

I. Introduction

A. Background

1. An estimated 62,000 to 125,000 Vermonters of all ages experience some degree of hearing loss. 2020 Deaf, Hard of Hearing and DeafBlind Advisory Council Annual Report to the Governor and General Assembly, January 15, 2020 at p.5.¹ The percentage of Vermonters with hearing loss increases by age cohort. For example, an estimated 50% of Vermonters over the age of 65, and up to 79% of those aged 80 and older, suffer hearing loss. Id. Hearing loss can lead to negative health outcomes, including cognitive decline, incident dementia, falls, depression, reduced quality of life, and increased number of emergency department visits and hospitals. Id. at p.4. Further, it has been correlated with social isolation, inability to work, and inability to travel, among numerous other limitations. Id. Proper hearing aids can prevent or help address these negative health, social, and professional outcomes.

2. The main barrier to consumers utilizing hearing aids is cost. Sixty-four percent of people with “severe hearing loss reported they could not afford a hearing aid” to purchasing a hearing aid. Id. at p.4. Adults in rural communities—like most Vermont communities—cite lack of easy access to hearing healthcare, lack of insurance coverage, and the high cost of hearing aids as additional barriers. Id. at p.5-6.

3. A hearing aid (“Hearing Aid”) is defined by the Food, Drug and Administration (the “FDA”) regulations as “any wearable device designed for, offered for the purpose of, or represented as aiding persons with or compensating for, impaired hearing.” Final Rule Establishing Over-the-Counter Hearing Aids, 87 FR 50698-01, (Aug. 17, 2022) at § 800.30 and 2022 WL 3369463(F.R.).

¹

https://dail.vermont.gov/sites/dail/files//documnets/Final_DHHDB_Council_Report_December_2020.pdf., lasted visited Mar. 23,2022.

Hearing Aids can be programmed to simultaneously amplify and suppress different sounds. As a result, they can, for example, amplify a speaker's voice while suppressing loud background noise in a public place.

4. Hearing Aids are FDA regulated as restricted class I or class II medical devices, depending upon on their nature. Until recently, Hearing Aids have always required prescriptions. As detailed below, the FDA finalized rules for the sale of certain² over-the-counter hearing aids, effective October 17, 2022.

5. The FDA requires that owners or operators of businesses involved in the production and/or distribution of medical devices intended for use in the United State register annually with the FDA. This process is known as “establishment registration.”³ To be clear, the establishment registration process merely provides the FDA with the *location* of relevant medical device establishments; it does *not* involve FDA evaluation or approval of the establishments or the devices they produce.

6. Hearing Aids are also regulated by the State of Vermont. That is, as discussed in greater detail below, one must obtain a license from the State of Vermont in order to sell, offer to sell, or otherwise hold oneself out as capable of selling Hearing Aids.

7. Key to this complaint: The FDA broadly defines what devices are Hearing Aids. While Hearing Aids include both “traditional” hearing aids and personal sound amplification products (“PSAP”), there are important distinctions between them. Generally, a PSAP is a wearable electronic product that is *not* intended to compensate for impaired hearing. Rather, it is intended for non-hearing-impaired consumers to amplify *all sounds* in a given environment. A PSAP is like a

² An over-the-counter hearing aid is an air-conduction hearing aid intended for a person age 18 or older to compensate for perceived mild to moderate hearing impairment. *Id.*

³ 21 CFR 807.

megaphone pointed at the inner ear. Individuals use PSAPs for hunting (to hear any/all animal sounds in their environment) or to attend lectures (where no background noise is anticipated), among other activities.

8. A PSAP can be unhelpful—and potentially harmful—to an individual with hearing impairment. While a traditional hearing aid is typically (a) prescribed by a physician required to inform the patient of potential related risks and (b) fitted by an audiologist, a PSAP is neither. While a traditional hearing aid selectively amplifies a speaker’s voice over the din of public background noise, a PSAP amplifies both the speaker’s voice *and* the background noise, potentially making it *more* difficult for the listener to hear the speaker, and potentially harming the listener’s ears.⁴

9. The health risks of PSAPs may include, but are not limited to, the absence of relevant warnings from healthcare professionals regarding the potential negative impact of the device on an individual’s hearing and pre-existing hearing conditions; the lack of testing and diagnosis prior to purchase to ensure that the device is beneficial and not harmful; and actual hearing damage from the over-amplification of all sounds, rather than those specifically targeted to the consumer’s ears.

B. Background of the Authorization of Over-The-Counter Hearing Devices

10. In 2017, Congress passed a law permitting the *future sale* of certain over-the-counter (“OTC”) Hearing Aids for consumers over the age of 18 with mild to moderate hearing loss. See FDA Reauthorization Act of 2017 (“FDARA”), Section 709. Importantly, FDARA, Section 709 was not-self implementing. It required the FDA to promulgate regulations regarding the sale of these particular OTC products prior to being considered effective. Id.

⁴ Another way to think of the difference between a hearing aid and a PSAP is that a hearing aid is akin to an equalizer on a home stereo that can fine tune a range of simultaneous sounds, while a PSAP only offers a single volume control.

11. The FDA has been explicit that FDARA Section 709 would not be effective until promulgation of the relevant regulations.⁵

12. On August 17, 2022, pursuant to FDARA Section 709, the FDA issued its final regulations establishing the Over-the-Counter Hearing Aid market. These regulations became effective October 17, 2022. Thus, sales of OTC Hearing Aids prior to October 17, 2022 were unauthorized.

C. A New, Unauthorized Market

13. After Congress' 2017 passage of FDARA Section 709 (but prior to October 17, 2022), and despite that OTC Hearing Aids remained unauthorized, new OTC hearing device companies such as Nano flooded the market, offering hearing devices to consumers in violation of FDA and state law. Since 2017, Defendants have unfairly and deceptively marketed, promoted and sold over-the-counter Hearing Aids throughout the United States, including the State of Vermont. Nano has conducted over 800 transactions in Vermont at a cost of over \$200,000 to Vermonters.

14. Nano deceptively and aggressively markets and sells, through search engine optimization, pop-up advertisements, and cookies low-quality PSAPs and inferior Hearing Aids as high-quality Hearing Aids. To the extent Nano has sold OTC Hearing Aids in Vermont those sales were unauthorized under federal and state laws; Nano omitted their OTC Hearing Aids' unauthorized nature from consumers; and Nano deceived consumers as to its OTC Hearing Aids' quality and effectiveness. Nano's website advances these and other deceptions, including false

⁵ In a letter dated June 24, 2018, from the FDA to Hearing Aid Manufacturers, the FDA clearly states "the OTC hearing aid category, as defined by FDARA section 709, does not exist until the effective date of published final regulation. Until that time, no products that are claimed to address hearing loss are, or can claim to be, OTC hearing aids within the meaning of FDARA section 709. Currently, hearing aids continue to be restricted devices, for which sales must follow applicable federal and state requirements." Maisel, William, "Letter to Hearing Aid Manufacturer", July 24, 2018; <https://www.fda.gov/media/114844/download> (last visited Sept. 23, 2022).

suggestions that its products are FDA-approved; fake product reviews; and false representations that its products are American-made. Egregiously, Nano’s website also prompts consumers to take a sham hearing test that invariably recommends the purchase of Nano’s most expensive OTC hearing product, whatever the hearing test’s outcome. If an unsatisfied consumer ultimately attempts to return one of Nano’s OTC hearing products, Nano unlawfully induces the consumer into keeping the device past the point when returns are possible. Throughout, consumers are left in the dark as to the potential and serious health risks that Nano’s OTC Hearing Aids present. Further, believing the results and recommendations of Nano’s online hearing test, consumers may be deterred from seeking the professional diagnoses and care they need. Nano’s unlawful perpetual sales lure consumers on a continuous basis into Nano’s problematic products and practices.

II. Parties, Jurisdiction, and Venue

A. Plaintiff

15. The Vermont Attorney General (“Attorney General”) is authorized under the Vermont Consumer Protection Act, 9 V.S.A § 2458, to sue to enforce the CPA’s prohibitions on unfair and deceptive acts and practices in commerce.

16. The Attorney General also has the right to appear in any civil action in which the State has an interest. 3 V.S.A. §§ 157. The Attorney General has an interest in ensuring that entities that do business in Vermont do so in a lawful manner.

B. Defendants

17. Until March 26, 2021, Defendant Charles Crawford (“C. Crawford”) was the principal owner of Global Enterprises Holding LLC, a Delaware limited liability company (“GEH”), a member managed entity. Mr. Crawford was responsible for all aspects of Nano’s business,

including determining the overall business plan, deciding what products sell. Defendant Crawford was engaged in, aware of and condoned the conduct described in this Complaint. Defendant Crawford had authority to control and knowledge of said conduct.

18. Defendant GEH is the sole manager and member of King Crawford Enterprises LLC.

19. Defendant King Crawford Enterprises, LLC, (“King Crawford”) is an Arizona limited liability company and has its principal place of business at 16427 N. Scottsdale Road, Scottsdale, Arizona, 85254. King Crawford conducts business as Nano Hearing Aids (King Crawford, LLC d/b/a/ Nano Hearing Aids), Nano Hearing Technology (King Crawford, LLC d/b/a/ Nano Hearing Technology), and Nano (King Crawford LLC d/b/a/ Nano).

20. On March 26, 2021, Defendant Nano Hearing Tech OPCO, LLC, (“NHTO, LLC”) a Delaware limited liability company, purchased 76% of GEH, and its Nano Hearing Aid businesses. NHTO, LLC’s principal place of business is 4225 Executive Square, Suite 600, La Jolla, CA 92037.

21. Sancus Capital Group LLC, a private equity firm based in La Jolla, CA, claims an ownership interest in Nano Hearing Aids and its businesses. Sancus Capital Group LLC’s principal place of business is 4225 Executive Square, Suite 600, La Jolla, CA 92037.

22. Defendants’ primary business is and/or was marketing and selling OTC hearing aids and accessories.

23. Defendants acting individually, jointly, and by and through its subsidiaries and marketing companies, committed all the acts alleged in this Complaint.

24. At all relevant times, Defendants marketed, sold, or offered to sell their products in Vermont.

C. Jurisdiction and Venue

25. This Court has jurisdiction over the subject matter of this action, personal jurisdiction over the Defendants and authority to grant the relief requested pursuant to 12 V.S.A. § 913(b).

26. At all relevant times, Defendants purposely availed themselves of this forum through, amount other things, the conduct described herein.

27. Venue in this Court is proper because Defendants conducted business in the State of Vermont, County of Washington.

28. This action is in the public interest.

III. The Law

29. The Vermont Consumer Protection Act, 9 V.S.A. § 2453(a), prohibits unfair or deceptive acts or practices in commerce.

30. The Vermont Attorney General may bring an action under the CPA, 9 V.S.A. § 2458(b), against any person using or about to use any method, act, or practice declared to be unlawful under 9 V.S.A. § 2453 when such proceedings would be in the public interest.

31. The Vermont Attorney General is authorized to make consumer-protection-related rules and regulations. 9 V.S.A. § 2453(c). Under Rule CP 110, effective Jan., 28, 1974, it is considered a deceptive trade act under 9 V.S.A. § 9453(a) for a seller of goods to solicit purchases through “the use of former price comparisons, retail price comparisons, comparable value comparisons, or other miscellaneous price comparisons which are false or deceptive.”

32. Further, pursuant to Vermont’s Audiologists and Dispenser’s Law, a person may not “dispense hearing aids or hold oneself out as being permitted to do so... unless the person is licensed

in accordance with this chapter.” 26 V.S.A. § 3285(a).⁶ Likewise, an unlicensed person may not “dispense or attempt to dispense hearing aids or hold himself or herself out as being able to dispense hearing aids.” 26 V.S.A. § 3291 (collectively referred to as “Vermont’s Audiologists and Dispensers Law”).

33. Also, pertinent here, Hearing Aids are federally regulated. See 21 CFR 801.420. Pursuant to federal law, the sale of over-the-counter Hearing Aids has been historically unauthorized and was remained unauthorized until October 17, 2022. See FDARA, Section 709.

IV. The Facts

A. Nano Sells its OTC Hearing Aids in Vermont.

34. In 2017, Defendants began to market and sell OTC Hearing Aids and related accessories and warranty plans (herein “Nano Products”) throughout the nation, including Vermont.

35. Defendants sell these products through an online store at <https://nanohearingaids.com>.

36. Nano primarily markets and promotes these products online, through paid airtime infomercials and mailers.

37. Nano manages all marketing and promotions itself. It does not hire third parties or consultants to prepare content, advertisements, and/or sales scripts.

38. From January 2018 through July 2021, Nano sold at least \$200,000 worth of Nano Products and warranties in Vermont to approximately 800 Vermont consumers.

⁶ Vermont law defines a “hearing aid” as “an amplifying device to be worn by a person who is hard of hearing to improve hearing, including any accessories specifically used in connection with such a device, but excluding theater- or auditorium-wide-area listening devices, telephone amplifiers, or other devices designed to replace a hearing aid for restricted situations.” 26 V.S.A. § 3281(5).

B. Nano’s Marketing and Sales of OTC Hearing Aids in Vermont are Misleading and Unauthorized.

39. As alleged in detail below, Nano’s marketing and sales of OTC Hearing Aids in Vermont reflect multiple layers of deception. Nano deceptively markets and sells low-quality Hearing Aids and PSAPs as high-quality Hearing Aids. To the extent Nano has sold Hearing Aids in Vermont, those sales were unauthorized under federal and state laws; Nano omitted their Hearing Aids’ unauthorized nature from consumers; and Nano deceived consumers as to its Hearing Aids’ quality. Nano’s website advances these and other deceptions, including false suggestions that its products are FDA-approved; fake product reviews; and false representations that its products are American-made. Eggregiously, Nano’s website also prompts consumers to undertake a sham hearing test that invariably recommends the purchase of Nano’s most expensive OTC Hearing Aids, whatever the hearing test’s outcome. If an unsatisfied consumer ultimately attempts to return one of Nano’s OTC hearing products, they are further deceived by Nano into keeping the device past the point when returns are possible. Throughout, consumers are left in the dark as to the potential and serious health risks that Nano’s OTC hearing products present. Further, believing the results and recommendations of Nano’s online hearing test, consumers may be averted from seeking the professional hearing diagnoses and care they need. Nano’s unlawful perpetual sales lure consumers on a continuous basis into Nano’s problematic products and practices.

a. *Nano Misrepresents the Nature and Quality of its Products.*

40. Nano misrepresents the fundamental nature and quality of its products.

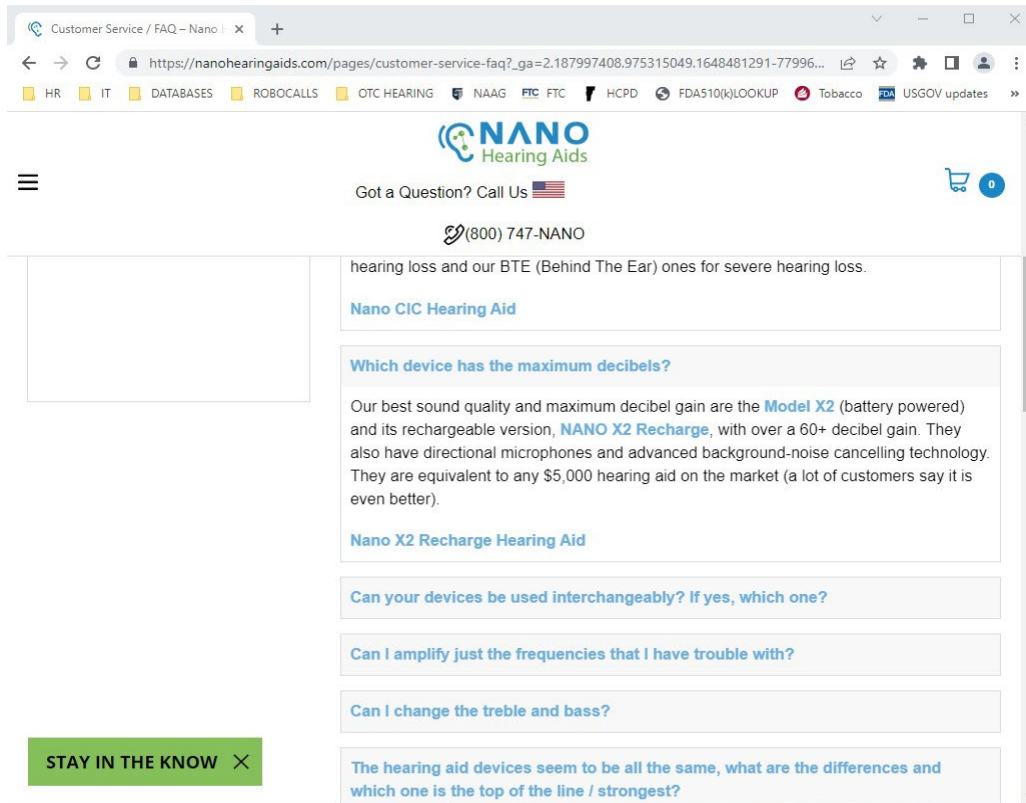
41. Nano has marketed and sold at least four different model OTC hearing products in Vermont: CIC Analog, CIC Digital, X2R, and Nano Sigma Plus (collectively, the “Nano OTC Products”). Nano has offered these products for sale individually or bundled with other items, such as chargers and batteries.

42. Nano markets its OTC Products as high-quality Hearing Aids. However, these products are either low-quality PSAP devices or low-quality Hearing Aids.

43. Hearing Aids, for example, contain processors that provide directional microphone arrays and background noise canceling. These processors allow Hearing Aids to, for example, amplify the voice of someone speaking to the device-wearer while simultaneously suppressing background noise. By contrast, and as described above, PSAPs act as megaphones pointed at the inner ear, simply amplifying all sounds in a given environment.

44. Nano’s website claims, for example, that, “[o]ur best sound quality and maximum decibel gain are the Model X2 (battery powered) and its rechargeable version, <https://nanohearingaids.com/products/new-x2r>, with over a 60+ decibel gain. They also have directional microphones and advanced background-noise cancelling technology. They are equivalent to any \$5,000 hearing aid on the market (a lot of customers say it is even better).” <https://nanohearingaids.com/pages/customer-service-faq?>⁷ (see below screen shot.)

⁷ https://nanohearingaids.com/pages/customer-service-faq?_ga=2.187997408.975315049.1648481291-779967585.1648481291&_gac=1.41707030.1648481291.EAIaIQobChMIhO7Rq4_p9gIVDjizAB2-nw_KEAAYASAAEgJO_D_BwE&gclid=EAIaIQobChMIhO7Rq4_p9gIVDjizAB2-nw_KEAAYASAAEgJO_D_BwE, (last visited Mar. 28, 2022).



45. But Nano’s claims about its Model X2 hearing device are deceptive. The Model X2 lacks directional microphones and noise-cancelling technology. The Model X2 is not a Hearing Aid—let alone the equivalent of a \$5,000 Hearing aid, as marketed.

46. Nano also promotes its CIC devices as high-quality Hearing Aids which have digital chips that eliminate all the unnecessary background noise at every hearing loss.⁸ However, the CIC

⁸ https://nanohearingaids.com/pages/customer-service-faq?_ga=2.187997408.975315049.1648481291-779967585.1648481291&_gac=1.41707030.1648481291.EAIAIQobChMIhO7Rq4_p9gIVDjizAB2-nw_KEAAYASAAEgJO_D_BwE&gclid=EAIAIQobChMIhO7Rq4_p9gIVDjizAB2-nw_KEAAYASAAEgJO_D_BwE; last visited Mar. 28, 2022.; and https://www.alibaba.com/product-detail/Hearing-Cic-Aid-Cic-New-Hearing_1600525106157.html?spm=a2700.galleryofferlist.normal_offer.d_image.24433ed1pp4Y6Y&s=p (lasted visited Sept. 21, 2022).

models merely amplify sound. They are PSAPs and not Hearing Aids. Similar PSAP devices can be purchased online for under \$50.00 on websites like Alibaba.⁹

b. Nano's Unlawful Hearing Aids

47. Prior to the October 17, 2022 FDA OTC hearing aid rule change, federal law prohibited Nano from selling OTC hearing aids. FDARA, Section 709.

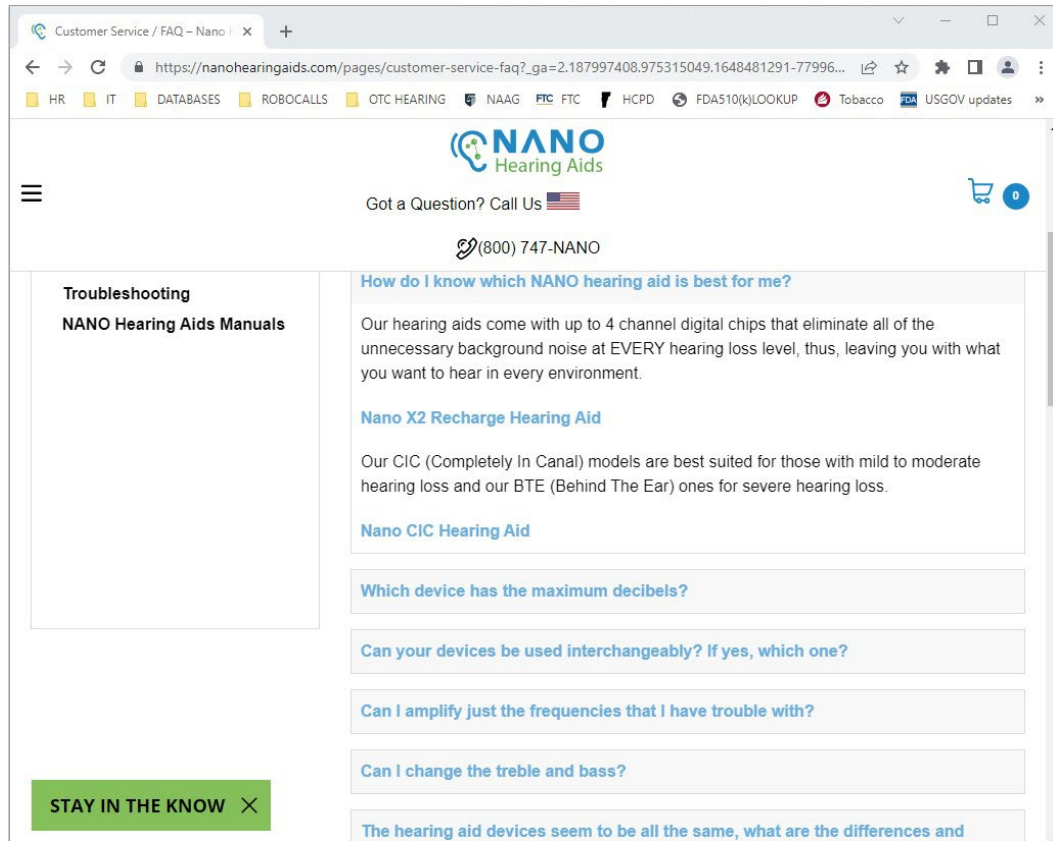
48. 49. Because Nano failed to obtain a license to dispense hearing aids in Vermont as required by 26 V.S.A. §§ 3285, 3291, Nano was also in violation of Vermont law until the October 17, 2022 FDA OTC hearing aid rule change.

49. 49. Nano's deceptive product claims remain unlawful following the passage of the FDA OTC Hearing Aid rule change.

50. Nano's website deceptively claims that Nano has products for every hearing loss level. For example, Nano claims that "Our CIC (Completely In Canal) models are best suited for those with mild to moderate hearing loss and our BTE (Behind The Ear) ones for severe hearing loss."¹⁰ (See screenshot below.) Likewise, Nano claims "[o]ur hearing aids come with up to 4 channel digital chips that eliminate all the unnecessary background noise at EVERY hearing loss level, thus, leaving you with what you want to hear in every environment." Id.

⁹ https://www.alibaba.com/product-detail/Rechargeable-Hearing-Aid-CIC-Invisible-Ear_1600450913005.html?spm=a2700.galleryofferlist.normal_offer.d_image.6d4a23feCkDvyz&s=p

¹⁰ https://nanohearingaids.com/pages/customer-service-faq?_ga=2.187997408.975315049.1648481291-779967585.1648481291&_gac=1.41707030.1648481291.EAIaIQobChMIhO7Rq4_p9gIVDjizAB2-nw_KEAAYASAAEgJO_D_BwE&gclid=EAIaIQobChMIhO7Rq4_p9gIVDjizAB2-nw_KEAAYASAAEgJO_D_BwE (last visited Mar. 28, 2022).



51. However, both the FDARA, Section 709 and the October 17, 2022 FDA regulations clearly limit the scope of OTC Hearing Aids to only the sale of OTC Hearing Aids for “perceived mild to moderate hearing loss”¹¹ will be authorized. The sale of OTC Hearing aids for severe hearing loss will remain unauthorized.

52. Nano’s marketing and sales of unauthorized OTC Hearing aids in Vermont are deceptive acts and practices in commerce.

¹¹ See FDA Reauthorization Act of 2017, 131 STAT 1066, Sect. 709 A(1)A(ii).

c. *Nano's Website Contains Numerous Misrepresentations Regarding its OTC Hearing Aids.*

53. Defendants' primary marketing and promotional tool is Nano's website located at: <https://nanohearingaids.com>. The website provides consumers with information about Nano's products; an online hearing test that purportedly directs consumers to appropriate Nano hearing device products; a link to an allegedly independent hearing aid review website; and allegedly authentic Nano product reviews. Nano's website is deceptive in numerous ways.

i. *Nano's Website Misrepresents Nano's FDA "Registration" as FDA "Approval."*

54. Nano's website implies that Nano's OTC Products have been approved by the FDA. They have not. Specifically, Nano's website states: "You can trust our products because they've been registered with the FDA." www.nanohearingaids.com (See screenshot below). This representation implies that the FDA has reviewed Nano's products against certain regulatory standards and approved them. Otherwise, there would be no basis for Nano's related invitation of "trust." Underscoring this implied message, the representation sits below an infographic reflecting the FDA logo above a "check mark"—a symbol that likewise indicates approval. However, as explained below, while Nano has registered certain of its products with a certain FDA database, this registration is not the same as FDA approval and therefore not a basis for inviting consumer "trust."



Registered with the FDA

You can trust our products because they've been registered with the FDA



Affordable

We've eliminated the middleman, so customers always pay the lowest prices



Money Back Guarantee

You get 45 full days to test drive your NANO hearing aid. If for any reason, you're unsatisfied, we'll give you a full refund. No quibbling or quarreling



Outstanding Customer Care

Our world class customer service team stands ready to assist you in whatever way they can

55. Owners or operators of establishments involved in the production and distribution of medical devices intended for use in the U.S. are required to register annually with the FDA. This process is known as “establishment registration.” 21 C.F.R. § 807.

56. When an establishment registers and lists its devices, the resulting entry in the FDA’s Establishment Registration & Device Database (“ERD Database”) indicates only that the company in question has provided the FDA with basic company and product information. Critically, a company’s registration of a purported medical device does not indicate that the FDA has reviewed or approved the device pursuant to FDA laws and regulations.

57. As the ERD Database explains: “Registration of a device establishment, assignment of a registration number, or listing of a medical device does not in any way denote approval of the establishment or its products by FDA.”¹² “To be clear,” the FDA has elsewhere explained, “the FDA does not issue any type of registration certificates to medical device establishments that register with the agency using our Establishment Registration & Device Listing system.”¹³ In fact, the FDA has

¹² <https://www.accessdata.fda.gov/scripts/cdrh/cfdocs/cftrl/textsearch.cfm>, last visited September 7, 2022.

¹³ <https://www.fda.gov/news-events/fda-brief/fda-brief-fda-calls-certain-firms-stop-producing-and-issuing-misleading-fda-registration>; Mar. 3, 2021, last visited Aug. 5 2022.

cautioned that some companies sell medical devices in manners that “deceptively indicat[e] [the] FDA’s approval, clearance, authorization or review establishments.”¹⁴ Specifically, and pertinent here, the FDA has indicated that “some device manufacturers and distributors are using registration certificates to create misimpression that FDA has reviewed, approved, cleared, or authorized their products.”¹⁵

58. Also of note, the FDA restricts how private companies are permitted to use the FDA logo. According to the FDA, “[t]he FDA logo is for the official use of the U.S. Food and Drug Administration (FDA) and not for use on private sector materials. To the public, such use would send a message that FDA favors or endorses a private sector organization or the organization’s activities, products, services, and/or personnel (either overtly or tacitly), which FDA does not and cannot do.”¹⁶ Thus, Nano’s use of the FDA logo is contrary to FDA policy and deceptive to consumers.

59. Nano has registered its OTC Products with the FDA for the purposes of the ED Database but has not obtained FDA approval for these devices. Nano’s representations and graphics implying otherwise are flatly deceptive.

ii. Nano’s Online Hearing Exam is Likewise Deceptive.

60. Nano’s website also purports to provide an online “Hearing Test” (“Hearing Test”).¹⁷ This Hearing Test is presented as a hearing exam that enables consumers to determine which Nano OTC Product they should purchase. Specifically, per Nano’s website, the Hearing Test provides an

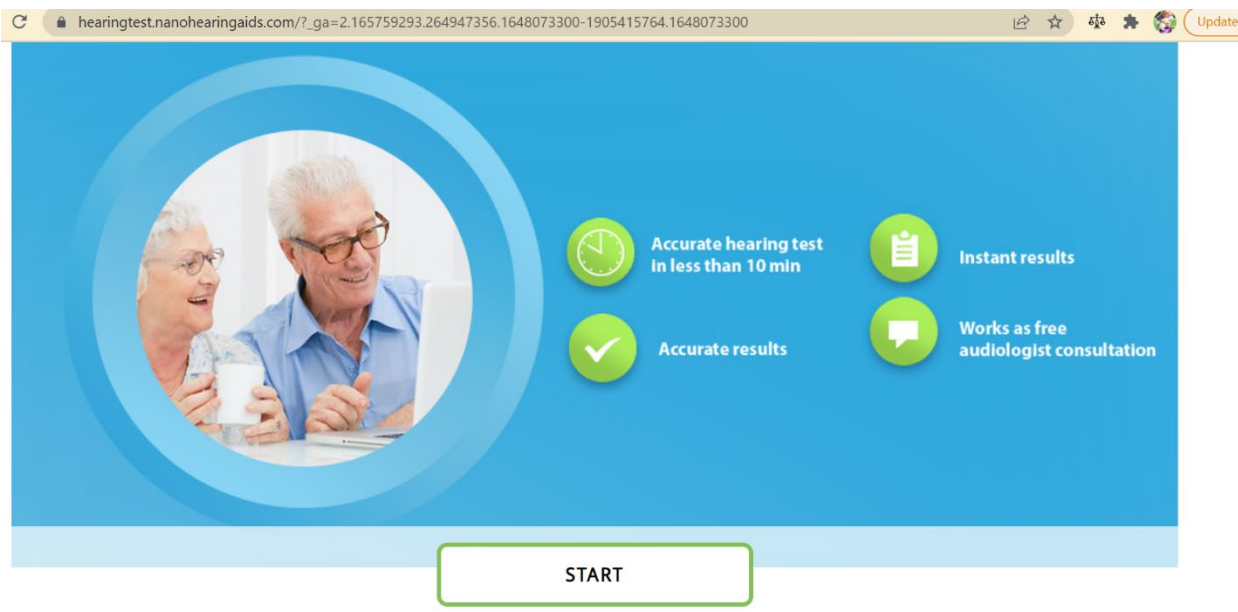
¹⁴ Id.

¹⁵ Id.

¹⁶ <https://www.fda.gov/about-fda/website-policies/fda-logo-policy>

¹⁷ https://hearingtest.nanohearingaids.com/?_ga=2.72023763.1119521524.1662948095-2040961976.1662599284&_gac=1.48684116.1662601688.Cj0KCQjwguGYBhDRARIsAHgRm4-D-tsa7V-N7HTWNNYR-HCnhVJ4iHw3Q5iqubRp3xNQhin4u2iWLOMaAlysEALw_wcB

“accurate hearing test” in less than ten minutes and “works as free audiologist consultation.” Id.
(See screenshot below.)



See https://hearingtest.nanohearingaids.com/?_ga=2.165759293.264947356.1648073300-1905415764.1648073300; last visited on Mar. 23, 2022.

61. The Hearing Test works in the following manner. First, it prompts the user to don headphones. Then, for each ear separately, at the user’s initiation, the website plays tones of increasing volume. When the user can first “barely hear” the given tone, the user clicks a button indicating as much.¹⁸

62. The website prompts the user to repeat this test for each ear at three different tonal frequencies--500Hz, 2000Hz, and 4000Hz.

63. At the conclusion of the test, the website makes two key representations to the consumer. First, it indicates the consumer’s level of hearing health along the following range: “healthy hearing,” “at risk,” “impaired,” “significantly impaired,” or “severely impaired. Nano’s

¹⁸ <https://hearingtest.nanohearingaids.com/step-3> (last visited September 11, 2022).

hearing profile is nothing but a bar graph graphic assigning the consumers test results a value in one of these ranges. Second, the Hearing Test indicates whether a Nano hearing device is appropriate for the consumer, and, if so, which device is most appropriate.

64. The Hearing Test is deceptive in two primary ways. First, whatever the consumer's test outcome in terms of hearing health level, the website recommends that the consumer purchase Nano's most expensive OTC Product—the Nano Sigma. This fact reflects that Nano is misleading with regard to both the purpose and accuracy of the Hearing Test.

65. Second, the website implies that professional audiologists review each consumer's Hearing Test results and would follow up with a consumer where medical concerns present themselves. Neither are true.

66. Specifically, Nano's website states:

“WHAT HAPPENS AFTER THE TEST. After you complete the online test, our audiology team reviews your results and establishes baseline settings for your hearing devices. As you wear your devices over the next few weeks, your audiologist will use your feedback to fine-tune them based on how you hear in the real world (as opposed to how you hear in a quiet room with headphones on).”¹⁹

67. However, Nano does not employ professional audiologists to review consumers' test results. Indeed, it has no “audiology team.” As mentioned above, whatever a consumer's test results, Nano's recommendation to the consumer is automatic: the consumer should purchase Nano's most expensive OTC Product.²⁰

68. Further, Nano's website states :

“ONLINE HEARING TESTS VS. TESTING AT AN AUDIOLOGIST'S OFFICE

The tests that you receive at an audiologist's office are designed not only to measure how well you hear but also to identify any conditions that may require medical intervention.

¹⁹ <https://hearingtest.nanohearingaids.com/step-1>, last visited March 28, 2021.

²⁰ Even if Nano maintained hearing specialists on staff, it is unlikely that any such staff review consumer Hearing Test results. When the consumer completes the Hearing Test, the results and recommendations are presented immediately. There is no time-lag during which any such review could occur.

Our test is designed only to provide us with enough information *to create your personal hearing profile and program your hearing devices*. However, if your *results indicate any medical conditions beyond common hearing loss, we may advise you to seek further care.*”²¹

Emphasis added.

69. However, Nano has never contacted a consumer to address medical concerns regarding a consumer’s Hearing Test results.²²

70. Nano’s sales scripts direct staff to identify themselves to consumers as “hearing specialists” despite that sales staff have no related specialized medical training or advanced degrees.

71. Further, even if Nano maintained hearing specialists on staff, it is unlikely that any such staff review online Hearing Test results, as the website produces these results instantly (at the end of the test on the last screen), along with a “Nano Bundle” product recommendation allegedly based on a consumer’s unique test results. The results are emailed to the consumer in an email laden with advertising cookies.

72. Nano’s online Hearing Test with its deceptive claims not only steer consumers to its most expensive device, but it may hinder those consumers who’s hearing loss require intervention from a professional health care provider from seeking that help and leading to further harms.

²¹ https://hearingtest.nanohearingaids.com/?_ga=2.255655104.975315049.1648481291-779967585.1648481291&_gac=1.140716550.1648487290.EAIaIQobChMI6cH9wKXp9gIV4oFbCh1TpA94EAAYAiAAEgLFavD_BwE&gclid=EAIaIQobChMI6cH9wKXp9gIV4oFbCh1TpA94EAAYAiAAEgLFavD_BwE (last viewed Oct. 13, 2022).

²² For example, a consumer who indicates during the Hearing Test they can only hear the very loudest test tone at each frequency is simply recommended to a Nano OTC Product without any follow up from Nano. . These representatives are likewise deceptive and dangerous to consumers.

iii. Nano Created a False Hearing Aid Review Website to Deceptively Promote its Products.

73. Nano’s website links to a webpage--www.besthearingaidreview.com—that appears to be the website of an independent organization that provides news, information, and reviews regarding hearing aid products. This website appears to incidentally, frequently recommend Nano products.

74. However, this website is not independent. Nano publishes it. Its ownership of the site is buried in the fine print—not clear and conspicuous.

75. And of course, this website does not “review” varieties of “hearing aid products.” It reviews and promotes Nano OTC Products exclusively. Further, this website promotes Nano’s OTC Products using patently fake content, like an “article” written by a purported audiologist about the story of a patient whose hearing was allegedly dramatically improved by Nano hearing aids.²³ Per a Google Lens search, the photo of the alleged patient is an unattributed copy of a photo previously printed by The Guardian newspaper.²⁴

76. Nano’s efforts to clandestinely lead consumers to its products are deceptive.

iv. Nano Unlawfully Promotes its Products for Children.

77. OTC Hearing Aids are meant for consumers 18 years of age older. The FDA’s final Rule expressly prohibits sales to or for a person under the age of 18. 21 CFR § 800.30 (c) (A) (A), and 5(g), effective October 17, 2022.

²³ <https://besthearingaidreviews.com/new-hearing-breakthrough-hcr2/> (last visited September 7, 2022).

²⁴ <https://www.theguardian.com/money/2010/oct/15/grandparents-win-state-pension-rights> (last visited, September 7, 2022).

78. Nano is aware of this restriction. In Nano’s Refund Policy, the company states three times that its hearing aids are not to be used by children. This exhortation appears in the company’s Purchase Terms, Bona Fide Evaluation period Process Section 3, and Important Notice.

79. However, despite this prohibition, Nano has published 3 articles that specifically recommend Nano to be used by teens or children. On nanohearingaids.com, two articles, “8 Early Warning Signs of Dementia in Teens” and “4 Best Hearing Aids for Children (Pediatric Hearing Aids),” both published in early 2022, explicitly recommend Nano for children. On Nano’s other site, besthearingaidreviews.com, the front page advertises an article titled “Teen Hearing Aids: What Are the Best Hearing Aids for Teens?” that was published in early 2019 and modified at least once later that same year. These articles appear to be written by hearing experts or specialists; however, they are unverified articles that misleadingly promotes its products to this age group.

v. Nano’s Other Deceptive Acts Online

80. Nano has undertaken numerous additional deceptive acts to promote its OTC Products online. For example, Nano falsely claims that its products are designed in the USA. Nano’s webpage claims that “Nano is a proud American Company supporting American jobs” and “Our products are designed in the USA.” But Nano’s products are designed and manufactured in China²⁵.

²⁵ According to the website <https://www.importyeti.com/>, over its years in business Nano has used several US addresses to receive at least 9 significant shipments of products labeled “sound amplifiers” and “hearing aids” directly from at least 3 Chinese manufacturers: Xiamen Retone Hearing Technology Co, Huizhou Jinghao Medical Technology, and Shenzhen Zhongde Audio Technical Co Ltd. Internet searches of these three companies reveal their products are sold through Alibaba as well as directly to importers by the companies themselves. Comparisons of images of these companies hearing products on Alibaba are nearly indistinguishable from images of Nano Hearing Aids, and indeed some are likely the exact same images. All three of these Chinese companies are original design manufacturing “ODM” companies.

ODM’s are also referred to as “private labeling” companies, where an importer such as Nano selects an already-existing product design from a factory catalog, makes a few small changes and sells it under their own brand name. Changes can include things like packaging or

vi. Nano Engages in Deceptive Tactics to Avert Customers Effectuating Returns.

81. Nano provides consumers 45 days to make returns. However, if a consumer initiates a return, Nano attempts to misleadingly head off that consumer at the pass.

82. Specifically, if a consumer initiates a return, Nano's sales staff are directed by training and sales script to inform the consumer of a "60-day hearing challenge." According to the script, Nano's sales staff should inform consumers that:

For a limited time, Nano is doing a 60-day hearing challenge
What does this mean? If you wear your hearing aids every day for
up to 60 days, Nano will give you a \$200 store credit to use for
future Hearing aid purchases or upgrading to another model!

Why? We've discovered that the #1 reason why some customers
give up on hearing aids is because they didn't wear their hearing
aids every day for at least 21 days. Your brain needs time to get
used to hearing sounds it hasn't heard in years. Thus, every time
you start off wearing your hearing aids, you'll hear some
background noise and a few sounds that might seem weird at first
but will go away after you wear you rehearing aids for 60 days.

83. In presenting the 60-day hearing challenge, Nano fails to disclose to consumers that a consumer who remains dissatisfied with the OTC Product *after* the 60-day challenge is unable to return the product at that time because the 45-day return period has invariably expired.

84. Nano's failure to disclose to consumers that returns after the 60-Day Challenge are impossible is deceptive and unfair to consumers in violation of the CPA.

product bundles, colors and branding, and some limited adjustments to components or functionality. Nano is simply an importer of very low-budget Chinese-made, Nano-branded sound amplifiers and hearing aids, and sells them to unassuming customers through deceptive marketing at a significant profit. Rather than "eliminating the middleman" as their website suggests, Nano is in fact the middleman.

d. *Nano's Perpetual Sales are Misleading to Consumers and in Violation of the Vermont Consumer Protection Rule 110*

85. Under Consumer Protection Rule 110 (“CP 110”), it is considered a deceptive trade practice under 9 V.S.A. §2453(a) for a seller of goods to solicit purchases through “the use of former price comparisons, retail price comparisons, comparable value comparisons, or other miscellaneous price comparison which are false or deceptive.”²⁶ Violations of this rule include fictitious pricing, such as perpetually listing an item on sale such that there is no genuine, higher non-sale price.

86. Nano perpetually lists their products as being on sale. The “St. Patrick’s Day Sale” rolls into the “Spring Sale,” which rolls into the “Summer Sale,” which rolls into the “So Long Summer Sale,” which rolls into the “Labor Day Sale,” “Grandparents Day” and Fall Sale,” and so on with no non-sale days in between.

87. The Nano website lists sale prices next to fictitious (crossed out) “regular” prices.²⁷ In reality, an OTC Product’s purchase price is always the sale price and never the “regular” price listed.²⁸ At least since 2021, Nano’s website offered the same sale prices under various names and themes. One example of these series of sale is the August 2022, “So Long Summer Sale” that list the following sales:

²⁶ This Rule mirrors 16 CFR § 23.1 of the Federal Trade Commission Act, which includes examples of violations for practices such as “perpetual sale” of merchandise.

²⁷ See https://nanohearingaids.com/collections/hearing-aids?utm_source=google&utm_medium=cpc&wickedsource=google&wickedid=Cj0KCQjwrs2XBhDjARIsAHVymmRwI8k5wegw5_qLuuX9dEiwtJvV4iqBe3JVTCdD4cFuzocrRgrv2WwaAiCzEALw_wcB&wickedid=587031841174&wv=3.1&utm_medium=cpc&utm_source=google&utm_term=nano%20hearing%20aids&device=c&network=g&matchtype=e&utm_campaign=EN-S-B|Nano-Hearing-Aids-Brand&utm_ag=Brand-Keywords&gclid=Cj0KCQjwrs2XBhDjARIsAHVymmRwI8k5wegw5_qLuuX9dEiwtJvV4iqBe3JVTCdD4cFuzocrRgrv2WwaAiCzEALw_wcB, last visited Aug. 10, 2022.

²⁸ *Id.*

- “So Long Summer Sale 85% OFF - The Nano CIC “Completely In Canal” Recharge[able] Hearing Aids only \$297! Save \$1,703” with the text “On Sale \$297.00 ~~\$2,000.00;~~”
- “So Long Summer Sale 54% OFF - Nano RX2000 Digital Rechargeable Hearing Aid Only \$597! Save \$692!” with the text “On Sale \$597.00 ~~\$1,289;~~”
- “So Long Summer Sale 77% OFF - The NEW Nano Sigma + Plus... Only \$697! Save \$2,300!” with the text “On Sale \$697.00 ~~\$2,997.00;~~”
- “So Long Summer Sale 83% OFF- The Nano X2 Recharge Only \$497! Save \$2,500!” with the text “On Sale \$497.00 ~~\$2,997.00;~~”
- “So Long Summer Sale 75% OFF - The Nano CIC Digital Recharge Hearing Aids Only \$497! Save \$1,503!” with the text “On Sale \$497.00 ~~\$2,000.00;~~”
- “So Long Summer Sale 69% OFF- The Nano RX2000 Rechargeable Hearing Aid Only \$397! Save \$892!” with the text “On Sale \$397.00 ~~\$1,289.00;~~”
- “So Long Summer Sale 80% OFF - The Nano X2 Only \$397! Save \$1,600!” with the text “On Sale \$397.00 ~~\$1,997.00;~~”
- “So Long Summer Sale 72% OFF– The SX2000 Only \$997! Save \$2,503!” with the text “On Sale \$997.00 ~~\$3,500.00;~~” and
- “So Long Summer Sale 39% OFF - The Yearly Elite Protection Plan \$79 Only \$79! Save %50!” with the text “On Sale \$79.00 ~~\$129.00;~~”

www.nanohearingaids.com

88. Nano merely replaces the name of the sale but keeps the pricing text the same to appear as a special. For example, in September 2022, the “So Long Summer Sale” has been changed to the “Grandparent Sale,” and is now the “Fall Sale.” However, none of the other text changes.

Equally deceptive is the countdown clock banner at the top of the webpage leading consumers to believe the sale is for a limited time and set to expire²⁹.

89. Nano's products are on perpetual sale in violation of Vermont's Rule CP 110 and therefore a violation of the CPA.³⁰

V. VIOLATIONS OF THE LAW

COUNT ONE

Dispensing Hearing Aids without a Vermont License Violated 26 V.S.A § 3285

90. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs as though fully set forth herein.

91. Vermont's laws governing Audiologists and Hearing Aid Dispensers prohibit the dispensing of hearing aids unless the person is licensed in Vermont. 26 V.S.A. § 3285(a).

92. Defendants have dispensed hearing aids in Vermont since 2017.

93. Defendants failed to receive a Vermont license to distribute hearing aids as was required until October 17, 2022 and are therefore is subject to penalties pursuant to 3 V.S.A. § 127.

Violations of Vermont Professions and Occupations statutes are considered unfair and

deceptive acts in commerce and Defendants' conduct thereby violates 9 V.S.A. § 2453(a) .

COUNT TWO

Deceptive Acts and Practices

Violations of the Vermont Consumer Protection Act

²⁹ <https://nanohearingaids.com/collections/hearing-aids> (last visited Sept. 23, 2022).

³⁰ Nano's sales staff are likewise trained and directed by sales script to mislead consumers by indicating: "I highly recommend you place the order with me, and I can also get you special deals that are only available with me...." In fact, there are no "special deals" available "only" with a specific salesperson. Indeed, per Nano's sales script, Nano's sales staff are uniformly directed to make these deceptive representations to each consumer.

94. Plaintiff repeats and re-alleges each and every allegation set forth in the preceding paragraphs as though fully set forth herein.

95. The Vermont Consumer Protection Act prohibits unfair methods of commerce and unfair and deceptive acts and practices in commerce. 9 V.S.A. § 2453(a).

96. Defendants engaged in deceptive acts or practices in commerce by:

- a. Misrepresenting devices as Hearing Aids when they were PSAPS;
- b. Misrepresenting the quality and effectiveness of their Nano hearing products;
- c. Failing to disclose and/or concealing from consumers that the Nano over-the-counter products are meant for mild to moderate hearing loss and are not appropriate for every type of hearing loss;
- d. Misrepresenting that the OTC products were equivalent to Hearing Aids provided by an audiologist who has tested the buyer and designed a hearing aid for that individual;
- e. Selling hearing devices as OTC products when they were not authorized by federal or state law to do so;
- f. Promoting their products by means of their deceptive online hearing test;
- g. Misrepresenting that Nano's Online Hearing Test is equivalent to an audiologist consultation;
- h. Misrepresenting that consumers' online hearing test results are reviewed by an audiology team;
- i. Misrepresenting that Nano would inform the consumers if his or her online hearing Test results indicated a medical condition beyond common hearing loss, and advise the consumer to seek further care;

- j. Creating a false Hearing Aid review cite to deceptively promote their products;
- k. Deceptively promoting their products to persons under 18 years of age through articles;
- l. Failing to disclose that OTC Hearing Aids are restricted to persons 18 years of age or older;
- m. Misrepresenting that the designs of Nano products are American made when they are not;
- n. Misrepresenting that Nano's salespeople are hearing experts;
- o. Failing to disclose and/or concealing from consumers that the 60-day challenge voids the 45-day return policy the consumer's ability to effectuate a return;
- p. Misrepresenting the product prices because the products are on perpetual sale in violation of CP Rule 110; and
- q. Misrepresenting prices by comparing current prices to fictitious former prices.

97. Defendants' misrepresentations and omissions about the Nano OTC Products are likely to mislead consumers. The meaning ascribed by consumers to Defendants' claims about the Nano products were reasonable given the nature of those claims. The misleading effects of Defendants' misrepresentations and omissions were material in that they were likely to affect consumers' decisions to purchase the Nano OTC Products.

98. As a result of the foregoing, Defendants have engaged or are engaging in deceptive acts or practices in commerce, in violation of the Vermont Consumer Protection Act, 9 V.S.A. § 2453(a).

COUNT THREE
Unfair Acts and Practices
Violations of the Vermont Consumer Protection Act

99. The State realleges and incorporates by reference each of the allegations contained in all the paragraphs of this Complaint as though fully alleged herein.

100. Defendants have engaged in unfair acts and practices by:

- a. Failing to be licensed to dispense hearing aids in the State of Vermont pursuant to Vermont's Audiologists and Dispensers Law;
- b. Misrepresenting devices as Hearing Aids when they were PSAPS;
- c. Misrepresenting the quality and effectiveness of their Nano hearing products;
- d. Failing to disclose and/or concealing from consumers that the Nano over-the-counter products are meant for mild to moderate hearing loss and are not appropriate for every type of hearing loss;
- e. Misrepresenting that the OTC products were equivalent to Hearing Aids provided by an audiologist who has tested the buyer and designed a hearing aid for that individual;
- f. Selling hearing devices as OTC products when they were not authorized by federal or state law to do so;
- g. Promoting their products by means of their deceptive online hearing test;
- h. Misrepresenting that Nano's Online Hearing Test is equivalent to an audiologist consultation;
- i. Misrepresenting that consumers' online hearing test results are reviewed by an audiology team;

- j. Misrepresenting that Nano would inform the consumers if his or her online hearing Test results indicated a medical condition beyond common hearing loss, and advise the consumer to seek further care;
- k. Creating a false Hearing Aid review cite to deceptively promote their products;
- l. Deceptively promoting their products to persons under 18 years of age through articles;
- m. Failing to disclose that OTC Hearing Aids are restricted to persons 18 years of age or older;
- n. Misrepresenting the reviews of their products by creating false review websites and testimonials;
- o. Misrepresenting that the designs of Nano products are American made when they are not;
- p. Deceptively misrepresenting who the founder of Nano is by posing as another person;
- q. Misrepresenting that Nano's salespeople are hearing experts;
- r. Failing to disclose and/or concealing from consumers that the 60-day challenge voids the 45-day return policy the consumer's ability to effectuate a return;
- s. Misrepresenting the product prices because the products are on perpetual sale; and
- t. Misrepresenting prices by comparing current prices to fictitious former prices.

101. Defendants have engaged and are continuing to engage in unfair acts and practices in commerce in violation of the Vermont Consumer Protecting Act, 9 V.S.A. § 2453(a), which offend public policy, and are immoral, unethical, oppressive and unscrupulous; and cause substantial injury to consumers and provide no offsetting benefit.

RELIEF SOUGHT

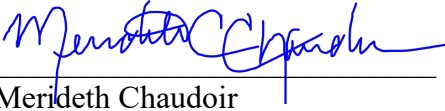
WHEREFORE, Plaintiff State of Vermont respectfully request that the Court enter judgement in its favor and the following relief:

1. A judgment determining that Defendants has violated the Vermont Consumer Protection Act;
2. A judgment determining that Defendants have violated Vermont's Audiologists and Hearing Aid Dispensers Law;
3. A judgment determining that Defendants dispensed hearing aids in violation of Vermont's licensing laws;
4. A permanent injunction prohibiting Defendants from engaging in the unfair and deceptive acts and practices identified herein;
5. A judgment requiring Defendants to provide restitution to all Vermont consumers who purchased Nano's hearing aids;
6. A judgment requiring Defendants to disgorge all profits obtained as a result of their violations of the Vermont Consumer Protection Act;
7. A judgment requiring Defendants to disgorge all profits obtained as a result of their violation of Vermont's Audiologists and Hearing Aid Dispensers Law;
8. Civil penalties of up to \$10,000 for each violation of the Vermont Consumer Protection Act;
9. Civil penalties of up to \$5,000 for each violation of Vermont's Audiologists and Hearing Aid Dispensers Law;
10. The award of investigative and litigation costs and fees to the State of Vermont; and
11. Such other and further relief as the Court may deem appropriate.

Dated: November 23, 2022

STATE OF VERMONT

SUSANNE R. YOUNG
ATTORNEY GENERAL

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