

UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
BOSTON DIVISION

FEDERAL TRADE COMMISSION,

Plaintiff,

v.

ZYCAL BIOCEUTICALS HEALTHCARE
COMPANY, INC., a corporation,

JAMES J. SCAFFIDI, individually and as an
officer of ZYCAL BIOCEUTICALS
HEALTHCARE COMPANY, INC.,

EXCELLENT MARKETING RESULTS, INC., a
corporation,

and

MICHAEL MCGAHEE, individually and as an
officer of EXCELLENT MARKETING
RESULTS, INC.,

Defendants.

Case No. _____

**COMPLAINT FOR PERMANENT
INJUNCTION AND OTHER
EQUITABLE RELIEF**

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

1. The FTC brings this action under Section 13(b) of the Federal Trade Commission Act (“FTC Act”), 15 U.S.C. § 53(b), to obtain permanent injunctive relief, rescission or reformation of contracts, restitution, the refund of monies paid, disgorgement of ill-gotten monies, and other equitable relief for Defendants’ acts or practices in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

JURISDICTION AND VENUE

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

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

PLAINTIFF

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

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

DEFENDANTS

6. Defendant ZyCal Bioceuticals Healthcare Company, Inc. (“ZyCal”) is a Delaware corporation that has multiple locations from which it does business, including Shrewsbury, Massachusetts and Tom’s River, New Jersey. ZyCal transacts or has transacted business in this District and throughout the United States. At times material to this Complaint, acting alone or in concert with others, ZyCal has advertised, marketed, distributed, or sold the ingredient Cyplexinol or oral products containing Cyplexinol to trade customers throughout the United

States. At times material to the Complaint, acting alone or in concert with others, ZyCal also has advertised, marketed, distributed, or sold its own Cyplexinol products under the brand name Ostinol to health professionals and consumers throughout the United States.

7. Defendant James J. Scaffidi is the president of ZyCal. At times material to this Complaint, acting alone or in concert with others, he has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of ZyCal set forth in this Complaint. Defendant Scaffidi and his family trust together own approximately eighty-six percent of ZyCal. Scaffidi runs the daily operations of the company, including creating and approving advertising content, hiring and firing employees, and entering into contracts on behalf of ZyCal. Defendant Scaffidi resides in this District and, in connection with the matters alleged herein, transacts or has transacted business in this District and throughout the United States.

8. Defendant Excellent Marketing Results, Inc. ("EMR") is a Delaware corporation with its principal place of business at 2055 Range Road, Clearwater, Florida 33765. EMR transacts or has transacted business in this District and throughout the United States. At times material to this Complaint, acting alone or in concert with others, EMR has advertised, marketed, distributed, or sold the orally-administered product StimTein, containing the active ingredient Cyplexinol, to consumers throughout the United States.

9. Defendant Michael McGahee is the president of EMR. At times material to this Complaint, acting alone or in concert with others, he has formulated, directed, controlled, had the authority to control, or participated in the acts and practices of EMR set forth in this Complaint. Defendant McGahee and his wife are EMR's sole shareholders. He holds a fifty percent share of the company and runs its daily operations, including creating and approving infomercial and

internet advertising content, and securing radio and television advertising spots. He personally appears in the StimTein infomercial, during which he makes many of the deceptive statements alleged in this Complaint. Defendant McGahee, in connection with the matters alleged herein, transacts or has transacted business in this District and throughout the United States.

COMMERCE

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

SUMMARY OF DEFENDANTS’ BUSINESS ACTIVITIES

11. Since at least 2009 and continuing until at least August 2018, EMR and McGahee (“the EMR Defendants”) have marketed StimTein, an ingestible capsule, through nationally advertised infomercials and other means. The EMR Defendants have represented that StimTein, taken as directed, grows bone and cartilage and thereby provides substantial and long-lasting relief from pain associated with debilitating joint ailments, including arthritis, and that these benefits are clinically proven. The active ingredient in StimTein that purportedly provides the advertised health benefits is Cyplexinol, which is manufactured and supplied by ZyCal and Scaffidi (“the ZyCal Defendants”).

12. The ZyCal Defendants first recruited the EMR Defendants as trade customers in or about 2009. In particular, the ZyCal Defendants encouraged the EMR Defendants to market a Cyplexinol product via an infomercial. The EMR Defendants agreed, branding the finished product as StimTein. At times material to the Complaint, the ZyCal Defendants supplied to the

EMR Defendants either the finished StimTein product or the ingredient Cyplexinol for use in StimTein.

13. The ZyCal Defendants also supplied the EMR Defendants with product information, clinical studies, and other promotional materials about the purported health benefits of Cyplexinol. The EMR Defendants incorporated the ZyCal Defendants' health benefit claims into their promotional materials for StimTein. For example, in 2009, the ZyCal Defendants provided talking points to the EMR Defendants about Ostinol, a ZyCal product with a Cyplexinol formulation similar to that of StimTein. The talking points emphasized that the product "stimulate[s] cells to grow bone tissue," "stimulate[s] cells to grow cartilage," and "contains a biologically active protein complex proven for 40 years and used clinically for 20 years to grow bone." These claims appeared prominently in StimTein advertising.

14. Since at least 2011, the ZyCal Defendants also have marketed the Cyplexinol ingredient or oral products containing Cyplexinol to other trade customers. The ZyCal Defendants provide to those trade customers product information and promotional materials with bone and joint claims substantially similar to the claims they have provided to the EMR Defendants.

15. Since at least 2014, the ZyCal Defendants also have advertised and marketed their own line of Cyplexinol products under the brand name Ostinol directly to consumers and health professionals (primarily chiropractors). The ZyCal Defendants sell Ostinol products in varying strengths and formulations. They have made, and continue to make, claims that Ostinol products grow bone and cartilage and thereby substantially reduce joint pain and discomfort, and that these benefits are clinically proven.

16. In truth and in fact, Defendants possess no competent and reliable scientific evidence that any Cyplexinol product, taken as directed, provides any of the health benefits advertised by Defendants, nor are any of the advertised benefits clinically proven.

DECEPTIVE ADVERTISING OF STIMTEIN

17. At times material to the Complaint, the EMR Defendants have advertised, offered for sale, sold, and distributed the oral product StimTein, containing the active ingredient Cyplexinol. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, StimTein is either a “food” or a “drug” as defined in Sections 15(b) and (c) of the FTC Act, 15 U.S.C. §§ 55(b), (c).

18. The EMR Defendants have advertised StimTein mainly through long- and short-form infomercials and internet marketing, including the website www.stimtein.com. They have represented directly and through consumer endorsements that StimTein grows new bone, including in persons with osteoporosis or osteopenia; that StimTein grows new cartilage; that StimTein provides substantial and long-lasting relief from joint pain, including pain caused by arthritis, bursitis, and stenosis; and that these benefits are clinically proven.

19. The EMR Defendants used the testimonial of a then-employee of EMR and the testimonial of the mother of another then-employee of EMR, as consumer endorsements of StimTein without disclosing their connections to the company. Both testimonialists claimed that StimTein eliminated their debilitating joint pain.

20. The EMR Defendants sold StimTein for approximately \$30-\$60 for a 30-day supply. From 2015 to 2018, Defendants generated approximately \$3.6 million in gross sales minus returns of StimTein.

21. To induce consumers to purchase StimTein, the EMR Defendants have disseminated or caused to be disseminated advertisements, packaging, and promotional materials, including, but not limited to, advertisements containing the following statements and depictions, among others:

a. StimTein infomercial excerpt (Jan. 2017)



[VOICEOVER]: If you have pain from arthritis, bursitis, stenosis



Or any other type of joint pain, and that includes back pain



In the next [sic], find out how to free yourself from that pain in a way you never dreamed possible! With a new scientific breakthrough that only uses an all natural non-drug supplement.

* * *

[Testimonialist Cindy Butler]: I couldn't pick up my kids. Literally, could not pick them up. And they're young and didn't understand why momma couldn't pick them up. This one little supplement changed my life. I run with my kids. I'm able to swim and play with my kids.



* * *

[Testimonialist Elaine M.]: I got out of bed and I didn't feel any pain. So that's when the lightbulb went off saying this product is really working.



* * *

[Dr. Donald C. DeFabio]: First time I saw these proteins come across my desk, I said, "ah here's another supplement." Once I started to see results, now it's one of my routine recommendations for people with joint pain or who have bone health concerns.

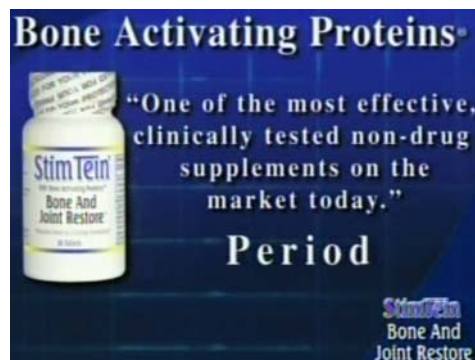


* * *

[VOICEOVER]: The bone activating proteins in StimTein are backed by 40 years of research. They have been reviewed in prestigious medical publications such as Arthritis, Research, and Therapy, The Journal of Biological Chemistry, and Arthritis and Rheumatism from the American College of Rheumatology. They have 20 years of clinical use in over 500,000 medical procedures along with clinical trials that proves [sic] they do in fact work.

* * *

When the bone activating proteins are present they activate replenishing cells around the bones so that they can actually use the existing building blocks to form new bone and cartilage. The end result is when you replace the missing bone activating proteins you get long term bone and joint health, and most importantly you get your life back. Our [StimTein] Bone and Joint Restore is clearly one of the most effective clinically tested non-drug supplements on the market today. Period.



[Infomercial Host (Michael McGahee)]: There are two university studies, one from Oxford, that show as we get older many of us stop making these bone activating proteins and that's when our bone and joint problems begin. Now they've been studied for over 40 years, with 20 years of clinical use, but we're bringing this medical breakthrough new to the public for the first time.



* * *

[Dr. Richard Garian]: That joint starts to decrease. That cartilage cushion between the joints. And when that happens we irritate the surrounding connective tissue, we irritate the surrounding blood supply. In order to restore the normal cushioning to that joint you need the raw ingredients. So these proteins provide the raw ingredients and as the tissue itself becomes healthier the pain becomes less and less and the function becomes higher and higher.



* * *

[Steven Lund]: ... With this product it helps rebuild it. It also sets the groundwork so now your calcium, phosphorous, other things you're taking will have something to land in. It's going to stimulate these cells to work properly so that they will build bone, they will build joints, they'll build the cartilage that you need to rebuild to stop the negative impact like you did when you were young.



* * *

[Infomercial Host (Michael McGahee)]: ... this is the picture that started the whole thing. These are actual x-rays of bone growing across a half inch gap in a person's leg. And guess what? Calcium had nothing to do with this. It was the proteins that produced the result. And it was a verification that they could do the same thing with cartilage and joints.



Now of course this was surgically done, but we wanted to see if the oral version of these natural proteins would produce an effect. So that's why we performed clinical tests and what you're seeing on this program are the amazing results. And it's something that could happen for you.

* * *

[Dr. DeFabio]: Osteoporosis ... and osteopenia, huge, huge problems today. It is so nice to be able to give my patients an option where they can stimulate their body to grow more bone. ... And I've seen these proteins improve people's bone density results – their DEXAs they're called – extremely well. One patient went from osteopenia to normal lumbar spine bone density in 14 months. 14 months! That's unheard of.

* * *

[Testimonialist Beverly Murray]: The main problem is my knees and pain and burning and the burning has been a real issue because you can feel that all the time. And the first thing I noticed was that the burn was gone. It was really gone.



* * *

[Testimonialist Kimberly Troop]: It hurt. If I lifted to get something out of the cupboard it, I would go to my knees and have to crawl to the table or to the chair and just sit there until that pain went away. And now, I noticed everytime I go to get something out the cupboard I don't have that pain anymore. ...



b. StimTein website excerpt (www.stimtein.com captured Mar. 13, 2017)

**Free Yourself From Pain In A Way
You Never Dreamed Possible**
**Joint Pain, Arthritis Pain, Bursitis Pain, Stenosis
Pain, Back Pain**

* * *

Case Histories

I started having pain all over my body, mainly my shoulders, knees and back. ... I had to get help out of bed in the morning and back in bed at night. And I literally couldn't pick up my kids. ...

It was debilitating to me. ... I used two different kinds of injectables, and then they put me on a medicine that required an IV for four hours. Plus I was up to 3,200 milligrams of over the counter medication a day

Then I tried StimTein® and it's changed my life. I pick up my kids, throw them around and play in the pool with them as well as give them piggy back rides to bed at night. I can step up stairs without a cane and I even work out now.

I'm completely free of all the medications. I only take the supplement three times a day. This one little supplement has changed my life

Cindy Butler
Owner Paradise Press
Results will vary.

* * *

Doctors Report Amazing Pain Relief Results

...

As a physician I get approached constantly. I'm inundated with products that are supposed to be the latest greatest thing. It gets frustrating for me to hear all the hype and not see the results... until I tried Stimtein [sic]. And I was very impressed. I was having transitory joint pain, which means that it moved around. ... It is quite surprising to me that I've noticed a big change in the joint pain that I was experiencing. I am not having pain now. And that was in a very short period of time; in less than two weeks.

* * *

Dr. Deborah Springer
Springer Chiropractic
Results will vary.

* * *

Long Term & Short Term Relief

Long-term relief with StimTein comes about because the body is forming cartilage and there is less pain since it is going through its natural re-building cycle.

* * *

Clinical Results

While there is no claim to heal or cure anything, the results of our clinicals speak for themselves. In one of the trials performed over a four-week period, 70% said they had a 50% decrease in pain and an amazing 100% said they experienced some relief.

22. In addition, the ZyCal Defendants supplied the EMR Defendants with advertising, packaging, and promotional materials, including, but not limited to, advertisements containing the following statements and depictions, among others:

a. Ostinol Talking Points excerpt (Aug. 2009)

Ostinol™ Bone and Cartilage Stimulating Proteins

...

How does Ostinol™ work in bone health?

"The proteins in Ostinol™ naturally stimulate cells to grow bone tissue so calcium can bind to it. Ostinol™ is the only product[,] which contains these proteins that are proven to activate stem cells which build bone tissue – a natural process known as **osteinduction**. Then calcium can bind to the tissue to make strong, healthy bones."

How is Ostinol™ different from other bone products?

"Ostinol™ works with your favorite calcium or bone product to address both parts of bone loss – the mineral (calcium) loss and the tissue loss. Only Ostinol™ contains a biologically active protein complex proven for 40 years and used clinically for 20 years to grow bone."

...

How does Ostinol™ work in joint health?

"The proteins in Ostinol™ naturally stimulate stem cells which absorb glucosamine and chondroitin to put them together to make cartilage. Ostinol™ is the only product which contains these proteins that are proven to activate stem cells which make cartilage – a natural process known as **osteinduction**. These cells absorb glucosamine and chondroitin to form cartilage, building strong, healthy joints."

23. The EMR Defendants incorporated bone- and cartilage-building claims described in Paragraph 22 into their own advertising for StimTein and continued to make those claims until August 2018. The StimTein infomercial heavily emphasizes the bone- and cartilage-growth claims and that decades of medical research purportedly backed those claims. According to infomercial host Defendant McGahee, “the bone activating proteins in StimTein are backed by 40 years of research. They have been reviewed in prestigious medical publications ... [and] have 20 years of clinical use in over 500,000 medical procedures along with clinical trials that proves [sic] they do in fact work.” These proteins “activate replenishing cells around bones so that they can actually use the existing building blocks to form new bone and cartilage.”

DECEPTIVE PRACTICES BY ZYCAL DEFENDANTS
FOR OSTINOL PRODUCTS

24. At times material to the Complaint, the ZyCal Defendants have advertised, offered for sale, sold, and distributed Ostinol products and other oral Cyplexinol products to trade customers, health professionals, and consumers. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, these products are either “foods” or “drugs” as defined in Sections 15(b) and (c) of the FTC Act, 15 U.S.C. §§ 55(b), (c).

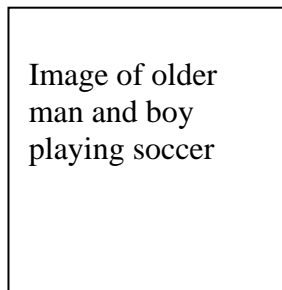
25. The ZyCal Defendants have sold Ostinol products to consumers and health professionals for approximately \$45-\$135 for a 30-day supply. From 2014 to 2017, they generated gross sales minus returns for Ostinol products of more than \$3.1 million to health professionals and more than \$1.5 million to consumers. During that time, they also made approximately \$1.9 million in sales of the ingredient Cyplexinol and Cyplexinol products to trade customers, including \$467,325 in sales to EMR.

ZyCal Defendants' Marketing to Health Professionals

26. At times material to the Complaint, the ZyCal Defendants have marketed Ostinol products to health professionals, primarily chiropractors, through internet and print marketing, including the website <https://rts.ostinol.com>. They have represented that Ostinol products grow bone or cartilage tissue and thereby substantially reduce joint pain and discomfort, and that these benefits are clinically proven.

27. To induce health professionals to purchase Ostinol products, the ZyCal Defendants have disseminated or caused to be disseminated advertisements, packaging, and promotional materials, including, but not limited to, advertisements containing the following statements and depictions, among others:

a. ZyCal health professionals brochure excerpt (Feb. 2018)



**Help your patients get
Their joints kicking again
Try Ostinol™ in 2018**

This revolutionary safe and natural product grows new cartilage tissue and works on inflammatory pathways, so joints feel a difference in 7 days!

**b. Regenerative Tissue Science health professionals website excerpt
(<https://rts.ostinol.com> captured Oct. 31, 2019)**

10 Years And Going Strong!

... As the world's creator of osteoinductive supplements, RTS is committed to leading the nutritional industry through biologically active products which turn on stem cells, affecting a paradigm shift in regenerative health and medicine. RTS, backed by experts from medicine and surgery, setting a new standard in natural medicine and nutritional health.

* * *

BONE HEALTH SUPPLEMENTS

...

Cyplexinol® is an all-natural stem cell signaling protein complex[,] which uniquely stimulates key pathways to support your body's ability to create new bone and cartilage tissue! This new class of nutrition provides health benefits no other product has ever delivered!

* * *

Ostinol® Advanced 250 mg

...

Ostinol® is a breakthrough in bone and joint health. ...

Ostinol® is:

- FAST – In a recent clinical study people reported less discomfort in as fast as 7 days*
- POWERFUL – New class of proteins used by doctors for years

Ostinol® is powered by Cyplexinol® Pro a complex of proteins naturally found in bones and joints which are functionally involved in the formation of bone and cartilage tissue. ...

Bioactive protein complexes are backed by over 50 years of scientific and medical research. Before being used as a nutritional supplement, this class of proteins was used clinically for years to grow bone and cartilage tissue post-operatively. Natural healthcare professionals have been using this powerful bioactive protein complex in Ostinol® as an oral supplement for bone and joint health with great clinical success and it is now available directly to you as the ultimate supplement in bone and joint health. ...

* * *

JOINT HEALTH SUPPLEMENTS

...

Ostinol® is powered by Cyplexinol®, a new class of nutritional ingredient. Cyplexinol® is an all-natural stem cell signaling protein complex which uniquely stimulates key pathways to support your body's ability to create new bone and cartilage tissue!* Once the new tissue begins to grow, it can absorb important nutrients (e.g., Glucosamine, Chondroitin, MSM, SAME, HA) that are necessary for the continued maintenance of strong joint cartilage. ...

* * *

Ostinol® Advanced 5X

...

- FAST – In a recent clinical study people reported less discomfort in as fast as 7 days
- POWERFUL – New class of proteins used by doctors for years*

Ostinol® Advanced 5X is powered by Cyplexinol® Pro a complex of proteins naturally found in bones and joints which are functionally involved in the formation of bone and cartilage tissue.* ...

Bioactive protein complexes are backed by over 50 years of scientific and medical research. Before being used as a nutritional supplement, this class of proteins was used by surgeons for years to grow bone and cartilage tissue post-operative. Now, natural healthcare professionals have this new class of powerful bioactive protein complex available in Ostinol® Advanced 5X as an oral supplement for bone and joint health.

...

For people who:

- need extreme single joint support
- suffer from severe problems in multiple joints

* * *

RTS PROFESSIONAL’S ADVANTAGE

POWERFUL PRODUCTS!

We run shoulder-to-shoulder with traditional allopathic medicine. Our patented proprietary active ingredient, Cyplexinol® has been clinically studied with amazing results! Providing more benefits than pharmaceuticals, Cyplexinol® is all-natural, safe, offers no side effects and has better results!

LASER FOCUS AREA OF SPECIALIZATION!

... Our active ingredient, Cyplexinol® is a new class of nutritional ingredient that can grow de novo tissue while patients are living their day to day lives.

...

ZyCal Defendants’ Consumer-Directed Marketing

28. At times material to the Complaint, the ZyCal Defendants have advertised, offered for sale, sold, and distributed Ostinol products to consumers mainly through internet marketing, including the websites www.ostinol.com and www.zycalbio.com. They have represented directly, and through consumer endorsements and the endorsement of registered dietician Katherine Spinks, that Ostinol products grow bone or cartilage tissue and thereby substantially reduce joint pain and discomfort, and that these benefits are clinically proven. They also used Spinks' endorsement without disclosing that she was a ZyCal sales representative at the time her endorsement was made.

29. To induce consumers to purchase Ostinol products, the ZyCal Defendants have disseminated or caused to be disseminated advertisements, packaging, and promotional materials, including, but not limited to, advertisements containing the following statements and depictions, among others:

**a. Ostinol consumer website excerpt
(www.ostinol.com captured on Oct. 23, 2019)**

BONE SUPPLEMENTS

...

Ostinol® is a breakthrough in bone and joint health. ... Ostinol® is powered by Cyplexinol®, a new class of nutritional ingredient. Cyplexinol® is an all-natural stem cell signaling protein complex[,] which uniquely stimulates key pathways to help support your body's ability to create new bone and cartilage tissue! This new class of nutrition provides health benefits no other product has ever delivered!

* * *

Ostinol Standard 150 mg

...

Ostinol® is:

- FAST – In a clinical study people had reported less discomfort in as fast as 7 days*
- POWERFUL – New Class of protein complexes used clinically to grow new bone and cartilage for over thirty years*

Ostinol® is powered by Cyplexinol®, a new class of nutritional ingredient. Cyplexinol® is an all-natural stem cell signaling protein complex which uniquely stimulates key pathways to help support your body's ability to create new bone and cartilage tissue! ...

* * *

Ostinol® Insta Joint

- POWERFUL! CLINICALLY TESTED, SCIENTIFICALLY PROVEN

...

- FAST - In a recent clinical study people reported improved comfort in as fast as 7 days
- POWERFUL - New class of protein complex used clinically to grow new bone and cartilage tissue for years.*

Ostinol® Insta Joint is powered by Cyplexinol®, a new class of nutritional ingredient. Cyplexinol® is an all-natural stem cell signaling protein complex which uniquely stimulates key pathways to help support your body's ability to create new bone and cartilage tissue! ...

* * *

WHAT OUR CUSTOMERS ARE SAYING!

Two years ago, I started taking Ostinol® 350s. I had a DEXA scan this week, and I was ecstatic because my numbers were so much better – my score increased 8%! The only thing I added or changed since 2015 was to start taking Ostinol®.

...

I have been taking Ostinol® 450s for several weeks, and have already seen improvement in my knees! I wasn't able to stand for very long periods due to my knee pain. Now I am able to be on my feet for several hours at a time.

...

I needed to let you know that I am a nutritionist caring for a 97-year-old patient who has experienced extensive reversal in bone condition since starting Ostinol™

just 3 ½ months ago! No other product I have worked with has shown anything even close to these results.

...

WHO NEEDS OSTINOL® FOR JOINT HEALTH?

There are over 60 million Americans struggling with joint problems and if you are one of them, then Ostinol® is the supplement for you!

Ostinol® products are the only supplements available on the market today that stimulate the body to grow healthy, new cartilage tissue.

...

WHO NEEDS OSTINOL® FOR BONE HEALTH?

If you are one of the 54 million Americans suffering from troublesome bone health, then Ostinol® is just right for you.

Ostinol® 450mg, 350mg, and 150mg are the only supplements available on the market today that stimulate the body to grow healthy, new bone tissue. These supplements provide a range of strengths for individuals who have mild, moderate, or severe bone loss.

Ostinol® dramatically improves the quality of life for people with troublesome bone health. ... Each supplement is powerful, safe, and effective, and takes only 7 days to work.

* * *

CLINICAL TRIALS & STUDIES

...

JOINT HEALTH SUPPORT

A 2013 clinical trial with 87 participants (55+ years old) who had moderate to severe joint discomfort involved the administration of 150 mg Ostinol® alone, once daily for 12 weeks. ... The statistically significant onset of action occurred by day 7. ... By week twelve 90% of participants experienced positive results and improved quality of life.

[View Study](#)

JOINT HEALTH SUPPORT

A 2015 clinical trial with 44 participants (55+ years) who had self-reported joint problems were enrolled in this trial. . . . The participants showed a 49% improvement in discomfort by week 4, 57% improvement in activity levels by week 4, and 80% improvement in affected joint strength after 4 weeks.

[View Study](#)

- b. Ostinol consumer website excerpt**
(www.ostinol.com/pages/clinical-trial-studies captured on Oct. 23, 2019)

CLINICAL TRIALS & STUDIES

ZyCal Bioceuticals Healthcare Co. [video clip]

[VOICEOVER] . . . Now ZyCal Bioceuticals ushers in a paradigm shift in molecular nutrition, bridging the gap between allopathic and natural medicine, manufacturing the only all natural ingredient proven to turn on stem cells and regenerate bone and cartilage tissue. . . .

And in 2006, specialists from surgery joined forces with leaders from J&J, P&G, and Unilever to create the first stem cell activating supplement and launched ZyCal Bioceuticals. This natural complex is the only substance, which provides the biochemical signal capable of turning on stem cells, transforming them into osteoblasts and chondrocytes, and producing new bone and cartilage tissue, a process known as osteoinduction. Today, ZyCal Bioceuticals presents this signaling ingredient to the natural medicine community as Cyplexinol®. . . .

Science, research, and quality are the hallmarks of ZyCal Bioceuticals as Cyplexinol is backed by multiple clinical trials. With each batch undergoing more than 30 rigorous tests by three independent laboratories. Guaranteeing results for you and your patients.

ZyCal is proud to be at the forefront of stem cell technology and tissue regeneration. Helping lead a future where proven medical science found in nature impacts so many lives. . . . Ostinol™, stem cell activating proteins, from surgery to supplement.

...

- c. ZyCal consumer website excerpt**
(www.zycalbio.com captured on Dec. 28, 2017)

Ostinol™ Standard contains 150mg of Cyplexinol® .90 Standard – Nature's BMP-Complex which activates stem cells to grow bone tissue so calcium and minerals can stick.

* * *

Ostinol™ Standard contains 350mg of Cyplexinol® .90 Standard – Nature’s BMP-Complex which activates stem cells to grow cartilage tissue so glucosamine and chondroitin can bind.

* * *

Ostinol™ Standard contains 450mg of Cyplexinol® bio-active protein-complex, which is clinically proven to activate your body’s natural cells to grow healthy new bone and cartilage tissue.

**d. ZyCal 2016 consumer website excerpt
(www.ostinol.com/take-charge/in-their-own-words
captured from <https://archive.org/web/> on Sept. 9, 2019)**

In Their Own Words

...

“Two weeks after starting the product, the arthritis in my feet was better and after three weeks, I could rotate my hands to play the piano again. Thank you for adding pain-free years to my life.” **Nell T., Austin Texas**

...

“In the 20 plus years that I have been working as a dietitian, I haven’t been as excited and eager to share a product with my patients as I am yours. The results have been remarkable and have enabled individuals to enjoy activities that they no longer thought were possible. ... Being able to prescribe these Bioceuticals to patients has brought them both increased mobility and hope for a healthier future. I encourage all healthcare practitioners to become knowledgeable about your product and how it can benefits their patients.” **Katherine Spink [sic], RD, South Carolina**

“The supplements are wonderful. I was able to postpone knee replacement surgery thanks to improved mobility after two weeks... and then I cancelled the surgery altogether after two months of taking your product. I may not be able to run a foot race, but I am off the cane totally and very comfortable with no pain and I am getting around beautifully. ...” **Sara Jo M.**

**e. 2016 ZyCal consumer website excerpt
(www.ostinol.com/take-charge/two-problems-one-solution
captured from <https://archive.org/web/> on Sept. 9, 2019)**

...

Two Problems, One Solution

Two health conditions, one breakthrough solution. That's the promise Ostinol™ makes to those struggling with poor bone and joint health.

Unlike all other products on the market, Ostinol™ is the first all-natural protein complex proven to grow new bone and cartilage tissue while helping fight inflammation. That's right, Ostinol™ doesn't just fortify like traditional supplements do, such as calcium, glucosamine and chondroitin ... we stimulate the cells that grow new, healthy tissue, helping improving YOUR bone and joint health.

As some people age, they lose the ability to produce enough of the vital, bio-active proteins found in Ostinol™, resulting in poor bone and joint health. These natural, key bio-active proteins are required, on a daily basis, to activate and transform key cells in our bones and joints so that new, healthy bone and cartilage tissue can be replenished.

Just one Ostinol™ capsule a day allows you to take charge of your body, recapturing that youthful feeling with healthier joints and stronger bones for a better quality of life.

The natural, bio-active proteins in Ostinol™ are so powerful that they have been clinically used for more than 25 years by orthopedic surgeons to safely grow bone tissue post-operative. Through a recent breakthrough, these powerful proteins are now available in an oral formulation that healthcare professionals have used for nearly 10 years while addressing a wide array of patients with bone and joint problems.

Today, these powerful bio-active proteins are available directly to you the consumers in three convenient strengths to address a variety of bone loss and joint health conditions.

Two chronic problems. One breakthrough solution. That's our Ostinol™ promise to you.

30. Based on the facts and violations of law alleged in this Complaint, the FTC has reason to believe that Defendants are violating or are about to violate laws enforced by the Commission. The ZyCal Defendants continue to disseminate deceptive advertisements and promotional materials representing that Ostinol products grow bone or cartilage tissue and thereby substantially reduce joint pain and discomfort, and that these benefits are clinically proven. The EMR Defendants were engaged in their deceptive advertising of StimTein for more than eight years and only stopped their unlawful conduct months after they received a Civil Investigative Demand from the FTC.

VIOLATIONS OF THE FTC ACT

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

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

33. Section 12 of the FTC Act, 15 U.S.C. § 52, prohibits the dissemination of any false advertisement in or affecting commerce for the purpose of inducing, or which is likely to induce, the purchase of food, drugs, devices, services, or cosmetics. For the purposes of Section 12 of the FTC Act, 15 U.S.C. § 52, StimTein and Ostinol products are either a “food” or “drug” as defined in Sections 15(b) and (c) of the FTC Act, 15 U.S.C. §§ 55(b), (c).

Count I

StimTein: False or Unsubstantiated Efficacy Claims by the EMR Defendants

34. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of StimTein, including through the means described in Paragraph 21, the

EMR Defendants have represented, directly or indirectly, expressly or by implication, that StimTein, taken as directed:

- A. Grows new bone, including in persons with osteoporosis and osteopenia;
- B. Grows new cartilage; and
- C. Provides substantial or long-lasting relief from joint pain and discomfort, including chronic or severe pain caused by arthritis, bursitis, and stenosis.

35. The representations set forth in Paragraph 34 are false or misleading or were not substantiated at the time the representations were made.

36. Therefore, the making of the representations as set forth in Paragraph 34 constitutes a deceptive act or practice and the making of false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

Count II

StimTein: False Establishment Claims by the EMR Defendants

37. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of StimTein, including through the means described in Paragraph 21, the EMR Defendants have represented, directly or indirectly, expressly or by implication, that StimTein, taken as directed, is:

- A. Clinically proven to grow new bone, including in persons with osteoporosis and osteopenia;
- B. Clinically proven to grow new cartilage; and

C. Clinically proven to provide substantial or long-lasting relief from joint pain and discomfort, including chronic or severe pain caused by arthritis, bursitis, and stenosis.

38. The representations set forth in Paragraph 37 are false.

39. Therefore, the making of the representations as set forth in Paragraph 37 constitutes a deceptive act or practice and the making of false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

Count III

StimTein: Deceptive Endorsement Claim by the EMR Defendants

40. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of StimTein, including through the means described in Paragraph 21, the EMR Defendants have represented, directly or indirectly, expressly or by implication, that the endorsements of Kimberley Troop and Beverly Murray reflect the experiences and opinions of ordinary impartial users of StimTein.

41. In fact, the endorsements of Kimberley Troop and Beverly Murray do not reflect the experiences and opinions of ordinary impartial users of StimTein because Kimberley Troop was an employee of Defendant EMR at the time her endorsement was made and Beverly Murray was the mother of a then-employee of Defendant EMR at the time her endorsement was made. Therefore, the representation set forth in Paragraph 40 is false or misleading in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count IV

StimTein: Deceptive Failure to Disclose Material Connections by the EMR Defendants

42. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of StimTein, including through the means described Paragraph 21, the EMR Defendants have represented, directly or indirectly, expressly or by implication, that the endorsements of Kimberley Troop and Beverly Murray reflect the experiences and opinions of users of StimTein.

43. In numerous instances in which the EMR Defendants have made the representation set forth in Paragraph 42, the EMR Defendants have failed to disclose that Kimberley Troop was an employee of Defendant EMR at the time her endorsement was made and Beverly Murray was the mother of a then-employee of Defendant EMR at the time her endorsement was made. These facts would be material to consumers in evaluating the endorsements of StimTein in connection with a purchase or use decision.

44. In light of the representations described in Paragraph 42, the EMR Defendants' failure to disclose the material information as set forth in Paragraph 43 constitutes a deceptive act or practice in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count V

StimTein: ZyCal Defendants' Provision of Means and Instrumentalities of Deception

45. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of StimTein, including through the means described in Paragraph 22 above, the ZyCal Defendants have provided the EMR Defendants with advertising, marketing,

and substantiation materials that contain false or misleading or unsubstantiated representations as set forth in Paragraphs 34 and 37 above.

46. By furnishing the EMR Defendants with the materials described in Paragraph 45, the ZyCal Defendants have provided the means and instrumentalities for the commission of deceptive acts and practices, in violation of Sections 5 and 12 of the FTC Act, 15 U.S.C. §§ 45(a) and 52.

Count VI

Ostinol Products: False or Unsubstantiated Efficacy Claims by the ZyCal Defendants

47. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Ostinol products, including through the means described in Paragraphs 22, 27 and 29, the ZyCal Defendants represent, directly or indirectly, expressly or by implication, that Ostinol products, taken as directed:

- A. Grow new bone;
- B. Grow new cartilage; or
- C. Provide rapid, substantial, or long-lasting relief from joint pain and discomfort, including joint pain and discomfort associated with arthritis or other degenerative bone and joint conditions.

48. The representations set forth in Paragraph 47 are false or misleading or were not substantiated at the time the representations were made.

49. Therefore, the making of the representations as set forth in Paragraph 47 constitutes a deceptive act or practice and the making of false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

Count VII

Ostinol Products: False Establishment Claims by the ZyCal Defendants

50. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Ostinol products, including through the means described in Paragraphs 22, 27, and 29, the ZyCal Defendants represent, expressly or by implication, that Ostinol products, taken as directed, are:

- A. Clinically proven to grow new bone;
- B. Clinically proven to grow new cartilage; or
- C. Clinically proven to provide rapid, substantial, or long-lasting relief from joint pain and discomfort, including joint pain and discomfort associated with arthritis or other degenerative bone and joint conditions.

51. The representations set forth in Paragraph 50 are false.

52. Therefore, the making of the representations as set forth in Paragraph 50 constitutes a deceptive act or practice and the making of false advertisements in violation of Sections 5(a) and 12 of the FTC Act, 15 U.S.C. §§ 45(a), 52.

Count VIII

Ostinol Products: Deceptive Endorsement Claim by the ZyCal Defendants

53. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Ostinol products, including through the means described in Paragraph

29, the ZyCal Defendants have represented, directly or indirectly, expressly or by implication, that the endorsement of registered dietitian Katherine Spinks reflects her impartial experience and opinion of Ostinol products.

54. In fact, the endorsement of Katherine Spinks does not reflect her impartial experience and opinion of Ostinol products because Katherine Spinks was a sales representative of Defendant ZyCal at the time her endorsement was made. Therefore, the representation set forth in Paragraph 53 is false or misleading in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

Count IX

Ostinol Products: Deceptive Failure to Disclose Material Connection by the ZyCal Defendants

55. In numerous instances in connection with the advertising, marketing, promotion, offering for sale, or sale of Ostinol products, including through the means described Paragraph 29, the ZyCal Defendants have represented, directly or indirectly, expressly or by implication, that the endorsement of Katherine Spinks reflects her experience and opinion of Ostinol products.

56. In numerous instances in which the ZyCal Defendants have made the representation set forth in Paragraph 55, they have failed to disclose that Katherine Spinks was a sales representative of Defendant ZyCal at the time her endorsement was made. This fact would be material to consumers in evaluating her endorsement of Ostinol products in connection with a purchase or use decision.

57. In light of the representations described in Paragraph 55, the ZyCal Defendants' failure to disclose the material information as set forth in Paragraph 56 constitutes a deceptive act or practice in violation of Section 5(a) of the FTC Act, 15 U.S.C. § 45(a).

CONSUMER INJURY

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

THIS COURT'S POWER TO GRANT RELIEF

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

PRAYER FOR RELIEF

Wherefore, Plaintiff FTC, pursuant to Section 13(b) of the FTC Act, 15 U.S.C. § 53(b), and the Court's own equitable powers, requests that the Court:

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

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

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

Respectfully submitted,

ALDEN F. ABBOTT
General Counsel

Dated: February 10, 2020

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