IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF COLUMBIA

GRAVITY DEFYER MEDICAL TECHNOLOGY CORP.,
ALEXANDER ELNEKAVEH,
10643 Glenoaks Boulevard
Pacoima, CA 91331, and

Plaintiffs,

v.

FEDERAL TRADE COMMISSION,
600 Pennsylvania Avenue, NW
Washington, DC 20580, and

THE UNITED STATES OF AMERICA,
United States Department of Justice
950 Pennsylvania Avenue, NW
Washington, DC 20530,

Defendants.

Case No. 1:22-cv-1157

COMPLAINT

On July 8, 2019, Defendant Federal Trade Commission ("FTC"), a federal agency created by and subject to the oversight of Defendant the United States of America, issued a Civil Investigative Demand to Plaintiff Gravity Defyer Medical Technology Corporation ("Gravity Defyer"). The agency sought to investigate pain reduction claims made in advertising for Gravity Defyer's footwear with VersoShock® soles. Nearly three years later, on February 17, 2022, the FTC issued a letter stating that the agency agreed that the unique supportive, shock-absorbing design of Gravity Defyer shoes provides requisite support for pain reduction claims, including the following identified by the agency in a non-exhaustive listing: "VersoShock technology . . . absorbs harmful shock, reducing pain and discomfort," "8+ hour comfort so that people can stay active and on their feet all day without pain," and "Absorb harmful energy from hard surfaces like cement and concrete and leave people feeling restored, revitalized and ready to get back on their

feet."[1] ***Thus, Plaintiffs and Defendants agree that when a consumer purchases Gravity Defyer shoes for pain relief, the consumer in fact receives pain relieving shoes.***

Prior to the FTC's investigation, Gravity Defyer commissioned the Olive View-UCLA Medical Center to design and conduct a randomized, double-blind, and controlled human clinical study to test the pain-relieving properties of its footwear. That study confirmed that Gravity Defyer shoes with VersoShock® soles provide relief for knee, back, foot, and ankle pain. During the course of the FTC's investigation, the *Journal of the American Podiatric Medical Association* conducted an extensive peer-review of the study (hereinafter "UCLA Study") and then published it in the journal's January/February 2022 issue.[2]

The FTC, for reasons unknown, has insisted through multiple years of investigation that the *Journal of the American Podiatric Medical Association* had rejected the UCLA Study for publication. Wrong on that point, the FTC then contrived all manner of other reasons the UCLA Study ought not be considered adequate substantiation.

For instance, the FTC apprised Gravity Defyer that the agency believes the study too small (52 participants) and too short (a five-week duration). That despite that footwear studies involving far fewer participants and shorter durations are generally accepted in the scientific community as competent proof of effects on pain.

Under the First Amendment commercial speech doctrine, the U.S. government may not ***prohibit*** advertising unless it is ***inherently*** misleading. If speech is only ***potentially*** misleading, the remedy is ***more disclosure, not speech restriction or prohibition***.

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[1] **Exhibit A**, Letter from Maria Del Monaco, Attorney, Federal Trade Commission, to J. Kathleen Bond, Lathrop GPM, LLP (Feb. 17, 2022) (hereinafter "FTC Feb. 17, 2022 Letter").

[2] **Exhibit B**, Ross, *et al.*, *Knee Pain Reduction Using a Shock-Absorbing Sole*, J AM POD MED ASSN 112(1) (Jan. 2022).

The FTC's "concerns" as to the UCLA Study are baseless and amount to unscientific conjecture. Gravity Defyer nevertheless has offered to add to its advertising any reasonable disclosures or qualifications that the FTC desires to address its "concerns" – for instance, disclosing the size and duration of the study. The FTC flatly rejected those offers – without even an attempt at establishing that reasonable disclosures would be insufficient to cure the agency's perception of misleadingness.[3]

While admitting the truth of numerous pain claims, the FTC's February 17 letter took the extraordinary and illogical position that it would prohibit "Gravity Defyer . . . and/or Mr. Elnekaveh" from making any "advertising claims *that cite or otherwise rely on*" the UCLA Study (emphasis added).[4]

In seeking to suppress any speech by Plaintiffs referencing the UCLA Study and barring Plaintiffs from using it at all in advertising, Defendants deprive Plaintiffs of their First Amendment rights. In turn, Defendants also violate Plaintiffs' Fifth Amendment due process rights where there is no administrative process Plaintiffs can use to compel the Defendants to honor Plaintiffs' First Amendment rights. Plaintiffs seek a narrow and specific declaratory judgment from this Court holding FTC's action unconstitutional under the First and Fifth Amendments.

THE PARTIES

1. Plaintiff Gravity Defyer Medical Technology Corporation is a California Corporation with its principal place of business at 10643 Glenoaks Boulevard in Pacoima, California. It is a medical technology company that manufactures and sells high-quality, durable,

[3] FTC Feb. 17, 2022 Letter.

[4] *Id.*

comfort footwear. Incorporated in 2008, Gravity Defyer currently has 56 employees and operates three retail stores. Gravity Defyer also sells its footwear products online and through various retailers across the United States. Gravity Defyer enjoys a small but loyal customer following in the U.S. shoe market.

2. Plaintiff Alexander Elnekaveh is a natural person and a citizen and resident of California. Gravity Defyer's advanced comfort footwear technology largely stems from the ingenuity of Mr. Elnekaveh, the company's Founder and Chair.

3. Defendant Federal Trade Commission is an independent agency of Defendant the United States of America, created by statute. 15 U.S.C. §§41–58. The FTC is empowered, among other things, to regulate health-related claims in advertising pursuant to its statutory authority to prohibit deceptive practices under Sections 5 and 12 of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52. The agency's powers to regulate advertising are derived solely from that statute. While the FTC may focus the weight of its vast resources against companies that are arguably engaged in the manufacture of unsafe products, the FTC has also targeted companies that bring admittedly safe, and even beneficial products to market.

JURISDICTION AND VENUE

4. This Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1337, and 1346 because all causes of action arise under the Constitution and laws of the United States.

5. Venue is proper in this district pursuant to 28 U.S.C. § 1391.

BACKGROUND FACTS

I. Gravity Defyer Is a Successful Small Business and a Leader in Innovative Footwear.

6. As Gravity Defyer's Founder, Mr. Elnekaveh has led the company's many years of research and development efforts. One of the most significant early steps he made for the company

was to secure a patent for Gravity Defyer's VersoShock® technology, an air-circulation-based spring system that absorbs shock from the ground up with each step.[5] Gravity Defyer developing a unique technology deemed non-routine or prior art under U.S. patent standards demonstrates the company's commitment to research and innovation.

7. Gravity Defyer is a company that, unlike its competitors, routinely invests in research and relies on a loyal base of repeat customers who benefit from its products.

8. Gravity Defyer shoes with VersoShock® soles receive top consumer ratings, with minimal consumer complaints.

II. Shoes with VersoShock® Soles Are Designed, and Proven, to Reduce Pain.

A. Design Features of the VersoShock® Sole Represent Significant Innovations that Combat Pain.

9. Each VersoShock® sole includes not only VersoShock® technology but also five other key features, all working synergistically to alleviate pain ordinarily induced by the pressure and shock of the weight-bearing effects of walking and running. The unique overall design represents the culmination of years of testing and consultation with experts in varied fields from podiatry and biomechanics to shoe materials.

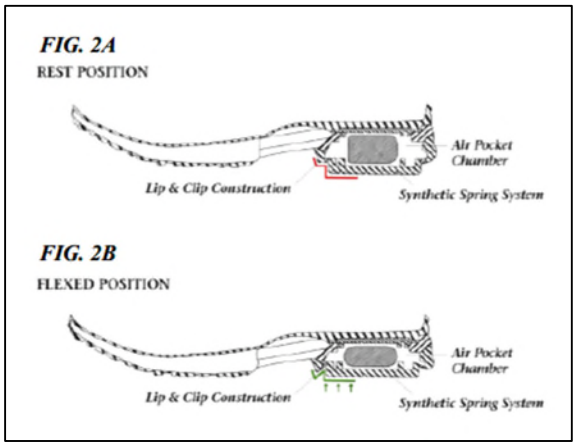
1. VersoShock® Technology

10. Gravity Defyer's VersoShock® technology was specifically designed to attenuate shock associated with walking and running, and thereby, alleviate pain associated with gait.

11. Although shoes designed with extra cushioning for running have existed since at least the 1970s, there has been limited research concerning how shoe design might affect shock absorption and foot spring. While "traditional athletic shoes have a one-part mechanism consisting

[5] *See* U.S. Patent No. 8,555,526.

of either air, gel, foam, or a spring" to assist with shock absorption and foot-spring in gait, VersoShock® uses a unique three-part construction.[6] The three parts are (1) a synthetic foam spring in the shoe's heel; (2) an air pocket chamber that surrounds the spring; and (3) a lip and clip design below the front portion of the heel, beneath the spring and air chamber (*see below* Figures 2A and 2B from the UCLA Study, at 6). The combined effect of these systems is to alleviate pain associated with the weight bearing effects of walking and running.



12. When the heel strikes the ground, the synthetic spring compresses to cushion, assisting the plantar fascia and pronation.[7] The lip and clip engages at the same time, providing a rocker or trampoline effect, also supporting pronation and augmenting the muscles in the foot in creating upward mobility.[8] This construction "reduce[s] shock force in the sagittal plane at heel strike" and "aids in propulsion at heel-off," providing a logical means by which to support and attenuate disruptions to the body's natural shock absorption.[9]

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6 UCLA Study, at 5.

7 *Id.*

8 *Id.*

9 *Id.*

2. The Five Other Key Attributes of the VersoShock® Sole

13. In addition to the VersoShock® technology, each VersoShock® sole contains five other proprietary attributes for energy management and stabilization. These include a unique internal shank, heel cup, and other features shown in laboratory testing to assist gait.

B. The UCLA Study Proves that Shoes with VersoShock® Soles Substantially Reduce Pain.

1. Qualifications of the Researchers

14. The well-credentialed podiatrists who conducted the UCLA Study are experts in the relevant fields to which Gravity Defyer's claims relate.

15. Lester J. Jones, D.P.M., M.S. Ed. served as the Primary Investigator for the study. Dr. Jones is board certified by the American Board of Podiatric Medicine and has practiced and taught podiatry. He currently serves as the Executive Associate Dean for Academic Affairs and a Professor of Podiatric Medicine at the College of Podiatric Medicine at Western University in Pomona, California. Dr. Jones's Master of Education and Doctor of Podiatric Medicine degrees are from the California College of Podiatric Medicine.

16. Aksone Nouvong, D.P.M., F.A.C.F.A.S. served as the Sub-Primary Investigator of the UCLA Study. Dr. Nouvong is board certified in foot surgery and a fellow of the American College of Foot and Ankle Surgeons American Professional Wound Care Association. Dr. Nouvong currently serves as Chair for the Department of Podiatric Surgery and Deputy Chief of Surgery at DVA Greater Los Angeles and Olive View-UCLA Medical Center. She is also a widely published researcher and serves as a Professor in the Department of Vascular Surgery at the David Geffen School of Medicine at UCLA, and as Associate Residency Director at Western University. Dr. Nouvong is a past member of the Board of Directors for the American College of Foot and Ankle Surgeons.

17. Arnold Ross, D.P.M., who has provided consultation on the development of Gravity Defyer shoes since approximately 2011, drafted the manuscript for the UCLA Study. Dr. Ross holds a Doctorate of Podiatric Medicine from the California School of Podiatric Medicine at Samuel Merritt University. He has practiced in Los Angeles, California for nearly 40 years and is board certified by the American Board of Podiatric Orthopedics and Primary Podiatric Medicine. Dr. Ross is also an Associate Professor of Biomechanics and Mechanical Orthopedics with Western University College of Podiatric Medicine.

2. Design and Execution

18. The objective of the UCLA Study was to compare the pain-relieving effects of shoes with Gravity Defyer's VersoShock® soles to those of control shoes with traditional soles.[10] Prior to the beginning of the UCLA Study, an institutional review board at the Olive View-UCLA Medical Center reviewed and approved the protocol.[11]

19. Researchers enrolled fifty-two (52) adult participants (ages 35-60, BMI 28.5) who were nurses, physical therapists, and other hospital personnel at Olive View-UCLA Medical Center, who reported standing for most of the workday.[12] Participants were identified as suffering from unilateral or bilateral knee pain during prolonged standing and activity. As described in the study, such knee pain is "extremely common" and "most commonly" caused by mechanical problems, arthritis, or injuries.[13]

20. Participants were randomly assigned to either the "intervention" group (unmarked Gravity Defyer shoes with the VersoShock® soles) or "control" group (Champion Anomaly shoes

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10 *Id.* at 2.

11 *Id.*

12 *Id.* at 2, 3, Table 1.

13 *Id.* at 1.

with all brand identifiers removed). Following a baseline clinic visit, researchers conducted two telephone interviews with participants at two and four weeks, and a final clinic visit occurred at five weeks.[14] At each visit and during each interview, participants rated their pain using the validated and generally accepted Universal Pain Assessment Tool for each of the following areas: right and left knee; back; right and left ankle; and right and left foot.[15] Pain scores for the right and left knee were aggregated to produce a total knee pain score.[16] Finally, a total pain score was aggregated over all body areas.[17]

3. Results and Conclusions

21. By the end of the study, "[p]ain reduction was significantly greater in the intervention group than in the traditional sole group for all assessed areas (all $P < .05$)."[18]

22. Specifically, participants in the intervention group experienced the following outcomes:

- Reduced overall knee pain versus control (p<0.0001);
- Reduced left knee pain versus control (p<0.0001);
- Reduced right knee pain versus control (p<0.0001);
- Reduced back pain versus control (p=0.01);
- Reduced left ankle pain versus control (p=0.04);
- Reduced right ankle pain versus control (p=0.02);
- Reduced left foot pain versus control (p=0.003);
- Reduced right foot pain versus control (p=0.004); and

14 *Id.* at 2.

15 *Id.* at 2–3.

16 *Id.* at 3.

17 *Id.*

18 *Id.* at 4 and Table 3.

- Reduced overall total pain versus control ($p<0.0001$).[19]

23. Participants in the intervention group experienced the following percentage pain reductions:

- An 85% reduction in knee pain versus a 15% increase in the control group ($p<0.0001$);
- A 91% reduction in back pain while the control group experienced only a 45% reduction ($p=0.01$);
- A 92% reduction in both left and right ankle pain, while the control group experienced only 32% and 42% reductions, respectively ($p=0.04$, $p=0.02$); and
- A 74% reduction in left foot pain versus a 24% reduction in the control group, and a 77% reduction in right foot pain versus 35% in the control group ($p=0.003$, $p=0.004$).[20]

24. The researchers reached the following conclusions:

> This randomized double blind controlled study demonstrated that a shoe sole designed to increase shock absorption can significantly relieve generalized knee pain during prolonged standing and walking, providing evidence for shoe design as a potential medical device.[21]

25. The researchers also observed as follows:

> The findings of this study may be of great significance for individuals with knee pain, particularly those whose jobs require prolonged walking or standing. This study also provides evidence that footwear designed to absorb shock may improve workplace functionality for jobs that require prolonged standing or walking. Finally, the results of this study are notable in conditions where the use of prefabricated and/or custom shoe inserts are beneficial, such as plantar fasciitis and lower-limb osteoarthritis.[22]

4. Publication of the UCLA Study

26. The UCLA Study was accepted for publication in August 2021 by the *Journal of the American Podiatric Medical Association*, and the study was published in the first issue of 2022. As the official journal of the American Podiatric Medical Association, this journal is the "oldest

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19 *Id.* at 4–5 and Table 3.

20 *Id.* at 4–5 and Table 4.

21 *Id.* at 7.

22 *Id.* at 6 (internal references omitted).

and most frequently cited peer-reviewed journal in the profession of foot and ankle medicine."[23]

27. Although a published, peer-reviewed, randomized, double-blind, controlled clinical study is far from required to support Gravity Defyer's health benefit claims, the company nevertheless sought out and funded that extremely high level of scientific support. As confirmed by publication in a premiere journal, the study results are not only statistically verified, but show clear clinical significance in reducing a variety of different types of pain associated with gait. Publication of findings following peer review in a premiere journal in the field indicates their general acceptance in the scientific community.

III. Defendants Seeks to Suppress Speech Based on the UCLA Study, in Violation of the First Amendment.

28. Under the First Amendment commercial speech doctrine, the U.S. government may not prohibit advertising unless it is provably, and thus, inherently misleading.[24] If speech is only potentially misleading, the remedy applied is more disclosure, not prohibition.[25]

29. The FTC, acting under authority granted it by the U.S. government, has a documented history of overreach in enforcement against health-related advertising claims based on clinical research.[26]

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[23] Journal of the American Podiatric Medical Association, *About* (n.d.), at japmaonline.org/page/about.

[24] *See, e.g.*, *Pearson v. Shalala*, 164 F.3d 650, 655, 659–660 (D.C. Cir. 1999); *Kimberly-Clark Corp. v. D.C.*, 286 F. Supp. 3d 128, 133 (D.D.C. 2017); *Peel v. Att'y Registration & Disciplinary Comm'n of Illinois*, 496 U.S. 91, 91 (1990) ("Although [the government] may prohibit misleading advertising entirely, it may not place an absolute prohibition on potentially misleading information if the information may also be presented in a way that is not deceptive.").

[25] *Id.*

[26] *See, e.g.*, *United States v. Bayer Corp.*, No. CV 07-01(JLL), 2015 WL 5822595, at *14 (D.N.J. Sept. 24, 2015) (upholding advertising claims based on clinical research); *FTC v. Garden of Life, Inc.*, 845 F. Supp. 2d 1328 (S.D. Fla. 2012), *aff'd in relevant part* 516 F. App'x 852 (11th Cir. 2013) (same).

30. On July 8, 2019, the FTC issued to Gravity Defyer a Civil Investigative Demand seeking to investigate pain reduction claims made in advertising for Gravity Defyer's footwear with VersoShock® soles.

31. The FTC investigation has been ongoing ever since, with virtual meetings with the staff attorneys leading the case, the Director of the FTC's Bureau of Consumer Protection, and the current four Commissioners, Chair Khan and Commissioners Phillips, Slaughter, and Wilson.

32. The FTC, for reasons unknown, insisted through multiple years of investigation that the *Journal of the American Podiatric Medical Association* had rejected the UCLA Study for publication. Proven wrong on that point, the FTC then contrived all manner of other reasons the UCLA Study might still be inadequate.

33. The following is a list of the FTC's unfounded, so-called "concerns": (1) the *Journal of the American Podiatric Medical Association* rejected the UCLA Study for publication, a point now definitively proven incorrect; (2) the UCLA Study was somehow inadequately powered, even though it showed statistically significant results, confirming adequate statistical power; (3) the UCLA Study was insufficiently blinded despite meeting the blinding requirements specified for clinical studies on shoes in prior FTC orders against Skechers and Reebok; (4) the secondary measures from the UCLA Study are somehow unreliable despite being pre-determined and all showing statistically significant results, (5) other Gravity Defyer VersoShock® shoes, for some unknown reason, may not be adequately similar to the tested shoe even though each has the same VersoShock® sole; (6) data from testing of a prior Gravity Defyer Super Walk® shoe should have been, for reasons entirely unknown, analyzed with the testing on the VersoShock® shoes; (7) for reasons unknown, Gravity Defyer purchasing and providing the control shoes, a Champion Anomaly shoe, was somehow nefarious, despite being standard research practice; (8) the study

was of inadequate duration at five weeks, even though prior FTC orders against Skechers and Reebok require clinical studies on shoes to be a mere week longer, at six weeks; (9) the very commonly used and validated pain measure the researchers selected and employed is somehow invalid where it uses a subjective survey instrument, even though pain is by definition a subjective state; (10) two study participants having taken over-the-counter pain medications somehow invalidates the study even though allowing pain medication increases the ethical and "real world" nature of the study, and even though, when data from those two participants are excluded, the study results all remain statistically significant; (11) four participants in the control group discontinuing use of their assigned shoe in the final two weeks of the study somehow matters even though the researchers were ethically obligated to allow such discontinuation, and even though, when data from those four participants are excluded, the study results all remain statistically significant, and (12) Olive View-UCLA Medical Center's participant consent form was somehow nefarious where it disclosed that Gravity Defyer shoes were being tested, as required by applicable state law governing human clinical investigations.

34. The FTC's above, misguided "concerns" as to the UCLA Study, even if not entirely based on conjecture (and they are) could, at most, call into question the general strength of the UCLA Study. None could prove the study invalid or render reference to the study misleading, especially if accompanied by qualification aimed at curing any perceived misleadingness.

35. Theoretically, if the FTC could show that a study's data was fabricated or otherwise fraudulent, the FTC could show that speech based on such a study would be provably, inherently misleading. The FTC, then, could possibly establish that all reasonable qualifications would fail to cure misleadingness. The FTC however has not, and certainly could not, make any such allegation in this case.

36. Despite failing to allege even that the UCLA Study was fundamentally flawed, such that speech based on it would be inherently misleading, the FTC has insisted that it must prohibit any and all speech about on the UCLA Study.

37. Gravity Defyer apprised the FTC of the First Amendment issues raised by the agency banning all speech referencing the UCLA Study. The FTC, however, remained steadfast in its position that it would prosecute the Defendants unless they committed to avoiding any reference in advertising to the UCLA Study.

38. In an effort to avoid litigation, but unwilling to relinquish its First Amendment speech rights, Gravity Defyer and Mr. Elnekaveh offered to apply whatever reasonable qualification the FTC demanded to address each of the FTC's "concerns" about the UCLA Study – even though the "concerns" FTC identified are entirely unfounded and scientifically invalid.

39. The FTC flatly rejected the offer, stating in its February 17, 2022 letter that "[a]s we have discussed, the Commissioners have indicated that" Gravity Defyer must not "make any advertising claims that cite or otherwise rely" on the UCLA Study and "your proposed [qualified] language is also unacceptable."[27]

40. Strangely, the same letter indicated the Commissioners' belief that the unique design of the Gravity Defyer shoes was sufficient by itself to substantiate a wide variety of pain relief claims such as, "With VersoShock technology that absorbs harmful shock, reducing pain and discomfort," "8+ hour comfort so that people can stay active and on their feet all day without pain," and "Absorb harmful energy from hard surfaces like cement and concrete and leave people feeling restored, revitalized and ready to get back on their feet."[28]

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27 FTC Feb. 17, 2022 Letter.

28 *Id.*

41. ***Effectively, Defendants would allow pain relief claims for Gravity Defyer footwear with VersoShock® soles, but not any speech referencing or relying on the UCLA Study, a clinical study supporting those same pain relief claims.***

42. Plaintiffs have diligently sought to avoid litigation with Defendants. They have done so even though the position taken by, and the threats made by, the FTC violate Plaintiffs' First Amendment rights to freedom of speech and Fifth Amendment rights to due process. Plaintiffs have reached an impasse with Defendants, and Defendants have threatened Plaintiffs with suit unless they relinquish their First Amendment rights.

43. On April 22, 2022, the FTC made clear that it would file suit against Plaintiffs and that the "Commission has voted (unanimously) and the case has been referred to the Department of Justice pursuant to 15 U.S.C. § 56(a)(1)."[29] With that vote and referral, Defendants will soon commence litigation against Gravity Defyer and Mr. Elnekaveh, alleging deceptive advertising in violation of the Federal Trade Commission Act, 15 U.S.C. §§ 45 and 52.

44. By seeking to deprive Plaintiffs of their First Amendment commercial speech rights, Defendants deprive Plaintiffs of their right to continue to engage in marketing and sale of its unique, clinically tested, pain-relieving footwear.

45. There is no administrative process Plaintiffs can use to compel Defendants to honor Plaintiffs' First Amendment speech rights.

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[29] **Exhibit C**, Email from Maria Del Monaco, Attorney, Federal Trade Commission, to J. Kathleen Bond, Lathrop GPM, LLP (Apr. 22, 2022).

FIRST CLAIM FOR RELIEF

Declaratory Relief, First Amendment Freedom of Speech

46. Plaintiffs hereby incorporate by reference the preceding paragraphs as though fully set forth herein.

47. An actual controversy has arisen and does now exist between Plaintiffs and Defendants with respect to Plaintiffs' First Amendment speech rights.

48. By seeking to suppress any and all speech referencing the UCLA Study, including even qualified advertising claims, Defendants violate Plaintiffs' First Amendment rights to freedom of speech.

49. The FTC has communicated its intention to commence immediately the litigation it has repeatedly threatened against Plaintiffs.

50. Defendants' actions described above create a direct and immediate dilemma for Plaintiffs, to either waive their First Amendment rights, or to exercise those rights and face litigation by Defendants.

51. Plaintiffs accordingly seek a declaration that Defendants' actions constitute a present and ongoing violation of Plaintiffs' First Amendment rights to freedom of speech.

SECOND CLAIM FOR RELIEF

Declaratory Relief, Fifth Amendment Due Process

52. Plaintiffs hereby incorporate by reference the preceding paragraphs as though fully set forth herein.

53. Plaintiffs have a constitutionally protected liberty interest in the free expression of truthful commercial advertising referencing the UCLA Study; in Gravity Defyer's reputation as a

law-abiding footwear seller with which others may contract without fear of FTC enforcement; and in their right to pursue a living through marketing and sale of footwear.

54. Plaintiffs have a property interest in the scientific research supporting the pain relieving effects of their footwear with VersoShock® soles.

55. Defendants have violated Plaintiffs' Fifth Amendment due process rights by depriving them of their liberty and property interests without due process of law, by failing to honor Plaintiffs' First Amendment speech rights.

56. There is no administrative process Plaintiffs can use to compel the FTC to honor Plaintiffs' First Amendment speech rights.

57. Plaintiffs accordingly seek a declaration that Defendants' insistence on banning any and all speech based on the UCLA Study constitutes a present and ongoing violation of Plaintiffs' Fifth Amendment due process rights.

PRAYER FOR RELIEF

WHEREFORE, Plaintiffs pray that this Court:

1. On the First Claim for Relief, for a declaration that: Defendants' insistence on banning all speech based on the UCLA Study constitutes a present and ongoing violation of Plaintiffs' First Amendment rights to freedom of speech;

2. On the Second Claim for Relief, for a declaration that: Defendants' insistence on banning any and all speech based on the UCLA Study constitutes a present and ongoing violation of Plaintiffs' First Amendment rights to freedom of speech, and in turn, a present and ongoing violation of Plaintiffs' Fifth Amendment due process rights;

3. For costs of suit incurred herein; and

4. For such other relief as the Court deems just and proper.

DATED: April 26, 2022

Respectfully submitted,

/s/ Samuel A. Butler

Samuel A. Butler (#D00479)
J. Kathleen Bond (DC Bar #985786;
application for D.D.C. admission filed)
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EXHIBIT A

United States of America
FEDERAL TRADE COMMISSION
East Central Region

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CONFIDENTIAL SETTLEMENT COMMUNICATION

February 17, 2022

VIA EMAIL TO:

J. Kathleen ("Katie") Bond, katie.bond@lathropgpm.com
Samuel A. Butler, samuel.butler@lathropgpm.com
Jonathan W. Emord, jemord@emord.com

RE: Gravity Defyer Medical Technology Corporation and Alexander Elnekaveh

Dear Katie, Sam, and Jonathan:

Thank you for your letter dated February 15, 2022. As we have discussed, the Commissioners have indicated that any settlement should not allow Gravity Defyer Medical Technology Corporation ("Gravity Defyer") and/or Mr. Elnekaveh to make advertising claims that cite or otherwise rely on the study that you have provided to us as substantiation. Accordingly, the qualifying language at the top of page 2 of your February 15, 2022 letter, which you propose to add to Gravity Defyer's current advertising, is unacceptable.[1]

We want to make clear, however, that we believe there are claims that Gravity Defyer could make moving forward, including a number of advertising claims that Gravity Defyer has made in the past, and that you have included in your September 21, 2021 white paper and expert report. For instance:

- Gravity Defyer shoes with VersoShock soles have "VersoShock technology that absorbs harmful shock, reducing pain and discomfort"
- Shoes with VersoShock soles "absorb harmful energy from hard surfaces like cement and concrete and leave people feeling restored, revitalized and ready to get back on their feet"

[1] Your proposed language is also unacceptable because it refers to non-knee pain. It has been our understanding that your clients were willing to give up those claims in order to settle and we have noted that Gravity Defyer's website no longer includes such claims.

- Gravity Defyer shoes with VersoShock soles provide "8+ hour comfort so that people can stay active and on their feet all day without pain"

See September 21, 2021 white paper, p. 16. We are also willing to discuss the additional claim that Gravity Defyer shoes with VersoShock soles "provide shock absorption to relieve pressure that may result in . . . knee pain." We are, moreover, open to advertising claims stating that wearing Gravity Defyer shoes may result in reduced knee or foot pain as a result of prolonged standing or walking, so long as the qualifying language (i.e., "as a result of prolonged standing or walking") is included. Finally, Gravity Defyer may continue to make truthful claims about the design of its shoes.

As you heard during the Commission meetings, we would like to reach a settlement that is acceptable to all parties and that enables Mr. Elnekaveh to return to the business of selling shoes. As you know from our previous communications, such a settlement would include a monetary component and your clients' agreement to a stipulated order. If your clients are willing to cease making advertising claims based on the study, please let us know and we would be happy to discuss the remaining aspects of the settlement with you. In that case, we would hope to build on the compromises that the parties have previously reached.

Sincerely,

Maria Del Monaco

Maria Del Monaco

cc via email to:
Dana C. Barragate
Matthew M. Scheff
Adrienne M. Jenkins

EXHIBIT B

CLINICALLY SPEAKING

Knee Pain Reduction Using a Shock-Absorbing Sole

Arnold S. Ross, DPM, MS*†
Lester J. Jones, DPM, MSEd‡§

Background: The biomechanics of the foot and leg are responsible for shock absorption during human gait. Lack of shock absorption is known to be a key component of knee pain. This study compares a new model of shoe sole with a built-in modification intended to absorb shock with a traditional sole shoe to examine whether shoe design modifications can help alleviate knee pain.

Methods: A double-blind randomized controlled study was performed. Fifty-two adults with overuse symptoms of knee pain, either unilateral or bilateral, were enrolled and randomly assigned to use the intervention sole or the traditional sole shoes. For 5 weeks, participants wore either the shoe with the intervention sole or the shoe with the traditional sole, rating their knee pain on a 10-point visual analog scale at study onset, midway, and study completion.

Results: After 5 weeks, participants using the intervention sole shoe reported an average reduction in knee pain of 85%, significantly better than participants using the traditional sole shoe ($P < .001$), whose average pain scores increased. Positive effects on back and foot pain were also observed in those with the intervention sole shoe compared with the traditional sole shoe.

Conclusions: The intervention shock-absorbing sole represents an approach to midsole and outsole construction that can potentially increase shock absorption and decrease knee pain during prolonged standing and walking. (J Am Podiatr Med Assoc 112(1), 2022)

Knee pain is extremely common in young and older adults alike, and it is most commonly caused by injuries, biomechanical problems in gait, and arthritis.[1,2] Lack of shock absorption is known to be a key component of knee pain and is an important risk factor for osteoarthritis.[2] Although surgical repair is sometimes necessary to address severe cases of knee pain, many types of knee pain respond well to self-care measures,[3] such as physical therapy,[4] knee braces,[5] orthotic devices,[6] and shoe design.[7] Other causes of knee pain include excess weight[8] or a decrease in muscle flexibility or strength,[9] which may cause a corresponding reduction in shock absorption.

The biomechanics of the foot and leg are responsible for shock absorption during human gait.[10] To achieve this shock-absorbing function, the orientation of the foot and lower leg act as a "terrain adapter," leveling the gait pattern during walking.[11] During typical human ambulation, the ground reaction forces from the impact of the heel striking the ground result in compressive shock at the start of the stance phase of gait, known as heel contact.[12–15] During heel contact of a typical healthy gait pattern, the subtalar and midtalar joints pronate, and the lower extremity internally rotates faster than the femur, known as the knee adduction moment, transferring momentum from the ankle to the lower leg and allowing knee flexion to mechanically absorb shock.[10,11] To do so, the knee requires normal subtalar joint motion. However, if any of these joint or limb movements are inhibited, abnormal shock absorption can occur, potentially inducing pain and causing injury over time. Indeed, even prolonged standing has demonstrated a negative effect on pain at the knee.[16,17]

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The role of footwear in accentuating shock absorption and decreasing pain has been debated within the field. Whereas one study found no association between physical activity or shoe type and knee pain,[18] others demonstrated that shoe design decreases the knee adduction moment while walking.[19–21] For example, Taniguchi et al[22] designed footwear that significantly decreased shock absorption during the early stance phase. Furthermore, Zhang et al[23] found that shoes with a soft midsole had significantly lower ground reaction forces than shoes with normal and hard midsoles. In contrast, Kelly et al[24] found that traditionally constructed running shoes alter the mechanical function of the foot, suggesting that they impede the springlike function by reducing compression of the longitudinal arch and hindering rise and recoil. This then reduces muscle activation in the foot, with disuse leading to weakness and eventual atrophy. These studies corroborate the important role that appropriately designed footwear can play in walking without pain.

Among shock-absorbing shoes, design matters and varies greatly. As previously mentioned, the springlike function of the lower limb is an important factor to the propulsion phase of the gait cycle, and footwear designed to reduce shock should also enhance, rather than hinder, this function.[19] The most promising footwear interventions are shock-reducing modifications of the sole unit incorporated into the shoes' construction, rather than a removable insert.[25,26] Measurements of shock attenuation effectiveness over time demonstrated the importance of material (foam, air, gel, springs), chemical, and mechanical factors when designing a shock-absorbing sole.[27–29] Although statistically significant shock reduction can be achieved, the fit between the shoe and the foot influences shock transmission, as does the design of the shoe.[26,27] When combined, increased shock absorption at contact phase and return of energy through a springlike action during propulsion are key factors to the potential for increased walking efficiency through shoe design.

This study investigates a new model of shoe to examine whether shoe design modifications help alleviate knee pain by reducing shock. The primary hypothesis is that after 5 weeks, participants who wore the shoes with intervention soles will report greater pain relief than those who wore the traditional sole shoe.

Materials and Methods

The research protocol was approved in advance of its application to human participants by the institutional review board of the Education Research Institute for the Olive View UCLA Medical Center (Sylmar, California). All of the participants gave written informed consent to participate at their initial visit with the research team.

Study Participants

Staff at Olive View UCLA Medical Center with knee symptoms related to overuse during prolonged standing and daily activities were recruited for this study. The study sample consisted of participants who spend most of their workday on their feet and who reported knee pain (unilateral or bilateral). Additional inclusion criteria were age (35–60 years) and shoe size (7–9½ for females and 9–12 for males, measured using an industry-standard Brannock device). The sample size was determined using statistical power analysis before recruitment began.

Participants were first screened to determine whether they had overuse knee pain issues associated with prolonged standing and ambulation that were not secondary to other pathologic conditions, such as osteoarthritis. Exclusion criteria included a history of major surgery in the foot, ankle, knee, hip, or back; the inability to walk without an assistive device; a history of a major foot deformity, including severe flatfoot, Charcot's foot, or other rigid foot pathologic disorders; poorly controlled diabetes; peripheral vascular disease limiting ambulation; autoimmune or inflammatory diseases, including rheumatoid arthritis, lupus, and scleroderma; peripheral neuropathy or any significant deviations from reference ranges of motion of the foot, knee, or hip during ambulation; any serious chronic condition that can affect walking; and knee pain secondary to knee pathology deemed nontreatable with conservative therapy.

Participants who met the inclusion criteria took part in three clinic visits and two telephone interviews in a 6-week period. During the first clinic visit, after confirming the inclusion criteria, participants completed a medical history questionnaire and received a musculoskeletal examination, which examined knee position and gait pattern against the exclusion criteria. Each participant's anthropomorphic measurements were taken (weight and height), and their shoe size was measured to ensure an accurate fit.

Pain Assessment

During the initial clinic visit, each participant was asked to rate their general pain during general daily

activities according to the Universal Pain Assessment Tool (UPAT) (Fig. 1). Participants were asked about the pain they experience during standing and walking for each of the following areas: right and left knee, back, right and left ankle, and right and left foot. The UPAT is a psychometric response scale that measures patients' subjective experience of pain by asking them to rate their pain on a scale from 1 to 10, with 10 being the worst possible pain.

Shoe Type Randomization

Participants were randomly assigned to one of two groups by study assistants who blindly dispensed shoes to the participants, alternating between intervention sole and traditional sole shoes. The study assistants did not access previous information about the participants, other than shoe size, and shoes were handed out randomly. A separate group of study evaluators, who had no contact with the study assistants, did not know which shoe each participant was assigned. During the second visit, participants received either the shoes with the intervention soles or a traditional sole shoe, according to random assignment, and a copy of the UPAT to use during the phone interviews. Participants were asked to wear the shoes for the duration of the study and to keep track of any adverse or positive effects of the shoes.

The traditional sole shoe was an existing Champion Sport shoe (Anomaly; Gravity Defyer Corp, Pacoima, California) with a nylon mesh upper and a crepe/ethylene vinyl acetate sole. The intervention shoe had the VersoShock sole (model: Mighty Walk; Gravity Defyer Medical Technology Corp, Pacoima, California). All of the identifiers for the brand of shoe were removed, including all tags and branding.

Follow-up

Participants were interviewed twice: after 2 and 4 weeks of wearing the shoes. During each phone interview, participants were asked to rate their general pain in each pain area (right and left knee, back, right and left ankle, and right and left foot) on the UPAT, as well as whether they had experienced any change in body weight, activity level, or medical history since the previous inter-view.

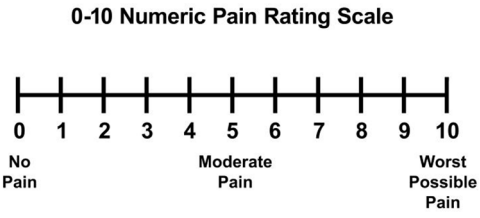

Figure 1. Universal Pain Assessment Tool (UPAT).

After 5 weeks of wearing the shoes, participants returned for a final in-person clinic visit. Each participant was asked to rate their general pain in each pain area (right and left knee, back, right and left ankle, and right and left foot) using the UPAT. They also underwent another physical examination, including weight and height.

At the end of the study, participants were asked to return the shoes they used during the study. All of the participants, regardless of condition, were given a voucher to receive a pair of the intervention shoes and a $150 Visa gift card.

Data Analysis

The data were analyzed by Kelly Statistical Consulting (Carlsbad, California) using a statistical software package (SAS, Version 9.3; SAS Institute Inc, Cary, North Carolina).

Unpaired t tests between the traditional sole and intervention sole groups were used to assess for differences in the group means of each demographic variable. Pain scores for the right and left knees were aggregated to produce a total knee pain score. The total pain score is the aggregate of scores over all of the body areas. An unpaired t test analyzed the difference in UPAT scores between groups at the beginning of the study. The change in pain score was calculated as the pain score at final assessment minus the score at baseline. Because not all of the patients reported pain in all of the areas, patients who reported a pain level of 0 were excluded because a reduction from 0 is impossible and their results would have skewed the overall results of the study. For patients with pain at baseline (score >0), the percentage change was calculated as the change in pain score divided by the baseline pain score. Mean change in pain and percentage change in pain were compared between the intervention sole and traditional sole groups with a repeated-measures mixed-effect model.

Results

Demographic Information

Fifty-two participants were enrolled in the study, all of whom met the inclusion criteria and reported generalized knee pain in one or both of their legs.

Table 1. Participant Demographic and Baseline Characteristics

Characteristic	Traditional Sole Shoe (n = 26)	Intervention Sole Shoe (n = 26)	All Participants (N = 52)
Sex (No. [%])			
Male	13 (50)	13 (50)	26 (50)
Female	13 (50)	13 (50)	26 (50)
Age (mean [range] [years])	46 (35–57)	46 (35–60)	46 (35–60)
Race (No. [%])			
American Indian or Alaskan Native	0	2 (8)	2 (4)
Asian	4 (15)	5 (19)	9 (17)
Black	5 (19)	2 (8)	7 (14)
Hispanic	2 (8)	3 (12)	5 (10)
White	12 (46)	11 (42)	23 (44)
Other	3 (12)	3 (12)	6 (12)
Ethnicity (No. [%])			
Hispanic	12 (46)	14 (54)	26 (50)
Non-Hispanic	13 (50)	11 (42)	24 (46)
Unknown	1 (4)	1 (4)	2 (4)
Weight (mean [range] [kg])	82.1 (55.1–114.4)	78.8 (50.8–106.1)	80.5 (50.8–114.1)
Height (mean [range] [cm])	170.7 (152.4–182.9)	165.9 (152.4–180.3)	168.3 (152.4–182.9)
BMI (mean [range])	28.3 (17.9–48.8)	28.6 (20.5–41.0)	28.5 (17.9–48.8)

Abbreviation: BMI, body mass index (calculated as weight in kilograms divided by height in meters squared).

After random distribution between shoe groups, 50% of the participants (n = 26) received the intervention sole shoes and 50% (n = 26) received the traditional sole shoes. Table 1 summarizes the participant characteristics of the sample. Each group was diverse in age, sex, race, ethnicity, weight, height, and body mass index and was statistically equivalent on the basis of race, height, weight, and body mass index (all $P > .05$).

Baseline Pain Scores

The primary hypothesis was that after 5 weeks, participants who wore the shoes with intervention soles would report greater pain relief than the control group wearing the traditional sole shoe. Among participants, similar baseline total pain scores were calculated for the ankles and the feet ($P > .05$). Table 2 summarizes the baseline pain scores, using the UPAT rating scale. There was no significant difference between groups regarding baseline pain scores ($P = .6719$).

Participants using the intervention sole shoe reported an average reduction in generalized knee pain of 85% (95% confidence interval [CI], 75%–95%) on a 10-point scale. Table 3 summarizes the change in pain scores from baseline, using the UPAT rating scale. Pain reduction was significantly greater in the intervention group than in the traditional sole group for all of the assessed areas (all $P < .05$), with the most significant findings in overall total pain, overall knee pain, right knee pain, and left knee pain (all $P < .0001$).

Table 4 summarizes the mean percentage change in pain across all pain areas for participants with a baseline pain score greater than 0. Pain scores in the right knee decreased by 86% (95% CI, –74% to –98%) and increased by 7% (95% CI, –14% to 27%) in

Table 2. Baseline Universal Pain Assessment Tool Scores

	Universal Pain Assessment Tool Scores (Mean [Range])		
Body Area	Traditional Sole Shoe (n = 26)	Intervention Sole Shoe (n = 26)	All Participants (N = 52)
Back	1.7 (0–6)	2.9 (0–9)	2.3 (0–9)
L Knee	4.1 (0–9)	3.8 (0–7)	3.9 (0–9)
R Knee	4.0 (0–9)	4.2 (0–8)	4.1 (0–9)
L Ankle	1.1 (0–6)	0.9 (0–6)	1.0 (0–6)
R Ankle	0.5 (0–6)	0.9 (0–5)	0.7 (0–6)
L Foot	1.3 (0–7)	1.8 (0–8)	1.5 (0–8)
R Foot	1.0 (0–5)	1.5 (0–8)	1.3 (0–8)

Abbreviations: L, left; R, right.

Table 3. Change in Pain Scores for All of the Participants

Body Area and Sole Type	Pain Score (Mean ± SE)		Change (Mean [95% CI])	*P* Value
	Baseline	Final		
Primary				
Knee intervention	8.0 ± 0.7	1.2 ± 0.4	–6.8 (–8.3 to –5.3)	<.0001
Knee traditional	8.1 ± 0.7	8.3 ± 0.7	0.2 (–1.3 to 1.7)	
R Knee intervention	4.2 ± 0.5	0.7 ± 0.3	–3.5 (–4.5 to –2.5)	<.0001
R Knee traditional	4.0 ± 0.5	4.2 ± 0.4	0.2 (–0.8 to 1.2)	
L Knee intervention	3.8 ± 0.4	0.5 ± 0.2	–3.3 (–4.2 to –2.4)	<.0001
L Knee traditional	4.1 ± 0.5	4.1 ± 0.5	–0.0 (–0.9 to 0.9)	
Secondary				
Back intervention	2.9 ± 0.5	0.3 ± 0.2	–2.6 (–3.4 to –1.7)	.01
Back traditional	1.7 ± 0.4	1.1 ± 0.4	–0.6 (–1.5 to 0.3)	
L Ankle intervention	0.9 ± 0.3	0.1 ± 0.1	–0.8 (–1.5 to –0.1)	.04
L Ankle traditional	1.1 ± 0.4	0.8 ± 0.4	–0.3 (–0.9 to 0.4)	
R Ankle intervention	0.9 ± 0.3	0.1 ± 0.1	–0.8 (–1.5 to –0.1)	.02
R Ankle traditional	0.5 ± 0.3	0.7 ± 0.3	0.2 (–0.4 to 0.9)	
L Foot intervention	1.8 ± 0.5	0.5 ± 0.2	–1.3 (–2.2 to –0.4)	.003
L Foot traditional	1.3 ± 0.4	1.8 ± 0.5	0.5 (–0.4 to 1.5)	
R Foot intervention	1.5 ± 0.5	0.4 ± 0.2	–1.1 (–2.0 to –0.2)	.004
R Foot traditional	1.0 ± 0.4	1.7 ± 0.5	0.7 (–0.2 to 1.6)	
Total all pain intervention	15.9 ± 1.7	2.5 ± 0.8	–13.4 (–17.1 to –9.7)	<.0001
Total all pain traditional	13.6 ± 1.6	14.4 ± 1.4	0.8 (–2.8 to 4.5)	

Abbreviations: CI, confidence interval; L, left; R, right.

the intervention and control groups, respectively, and pain scores in the left knee decreased by 87% (95% CI, –75% to –98%) and 3% (95% CI, –25% to 19%) in the intervention and control groups, respectively. Both of these differences were significant ($P < .0001$) (Fig. 3). Overall knee pain decreased by 85% (95% CI, –75% to –95%) for the intervention group but increased by 15% (95% CI, –11% to 42%) for the traditional sole group, a significant difference ($P = .01$). Overall pain decreased by 84% (95% CI, –76% to –92%) for the intervention group while increasing by 38% (95% CI, –3% to 78%) for the traditional sole group, a significant difference ($P < .0001$). Finally, the intervention group also reported significantly greater decreases in back pain ($P = .01$) and left foot pain ($P = .03$).

Discussion

After 5 weeks of wear, participants in the intervention group reported greater reduction in generalized pain across the knee, hip, and back than did the traditional sole group. Furthermore, participants with pain who wore the intervention sole shoes were significantly more likely to report decreased knee, back, and foot pain than those who received the generic shoe. Whereas the intervention group reported decreased pain, the control group reported increased overall general pain and knee pain.

These preliminary results indicate that sole technology designed to accentuate shock absorption may significantly reduce general knee pain compared with a traditional sole shoe. The construction of the shoe with the intervention sole was designed with the potential to increase shock absorption and return of energy during gait using a three-part construction (Fig. 2). The intention of this design was to work in tandem with the gait cycle to aid biomechanical propulsion and compressive shock absorption. Whereas traditional athletic shoes have a one-part mechanism consisting of either air, gel, foam, or a spring, the intervention shoe consists of 1) a compressible foam block heel, 2) a clip and lip trampoline-stretch type of energy return, and 3) a small air hole that controls the air flow from heel to forefoot. Specific to the design of this shoe (Fig. 2), the clip and lip construction allows stretch to occur, creating tension, and at propulsion, offering upward mobility of the outer heel plate as the shoe raises from the ground. Finally, an air pocket chamber between the synthetic spring and the clip and lip has a pneumatic effect, allowing air to pass slowly from the posterior chamber through a small hole in the anterior chamber into the forward portion of the shoe. The design of the intervention sole attempts to reduce shock force in the sagittal plane at heel strike, and this pneumatic effect aids in propulsion at heel-off.

Table 4. Change in Pain Scores for Participants with a Baseline Pain Score Greater than 0

Body Area and Sole Type	Pain Score (Mean ± SE)		Change (Mean [95% CI])	*P* Value
	Baseline	Final		
Primary				
Knee intervention	8.0 ± 0.7	1.2 ± 0.4	–6.8 (–8.3 to –5.3)	<.0001
Knee traditional	8.1 ± 0.7	8.3 ± 0.7	0.2 (–1.3 to 1.7)	
R Knee intervention	4.2 ± 0.5	0.7 ± 0.3	–3.5 (–4.5 to –2.5)	<.0001
R Knee traditional	4.0 ± 0.5	4.2 ± 0.4	0.2 (–0.8 to 1.2)	
L Knee intervention	3.8 ± 0.4	0.5 ± 0.2	–3.3 (–4.2 to –2.4)	<.0001
L Knee traditional	4.1 ± 0.5	4.1 ± 0.5	–0.0 (–0.9 to 0.9)	
Secondary				
Back intervention	2.9 ± 0.5	0.3 ± 0.2	–2.6 (–3.4 to –1.7)	.01
Back traditional	1.7 ± 0.4	1.1 ± 0.4	–0.6 (–1.5 to 0.3)	
L Ankle intervention	0.9 ± 0.3	0.1 ± 0.1	–0.8 (–1.5 to –0.1)	.04
L Ankle traditional	1.1 ± 0.4	0.8 ± 0.4	–0.3 (–0.9 to 0.4)	
R Ankle intervention	0.9 ± 0.3	0.1 ± 0.1	–0.8 (–1.5 to –0.1)	.02
R Ankle traditional	0.5 ± 0.3	0.7 ± 0.3	0.2 (–0.4 to 0.9)	
L Foot intervention	1.8 ± 0.5	0.5 ± 0.2	–1.3 (–2.2 to –0.4)	.003
L Foot traditional	1.3 ± 0.4	1.8 ± 0.5	0.5 (–0.4 to 1.5)	
R Foot intervention	1.5 ± 0.5	0.4 ± 0.2	–1.1 (–2.0 to –0.2)	.004
R Foot traditional	1.0 ± 0.4	1.7 ± 0.5	0.7 (–0.2 to 1.6)	
Total all pain intervention	15.9 ± 1.7	2.5 ± 0.8	–13.4 (–17.1 to –9.7)	<.0001
Total all pain traditional	13.6 ± 1.6	14.4 ± 1.4	0.8 (–2.8 to 4.5)	

Abbreviations: CI, confidence interval; L, left; R, right.

The findings of this study may be of great significance for individuals with knee pain, particularly those whose jobs require prolonged walking or standing. This study also provides evidence that footwear designed to absorb shock may improve workplace functionality for jobs that require prolonged standing or walking.[22] Finally, the results of this study are notable in conditions where the use of prefabricated and/or custom shoe inserts are beneficial, such as plantar fasciitis[29,30] and lower-limb osteoarthritis.[31]

The absence of pain in the lower extremities is often dependent on the appropriate movement of the foot during walking.[26,27] The findings of this study are in line with similar shoe-based intervention studies that found benefits to foot function with inserts or specially designed shoes. For example, a study comparing barefoot and shod running found that shoes can improve the springlike action of the foot during gait.[24] Another study of viscoelastic shoe inserts demonstrated benefits to pain reduction in adults with low back pain.[25] Finally, Paterson et al[19] expanded this concept, validating the criteria by which to compare walking shoes by measuring the shoe's effect on the knee adduction moment.

To the contrary, the present study contradicts the findings of Atukorala et al[18] and Theisen et al[32] that suggest no connection between shoe type and knee pain. Atukorala et al[18] used patient reports of knee pain flare over a 10-day interval to question whether knee pain is even related to the shoes worn or physical activity performed in adults with knee osteoarthritis. In their findings, although physical activity decreased directly before a pain flare, there was no association between either physical activity or type of shoes worn the day before the pain flare in these participants. The discrepancy may be due to the longer duration of this study. Atukorala et al[18] considered only shoes worn the day before a pain flare

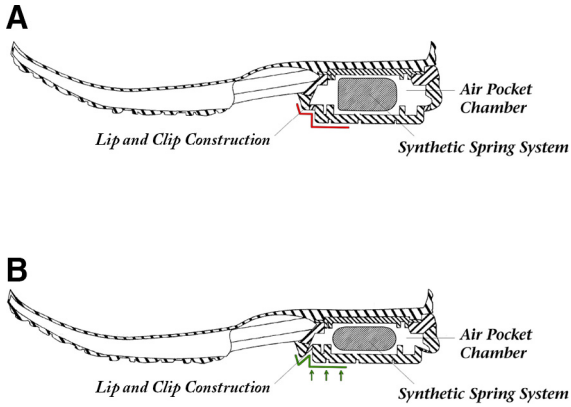

Figure 2. Cross-sectional illustrations of the design of the intervention sole at rest (A) and in a flexed position (B). (Reprinted with permission from Gravity Defyer Medical Technology Corp.)

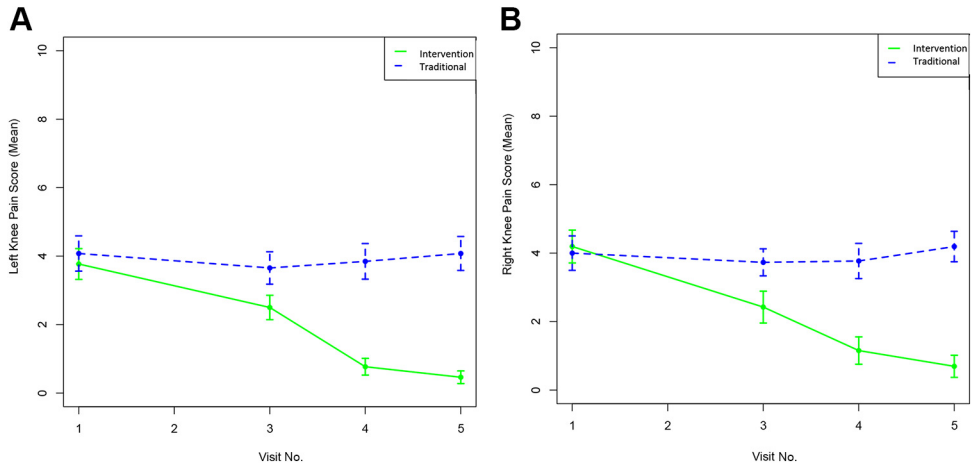

Figure 3 Mean left (A) and right (B) knee pain scores by visit and sole type. Error bars represent standard error.

instead of considering shoe use and pain scores over a longer period, as in the present study. Similarly, Theisen et al[32] found no influence of midsole stiffness on running-related injuries. In their study, runners with either a soft or hard midsole reported no difference in prevalence of pain that impeded running activities. Although this study was conducted over a longer period (5 months), the intervention was focused on the stiffness of the midsole rather than on shock absorption of the heel. With variable findings as far as the influence of shoes with multiple components and materials on pain relief, shoe design remains an important area of study.

There are several limitations to this study. A generalized pain reporting scale was chosen to describe participant general joint pain. This analysis allows for the impact of the shoe to be aligned with the day-to-day pain that is experienced by those with joint pain. Further study is required to determine the mechanisms of this pain relief and how it relates to the shoe sole design. Furthermore, a general participant population was used, without specificity in the underlying cause of knee pain, nor the specific area of knee pain.

Conclusions

This randomized, double-blind, controlled study demonstrated that a shoe sole designed to increase shock absorption can significantly relieve generalized knee pain during prolonged standing and walking, providing evidence for shoe design as a potential medical device. Future studies should identify whether pain relief is more prominent in specific areas of the knee.

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Conflict of Interest: None reported.

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EXHIBIT C

From: Del Monaco, Maria <mdelmonaco@ftc.gov>
Sent: Friday, April 22, 2022 9:27 AM
To: Bond, Katie; Butler, Samuel A.; jemord@emord.com
Cc: Barragate, Dana C.; Scheff, Matthew; Jenkins, Adrienne M.
Subject: RE: Gravity Defyer -- Status Update

Dear Katie, Sam, and Jonathan:

As we advised in previous communications, we were granted additional time to negotiate with you, which could only be extended on a showing of substantial progress towards settlement. Since no progress towards settlement was made, the Commission has voted (unanimously) and the case has been referred to the Department of Justice pursuant to 15 U.S.C. §56(a)(1). Thus, we are no longer able to negotiate with you at this time.

Maria

Maria Del Monaco
Federal Trade Commission | East Central Region
1111 Superior Avenue, Suite 200 | Cleveland, OH 44114
t: 216.263.3405 | mdelmonaco@ftc.gov

CIVIL COVER SHEET

JS-44 (Rev. 11/2020 DC)

I. (a) PLAINTIFFS
GRAVITY DEFYER MEDICAL TECHNOLOGY CORP. and ALEXANDER ELNEKAVEH

(b) COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF Los Angeles, CA
(EXCEPT IN U.S. PLAINTIFF CASES)

DEFENDANTS
FEDERAL TRADE COMMISSION and THE UNITED STATES OF AMERICA

COUNTY OF RESIDENCE OF FIRST LISTED DEFENDANT _____
(IN U.S. PLAINTIFF CASES ONLY)
NOTE: IN LAND CONDEMNATION CASES, USE THE LOCATION OF THE TRACT OF LAND INVOLVED

(c) ATTORNEYS (FIRM NAME, ADDRESS, AND TELEPHONE NUMBER)
Lathrop GPM, LLP
600 New Hampshire Avenue, NW
The Watergate - Suite 700
Washington, DC 20037
Phone (202) 295-2200

ATTORNEYS (IF KNOWN)

II. BASIS OF JURISDICTION
(PLACE AN x IN ONE BOX ONLY)

- ○ 1 U.S. Government Plaintiff
- ○ 3 Federal Question (U.S. Government Not a Party)
- ◉ 2 U.S. Government Defendant
- ○ 4 Diversity (Indicate Citizenship of Parties in item III)

III. CITIZENSHIP OF PRINCIPAL PARTIES (PLACE AN x IN ONE BOX FOR PLAINTIFF AND ONE BOX FOR DEFENDANT) **FOR DIVERSITY CASES ONLY!**

	PTF	DFT		PTF	DFT
Citizen of this State	○ 1	○ 1	Incorporated or Principal Place of Business in This State	◉ 4	○ 4
Citizen of Another State	○ 2	○ 2	Incorporated and Principal Place of Business in Another State	○ 5	○ 5
Citizen or Subject of a Foreign Country	○ 3	○ 3	Foreign Nation	○ 6	○ 6

IV. CASE ASSIGNMENT AND NATURE OF SUIT

(Place an X in one category, A-N, that best represents your Cause of Action and one in a corresponding Nature of Suit)

○ **A. *Antitrust***
- ☐ 410 Antitrust

○ **B. *Personal Injury/ Malpractice***
- ☐ 310 Airplane
- ☐ 315 Airplane Product Liability
- ☐ 320 Assault, Libel & Slander
- ☐ 330 Federal Employers Liability
- ☐ 340 Marine
- ☐ 345 Marine Product Liability
- ☐ 350 Motor Vehicle
- ☐ 355 Motor Vehicle Product Liability
- ☐ 360 Other Personal Injury
- ☐ 362 Medical Malpractice
- ☐ 365 Product Liability
- ☐ 367 Health Care/Pharmaceutical Personal Injury Product Liability
- ☐ 368 Asbestos Product Liability

○ **C. *Administrative Agency Review***
- ☐ 151 Medicare Act

Social Security
- ☐ 861 HIA (1395ff)
- ☐ 862 Black Lung (923)
- ☐ 863 DIWC/DIWW (405(g))
- ☐ 864 SSID Title XVI
- ☐ 865 RSI (405(g))

Other Statutes
- ☐ 891 Agricultural Acts
- ☐ 893 Environmental Matters
- ☐ 890 Other Statutory Actions (If Administrative Agency is Involved)

○ **D. *Temporary Restraining Order/Preliminary Injunction***

Any nature of suit from any category may be selected for this category of case assignment.

(If Antitrust, then A governs)

○ **E. *General Civil (Other)*** OR ○ **F. *Pro Se General Civil***

Real Property
- ☐ 210 Land Condemnation
- ☐ 220 Foreclosure
- ☐ 230 Rent, Lease & Ejectment
- ☐ 240 Torts to Land
- ☐ 245 Tort Product Liability
- ☐ 290 All Other Real Property

Personal Property
- ☐ 370 Other Fraud
- ☐ 371 Truth in Lending
- ☐ 380 Other Personal Property Damage
- ☐ 385 Property Damage Product Liability

Bankruptcy
- ☐ 422 Appeal 27 USC 158
- ☐ 423 Withdrawal 28 USC 157

Prisoner Petitions
- ☐ 535 Death Penalty
- ☐ 540 Mandamus & Other
- ☐ 550 Civil Rights
- ☐ 555 Prison Conditions
- ☐ 560 Civil Detainee – Conditions of Confinement

Property Rights
- ☐ 820 Copyrights
- ☐ 830 Patent
- ☐ 835 Patent – Abbreviated New Drug Application
- ☐ 840 Trademark
- ☐ 880 Defend Trade Secrets Act of 2016 (DTSA)

Federal Tax Suits
- ☐ 870 Taxes (US plaintiff or defendant)
- ☐ 871 IRS-Third Party 26 USC 7609

Forfeiture/Penalty
- ☐ 625 Drug Related Seizure of Property 21 USC 881
- ☐ 690 Other

Other Statutes
- ☐ 375 False Claims Act
- ☐ 376 Qui Tam (31 USC 3729(a))
- ☐ 400 State Reapportionment
- ☐ 430 Banks & Banking
- ☐ 450 Commerce/ICC Rates/etc
- ☐ 460 Deportation
- ☐ 462 Naturalization Application
- ☐ 465 Other Immigration Actions
- ☐ 470 Racketeer Influenced & Corrupt Organization
- ☐ 480 Consumer Credit
- ☐ 485 Telephone Consumer Protection Act (TCPA)
- ☐ 490 Cable/Satellite TV
- ☐ 850 Securities/Commodities/ Exchange
- ☐ 896 Arbitration
- ☐ 899 Administrative Procedure Act/Review or Appeal of Agency Decision
- ☐ 950 Constitutionality of State Statutes
- ☐ 890 Other Statutory Actions (if not administrative agency review or Privacy Act)

○ **G. *Habeas Corpus/ 2255***	○ **H. *Employment Discrimination***	○ **I. *FOIA/Privacy Act***	○ **J. *Student Loan***
☐ 530 Habeas Corpus – General ☐ 510 Motion/Vacate Sentence ☐ 463 Habeas Corpus – Alien Detainee	☐ 442 Civil Rights – Employment (criteria: race, gender/sex, national origin, discrimination, disability, age, religion, retaliation) *(If pro se, select this deck)*	☐ 895 Freedom of Information Act ☐ 890 Other Statutory Actions (if Privacy Act) *(If pro se, select this deck)*	☐ 152 Recovery of Defaulted Student Loan (excluding veterans)
○ **K. *Labor/ERISA (non-employment)***	◉ **L. *Other Civil Rights (non-employment)***	○ **M. *Contract***	○ **N. *Three-Judge Court***
☐ 710 Fair Labor Standards Act ☐ 720 Labor/Mgmt. Relations ☐ 740 Labor Railway Act ☐ 751 Family and Medical Leave Act ☐ 790 Other Labor Litigation ☐ 791 Empl. Ret. Inc. Security Act	☐ 441 Voting (if not Voting Rights Act) ☐ 443 Housing/Accommodations ☒ 440 Other Civil Rights ☐ 445 Americans w/Disabilities – Employment ☐ 446 Americans w/Disabilities – Other ☐ 448 Education	☐ 110 Insurance ☐ 120 Marine ☐ 130 Miller Act ☐ 140 Negotiable Instrument ☐ 150 Recovery of Overpayment & Enforcement of Judgment ☐ 153 Recovery of Overpayment of Veteran's Benefits ☐ 160 Stockholder's Suits ☐ 190 Other Contracts ☐ 195 Contract Product Liability ☐ 196 Franchise	☐ 441 Civil Rights – Voting (if Voting Rights Act)

V. ORIGIN

◉ 1 Original Proceeding ○ 2 Removed from State Court ○ 3 Remanded from Appellate Court ○ 4 Reinstated or Reopened ○ 5 Transferred from another district (specify) ○ 6 Multi-district Litigation ○ 7 Appeal to District Judge from Mag. Judge ○ 8 Multi-district Litigation – Direct File

VI. CAUSE OF ACTION (CITE THE U.S. CIVIL STATUTE UNDER WHICH YOU ARE FILING AND WRITE A BRIEF STATEMENT OF CAUSE.)
First and Fifth Amendment to the Constitution--deprivation of free speech rights and due process

VII. REQUESTED IN COMPLAINT ☐ CHECK IF THIS IS A **CLASS ACTION** UNDER F.R.C.P. 23 **DEMAND $** 0 **JURY DEMAND:** Check YES only if demanded in complaint **YES** ☐ **NO** ☒

VIII. RELATED CASE(S) IF ANY (See instruction) **YES** ☐ **NO** ☒ If yes, please complete related case form

DATE: April 26, 2022 **SIGNATURE OF ATTORNEY OF RECORD** /s/ Samuel A. Butler

INSTRUCTIONS FOR COMPLETING CIVIL COVER SHEET JS-44
Authority for Civil Cover Sheet

The JS-44 civil cover sheet and the information contained herein neither replaces nor supplements the filings and services of pleadings or other papers as required by law, except as provided by local rules of court. This form, approved by the Judicial Conference of the United States in September 1974, is required for the use of the Clerk of Court for the purpose of initiating the civil docket sheet. Consequently, a civil cover sheet is submitted to the Clerk of Court for each civil complaint filed. Listed below are tips for completing the civil cover sheet. These tips coincide with the Roman Numerals on the cover sheet.

I. COUNTY OF RESIDENCE OF FIRST LISTED PLAINTIFF/DEFENDANT (b) County of residence: Use 11001 to indicate plaintiff if resident of Washington, DC, 88888 if plaintiff is resident of United States but not Washington, DC, and 99999 if plaintiff is outside the United States.

III. CITIZENSHIP OF PRINCIPAL PARTIES: This section is completed only if diversity of citizenship was selected as the Basis of Jurisdiction under Section II.

IV. CASE ASSIGNMENT AND NATURE OF SUIT: The assignment of a judge to your case will depend on the category you select that best represents the primary cause of action found in your complaint. You may select only one category. You must also select one corresponding nature of suit found under the category of the case.

VI. CAUSE OF ACTION: Cite the U.S. Civil Statute under which you are filing and write a brief statement of the primary cause.

VIII. RELATED CASE(S), IF ANY: If you indicated that there is a related case, you must complete a related case form, which may be obtained from the Clerk's Office.

Because of the need for accurate and complete information, you should ensure the accuracy of the information provided prior to signing the form.

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

GRAVITY DEFYER MEDICAL TECHNOLOGY CORP., ALEXANDER ELNEKAVEH,

Plaintiff(s)

v.

FEDERAL TRADE COMMISSION, THE UNITED STATES OF AMERICA,

Defendant(s)

Civil Action No. 1:22-cv-1157

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

FEDERAL TRADE COMMISSION
600 Pennsylvania Avenue, NW
Washington, DC 20580

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Samuel A. Butler
J. Kathleen Bond
Lathrop GPM, LLP
600 New Hampshire Avenue, NW
The Watergate - Suite 700
Washington, DC 20037

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:22-cv-1157

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc:

AO 440 (Rev. 06/12; DC 3/15) Summons in a Civil Action

UNITED STATES DISTRICT COURT

for the

District of Columbia

GRAVITY DEFYER MEDICAL TECHNOLOGY CORP., ALEXANDER ELNEKAVEH,

Plaintiff(s)

v.

FEDERAL TRADE COMMISSION, THE UNITED STATES OF AMERICA,

Defendant(s)

Civil Action No. 1:22-cv-1157

SUMMONS IN A CIVIL ACTION

To: *(Defendant's name and address)*

THE UNITED STATES OF AMERICA
950 Pennsylvania Avenue, NW
Washington, DC 20530

A lawsuit has been filed against you.

Within 21 days after service of this summons on you (not counting the day you received it) — or 60 days if you are the United States or a United States agency, or an officer or employee of the United States described in Fed. R. Civ. P. 12 (a)(2) or (3) — you must serve on the plaintiff an answer to the attached complaint or a motion under Rule 12 of the Federal Rules of Civil Procedure. The answer or motion must be served on the plaintiff or plaintiff's attorney, whose name and address are:

Samuel A. Butler
J. Kathleen Bond
Lathrop GPM, LLP
600 New Hampshire Avenue, NW
The Watergate - Suite 700
Washington, DC 20037

If you fail to respond, judgment by default will be entered against you for the relief demanded in the complaint. You also must file your answer or motion with the court.

ANGELA D. CAESAR, CLERK OF COURT

Date: _____

_____
Signature of Clerk or Deputy Clerk

Civil Action No. 1:22-cv-1157

PROOF OF SERVICE

(This section should not be filed with the court unless required by Fed. R. Civ. P. 4 (l))

This summons for *(name of individual and title, if any)* _____ was received by me on *(date)* _____ .

❒ I personally served the summons on the individual at *(place)* _____ on *(date)* _____ ; or

❒ I left the summons at the individual's residence or usual place of abode with *(name)* _____ , a person of suitable age and discretion who resides there, on *(date)* _____ , and mailed a copy to the individual's last known address; or

❒ I served the summons on *(name of individual)* _____ , who is designated by law to accept service of process on behalf of *(name of organization)* _____ on *(date)* _____ ; or

❒ I returned the summons unexecuted because _____ ; or

❒ Other *(specify):*

My fees are $ _____ for travel and $ _____ for services, for a total of $ 0.00 .

I declare under penalty of perjury that this information is true.

Date: _____

_____
Server's signature

_____
Printed name and title

_____
Server's address

Additional information regarding attempted service, etc: