomb’s law of physics, like charges, such as negative ions, repel each other and opposite charges attract one another. There are ions in the air around us. The level of ions in the environment depends on the weather, humidity, and how much ozone is in the air. Dust particles also can carry a charge. T. 272. Ionization is largely directed at the concept of atoms. Ionizing a collection of atoms turns them into a plasma. It is problematic to refer to an object being ionized because it would turn into a plasma and cease to exist. T. 273.

It is possible to place a charge on a C-shaped metal bracelet. T. 277. However, Coulomb’s law of physics says that the bracelet would then attract opposite charges, from the skin and the environment around it, until the charge is neutralized. T. 278. The length of time the charge would stay on the bracelet would depend on the amount of charge applied, but would be at most seconds to minutes. T. 278. According to Dr. Wikswo, there are no scientifically plausible means of maintaining a charge on a metal bracelet for longer than seconds to at the most a few minutes, regardless of the type of metal used. T. 285.

Dr. Wikswo explained that it is possible to implant an ion within the metal. T. 278-79. Upon implantation, the bracelet would “transiently” carry a net electric charge. T. 279-80. Such an electric charge, however, would stay on the bracelet only on the order of a

“billionth of a billionth of a second” because the electrons are free to move and rearrange themselves so as to eliminate any electric field in the metal. T. 279. So, even though the implanted ion remains in the bracelet, the bracelet would not continue to emit or attractions due to the ion’s presence. T. 279-80.

A voltage of physiological importance is one that is “of a size comparable to what would occur in a biological system.” T. 275. The size of such a voltage depends on what the system is. T. 275. An electrocardiogram measurement of the voltage between two hands or between a hand and a foot is in the range of millivolts (one-thousandths of a volt). T. 275.

A charge on an everyday metal object, like a bracelet, is not great enough to have a physiological effect on the body. T. 276. Dr. Wikswo testified that natural electrical interaction, for example, in the form of corrosion, could take place between a metal bracelet—“charged” or uncharged—and the skin. T. 280-81. Such voltages, however, would not be great enough to have a physiological effect on the body. T. 281.

The term “polarization” in electrical usage largely applies to molecules where one side of the molecule has a different charge than the other. T. 282. It is incorrect to use the term polarization for metals, because static electric fields cannot exist in metal. T. 283-84. It is possible to separate the charges in metal through the application of an electric field, but the charges would redistribute themselves in possibly a billionth of a billionth of a second once the metal was removed from the electric field. T. 284.

As a scientist, Dr. Wikswo would want to see a test conducted with a high impedance electrometer to show that a metal bracelet could maintain a charge for more than a few

minutes. T. 285-87. Dr. Wikswow did no testing on the Q-Ray bracelet. T. 297.

Dr. Tiller does not know how the Q-Ray bracelet is manufactured. T. 915. His testimony regarding ions being implanted in the Q-Ray bracelet was speculation. T. 915. He did not test the bracelet for the presence of an electrical charge, “polarization,” or “ionization.” Dr. Tiller nonetheless was called by Defendants to testify about whether the Q-Ray bracelet *could* be implanted with ions. He testified that it is possible for ions to be implanted in a C-shaped metal object like a Q-Ray bracelet, that is, “[y]ou could just put them on the surface, or you could ... bury them in the surface on the order of a micron [deep].” T. 906.

He stated that if ions are implanted below the surface of a metal, the area where the subsurface ion is located will stay polarized for years. T. 914. Most significantly, however, Dr. Tiller testified that electrons in the metal will move into that area to equilibrate the electrical potential and locally neutralize the charge. T. 913. Dr. Tiller also testified that this movement of electrons will cause a change in the surface voltage, at which point “fate” tries to “screen” that surface voltage by pulling ions from the air or the body to neutralize it. T. 913. Accordingly, like Dr. Wikswow, Dr. Tiller testified that insofar as the surface of the bracelet is concerned, nature will try to “neutralize – electrically neutralize these things.” T. 912.

Asked whether an “everyday” metal would have enough charge to effect biological material, Dr. Tiller noted that metals have an electrical field and current flow, which can cause effects like corrosion. T. 909-12. For example, some people’s skin will turn green if they wear copper; this is a kind of chemical corrosion. T. 906-07. He stated that it “would

be foolhardy to presume that this charge transfer” would have no biological effects, but did not offer *any* testimony about what those effects might be. T. 912.

Finally, asked whether it mattered that the material had been ionized, Dr. Tiller testified that the interaction between a metal bracelet and the skin would occur for *any* kind of material, to different degrees. T. 915. He offered no testimony suggesting that ionization would make a material difference in the amount of ion transfer between a metal bracelet and the environment around it, including the skin, on a long-term basis.

In the absence of any test results on the Q-Ray bracelet by means of a high impedance electrometer or other device to show the Q-Ray bracelet has received, maintains and/or emits a charge, the Court accepts the analysis and opinions of Dr. Wikswo over Dr. Tiller. Defendants have failed to provide any showing that “ionized” is anything more than a clever marketing rubric developed by Que Te Park because he could not use the term “polarized.”

3. Dr. Yurasek - Asian or Traditional Chinese Medicine.

Dr. Frank Yurasek holds a Masters degree and Ph.D. in Oriental Medicine and was proffered by Defendants to provide information regarding eastern Asian or Traditional Chinese Medicine. T. 919, 922-23.

Dr. Yurasek agrees that the majority of studies on Traditional Chinese Medicine, including studies from China, do not meet the Western standard of research, which is a double-blind, placebo-controlled, clinical trial. T. 943-46. Much of the research on Traditional Chinese Medicine is derived from observational data and is not double-blind or placebo-controlled. T. 946. Dr. Yurasek is aware of an alternative medicine treatment,

acupuncture, that has been scientifically validated using Western standards of research, and he agrees that it is possible to conduct a study of the Q-Ray bracelet on pain relief using Western standards of research. T. 947-48.

Dr. Yurasek has never heard of the concept of ionization correlating to principles of Traditional Chinese Medicine. He never studied ionization while earning his degrees in Oriental Medicine. *Stipulated*, T. 951-52. Dr. Yurasek testified that the concept of ionization is not a part of Traditional Chinese Medicine and that he is not able to offer an opinion on the movement of positive and negative ions in the body. T. 952. Dr. Yurasek agrees that it is not possible to identify a definitive mechanism of action for the Q-Ray bracelet and that the mechanisms of action for acupuncture and acupressure are different from any theoretical mechanism for the Q-Ray bracelet. T. 952-57.

Dr. Yurasek has no basis to offer an expert opinion as to whether the Q-Ray bracelet is an effective treatment for pain. His proffered testimony regarding Traditional Chinese Medicine is not relevant to whether the Q-Ray bracelet is an effective treatment to relieve pain. Rather, his testimony supports the conclusion that QT and Que Te Park have promoted the relationship between the Q-Ray bracelet and Traditional Chinese Medicine as a marketing device which is a disservice to the practitioners of this ancient art. Defendants have sought to clothe the Q-Ray bracelet with the credibility of Traditional Chinese Medicine and thereby deceive consumers.

Dr. Yurasek knows very little about the Q-Ray bracelet. He was not provided any studies on the Q-Ray bracelet (including any studies from China or Japan), he did not

perform any studies on the Q-Ray bracelet, he has no knowledge or opinion as to whether the bracelet is electronically charged, and he has no knowledge as to whether the bracelet is actually ionized. T. 958-59. Dr. Yurasek's opinion that the Q-Ray bracelet aids in the restoration of the basic state of relative balance between Yin and Yang is based merely on theory and not any scientific studies or testing. T. 948-49.

Dr. Yurasek's opinion that the Q-Ray bracelet reduces perceptions of pain is based exclusively on his personal use of the bracelet on two brief occasions and by the use of the bracelet by a half-dozen of his patients. Dr. Yurasek never prescribed the Q-Ray bracelet as a sole or primary treatment to any of his patients and these patients may have been taking medication for pain relief or used other treatments for pain relief while wearing the Q-Ray bracelet. He agreed that if any of his patients experienced pain relief, it was not necessarily due to the use of a Q-Ray bracelet. T. 949-51. At best, Dr. Yurasek's personal experiences with the Q-Ray bracelet and those of his patients provide anecdotal accounts of the effect of a Q-Ray bracelet.

4. Dr. Olshansky - Electrophysiology, Complementary and Alternative Medicine and the Placebo Effect.

Dr. Olshansky is a Professor of Medicine and the director of Cardiac Electrophysiology at the University of Iowa Hospitals. He was called by Defendants to render opinions in the fields of electrophysiology, complementary and alternative medicine, and the placebo effect. Dr. Olshansky is also an expert in cardiology. T. 1092, 1104-05.

Dr. Olshansky has not seen any studies on the Q-Ray bracelet and he has not used it personally or prescribed it to his patients. Dr. Olshansky offers no opinion as to whether the Q-Ray bracelet is an effective treatment for pain nor does he offer any other opinions on the Q-Ray bracelet.

Dr. Olshansky testified that one definition of placebo is “an inert or innocuous treatment that works not because of the therapy itself but because of its suggestive effect.” T. 1141-42. Dr. Olshansky agreed that “[p]lacebo therapy depends on the power of a patient’s belief that the therapy will be effective.” T. 1142. Consumer expectations are extraordinarily powerful in creating a placebo effect. T. 1143. Consumer expectations can be created by many externalities that are concurrent with treatment. T. 1143. As Dr. Olshansky explained, the placebo effect that results from consumer expectations includes providing a pain relief “product in a setting with others around you who are all, you know, in a group setting so that somebody is saying that this is going to provide pain relief and it’s all jazzed up with posters showing pain relief and whatnot and then somebody says, my God, I got pain relief, . . . might affect the next person in line in their expectation that they would

get the same relief. . . .” T. 1146. This is essentially the scenario captured in Defendants’ infomercials at the trade shows where the Q-Ray bracelet was given to consumers prior to them being filmed for the infomercial. *See* PX 39; PX 46; PX 48; PX 50. Thus, the environment Defendants created at their trade shows likely contributed to the placebo effect of those consumers who felt better after putting on a Q-Ray bracelet.

Dr. Olshansky testified that from the 1970’s through the mid-1990’s the scientific community believed that a placebo effect was “inherently without value.” However, that paradigm shifted in the mid-1990’s. T. 1111-14. This timing is particularly important because it places the purported shift from scientific disbelief to belief in placebo effects immediately after the decision in *FTC v. Pantron I Corp.*, 33 F.3d 1088 (9th Cir. 1994). However, an FDA case, *United States v. An Article . . . Acu-Dot . . .*, 483 F. Supp. 1311, 1314 n.3 (N.D. Ohio 1980), clearly demonstrates that the endorphin pain relief theory resulting from a placebo effect was well known as early as 1980. Although his testimony was engaging, Dr. Olshansky’s testimony adds no scientific support to the claims surrounding the Q-Ray bracelet.

M. DECEPTIVE ADVERTISING OF DEFENDANTS’ REFUND POLICY

1. Defendants Advertised a 30-Day Money Back Guarantee.

QT advertised a 30-day refund policy on its television infomercials for the Q-Ray bracelet (“30-Day Satisfaction Guarantee”). *Stipulated.* Defendants advertised the 30-Day Satisfaction Guarantee to further induce consumers to purchase the Q-Ray bracelet. PX 4 at ¶ 14.

In the Complaint infomercial, the host, Early, states, “Try your Q-Ray ionized bracelet

risk-free for a full 30 days and start getting immediate relief the very first time you try it on, or simply return it for a full refund of your purchase price.” *Stipulated*. This unambiguous message is reinforced by the onscreen writing stating, “RISK FREE OFFER Your Q-Ray comes with our money back guarantee!” PX 40 at 14:2-3. The 30-day Satisfaction Guarantee is explicit in this language. Similar representations are made during the ordering instructions where the off-screen announcer says, “And remember, your Q-Ray ionized bracelet is backed by our ironclad money back guarantee. If you are not absolutely 100 percent satisfied, just send your Q-Ray back for a full refund of your purchase price.” PX 40. This is again reinforced by the onscreen writing stating, “Your Q-Ray Ionized Bracelet is backed by our 30 Day Money Back Guarantee.” PX 40 at 18:12-20. These statements, or similar statements are repeated, both verbally and in onscreen writing, throughout the remainder of the infomercial. PX 40 at 31:8-16; 32:14-16; 38:25-39:1; 39:4-7; 39:22-25; 40:18-20; 42:16-23; 45:25-46:1; 43:7-8; 44:4-5; 44:19-20; 47:6-15; 47:21-22; 49:15-23.

Defendants represented that the 30-Day Satisfaction Guarantee permits consumers to readily obtain a full refund of the purchase price if they return the Q-Ray bracelet within 30 days. PX 4 at ¶ 23. *Stipulated as to QT, Inc. only*. In addition to the telephone number provided, the television infomercial directs customers to Defendants’ website, www.qray.com, so they can order Q-Ray bracelets via the Internet as well. PX 4 at ¶ 14. *Stipulated as to QT, Inc. only*. QT displayed its website URL on its television infomercials for the Q-Ray bracelet. *Stipulated*. For example, during the Complaint infomercial, “www.QRay.com” was displayed onscreen periodically throughout the entire program.

Stipulated.

During the Prime Time infomercial, an off-screen announcer states, “The Q-Ray Ionized Bracelet is made with a natural finish and comes with an unconditional 30-day money back guarantee. Call now. You have nothing to lose, but pain.” Simultaneously, information about the 30-Day Satisfaction Guarantee and placing an order appears on screen: “30 Day Money Back Guarantee; Q-Ray, Plus S&H, 30 Day Money Back Guarantee, Less S&H, Check Out Our Website, QRAY.COM, Your Prescription For Good Health.”

Stipulated.

Similar instructions that refer viewers to QT’s website appear onscreen throughout the entire infomercial. Similarly, the text “www.Qray.com” flashes on and off the screen throughout the entire Onyx infomercial. The infomercials for the Q-Ray bracelet increased traffic on QT’s website. *Stipulated.*

2. Defendants’ 30-Day Satisfaction Guarantee is deceptive.

a. All consumers who bought the Q-Ray bracelet were not entitled to the advertised refund policy.

Despite the heavily advertised 30-Day Satisfaction Guarantee for any Q-Ray bracelet purchaser, Defendants’ refund policies varied based on the type of bracelet purchased and the method of purchase. *See e.g.*, PX 102. As of December 12, 2002, the refund policy for the Standard, Deluxe, and Black Ball styles of the Q-Ray bracelet ordered online was a 10-day satisfaction guarantee. The only style of bracelet with the 30-Day Satisfaction Guarantee on the Q-Ray website was the least expensive style, the Natural finish bracelet. PX 322-323.

Until early 2003, QT had different refund policies for television-based sales and

Internet-sales. PX 7 at No. 101; *see also* PX 219. The refund policy for Internet sales was 10 days from delivery date as approved by Defendant Que Te Park. PX 7 at No. 102; PX 8 at Nos. 122-123; *see also* PX 219. Que Te Park was not sure why the policy for Internet sales was shorter but he said the company did not sell as many bracelets online so they kept the policy different. PX 19 at 316:6-14. Defendants' infomercial advertising failed to alert consumers to the different online purchase refund policy. *See* PX 39-40; PX 46-51.

Defendants' refund policy changed some time between January 2003 and May 2003 to give the 30-Day Satisfaction Guarantee to all consumers, whether purchasing by telephone or online. The refund policy for internet sales changed to 30 days sometime in 2003. *Stipulated.* Defendants also adopted an internal policy of 45 days from the published shipped date on the invoice. DX 312 at 53:11-54:24; T. 1089.

Furthermore, the Q-Ray website did not prominently disclose the fact that most bracelet styles sold online were not entitled to the same 30-Day Satisfaction Guarantee that was heavily promoted on television. For example, in December 2002, the order pages on the Q-Ray website for Standard and Deluxe style bracelets featured a picture of each style with the phrase "SATISFACTION GUARANTEED!" in large font below the image and a click button link to purchase the item. A text link in small font and lower caps stating, "click here for details," appeared less prominently next to the phrase "SATISFACTION GUARANTEED!" Only if a consumer clicked on the link would he or she find out that the

Internet refund policy was much shorter than the one advertised in the infomercial. PX 322-23.

Many consumers expressed confusion over the 30-Day Satisfaction Guarantee and whether the same refund policy advertised in the infomercial was honored for online purchases. They stated that it was not clearly disclosed in the infomercials or on the website whether the same refund policy applied to online purchases. Indeed, some consumers who ordered online and attempted to get refunds complained when they found out after the fact that online purchases were not entitled to the same refund policy advertised in the infomercial. PX 16-17; PX 185-194.

Aaron Dacken (“Dacken”), an employee of QT, authored a document regarding the different refund policies for different styles of bracelets on or about June 5, 2002. *Stipulated.* The refund period for the natural series and silver deluxe bracelet styles was 30 days as of June 2002. *Stipulated.* The refund period for the standard and blackball series bracelet styles was 10 days as of June 2002. *Stipulated.* The refund period for the combo deluxe bracelet style ordered through the infomercials was 30 days from delivery as of June 2002. PX 7, No. 99; PX 8, No. 119. The refund period for the combo deluxe bracelet style ordered online was 10 days from delivery as of June 2002. PX 7, No. 100; PX 8, No. 120. As of December 2002, although the then-current infomercial was advertising the 30-Day Satisfaction Guarantee for the Deluxe Combo style Q-Ray bracelet, the refund policy for the same bracelet ordered online was a 10-day satisfaction guarantee. PX 39-40; PX 322-323.

Moreover, from 2000 to August 2002, the warehouse employees only provided a 10-

day return policy to consumers who purchased the Deluxe Combo bracelet even if the consumer ordered by calling the toll-free number given in the television infomercial and was clearly entitled to the 30-Day Satisfaction Guarantee advertised on television. PX 219. The infomercials that aired between 2000 and 2003 failed to disclose that the 30-Day Satisfaction Guarantee was not available for certain styles of bracelets purchased. *See* PX 39-40; PX 46-51.

b. Many consumers had difficulty in obtaining refunds.

Defendants knew they had problems with customer service complaints and refunds from the inception of their television advertising. PX 19 at 68:17-69:14. *See also* PX 238. Que Te Park has final approval over refund policies. PX 19 at 316:23-317:1. QT started handling its own returns in the second part of 2002 because they had “very bad experience with another outsourcing company.” PX 19 at 310:16-25. QT has employed its own customer service representatives to answer consumer inquiries since approximately the fourth quarter of 2002. *Stipulated.*

QT experienced delays in processing refund requests, starting at least as early as the second half of 2002. PX 7 No. 113; PX 8 No. 140. QT received complaints in the second half of 2002 from customers who were unable to get through to representatives on QT’s phone lines. PX 7 No. 117; PX 8 No. 148. QT received complaints in the second half of

2002 from customers who never received responses to their phone messages or electronic mail inquiries. PX 7 No. 121; PX 8 No. 155.

QT experienced delays in processing refund requests in the first half of 2003. PX 7 No. 114; PX 8 No. 142. QT received complaints in the first half of 2003 that consumers had returned the Q-Ray bracelet but had not received a refund. PX 7 No. 110; PX 8 No. 134. QT received complaints in the first half of 2003 from customers who never received responses to their phone messages or electronic mail inquiries. PX 7 No. 122; PX 8 No. 157. QT received complaints in the first half of 2003 from customers who were unable to get through to representatives on QT's phone lines. PX 7 No. 118; PX 8 No. 149.

Dacken's job titles during the time he was employed by QT included customer service team leader, customer service supervisor, and customer service manager. *Stipulated.* Dacken's job responsibilities included communicating company refund policies to consumers, applying company refund policies to consumer refund requests, and responding to customer complaints. *Stipulated.*

Dacken wrote a memo on or about October 10, 2002 to Customer Service regarding reducing refund returns. He stated, "Per Mr. Park, we have been charged with the task of decreasing the number of refund returns." The memo also stated, "the processing time for returns is decreasing and should continue to do so until the Returns Department is processing returns within 24 hours of delivery, so the exchanges and upgrades will not be taking 2-3 weeks, as has been the case." *Stipulated.*

Crystal Holloway ("Holloway") has been employed by QT as senior customer service

manager since February 2003. *Stipulated.* Holloway received complaints from customers who returned their bracelets but did not receive a refund. PX 312 at 62:6-9. Holloway testified that she recognized the e-mail in which she wrote, “Complaints are low compared to three to four months ago when we were receiving around five to six daily,” and stated that she was referring to complaints from the Better Business Bureau (“BBB”) and Attorney General. PX 312 at 64:9-65:14; PX 184. Holloway was aware of complaints from consumers who were not able to get through to representatives on the customer service phone lines. PX 312 at 81:6-10. Holloway was aware of complaints from customers that they never received responses to their e-mails or phone messages. PX 312 at 83:1-6.

Charles Park oversaw customer service and operations (fulfillment department) as an executive at QT and had authority to make decisions in those departments but consulted Que Te Park for major decisions. PX 21 at 60:6-11, 61:4-62:2; T. 1057-59, 1066, 1088. While he was VP of general management, Charles Park was responsible for creating policies for the customer service department in conjunction with the customer service managers, Dacken and Holloway. PX 21 at 63:5-13. Charles Park implemented new procedures and adopted new forms to expedite the return process. T. 998-1003; DX 36, 47. As of the time of trial, all of the current return issues had been resolved. T. 1085-86.

QT had a 25-percent return rate between 2000 and 2003, which includes the time period Charles Park was responsible for the customer service department. T. 1082.

Although Defendants claim that QT no longer has problems with refunds and returns to consumers and that all consumers that request a refund get a refund pursuant to the 30-Day

Satisfaction Guarantee, Charles Park testified that when QT revised its policy in mid-2003 to give all consumers the 30-Day Satisfaction Guarantee, the change was prospective and not retroactive. Therefore, consumers that previously were denied refunds because they were given only a 10-day satisfaction guarantee did not receive their refunds. T. 1086-88.

Charles Park would inform Que Te Park, at least once a week, about major issues with customer service; for example, problems with refund processing, call volume or customer service initiatives, and complaints from consumers. PX 21 at 85:24-87:9; T. 1087-88.

Many consumers complained to the BBB and state Attorney General offices about problems obtaining refunds for the Q-Ray bracelet. *See e.g.*, PX 184; PX 216-217, PX 220. As of May 20, 2003, QT had an “unsatisfactory” record with the BBB because of its return and refund problems. T. 598.

Numerous consumers complained directly to QT about general dissatisfaction with the Q-Ray bracelet and problems regarding Defendants’ customer service and refund policy. *See e.g.*, PX 203-208; PX 210; PX 212; PX 220. In particular, a number of consumers complained about the difficulty in obtaining refunds and/or not receiving refunds at all after they returned their bracelets. Many consumers complained that they did not receive refunds in a timely manner or that they were unable to even get in touch with QT’s customer service

– the phone lines were often busy, voice mail boxes were often full, or voice mail and email messages were not returned. PX 200, PX 203-210, PX 212-217, PX220.

Defendants failed to honor their unconditional 30-Day Satisfaction Guarantee as advertised and failed to provide readily available refunds as claimed.

N. CONSUMER INJURY / SALES / PROFITS

1. Cost.

The retail price of the Q-Ray bracelet sold by QT ranges from \$49.95 to \$249.95. *Stipulated.* QT's wholesale cost for the Q-Ray bracelet ranges between \$7.50 and \$28 depending on the style. PX 7 No. 36; PX 8 No. 38; PX 19 at 32:7-18. Defendants thus marked up the bracelet *over 650 percent* in setting the retail price to consumers.

2. Total Sales of the Q-Ray Bracelet.

QT's gross sales of the Q-Ray bracelet from January 1, 1996 through June 30, 2003 were \$137,172,907. *Stipulated.*

QT's gross "consumer direct" sales for the period were \$114,609,182. *Stipulated.*

QT's net sales direct to consumers from January 1, 1996 through June 30, 2003 were \$87,476,933. *Stipulated.*

3. Total Sales Since Inception of Infomercials.

There was a substantial jump in sales of the Q-Ray bracelet after the infomercials started airing in 2000 and that significant increase in sales continued as the infomercials kept

airing. T. 96-97. Que Te Park testified that prior to the infomercials starting in the second half of 2000, he only sold sunglasses at wholesale. T. 322.

QT's gross sales direct to consumers in 2000 were \$6,190,566, compared to \$175,488 in 1999. *Stipulated.*

QT's gross sales of the Q-Ray bracelet from January 1, 2000 through June 30, 2003, when the infomercials were airing, were \$125,905,492. *Stipulated.*

- i. Of this amount, \$114,152,089 were gross sales direct to consumers and \$11,753,403 were gross sales to wholesalers. *Stipulated.*
- ii. Of this amount, \$27,132,249 was refunded to consumers and \$348,470 was refunded to wholesalers. *Stipulated.*

Thus QT's net sales from January 1, 2000 through June 30, 2003, when the infomercials were airing, were \$98,424,773. *Stipulated.*

- i. Net sales direct to consumers from January 1, 2000 through June 30, 2003 were \$87,019,840. *Stipulated.*
 - a. Net sales direct to consumers in the year 2000 totaled \$5,538,850. *Stipulated.*
 - b. Net sales direct to consumers in the year 2001 totaled \$14,759,120. *Stipulated.*
 - c. Net sales direct to consumers in the year 2002 totaled \$37,177,379. *Stipulated.*
 - d. Net sales direct to consumers from January 1, 2003 through June 30, 2003 totaled \$29,544,491. *Stipulated.*
- ii. Net sales to wholesalers from January 1, 2000 through June 30, 2003 were \$11,404,933. *Stipulated.*

QT's net profit for the years 1996 through September 2003 was approximately

\$22,600,000. T. 363-64; PX 70.

- i. QT's net profit for 2000 was approximately \$440,000. PX 70.
- ii. QT's net profit for 2001 was approximately \$860,000. PX 70.
- iii. QT's net profit for 2002 was approximately \$9,100,000. T. 363-64; PX 70.
- iv. QT's net profit for 2003 was approximately \$12,100,000. T. 363-64; PX 70.

O. DEFENDANTS CONTINUE TO ADVERTISE AND SELL THE Q-RAY BRACELET.

Defendants have continued to disseminate print advertisements, short-spot television ads, program-length infomercials, as well as Internet advertising and emails during the course of this litigation. The infomercials continue to air nationally on a variety of television channels and print advertisements have appeared in national publications. T. 603-05; PX 261-62.

Under the terms of the stipulated preliminary injunction entered into by the parties, Defendants are prohibited from making or assisting others in making, directly or by implication, any materially false or misleading oral or written statement or representation in connection with the advertising, marketing, promotion or offer for sale of the Q-Ray bracelet. PX 3.

In November 2005, the FTC contacted Defendants regarding a then-currently airing infomercial for the Q-Ray bracelet that contains implicit and express claims of pain-relief and

efficacy. The FTC advised Defendants of its concern that such claims violate the terms of the preliminary injunction. T. 603-04. The Court is not deciding any claims concerning the November 2005 infomercial as part of this trial.

In addition, Defendants are in the process of developing new “ionized” products, including an ionized ring, pendant and other products. T. 343-44. The fact that Defendants continue to market the Q-Ray bracelet demonstrates the necessity for a permanent injunction in order to ensure that any future marketing of the Q-Ray bracelet or related products does not violate the Act.

V. CONCLUSIONS OF LAW.

A. JURISDICTION AND VENUE.

This action is brought under Section 13(b) of the Federal Trade Commission Act (“the Act”) for violations of Sections 5 and 12 of the Act. 15 U.S.C. §§ 45, 52, 53. This Court has jurisdiction over the subject matter of this action pursuant to 28 U.S.C. §§ 1331, 1337(a), and 1345, and 15 U.S.C. §§ 45(a) and 53(b). The parties have consented to a Magistrate Judge’s jurisdiction pursuant to 28 U.S.C. § 636(c)(1).

Venue is proper in this district under 28 U.S.C. § 1391(b) and (c) and 15 U.S.C. § 53(b) because Defendants reside in this district and a substantial part of the alleged events or omissions giving rise to the FTC’s claims occurred in this district.

1. The Q-Ray Bracelet is a device.

In addition, the FTC contends that this Court has jurisdiction over this matter pursuant to 15 U.S.C. § 52 because the Q-Ray Bracelet is a device. Defendants deny this contention.

Section 52(a) states:

It shall be unlawful for any person, partnership, or corporation to disseminate, or cause to be disseminated, any false advertisement—

(1) By United States mails, or in or having an effect upon commerce, by any means, for the purpose of inducing, or which is likely to induce, directly or indirectly the purchase of food, drugs, *devices*, services, or cosmetics; or

(2) By any means, for the purpose of inducing, or which is likely to induce, directly or indirectly, the purchase in or having an effect upon commerce, of food, drugs, *devices*, services, or cosmetics.

(emphasis added). Thus, for Defendants' advertisements to fall under the regulatory mandates of § 52(a), the Court must find that the Q-Ray Bracelet constitutes a food, drug, device, service, or cosmetic.

For the purposes of § 52, 15 U.S.C. § 55(d) defines "device" as 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 man or other animals,

or

(3) intended to affect the structure or any function of the body of man or other animals,

and

which does not achieve any of its principal intended purposes through chemical action within or on the body of man or other animals *and* which is not dependent upon being metabolized for the achievement of any of its

principal intended purposes.

(emphasis added).

In *United States v. Universal Management Services, Inc.*, 191 F.3d 750, 754 (6th Cir. 1999), the defendants sold and distributed electric gas grill igniters outfitted with finger grips and marketed them as pain-relieving devices. The defendants argued that their product did not have any effect on the structure or function of the body and was thus not a device. *Id.* at 755. The statute at issue was the Federal Food, Drug & Cosmetic Act, 21 U.S.C. § 321(h) (“FDCA”), whose definition of “device” is essentially identical to the definition in 15 U.S.C. § 55(d).¹⁷ After discussing the defendants’ argument, the court stated that “[the defendants] also assert their product relieves pain. As such, the products are intended to affect the function of the body and are, therefore, devices under 21 U.S.C. § 321(h)(3).” *Universal Mgmt. Services*, 191 F.3d at 755.

In another case analyzed under 21 U.S.C. § 321(h), the court in *United States v. One Unlabeled Unit*, 885 F. Supp. 1025, 1027-1028 (N.D. Ohio 1995), found that a vinyl-covered bed with audio speakers mounted on its side was a device. The defendant argued that the bed

¹⁷ The term “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 ...
(2) intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals, or
(3) intending to affect the structure or any function of the body of man or other animals, and which does not achieve its primary intended purpose through chemical action within or on the body of man or other animals and which is not dependent upon being metabolized for the achievement of its primary intended purposes.
Universal Mgmt. Services, 191 F.3d at 755 (citing 21 U.S.C. 321(h)).

was intended primarily for the purpose of relaxation and other health benefits flowed from relaxation. *Id.* at 1028. The court disagreed, however, and noted that the brochure for the bed made greater health-related claims, including claims related to improved circulation and balance, and a testimonial suggested the bed reduced the need for insulin, reduced cholesterol, reduced arthritis pain, and relieved indigestion. *Id.* Thus, the court held that “[t]hese are uses ‘in the cure, mitigation, treatment, or prevention of disease.’ Hence, [the bed] is a “device” subject to FDA regulation.” *Id.*

When considering a device under the FDCA, “the ‘intended’ uses of a device must be determined from objective evidence in promoting, distributing and selling the device.” *One Unlabeled Unit*, 885 F. Supp. at 1028. Therefore, courts look to “the [seller’s] intent, as determined or inferred from labeling, promotional material, advertising, or any other relevant source, which controls, and not the actual physical effect on the human body.” *U.S. v. Kasz Enterprises, Inc.*, 855 F. Supp. 534, 539 (D.R.I. 1994).

In this case, as explained in Section IV.G., *supra*, Defendants represented that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain, including, but not limited to, musculoskeletal pain, sciatic pain, persistent headaches, sinus problems, tendinitis, or injuries. Defendants clearly *intended* the Q-Ray bracelet to be used in the cure, mitigation, treatment, or prevention of disease in their customers and they *intended* the Q-Ray bracelet to affect the structure and function of their customers’ bodies. The purpose of the Q-Ray bracelet was pain relief, and like *Universal Management Services*, such pain-relief intentions carry significant weight with this Court.

Furthermore, no credible evidence was presented that any of the Q-Ray bracelet's principal intended purposes are achieved through chemical action within or on the human body. Yet, even if the Q-Ray bracelet worked via chemical reaction within or on the human body, the Q-Ray bracelet would then constitute a drug under 15 U.S.C. § 55(c)¹⁸. *U.S. v. 22 Rectangular or Cylindrical Finished Devices, More or Less, * * * the Ster-O-Lizer MD-200 * * **, *Halogenic Products Co.*, 714 F. Supp. 1159, 1164 n.13 (D. Utah 1989) (“The only apparent distinction between a ‘drug’ and a ‘device’ under the [FDCA] is that articles dependent upon chemical action or being metabolized fall within the definition of a “drug” rather than a ‘device.’”); *see also Universal Mgmt. Services*, 191 F.3d at 755 n.2 (stating that if the defendants were correct that the gas igniter operates through chemical action, it would likely be subject to regulation as a drug or drug delivery device under the FDCA).¹⁹ Finally,

¹⁸ The term “drug” means (1) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (2) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (3) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (4) articles intended for use as a component of any article specified in clause (1), (2), or (3); but does not include devices or their components, parts, or accessories.

¹⁹ Again, the definition for “drug” under 21 U.S.C. 321 is essentially identical to the definition in 15 U.S.C. 55(c). “Drug” is defined in 21 U.S.C. 321 as follows: The term “drug” means (A) articles recognized in the official United States Pharmacopoeia, official Homoeopathic Pharmacopoeia of the United States, or official National Formulary, or any supplement to any of them; and (B) articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease in man or other animals; and (C) articles (other than food) intended to affect the structure or any function of the body of man or other animals; and (D) articles intended for use as a component of any article specified in clause (A), (B), or (C). A food or dietary supplement for which a claim, subject to sections 343(r)(1)(B) and 343(r)(3) of this title or sections 343(r)(1)(B) and 343(r)(5)(D) of this title, is made in accordance with the requirements of section 343(r) of this title is not a drug solely because the label or the labeling contains such a claim. A food, dietary ingredient, or dietary supplement for

there was no evidence presented that the achievement of the Q-Ray bracelet's intended principal purposes depends upon the bracelet being metabolized.

Thus, based on Defendants' advertisements, *Universal Management Services*, and *One Unlabeled Unit*, the Court finds that the Q-Ray bracelet is: (1) intended for use in the cure, mitigation, treatment, or prevention of disease in humans; and (2) intended to affect the structure and function of the human body. The Court also finds that: (a) none of its principal intended purposes are achieved through chemical action within or on the human body; and (b) the achievement of its intended principal purposes does not depend upon the Q-Ray bracelet being metabolized. Therefore, this Court finds that the Q-Ray bracelet is a device, and the Court also has jurisdiction over this matter pursuant to 15 U.S.C. § 52.

2. The Court Has Authority Under Section 13(b) of the Act To Grant Equitable Relief, Which Includes Restitution and Rescission.

Defendants argue that the Court's power to award damages under Section 13(b) of the Act ("Section 13(b)") is limited. The Court can, however, award monetary relief by reason of its equitable powers of rescission and restitution. Section 13(b) authorizes the FTC to initiate federal district court proceedings to enjoin violations of any provision of law enforced by the FTC, including the dissemination of false advertisements and unfair and deceptive acts of commerce. 15 U.S.C. § 53(b). Section 13(b) also provides "[t]hat in proper cases the [FTC] may seek, and after proper proof, the court may issue, a permanent

which a truthful and not misleading statement is made in accordance with section 343(r)(6) of this title is not a drug under clause (C) solely because the label or the labeling contains such a statement.

injunction.” *Id.* Furthermore, “in a proceeding under [S]ection 13(b), the statutory grant of authority to the district court to issue permanent injunctions includes the power to order any ancillary equitable relief necessary to effectuate the exercise of the granted powers.” *FTC v. Amy Travel Service, Inc.*, 875 F.2d 564, 572 (7th Cir. 1989). Lastly, “[r]escission and restitution are proper forms of equitable relief.” *Id.* at 571.

B. BACKGROUND LAW.

The FTC brought this action under sections 5(a) (“Section 5(a)”) and 12 (“Section 12”) of the Act. 15 U.S.C. §§ 45(a), 52. Section 5(a) makes unlawful “unfair or deceptive acts or practices in or affecting commerce.” Section 12(a) specifically targets false advertising. Section 12(b) also declares that “[t]he dissemination or the causing to be disseminated of any false advertisement within the provisions of subsection (a) of this section shall be an unfair or deceptive act or practice in or affecting commerce within the meaning of [Section 5].” Thus, a violation of Section 12, dissemination of a false advertisement, constitutes a violation of Section 5(a).

For purposes of Section 12, 15 U.S.C. § 55 defines “false advertisement” as “an advertisement, other than labeling, which is misleading in a material respect.” Regarding Section 5(a), “[t]he FTC may establish corporate liability under section 5 with evidence that a corporation made material misrepresentations likely to mislead a reasonable consumer.” *FTC v. Bay Area Bus. Council, Inc.*, 423 F.3d 627, 635 (7th Cir. 2005). Therefore, for both Sections 5(a) and 12, the Court must determine whether any of Q-Ray’s advertisements were misleading in a material respect. *See Kraft, Inc. v. FTC*, 970 F.2d 311, 314 (7th Cir. 1992);

Bay Area Bus. Council, Inc., 423 F.3d at 635. Finally, the Court’s inquiry can be articulated in the following three-part test: an advertisement will be found misleading and deceptive if (1) there is a representation, omission, or practice that (2) is likely to mislead consumers acting reasonably under the circumstances, and (3) the representation, omission, or practice is material. *Kraft, Inc.*, 970 F.2d at 314; *F.T.C. v. Pantron I Corp.*, 33 F.3d 1088, 1095 (9th Cir. 1994).

1. What claims are conveyed in QT’s advertisements?

The Court first must determine what claims are conveyed in QT’s advertisements. *Kraft, Inc.*, 970 F.2d at 314. There are two types of advertising claims: express and implied. *See id.* at 318. “Express claims directly represent the fact at issue while implied claims do so in an oblique or indirect way.”²⁰ *Id.* at 318 n.4. The meaning of an advertisement, the claims or net impressions communicated to reasonable consumers, is a question of fact. *National Bakers Servs., Inc. v. FTC*, 329 F.2d 365, 367 (7th Cir. 1964). In determining what messages or claims an ad communicates to reasonable consumers, the Court looks to the overall, net impression made by the advertisement to determine whether the net impression is such that the ads would be likely to mislead reasonable consumers. *F.T.C. v. U.S. Sales Corp.*, 785 F. Supp. 737, 745 (N.D. Ill. 1992); *see FTC v. Colgate-Palmolive Co.*, 380 U.S.

²⁰ “To illustrate, consider the following. Suppose a certain automobile gets poor gas mileage, say, 10 miles per gallon. One advertisement boasts that it gets 30 miles per gallon while another identifies the car as the ‘Miser,’ depicts it rolling through the countryside past one gas station after another, and proclaims that the car is inexpensive to operate. Both ads make deceptive claims: the first does so expressly, the second does so impliedly.” *Kraft, Inc.*, 970 F.2d at 318 n.4.

374 (1965) (the meaning of an advertisement may be determined by an examination of the ad itself).

Defendants argue that evidence regarding what claims an ad conveys to reasonable consumers should be given by an expert in consumer psychology or consumer behavior.²¹ Defendants cite *Amy Travel*, 875 F.2d 564, in support of their argument, but Defendants wrongly interpreted *Amy Travel* and thus their argument fails. In *Amy Travel*, the district court prevented an expert in travel marketing from commenting on consumer perceptions of the sales pitch at issue because the district court found that such testimony, how consumers would react to sales material, “should be given by an expert in consumer psychology or consumer behavior.” 875 F. 2d at 573. The Seventh Circuit upheld the district court’s decision, and Defendants improperly argue the district court’s finding out of context. The district court did not mandate that evidence on consumer reactions to advertisements must be given by an expert in consumer psychology or consumer behavior; it merely found that if a party wants to present expert testimony on the subject, an expert in consumer psychology or consumer behavior must be presented, and a travel marketing expert will not suffice. *Id.*

More broadly, Defendants argue that the FTC must present some extrinsic evidence (i.e., a consumer survey) to establish what claims the ads communicate to reasonable consumers. However, on a motion for summary judgment in *F.T.C. v. Febre*, No. 94 C 3625,

²¹ While Defendants present their arguments regarding what claims are communicated generally, the Court assumes Defendants are referring to implied claims. What is communicated in an express claim is obvious and apparent and no expert testimony would ever be needed. See *Kraft*, 970 F.2d at 318-19.

1996 WL 396117, at *4 (N.D. Ill. July 3, 1996), the defendants argued that a question of fact remained as to whether the alleged false impressions created by the advertisements were those of a reasonable consumer upon viewing the advertisements. The defendants “insist[ed] that no such determination [could] be made absent extrinsic evidence, i.e., a consumer survey regarding consumers’ reaction to the advertisements.” *Id.* The court found, however, that

[t]here is no authority for defendants’ contention that implied claims cannot be found to be deceptive absent extrinsic evidence. The courts and the FTC have consistently recognized that implied claims fall along a continuum from those which are so conspicuous as to be virtually synonymous with express claims to those which are barely discernible. It is only at the latter end of the continuum that extrinsic evidence is necessary.

Id. (citations omitted). Where implied claims are conspicuous and “reasonably clear from the face of the advertisements,” extrinsic evidence is not required. *Kraft, Inc.*, 970 F.2d at 320.

2. Are the claims misleading?

The FTC may use two theories to prove an advertisement is deceptive or misleading: (1) the “falsity” theory and (2) the “reasonable basis” theory. *Pantron*, 33 F.3d at 1096; *F.T.C. v. Sabal*, 32 F. Supp. 2d 1004, 1007 (N.D. Ill. 1998). Under the falsity theory, the FTC has the burden of proving that the express or implied claim in the advertisement is false. *Pantron*, 33 F.3d at 1096.

To prevail on the reasonable basis theory, the FTC must prove that Defendants lacked a reasonable basis for asserting that the claim was true. *Id.* However, the Court must first determine what level of substantiation Defendants were required to have for their advertising

claims, and this determination is a question of fact. *Id.*; *Sabal*, 32 F. Supp. 2d at 1007. Then, the Court must determine whether Defendants possessed that level of substantiation.²² *Pantron*, 33 F.3d at 1096; *Sabal*, 32 F. Supp. 2d at 1007. Defendants have the burden of establishing what substantiation they relied on for their product claims. The FTC has the burden of proving that Defendants' purported substantiation is inadequate, and the FTC need not conduct or present clinical studies showing that the product does not work as claimed. *See Sabal*, 32 F. Supp. 2d at 1008-09.

In assessing reasonable basis arguments, two different types of advertising claims may be at issue: (1) establishment claims and (2) non-establishment claims. *Thompson Medical Co. v. F.T.C.*, 791 F.2d 189, 194 (D.C. Cir. 1986). Establishment claims contain express or implied representations about the level of support for a particular claim (i.e., the claim states that a product has been found to be superior by scientific tests). *Id.* For such claims, the advertiser must possess the level of proof claimed in the ad. *Id.* For non-establishment claims, claims that do not assert a specific level of substantiation (i.e., a simple claim of efficacy), "the reasonable basis inquiry has been defined more flexibly." *Id.* For such non-establishment claims, the Court can look to a number of factors to determine what level of substantiation was required. *FTC Policy Statement Regarding Advertising Substantiation* (appended to *In re Thompson Med. Co.*, 104 F.T.C. 648, 839 (1984) [hereinafter "*FTC*

²² Defendants argue that the level of substantiation required would differ between the corporate and individual defendants. Defendants, however, offer no support for this proposition, and case law indicates that the standard is the same for both types of defendants. *E.g.*, *U.S. Sales Corp.*, 785 F. Supp. at 748-49.

Substantiation Policy Statement”). The factors include: (1) the type of claim; (2) the product; (3) the consequences of a false claim; (4) the benefits of a truthful claim; (5) the cost of developing substantiation for the claim; and (6) the amount of substantiation experts in the field believe is reasonable. *Id.*

Defendants claim that the *FTC Substantiation Policy Statement* only applies to proceedings before the FTC and not to litigated proceedings under the Act. However, at least one appellate court has relied upon the *FTC Substantiation Policy Statement* in resolving a case brought before the district court first and under the Act. *Pantron*, 33 F.3d at 1096 n.23. In *Pantron*, the court questioned why the FTC in that case did not pursue the reasonable basis theory and it cited the factors contained in the *FTC Substantiation Policy Statement* in that discussion. *Id.* Moreover, the Supreme Court has stated that the FTC’s judgment should be given great weight by reviewing courts when analyzing deceptive advertising cases. *Colgate-Palmolive Co.*, 380 U.S. at 385.²³ Thus, the *FTC Substantiation Policy Statement* may provide this Court with useful guidance regarding how to analyze and consider the claims at issue in the instant case. *See U.S. v. Locascio*, 357 F. Supp. 2d 536, 549 (E.D.N.Y. 2004) (“The FTC has attempted to provide some guidance regarding the legal standards which it applies in Section 12 cases and in October 1983, it issued the FTC Policy

²³ “This admonition is especially true with respect to allegedly deceptive advertising since the finding of a [§] 5 violation in this field rests so heavily on inference and pragmatic judgment. Nevertheless, while informed judicial determination is dependent upon enlightenment gained from administrative experience, in the last analysis the words ‘deceptive practices’ set forth a legal standard and they must get their final meaning from judicial construction. *Colgate-Palmolive Co.*, 380 U.S. at 385.

Statement on Deception, in which it sought to ‘provide guidance to the public’ regarding the ‘Commission’s enforcement policy against deceptive ads or practices.’” (quoting, FTC, *FTC Policy Statement on Deception*, October 14, 1983, at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>)).

3. Are the claims material?

“A claim is considered material if it ‘involves information that is important to consumers and, hence, likely to affect their choice of, or conduct regarding a product.’” *Kraft, Inc.*, 970 F.2d at 322 (quoting *Cliffdale Assocs.*, 103 F.T.C. 110, 165 (1984); *Federal Trade Commission Policy Statement on Deception* (appended to *Cliffdale Assocs.*, 103 F.T.C. at 175, 182) [hereinafter “*FTC Deception Policy Statement*”]). Pursuant to the *FTC Deception Policy Statement*, three types of claims are presumed to be material: (1) express claims; (2) implied claims where there is evidence that the seller intended to make the claim; and (3) claims that significantly involve health, safety, or other issues that would concern reasonable consumers. *Kraft, Inc.*, 970 F.2d at 322. Defendants, however, claim that the *FTC Deception Policy Statement* only applies to proceedings before the FTC, and not to litigated proceedings under the Act. Yet, at least one appellate court has relied upon the *FTC Deception Policy Statement* in resolving a case brought first before the district court and under the Act. *Pantron I*, 33 F.3d at 1096 n.19. In *Pantron*, the court stated that “[e]xpress product claims are presumed to be material,” and the court cited the *FTC Deception Policy Statement*. *Id.* Thus, the *FTC Deception Policy Statement* may provide this Court with useful guidance regarding how to analyze and consider the claims at issue in the instant case.

See U.S. v. Locascio, 357 F. Supp. 2d 536, 549 (E.D.N.Y. 2004) (“The FTC has attempted to provide some guidance regarding the legal standards which it applies in Section 12 cases and in October 1983, it issued the FTC Policy Statement on Deception, in which it sought to ‘provide guidance to the public’ regarding the ‘Commission’s enforcement policy against deceptive ads or practices.’” (quoting, FTC, *FTC Policy Statement on Deception*, October 14, 1983, at <http://www.ftc.gov/bcp/policystmt/ad-decept.htm>)).

C. COUNT I.

1. Defendants Conveyed The Claim In Their Advertising That the Q-Ray Bracelet Provides Immediate, Significant, Or Complete Pain Relief From Various Types of Pain.

The websites, brochures, packaging, and four infomercials aired by Defendants between 2000 and 2003 convey an overall, net impression that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain.²⁴ The claim conveyed in these advertisements was either express, or, if considered an implied claim, it was “so conspicuous as to be virtually synonymous with express claims.” *Febre*, 1996 WL 396117, at *4. The Court required no testimony from an expert in consumer psychology or consumer behavior to discern the claim set forth in these advertisements. Nor did the Court need the assistance of a consumer market survey to extrapolate the net impression of the advertisements. The claim was obvious and apparent from viewing the infomercials. Considering the overall, net impression made by Defendants’ advertisements, the Court finds

²⁴ For a more complete discussion of the facts of these advertisements, please see Section IV.G., *supra*.

that in their advertising Defendants conveyed the claim that the Q-Ray bracelet provides immediate, significant, or complete pain relief from various types of pain.

2. Defendants Claim That the Q-Ray Bracelet Provides Immediate, Significant, Or Complete Pain Relief From Various Types of Pain Is Misleading.

Having established that Defendants made the claim that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain, the FTC must show that this claim was misleading. As explained above, the FTC may use two theories to prove Defendants' claim was misleading: (1) the falsity theory and (2) the reasonable basis theory. Relying on the latter theory, the Court finds that Defendants lacked a reasonable basis to advertise that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain.²⁵

a. Defendants Were Required To Possess Competent And Reliable Scientific Evidence To Substantiate This Claim.

The Court must first determine what level of substantiation Defendants were required to possess for this claim. This is a question of fact, and Defendants bear the burden of establishing what substantiation they relied on for this claim. The FTC has the burden of proving that Defendants' purported substantiation is inadequate. At the crux of the Court's substantiation finding lies the fact that Defendants made a medical, health-related claim.

²⁵ Regarding the falsity theory, the substance of the FTC's case focused on the alleged lack of substantiation for Defendants' claims. Therefore, the Court analyzes Defendants' claim under the reasonable basis theory.

Asserting that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain is clearly a health-related, medical claim. No one would dispute that Tylenol makes medical, health-related claims in its commercials when it declares that the consumption of Tylenol provides relief from various types of pain. The Court sees no difference in Defendants' infomercials. Defendants unequivocally aver to the viewer: purchase and wear a Q-Ray bracelet and you will experience immediate, significant, or complete pain relief. Such a claim must be based on a heightened level of substantiation.

In other cases involving health-related claims, courts have upheld the FTC's requirement that in order to have a "reasonable basis" to make the claim at issue, an advertiser must possess "competent and reliable scientific evidence" to substantiate that claim. *See, e.g., Sterling Drug, Inc. v. FTC*, 741 F.2d 1146, 1156-57 (9th Cir. 1984). Therefore, Defendants must have possessed "competent and reliable scientific evidence" when they made the claim that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain. At issue in this case is what amounts to "competent and reliable scientific evidence."

At trial, Dr. Hochberg testified that at least one well-conducted, placebo-controlled, randomized, double-blind or sham-controlled clinical trial would be required by qualified experts in the field of pain due to rheumatic disease to support a claim that a product relieves or treats musculoskeletal pain. Dr. Feldstein also testified that a placebo-controlled, randomized, double-blind trial is the gold standard in the scientific community and depending on the claims an advertiser wishes to make, such a gold-standard study should be

attempted to support those claims. Dr. Hochberg said that a randomized, double-blind, placebo-controlled study of the Q-Ray bracelet could have been conducted to determine if the bracelet had an effect on pain relief. He also testified that anecdotal evidence is not sufficient to demonstrate the efficacy of a product to treat pain.

In *Sabal*, the court assessed the FTC's request for a preliminary injunction for an alleged Section 5 violation, based on the sale of over-the-counter hair loss products, under the reasonable basis theory. 32 F. Supp. 2d at 1007-08. In finding that the FTC demonstrated a likelihood of success on the merits, the court used the following standard as the appropriate level of substantiation: "all claims about the effectiveness of over-the-counter hair loss products must be supported by '[v]alid scientific evidence, including well-controlled, double-blind clinical tests' in order to prevent 'subjective and biased reporting by users and observers.'" *Id.* at 1007 (quoting *FTC v. California Pacific Research, Inc.*, No. CV-N-88-602BRT, 1991 WL 208470, at *4 (D. Nev. 1991), and citing *Pantron*, 33 F.3d at 1096 n.23). In *California Pacific Research*, the court analyzed the defendants' substantiation for the claims made regarding a hair-loss product. 1991 WL 208470, at *4. In finding the defendants liable for violations of Sections 5 and 12, the court found:

All four of the foreign studies identified by defendants fail to meet even the most fundamental requirements for scientific validity and reliability, thus rendering their results completely unreliable. For example, none of the studies: was placebo controlled or double-blinded; used validated, objective measurement techniques; generated sufficient statistically significant data; was reproducible; or was published in any peer-reviewed journal. Consequently, these are not valid, scientific studies and they do not constitute a reasonable basis for defendants' claims.

Id. at *5. Finally, in *FTC v. SlimAmerica, Inc.*, 77 F. Supp. 2d 1263, 1274 (S.D. Fla. 1999), the court, in finding that the defendant violated both Sections 5 and 12 in its sale of a weight-loss product, held that “[s]cientific validation of the defendants’ product claims requires a double blind study of the combination of ingredients used in [the weight-loss product].”

In the instant case, with medical, health-related claims, a well-conducted, placebo-controlled, randomized, double-blind study, the gold standard, should have been conducted. That is the level of substantiation Defendants must have to make the claim that the Q-Ray bracelet provides immediate, significant, or complete pain relief. Defendants would not be required to have a gold-standard study to substantiate the Q-Ray bracelet if they did not make such a strong, medical claim. The choice belonged to Defendants. For example, Defendants could have said, “The Q-Ray bracelet is a stylish bracelet that is fun to wear,” or, “The Q-Ray bracelet will look cool on your wrist.” Barely any substantiation would have been required for those claims. However, when Defendants made express, health-related claims that the Q-Ray bracelet relieves pain, scientific validity requires a gold-standard study to support such claims.

b. Defendants Did Not Possess The Requisite Level Of Substantiation.

The Court must next examine Defendants’ purported substantiation and determine whether Defendants possessed the requisite level of substantiation outlined above; namely, a gold-standard study. In *Pantron*, the Ninth Circuit examined the value of the evidence of the Helsinki Formula’s effectiveness other than the placebo effect. The court discredited much of the evidence for failing to adhere to scientific standards. The studies offered by the

defendants were neither blinded nor placebo-controlled. *Pantron*, 33 F.3d at 1098. Defendants in this case argue that the studies they had in their files were enough, and they did not need a gold-standard study. The Court disagrees and finds that given the nature of the claim, a strong medical claim that the Q-Ray bracelet will provide prompt pain relief, a gold-standard study was required.

After carefully reviewing all of the evidence, the Court finds that Defendants did not possess adequate substantiation to make the claim that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain. As explained below, the Q-Ray bracelet's placebo effect possesses no substantiation value. Thus, the Court must look to Defendants' other evidence of substantiation. Defendants' other purported substantiation, however, is scientifically flawed and simply inadequate to support their pain claim. The Court fully sets forth its substantiation conclusions in in Part IV.L., *supra*. However, the Court will highlight some of the relevant evidence below.

Dr. Hochberg testified that none of the studies conducted on the Q-Ray bracelet that he reviewed provided reliable scientific proof that the Q-Ray bracelet relieves pain. Specifically, Dr. Hochberg testified that the Manginelli, Chinese, Italian, and both Trapp studies do not provide reliable scientific evidence that the Q-Ray bracelet relieves pain. Dr. Feldstein, Defendants' own expert, testified that some of the studies Defendants relied upon (i.e. Chinese, Korean, Italian, Manginelli, Trapp) are "sadly lacking" from a statistical standpoint and they do not conform to the standard of randomized prospectively designed controlled studies. The Japanese study was a two-paragraph letter, which contained no data

or information on the Q-Ray bracelet's impact on pain. Dr. Hochberg testified that the Mayo Clinic study demonstrated that the Q-Ray bracelet is no more effective than a placebo effect at relieving pain.

Dr. Wikswo testified that there is no scientifically plausible means, besides a process using radioactive particles or vacuums, of maintaining charge on a metal bracelet for more than a few minutes, regardless of the type of metal of which the bracelet is constructed. He also testified that there is no scientifically plausible means by which a charged metal bracelet could cause health benefits in a human body. Dr. Tiller, on the other hand, testified that it was possible to implant ions in a C-shaped metal object like the Q-Ray bracelet and "it would be foolhardy to presume that" a charge transfer with the body would have no biological effects. However, Dr. Tiller does not know how the Q-Ray bracelet is manufactured; his testimony regarding the implantation of ions in the Q-Ray bracelet was purely speculative; he never tested the Q-ray bracelet for the presence of an electrical charge, polarization, or ionization; he never offered any testimony about what possible biological effects would be; and unlike Dr. Wikswo, Dr. Tiller is not qualified as an expert in biological physics or in any biological science. Therefore, his testimony is granted little or no weight. Next, Dr. Yurasek has no basis to offer an expert opinion as to whether the Q-Ray bracelet is an effective treatment for pain, and his testimony about Traditional Chinese Medicine is irrelevant regarding whether the Q-Ray bracelet relieves pain. Finally, Dr. Olshansky's testimony is not probative because he never tested the Q-Ray bracelet and his discussion of the placebo effect, as explained below, is not a sufficient basis for substantiation.

c. The Placebo Effect Possesses No Substantiation Value.

Defendants also assert that evidence of a placebo effect provides substantiation and helps them establish that they possessed “competent and reliable scientific evidence.” The FTC argues the opposite. In *Pantron*, the product at issue was a purported baldness cure called the Helsinki Formula. 33 F.3d at 1090. The defendants in *Pantron* advertised that the Helsinki Formula “arrest[ed] hair loss and stimulate[d] hair regrowth in baldness sufferers.” *Id.* at 1090. The court found that such efficacy representations were based solely on the product’s placebo effect. *Id.* at 1097-1101. The Ninth Circuit asked whether “as a matter of law, a seller can represent that its product is effective even when this effectiveness is based solely on the placebo effect.” *Id.* at 1099. The court held that a seller cannot, and it is materially misleading to make such representations. *Id.* 1099-1101. The court found that the FTC was not “required to prove that a product is ‘wholly ineffective’ in order to carry its burden of showing that the seller’s representations of product efficacy are ‘false.’” *Id.* at 1100. In fact, when “a product’s effectiveness arises solely as a result of the placebo effect, a representation that the product is effective constitutes a ‘false advertisement’ even though some consumers may experience positive results.” *Id.*

The court in *Pantron* found a Section 12 violation, which is also a Section 5 violation, under the falsity theory. *Id.* at 1096-1101. However, many of the court’s conclusions are equally relevant under the reasonable basis theory. In fact, the FTC abandoned the reasonable basis theory on appeal and the Ninth Circuit commented that “[t]his abandonment is puzzling, to say the least, because it is difficult to imagine how the [FTC] could fail to

prevail on a reasonable basis theory.” *Id.* at 1096 n.23.

Regarding its conclusion that efficacy representations based solely on the placebo effect are materially misleading, the *Pantron* court relied on the reasoning of the court in *United States v. An Article . . . Acu-Dot . . .*, 483 F. Supp. 1311 (N.D. Ohio 1980). In *Acu-Dot*, the court considered a medical device, the Acu-dot, which was “a small, pin-head sized magnet attached to the underside of a circular, adhesive patch.” *Id.* at 1312. The Acu-dot’s manufacturer represented that the device was “for temporary relief of occasional minor aches and pains of muscles and joints.” *Id.* at 1312-13. The government claimed that this representation was false or misleading. *Id.* at 1313. The court found that the Acu-dot did indeed “often ... achieve its claims of providing ‘temporary relief of occasional minor aches and pains of muscles and joints,’” but this positive result was solely the result of the placebo effect. *Id.* at 1314. Thus, the court found that even though the claims were not technically false, they were “‘misleading’ because the device is not inherently effective, its results being attributable to the psychosomatic effect produced by the advertising and marketing of the device. A kiss from mother on the affected area would serve just as well to relieve pain, if mother’s kisses were marketed as effectively as the Acu-dot device.” *Id.* at 1315. Finally, the court noted that “the real difficulty of this case is that a ‘placebo’ can work only by means of the artifice of its presentation to the patient -- the patient must be misled as to its inherent effectiveness.” *Id.* at 1314 n. 3.

In light of the persuasive reasoning found in *Pantron* and *Acu-Dot*, the Court finds that the placebo effect possesses no substantiation value. More substantiation is needed than

studies establishing the Q-Ray bracelet's placebo effect. As the court in *Acu-Dot* made clear, when a product's efficacy is based solely on the placebo effect, the advertiser must misrepresent the effectiveness of the product.²⁶ The customer must be duped. With the Q-Ray bracelet, if Defendants had represented that the bracelet possessed no pain-relieving properties but was simply an interesting piece of wrist jewelry, there would be no placebo effect. Moreover, if Defendants honestly advertised that the Q-Ray bracelet relieved pain because of its placebo effect, the placebo effect would be nil. For the placebo effect to work, a seed of hope must be planted in the mind of the consumer. The purchaser, based on the advertiser's representations, must believe that *the bracelet* will cure his or her pain. Thus, the advertiser must trick the customer into believing that an inherently ineffective bracelet actually relieves pain.

In this case, the placebo effect does nothing to substantiate the claim that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain. If Defendants had marketed the bracelet by touting its aesthetic beauty or honestly explaining the placebo effect, no placebo effect would have existed, and this case would likely not have been brought by the FTC. Instead, Defendants claimed that the Q-Ray bracelet relieves pain and described ionization, chi, ying, and yang, which cumulatively created the bracelet's placebo effect. That placebo effect is misleading. An advertiser cannot sell a product based solely on the placebo effect by misleading its customers and making them believe a worthless

²⁶ For purposes of this discussion, the Court assumes the Q-Ray bracelet's efficacy is based solely on its placebo effect. Defendants' other studies are discussed below.

product actually works. Evidence of a placebo effect does not constitute “competent and reliable scientific evidence” and it possesses no substantiation value.

In light of the above and the Court’s discussion in Section IV.L., *supra*, the Court finds that Defendants did not possess the requisite level of substantiation for the claim that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain. Not only did Defendants not have a gold-standard study in their possession, they did not even have a copper-standard study. Defendants’ purported substantiation was lacking and scientifically flawed. Therefore, because Defendants disseminated a medical, health-related claim, a heightened level of substantiation was required, and Defendants did not possess the required level of substantiation, the Court finds that Defendants lacked a reasonable basis for asserting that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain. Thus, Defendants’ claim is misleading.

3. Defendants Claim That The Q-Ray Bracelet Provides Immediate, Significant, Or Complete Pain Relief From Various Types of Pain Is Material.

Because Defendants’ claim is a medical, health-related claim, it is material. Defendants’ claim clearly involves information that is important to consumers and likely affected their choice to buy the Q-Ray bracelet. *Kraft, Inc.*, 970 F.2d at 322. Moreover, the *FTC Deception Policy Statement* presumes materiality for express claims and claims that significantly involve health, safety, or other issues that would concern reasonable consumer. *Id.* The claim at issue in Count I, that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain, forms the heart of Defendants’ advertisements.

The Q-Ray bracelet is about pain relief. Without question, this medical, health-related claim by Defendants is material. *See Kraft, Inc.*, 970 F.2d at 322 (“The [FTC] is entitled to apply, within reason, a presumption of materiality, *Colgate-Palmolive*, 380 U.S. at 392, and it does so with three types of claims: (1) express claims; (2) implied claims where there is evidence that the seller intended to make the claim; and (3) claims that significantly involve health, safety, or other areas with which reasonable consumers would be concerned.”).

Based on the above, the Court finds that Defendants’ claim that the Q-Ray bracelet provides immediate, significant, or complete relief from various types of pain is materially misleading. Therefore, the Court finds that Defendants violated Sections 5 and 12 of the Act.

D. COUNT II.

1. Defendants’ Advertising For The Q-Ray Bracelet Conveyed The Claim That Tests Proved That The Q-Ray Bracelet Relieves Pain.

The brochures, packaging, and four infomercials aired by Defendants between 2000 and 2003 convey an overall, net impression that tests proved that the Q-Ray bracelet relieves pain.²⁷ The claim conveyed in these advertisements was either express, or, if considered an implied claim, it was “so conspicuous as to be virtually synonymous with express claims.”

Febre, 1996 WL 396117, at *4. The Court required no testimony from an expert in consumer psychology or consumer behavior to discern the claim set forth in these advertisements. Nor did the Court need the assistance of a consumer market survey to

²⁷ For a more complete discussion of the facts of these advertisements, please see Section IV.H., *supra*.

extrapolate the net impression of the advertisements. The claim was obvious and apparent from viewing the infomercials. Considering the overall, net impression made by Defendants' advertisements, the Court finds that in their advertising Defendants conveyed the claim that tests proved that the Q-Ray bracelet relieves pain.

2. Defendants' Claim That Tests Proved That The Q-Ray Bracelet Relieves Pain Is Misleading.

Having established that Defendants made the claim that tests proved that the Q-Ray bracelet relieves pain, the FTC must show that this claim was misleading. As explained above, the FTC may use two theories to prove Defendants' claim was misleading: (1) the falsity theory and (2) the reasonable basis theory. Because Defendants' claim is inherently a substantiation claim, the falsity and reasonable basis theories collapse into the same inquiry: did Defendants possess adequate substantiation to make such a claim? Concluding that they did not, the Court finds both that Defendants' claim was false and Defendants lacked a reasonable basis to advertise that tests proved that the Q-Ray bracelet relieves pain. The Court's analysis of Defendants' substantiation is set forth in Sections IV.L. and V.C.2., *supra*.

3. Defendants' Claim That Tests Proved That The Q-Ray Bracelet Relieves Pain Is Material.

Defendants' claim in Count II is, again, a medical, health-related claim, and thus it is material. Defendants' claim clearly involves information that is important to consumers and likely affected their choice to buy the Q-Ray bracelet. *Kraft, Inc.*, 970 F.2d at 322. And again, the *FTC Policy Statement* presumes materiality for express claims and claims that

significantly involve health, safety, or other issues that would concern reasonable consumer. *Id.* The claim at issue in Count II, that tests proved that the Q-Ray bracelet relieves pain, further induces a customer to purchase a Q-Ray bracelet. The claim in Count I tells a potential customer that the Q-Ray bracelet relieves pain, and the claim in Count II assures the potential customer that tests establish that the Count I claim is true. Again, the Q-Ray bracelet is about pain relief, and this claim informs customers that the Q-Ray bracelets pain-relieving properties are tested and proven. Clearly, this medical, health-related claim in Count II is material.

Based on the above, the Court finds that Defendants' claim that tests proved that the Q-Ray bracelet relieves pain is materially misleading. Therefore, the Court finds that Defendants violated Sections 5 and 12.

E. COUNT III.

1. Defendants' Advertising For The Q-Ray Bracelet Conveyed The Claim That A 30-Day Refund Policy Existed For The Q-Ray Bracelet.

Through their television advertising, Defendants conveyed the claim that a 30-day refund policy existed for the Q-Ray bracelet.²⁸ The claim conveyed in these advertisements was either express, or, if considered an implied claim, it was "so conspicuous as to be virtually synonymous with express claims." *Febre*, 1996 WL 396117, at *4. The claim was obvious and apparent from viewing the infomercials. Considering the overall, net impression

²⁸ For a more complete discussion of the facts of these advertisements, please see Section IV.M., *supra*.

made by Defendants' advertisements, the Court finds that in their advertising Defendants conveyed the claim that a 30-day refund policy existed for the Q-Ray bracelet.

2. Defendants' Claim That A 30-Day Refund Policy Existed For The Q-Ray Bracelet Is Misleading.

Having established that Defendants made the claim that a 30-day refund policy existed for the Q-Ray bracelet, the FTC must show that this claim was misleading. As explained above, the FTC may use two theories to prove Defendants' claim was misleading: (1) the falsity theory and (2) the reasonable basis theory. Applying the former theory, the Court finds Defendants' claim that a 30-day refund policy existed for the Q-Ray bracelet is false.²⁹

Until early 2003, QT had different refund policies for television-based sales and Internet sales. Notwithstanding the strongly advertised 30-day refund policy for any Q-Ray bracelet purchaser, the refund policy for Internet sales was 10 days from the delivery date. Defendants' infomercial advertising, however, failed to inform consumers that the refund policy for online sales was different from the promised 30 days consumers learned about on television. Defendants' infomercial advertising did, however, display the company website URL to afford viewers the opportunity to order Q-Ray bracelets via the Internet. Yet, the Q-Ray bracelet website did not prominently disclose the fact that most bracelet styles sold online were not entitled to the 30-day refund policy so vigorously touted on the infomercials. Therefore, many consumers were confused as to what the actual refund policy for the Q-Ray

²⁹ For a more complete discussion of the Court's findings on Defendants' misleading refund policies, please see Section IV.M.2, *supra*.

bracelet was. Some consumers who purchased bracelets online complained when they later learned they were not entitled to the same refund policy they saw advertised on television. Thus, the Court finds that Defendants' claim that a 30-day refund policy existed for the Q-Ray bracelet is false. Defendants' advertising confused consumers and online purchasers of Q-Ray bracelets did not receive the 30-day refund they believed they were entitled to based on Defendants' infomercial representations.

Defendants were aware of the problems consumers were having trying to return their Q-Ray bracelet and obtain a refund. QT experienced delays in processing refund requests, beginning at least as early as the second half of 2002 and into the first half of 2003. Following the implementation of new procedures in 2003, QT no longer encounters refund problems. Defendants also changed their refund policy and began giving all Q-Ray bracelet purchasers, whether via telephone or online, the 30-day refund. However, these changes in 2003 were made prospectively, not retroactively. Thus, consumers who did not receive a refund because they were only given a 10-day refund never obtained a refund. This failure to retroactively provide refunds for confused consumers who were denied a refund provides further support for the Court's finding that Defendants' claim that a 30-day refund policy existed for the Q-Ray bracelet is false.

The Court does not find a violation in Defendants' troubles processing refunds in 2002 and the resulting delays that occurred. Sales of the Q-Ray bracelet grew significantly and Defendants experienced growing pains trying to meet their customers' needs. However, Defendants should have made their refund policy changes retroactive. Their failure to do so

makes their claim that a 30-day refund policy existed for the Q-Ray bracelet false.

Because of the confusion that resulted from Defendants' dubious advertising tactics, the failure of some online Q-Ray bracelet purchasers to receive a refund, and Defendants' decision to only prospectively apply their refund policy changes, the Court finds that the claim that a 30-day refund policy existed for the Q-Ray bracelet is false. Such a false claim constitutes a violation of Sections 5 and 12. The Court orders that the Q-Ray bracelet purchasers who attempted to obtain but were denied a refund by reason of the 10-day policy shall be given a refund, if they so desire. In light of the Court's findings above and the equitable relief it grants below, however, this distinction is merely academic because all Q-Ray bracelet purchasers will be entitled to a refund if they purchased their bracelet during the period of the four infomercials.

3. Defendants' Claim That A 30-Day Refund Policy Existed For The Q-Ray Bracelet Is Material.

Defendants' claim that a 30-day refund policy existed for the Q-Ray bracelet is an express claim. The express nature of the claim can be easily gleaned from viewing the infomercials. Thus, Defendants' claim is material. *See Kraft, Inc.*, 970 F.2d at 322 ("The [FTC] is entitled to apply, within reason, a presumption of materiality, *Colgate-Palmolive*, 380 U.S. at 392, and it does so with three types of claims: (1) express claims; (2) implied claims where there is evidence that the seller intended to make the claim; and (3) claims that significantly involve health, safety, or other areas with which reasonable consumers would be concerned."). Moreover, Defendants' promise of a 30-day refund clearly involves

information that is important to consumers and likely affected their choice to buy the Q-Ray bracelet. *Kraft, Inc.*, 970 F.2d at 322. Thus, the Court finds that Defendants' claim that a 30-day refund policy existed for the Q-Ray bracelet is material. *See F.T.C. v. Sierra Pacific Marketing, Inc.*, No. CV-S-93-134-PMP(RJJ), 1993 WL 78579, at *2 (D. Nev. Feb. 22, 1993) (temporarily restraining and enjoining defendants from making any statement or representation of material fact that is false or misleading, including but not limited to, any false representation about "any consumer's ability to obtain a refund").

F. QUE TE PARK'S RES JUDICATA AND COLLATERAL ESTOPPEL DEFENSES.

Individual Defendant Que Te Park argues that the FTC's charges against him are barred by the doctrines of res judicata and collateral estoppel.³⁰ The FTC contends that its complaint is not barred by either doctrine. "The preclusive effect of a state judgment in federal litigation depends on the rendering state's law." *Rogers v. Desiderio*, 58 F.3d 299, 301 (7th Cir. 1995). Thus, the Court will look to Illinois law in its consideration of Que Te Park's affirmative defenses. *Bottoms v. Ill. Dept. of Human Services*, No. 03 C 1881, 2004 WL 1403811, at *4 (N.D. Ill. June 22, 2004) ("To determine whether res judicata applies, we look to Illinois law to determine if Illinois courts would give preclusive effect to the state court judgment."); *Yardley v. City of Rockford*, No. 89 C 20007, 1991 WL 166970, at *2

³⁰ On June 26, 2006, this Court issued a Memorandum Opinion & Order granting Que Te Park leave to amend his answer to the FTC's complaint to assert the affirmative defenses of res judicata and collateral estoppel. On July 5, 2006, Que Te Park amended his answer and asserted those defenses.

(N.D. Ill. Feb. 11, 1991) (“This court must look to Illinois law on collateral estoppel to determine whether the [pending litigation] is precluded by the state court ruling.”).

In July 2003, Que Te Park was an individual defendant in the Circuit Court of Cook County in a class action case brought against QT, Inc. and Park. *Casey v. QT, Inc.*, Case No. 03 CH 1134 (“Class Action”). In the Class Action, a nationally certified class asserted claims on behalf of consumers in the United States for: (1) breach of the Uniform Commercial Code (“UCC”) implied warranty of merchantability; (2) breach of the UCC express warranty; (3) violation of the Illinois Consumer Fraud and Deceptive Business Practices Act; (4) breach of contract; and (5) unjust enrichment.

On November 16, 2005, the court in the Class Action directed a verdict in favor of Que Te Park individually (the “Directed Verdict”) and against the national class on all counts of the complaint asserted against Que Te Park.³¹ A bench trial in the Class Action concluded on January 3, 2006. A judgment in favor of the defendants was entered on January 3, 2006. A motion to reconsider was denied on May 1, 2006. The Class Action plaintiffs filed a notice of appeal on May 26, 2006. They did not appeal the Directed Verdict. The jurisdictional time to appeal the Directed Verdict expired on May 31, 2006.

1. The FTC’s Charges Against Que Te Park Are Not Barred By The Doctrine of Res Judicata.

“Under the doctrine of *res judicata*, a final judgment on the merits rendered by a court

³¹ A bench trial also transpired, but Defendant’s collateral estoppel and *res judicata* defenses stem solely from the Directed Verdict.

of competent jurisdiction acts as a bar to a subsequent suit between the parties involving the same cause of action.” *River Park, Inc. v. City of Highland Park*, 703 N.E.2d 883, 889 (Ill. 1998). The doctrine applies when the following three requirements are satisfied: “(1) there was a final judgment on the merits rendered by a court of competent jurisdiction, (2) there is an identity of cause of action, and (3) there is an identity of parties or their privies.” *Id.* However, “the doctrine of *res judicata* need not be applied where fundamental fairness so requires.” *Airtite v. DPR Ltd. P’ship*, 638 N.E.2d 241, 244 (Ill. App. 4th Dist. 1994).

In this case, *res judicata* does not apply because no identity of parties or their privies exists between the Class Action and the instant case. Que Te Park was a party to both suits, but the FTC was not a party to the Class Action. Furthermore, the FTC is not in privity with the private litigants who brought the Class Action for their individual benefits. *See Hayes v. State Teacher Certification Bd.*, 835 N.E.2d 146, 157 (Ill. App. 5th Dist. 2005) (“To be bound to a prior adjudication, a nonparty’s interests must be so closely aligned to those of a party that the party is the ‘virtual representative of that nonparty.’”) (citation omitted)). The plaintiffs in the Class Action were private citizens seeking relief under Illinois law. Here, the FTC is an independent agency of the United States charged by Congress with the enforcement of the Act. The FTC’s mission is protection of the public interest at large.

In *FTC v. Klesner*, 280 U.S. 19, 25-27 (1929), the Supreme Court explained the role of the FTC and distinguished private citizen suits and cases brought under Section 5. The FTC may file a complaint under Section 5 “only ‘if it shall appear to the [FTC] that a proceeding by it in respect thereof would be to the interest of the public.’” *Id.* at 27. With

private suits, however, “protection of the public is an incident of the enforcement of a private right.” *Id.* Thus, “to justify the [FTC] in filing a complaint under [S]ection 5, the purpose must be protection of the public. The protection thereby afforded to private persons is the incident.” *Id.* Moreover, “[p]ublic interest may exist although the practice deemed unfair does not violate any private right.” *Id.*

Defendants contend that “[a]lthough the FTC argues that it represents the ‘public’ as opposed to the ‘private’ citizens who filed the [Class Action], courts have recognized that the FTC is barred by res judicata from bringing a suit under the [Act] for alleged wrongs committed on members of the ‘public’ who have had their claims resolved in private litigation.” Def. Que Te Park’s Reply In Support Of His Motion To Assert Affirmative Defenses at 7. Defendants then cite to *F.T.C. v. AMREP Corp.*, 705 F. Supp. 119, 124 (S.D.N.Y. 1988). *AMREP*, however, only bolsters the FTC’s argument that no privity exists between it and the Class Action plaintiffs and that res judicata does not apply to the instant case.

In *AMREP*, the FTC sought relief on behalf of defrauded purchasers under Section 19(a)(2) of the Act (“Section 19(a)(2)”). *Id.* at 120. Section 19(a)(2) actions can only be brought after the conclusion of a Section 5 proceeding. *Id.* at 123 n.8; 15 U.S.C. § 57b(a)(2). Prior to the FTC’s Section 19(a)(2) action, some of the purchasers privately settled with the defendant while the FTC’s separate Section 5 action was pending. *AMREP*, 705 F. Supp. at 122. The FTC ultimately issued a final decision finding that the defendant had engaged in unfair and deceptive acts and practices. *Id.* at 121. The FTC also ordered the defendant to

cease and desist from making further false representations. *Id.* Then the FTC filed its Section 19(a)(2) action, and the defendant thus argued that res judicata precluded the purchasers who had already settled from seeking relief. *Id.* at 120-24. In granting defendant's res judicata defense, the court was clear about the scope of its ruling: "The motion does not seek to preclude the [FTC] from bringing suit for vindication of a public interest. Only to the extent that the FTC's suit seeks redress of the private claims of purchasers who have previously settled their claims is it barred." *Id.* at 124.

AMREP and the instant case are apples and oranges. This case *is* the substantive case to determine whether Que Te Park violated Sections 5 and 12 of the Act. This case *is* for vindication of the public interest. *AMREP* was completely different. The substantive decision had already been issued and the FTC was only barred from seeking Section 19(a)(2) relief for private claims. Most significantly, the *AMREP* court said the following: "the [FTC] argues that private litigants cannot foreclose the Government's right to bring an independent action to vindicate the public interest. That is true." *Id.* at 124. That is exactly what the FTC argues in this case, and thus the Court finds that the private citizen plaintiffs in the Class Action were not the "virtual representatives" of the FTC. Thus, the Court finds that no identity of parties or their privies exists between the Class Action and the instant case.

Finally, the Court concludes that, irrespective of the above findings, principles of fundamental fairness require that the doctrine of res judicata not be applied in this case. Barring a federal agency from pursuing its statutorily mandated duties because of private litigants' failure to prevail in a suit seeking vindication of private rights would frustrate the

Congressional goal of protecting the public through uniform application and enforcement of federal law. A race to the courthouse by government and class counsel would result, and the interests of fairness and justice would suffer. For these reasons, the Court finds that the FTC's charges are not barred by the doctrine of res judicata.

2. The FTC's Charges Against Que Te Park Are Not Barred By The Doctrine of Collateral Estoppel.

The doctrine of collateral estoppel precludes parties from relitigating an issue that “was actually or necessarily decided by a court of competent jurisdiction in [an] earlier proceeding.” *Hexacomb Corp. v. Corrugated Systems, Inc.*, 678 N.E.2d 765, 771 (Ill. App. 1st Dist. 1997). Collateral estoppel bars a claim when the following three requirements are satisfied: “(1) the issue decided in the first proceeding is identical with the one presented in the current action; (2) there was a final judgment on the merits in the prior adjudication; and (3) the party against whom estoppel is asserted was a party or in privity with a party to the prior adjudication.” *Casanova v. City of Chicago*, 793 N.E.2d 907, 916 (Ill. App. 1st Dist. 2003). Moreover, “[c]ollateral estoppel bars subsequent actions only as to the point or question *actually* litigated and determined in the prior suit and not as to matters that *might* have been litigated and determined. *Hexacomb*, 678 N.E.2d at 771. Thus, “for a previous judgment to be conclusive, it must appear clearly and certainly that the identical and precise issue was decided in the previous action.” *Id.* The party asserting collateral estoppel bears the “heavy burden” of proving “with clarity and certainty what was determined by the prior judgment.” *Id.* Finally, even where the three requirements have been satisfied, “collateral

estoppel must not be applied to preclude parties from presenting their claims or defenses unless it is clear that no unfairness results to the party being estopped.” *Talarico v. Dunlap*, 685 N.E.2d 325, 328 (Ill. 1997).

In this case, the FTC’s charges are not barred by the doctrine of collateral estoppel because, as explained above: (1) no identity of parties or their privies exists between the Class Action and the instant case; and (2) principles of fundamental fairness mandate that the doctrine not apply. Furthermore, collateral estoppel does not apply in this case because Que Te Park has not shown that any issue in the FTC’s case was “actually and necessarily” decided in the Class Action.

Que Te Park asserts that he was found not liable under the Illinois Consumer Fraud and Deceptive Business Practices Act (“Illinois Act”) in the Class Action. He states that the Illinois Act specifically provides that courts construing the Illinois Act shall give consideration “to the interpretations of the [FTC] and the federal courts relating to Section 5(a) of the [Act].” 815 ILCS 505/2. Thus, Que Te Park argues that the court in the Class Action would have considered whether Que Te Park could be held liable under the Act. This is his basis for asserting that the causes of action in this case are identical to the claims made by the plaintiffs in the Class Action.

Que Te Park’s argument fails for the following reasons: (1) Illinois courts are required to *consider* the Act; (2) Illinois courts are not required to determine liability under the Act; and (3) Que Te Park made no showing that the standards for liability under the Illinois Act are “identical” to the standards for such liability under the Act. In fact, the transcript of the

Class Action court's ruling granting the Directed Verdict indicate that some of the issues that appear to be pertinent in the Class Action court's ruling are not relevant to the FTC's case. Specifically, the Class Action court's ruling stated that, although evidence showed that Que Te Park reviewed and approved the company's marketing, no evidence demonstrated that any of the Class Action plaintiffs relied "on the words of Mr. Park as an individual as opposed to his just approving something that somebody in the company employ just wrote and incorporated into the various advertising materials that the company put out." PX 321. Meanwhile, to establish individual liability under the Act, a court focuses solely on the individual defendant's conduct and does not concern itself with consumer reliance. *See Bay Area Bus. Council*, 423 F.3d at 636 (stating that to establish individual liability, the FTC must show that the individual defendants "either participated directly in the deceptive acts or practices or had authority to control them" and "either knew or should have known about the deceptive practices."). Que Te Park failed to show that an issue in the FTC's case was "actually and necessarily" litigated in the Class Action. For these reasons, the Court finds that the FTC's charges are not barred by the doctrine of collateral estoppel.

G. INDIVIDUAL LIABILITY OF QUE TE PARK AND JUNG JOO PARK.

Having established liability for the corporate Defendants, the FTC must show that the individual defendants, Que Te Park and Jung Joo Park, (1) "either participated directly in the deceptive acts or practices or had authority to control them;" and (2) "either knew or should have known about the deceptive practices." *Bay Area Bus. Council*, 423 F.3d at 636. The FTC need not, however, prove subjective intent to defraud. *Id.* Rather, the FTC may satisfy

the “knowledge requirement with evidence that the individuals had ‘actual knowledge of material misrepresentations, reckless indifference to the truth or falsity of such misrepresentations, or an awareness of a high probability of fraud along with an intentional avoidance of the truth.’” *Id.* (quoting *Amy Travel Serv.*, 875 F.2d at 574).

1. Defendant Que Te Park Is Personally Liable For The Violations.

As of the date of the FTC’s complaint and at the present time, Que Te Park was and is the President of QT, QRC, and Bio-Metal. He has been the Chief Executive Officer of QT and QRC since at least 2001. Que Te Park is the sole shareholder of QT and QRC. In his capacity as President of QT and QRC, he is the signatory on all ten of QT’s bank accounts. Que Te Park and Ciprian were responsible for generating, collecting, reviewing, or evaluating substantiation for claims regarding the Q-Ray bracelet. Ciprian was responsible for collecting studies about the Q-Ray bracelet and for identifying researchers to conduct studies on the Q-Ray bracelet, and she reported to Que Te Park regarding proposed studies and consulted him for approval of the proposed studies.

Clearly, Que Te Park possessed the authority to control the corporate Defendants’ deceptive acts or practices and he participated directly in them. Next, the evidence shows that Que Te Park should have known about the deceptive practices, and, in fact, did know about them. Que Te Park was intimately involved with the business of the corporate Defendants and possessed more control and authority than any other employee. The Court finds Que Te Park individually liable for the violations.

2. Defendant Jung Joo Park Is Not Personally Liable For The Violations

Jung Joo Park was listed as the Secretary of QT and QRC for multiple years. As Secretary of those entities, she had signatory authority for eight of the ten QT and QRC corporate bank accounts. Jung Joo Park has worked for QT for fifteen years and she worked full-time at QT between 2001 and at least August of 2004. Notwithstanding Jung Joo Park's formal titles, however, she had no involvement in the actions that led to corporate liability in this case. Her responsibilities and duties at QT and QRC did not include the marketing of the Q-Ray bracelet or anything pertaining to the marketing of the Q-Ray bracelet.

When Que Te Park is out of the country, Jung Joo Park looks after the office. She has no set position and provides help around the office wherever it is needed. Jung Joo Park assists QT in short-staffed areas, which include helping with assembly and shipping and handling in the factory. Jung Joo Park also assists with employee relations, which include consulting with QT's Korean-speaking employees regarding internal conflicts between such employees.

Jung Joo Park did not participate directly in the deceptive acts and practices carried out by the corporate Defendants in this case. She also had no authority to control the deceptive acts and practices. Furthermore, the FTC failed to prove that Jung Joo Park either knew or should have known about the deceptive practices of the corporate Defendants. Thus, the FTC did not fulfill either element set forth in *Bay Area Business Council* to establish individual liability for Jung Joo Park.

The FTC correctly argues that an individual's authority to control the corporation's deceptive acts may be "evidenced by active involvement in business affairs and the making

of corporate policy, including assuming the duties of a corporate officer.” *Amy Travel*, 875 F.2d at 573. However, the Seventh Circuit does not limit its inquiry to whether an individual defendant was or was not a corporate officer. It makes a broader inquiry and evaluates the individual’s level of corporate involvement. *See id.* at 573-75; *Bay Area Bus. Council*, 423 F.3d at 636-38; *FTC v. World Media Brokers*, 415 F.3d 758, 764-66 (7th Cir. 2005). Even though Jung Joo Park was the Secretary of QT and QRC, she did not possess “a level of corporate involvement sufficient to demonstrate the requisite authority to control the corporate defendants.” *World Media Brokers*, 415 F.3d at 765.

Lastly, even if Jung Joo Park’s Secretary position was enough to establish her authority to control the corporate Defendants’ deceptive acts, the FTC failed to prove she either knew or should have known about the deceptive practices. The FTC provided no evidence regarding the knowledge element, and the facts in the record indicate that Jung Joo Park did not possess the requisite level of knowledge. The Court therefore finds Jung Joo Park not liable for any violations.

H. EQUITABLE RELIEF.

A district court’s authority to award monetary relief as an equitable remedy under Section 13(b) is broad. *See FTC v. Febre*, 128 F.3d 530, 534 (7th Cir. 1997). As explained above, Section 13(b) states “[t]hat in proper cases the [FTC] may seek, and after proper proof, the court may issue, a permanent injunction.” 15 U.S.C. § 53(b). “The district court’s authority to grant a permanent injunction also includes the power to grant other ancillary relief sought by the [FTC].” *Febre*, 128 F.3d at 534. Such jurisdiction gives a district court

the “authority to ‘order any ancillary equitable relief necessary to effectuate the exercise of the granted powers.’” *Id.* (quoting *Amy Travel Service*, 875 F.2d at 572. “The power to grant ancillary relief includes the power to order repayment of money for consumer redress as restitution or recession.” *Id.* Therefore, “Section 13(b) permits a district court to order a defendant to disgorge illegally obtained funds.” *Id.* at 537.

To calculate the appropriate size of disgorgement relief, a district court must engage in a two-step, burden-shifting analysis. The FTC must first “show that its calculations reasonably approximated the amount of customers’ net losses, and then the burden shifts to the defendants to show that those figures were inaccurate.” *Id.* at 535.

In this case, Defendants argue that a defendant’s profits, not sales, should be the basis for a damages award under the Act. Defendants cite *FTC v. Verity Int’l, Ltd.*, 443 F.3d 48 (2d Cir. 2006), in support of their argument, claiming that “[w]hen calculating damages under the [Act], awarding ‘the full amount lost by consumers’ can amount to reversible error.” Def. Post-Trial Brief at 49 (quoting *Verity Int’l*, 443 F.3d at 67). Defendants, however, misinterpreted *Verity Int’l*, took the above quotation out of context, and their argument is without merit.

In *Verity Int’l*, the Second Circuit approached disgorgement relief in the same manner as the Seventh Circuit in *Febre*. The Second Circuit stated that the burden-shifting “framework requires the FTC to first ‘show that its calculations reasonably approximated’ the amount of the defendants’ unjust gains, after which ‘the burden shifts to the defendants to show that those figures were inaccurate’”. *Verity Int’l*, 443 F.3d at 67 (quoting *Febre*, 128

F.3d at 535). Defendants correctly note that the Second Circuit vacated the district court's disgorgement figure because the "district court measured the appropriate amount of restitution as 'the full amount lost by consumers.'" *Id.* The court stated that the "appropriate measure for restitution is the benefit unjustly received by the defendants." *Id.* The end result in *Febre* and *Verity Int'l* is the same: the defendant's illegally gotten gains constitute the amount of restitution. The only difference between the two cases is how a district court calculates the defendant's unjust gains.

In *Verity Int'l*, the Second Circuit found that the district court erred by calculating the size of the disgorgement relief as "the full amount lost by consumers" because not all of the consumers' losses always end up in the pockets of the defendant. The Second Circuit explained its reasoning behind the two methods of measurement:

Undeniably, in many cases in which the FTC seeks restitution, the defendant's gain will be equal to the consumer's loss because the consumer buys goods or services directly from the defendant. Thus, in these cases it is not inaccurate to say that restitution is measured by the consumer's loss. But it is incorrect to generalize this shorthand and apply it as a principle in cases where the two amounts differ - for example, when some middleman not party to the lawsuit takes some of the consumer's money before it reaches a defendant's hands.

Id. at 68. Thus, the appropriate disgorgement figure is the defendant's unjust gains, and this figure can be calculated by measuring the full amount lost by consumers in a direct seller case, such as *Febre*, or, in the case where some of the consumer losses are diverted to a third party, such as *Verity Int'l*, by measuring the defendant's gain.

In the instant case, the Court orders the disgorgement of Defendants' \$22,500,000 in profits made during the period of the four infomercials plus interest. The Court also orders

that every Q-Ray bracelet purchaser during the period of the four infomercials is entitled to rescission and restitution in the form of a full refund. However, the total amount of restitution must not exceed \$87,019,840, which are Defendants' net sales to consumers from January 1, 2000 through June 30, 2003. Therefore, Defendants will be required to disgorge not less than \$22,500,000 nor more than \$87,019,840 in equitable relief. Thus, for example, if only \$10,000,000 is paid out in refunds, Defendants will pay a total of \$22,500,000. If \$40,000,000 is paid out in refunds, Defendants will pay a total of \$40,000,000. And if \$95,000,000 is claimed in refunds, Defendants will pay a total of \$87,019,840.

VI. CONCLUSION.

The marketing of the Q-Ray bracelet was deceptive, misleading, and violated the FTC Act. The Q-Ray bracelet was marketed principally by means of infomercials with a clear message conveyed to viewers that the Q-Ray bracelet provides immediate, significant or

complete pain relief. This claim lacks a scientific or medical basis. As a result, consumers were misled into buying the Q-Ray bracelet based on the deceptive and misleading ads. Defendants QT, QRC, Bio-Metal and Que Te Park are responsible for these violations.

In addition, the Q-Ray bracelet was marketed with a deceptive and confusing 30-day guarantee policy. While many refunds were made, some consumers were wrongfully denied refunds because of the confusion between the 10-day and 30-day refund policy that existed until sometime in 2003.

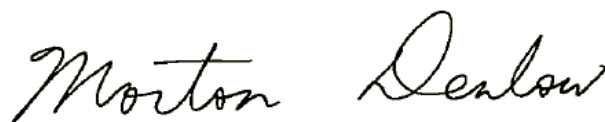
Accordingly, the Court will enter judgment in favor of the FTC and against Defendants QT, Inc., Q-Ray Company, Bio-Metal, Inc. and Que Te Park, jointly and severally, on all three counts of the complaint. These Defendants will be required to disgorge all of their profits from the sale of the Q-Ray bracelet from January 1, 2000 through June 30, 2003, and will be required to provide refunds to all persons who purchased a bracelet during that period.

In addition, permanent injunctive relief will be entered against these Defendants to prevent them from engaging in further deceptive conduct surrounding the sale of the Q-Ray bracelet or similar products.

Judgment will be entered in favor of Jung Joo Park on all counts because she was not shown to be an active participant in the deceptive and misleading practices.

The parties shall meet and confer and submit a proposed final judgment order to the Court on or before September 22, 2006, consistent with the Court's decision. The case is set for status and the entry of a final judgment on September 28, 2006.

SO ORDERED THIS 8th DAY OF SEPTEMBER, 2006



**MORTON DENLOW
PRESIDING MAGISTRATE JUDGE**

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