

COMMONWEALTH OF MASSACHUSETTS

SUFFOLK, ss.

SUPERIOR COURT DEPARTMENT
OF THE TRIAL COURT
CIVIL ACTION NO.

COMMONWEALTH OF MASSACHUSETTS,
Plaintiff,

v.

SCHOOL HEALTH CORPORATION,
Defendant.

COMPLAINT

Introduction

1. The Plaintiff Commonwealth of Massachusetts (the “Commonwealth”), by and through its Attorney General, Maura Healey, brings this enforcement action pursuant to the Massachusetts False Claims Act, G.L. c. 12, §§ 5A *et seq.* (the “MFCA”), against Defendant School Health Corporation (“School Health”) for its fraud on certain of the Commonwealth’s political subdivisions, including Framingham Public Schools, Winchester Public Schools, New Bedford Public Schools, the City of Malden, Bridgewater-Raynham Regional School District, Nahant School Department, Swampscott Public Schools and Wachusett Regional School District (collectively, the “Cities and Towns”).¹

2. School Health took advantage of the fear and supply shortages caused by the COVID-19 pandemic to sell an unproven and ineffective product to the Cities and Towns. In an intentional or reckless sales effort, the company made repeated false claims about the product’s

¹ The MFCA defines the term “political subdivision” as “a city, town, county or other governmental entity authorized or created by law, including public corporations and authorities.” A public school district is a political subdivision for the purposes of the MFCA. *See* G.L. c. 12, § 5A.

efficacy against the COVID-19 virus when those claims had no competent supporting data. In doing so, the company risked the health and safety of students, teachers, and support staff in Massachusetts public schools.

3. During the early months of the COVID-19 pandemic, as the demand for hand sanitizer reached unprecedented highs, public officials across the Commonwealth scrambled to obtain hand sanitizer for use in schools, municipal and town offices, and other public buildings. Some of these public officials turned to School Health for advice on which products could help reduce the spread of the COVID-19 virus.

4. In response, School Health pushed a product called Theraworx Protect on the Cities and Towns, claiming that it was a hand sanitizer which was proven to inactivate the COVID-19 virus and prevent its spread and that the product provided a multi-hour barrier against the COVID-19 virus.

5. These claims were false. In reality, Theraworx Protect was a cosmetic that contained no alcohol and therefore did not meet the United States Centers for Disease Control and Prevention (“CDC”) guidance on proper hand sanitizer usage during the COVID-19 pandemic.² Much to the contrary, in 1999, the United States Food and Drug Administration (“FDA”) had issued a Final Ruling on one of Theraworx Protect’s ingredients, colloidal silver, determining that, *inter alia*, products containing colloidal silver “are not generally recognized as safe and effective” and the “FDA is not aware of any substantial scientific evidence that supports the use of OTC colloidal silver ingredients . . . for disease conditions.”

6. Between March 2020 and July 2020, in reliance on School Health’s false

² As discussed *infra*, at all relevant times, the CDC’s guidance on “How to Protect Yourself” against COVID-19 recommended the use of hand sanitizer containing at least 60% alcohol when soap and water were not available.

representations regarding Theraworx Protect, the Cities and Towns purchased over \$100,000 of the product. But the Cities and Towns did not get a hand sanitizer that was proven to inactivate or kill the COVID-19 virus, as they had bargained for and believed they had purchased. Instead, they got a cosmetic that was worthless for protection against the COVID-19 virus.

Jurisdiction and Venue

7. The Attorney General is authorized to bring this action pursuant to G.L. c. 12, § 5C.

8. This Court has jurisdiction over the persons and subject matter of this action pursuant to G.L. c. 12, § 5C and G.L. c. 223A, § 3. All claims in this action arise from School Health's transaction of business in the Commonwealth.

9. Venue is proper in Suffolk County pursuant to G.L. c. 12, § 5C and G.L. c. 223, § 5.

Parties

10. Plaintiff is the Commonwealth, represented by the Attorney General, who brings this action in the public interest pursuant to G.L. c. 12, § 5C.

11. Defendant School Health is a corporation organized and existing under the laws of the State of Illinois with a principal place of business at 5600 Apollo Drive, Rolling Meadows, Illinois. On its website, School Health describes itself as "a national, full-service provider of health supplies and services to health professionals in educational settings from pre-school to college. . . . School Health goes beyond merely supplying products, providing product support, training, advisory services and exceptional customer care."³ Defendant School Health regularly transacts business in the Commonwealth.

³ <https://www.schoolhealth.com/about-school-health>

Facts

I. The Start of the COVID-19 Pandemic and the Rapid Rise in Demand for Hand Sanitizer

12. On February 1, 2020, Massachusetts announced its first confirmed case of the novel coronavirus.^{4, 5}

13. On February 11, the World Health Organization (the “WHO”) gave an official name to the disease caused by the novel coronavirus: Coronavirus Disease 2019, abbreviated as COVID-19 (“COVID-19”).⁶ The novel coronavirus that caused COVID-19 was named severe acute respiratory syndrome coronavirus 2, or SARS-CoV-2 (the “COVID-19 virus”).⁷

14. On February 29, the first death in the United States caused by the COVID-19 virus was reported in Kirkland, Washington, followed by two other confirmed cases in a nursing home in the same city.⁸ By March 5, it was clear that the COVID-19 virus was spreading quickly across the United States, with reported cases in 19 states.⁹

15. On March 10, Massachusetts Governor Charlie Baker declared a state of emergency in the Commonwealth.¹⁰ Soon after, the federal government followed suit and declared a national emergency.¹¹

⁴ <https://www.bphc.org/whatwedo/infectious-diseases/Infectious-Diseases-A-to-Z/covid-19/Pages/COVID-19-Timeline.aspx>

⁵ All dates listed in the Complaint are from 2020, unless otherwise noted.

⁶ <https://twitter.com/DrTedros/status/1227297754499764230>

⁷ <https://www.cdc.gov/coronavirus/2019-ncov/your-health/about-covid-19/basics-covid-19.html>

⁸ <https://www.nbcnews.com/news/us-news/1st-coronavirus-death-u-s-officials-say-n1145931>. Later, it would be reported that the first COVID-19 death in the United States actually occurred on February 6 and that the COVID-19 virus had been spreading undetected in American communities as early as late January.

<https://www.sfchronicle.com/bayarea/article/Exclusive-Autopsy-report-of-first-known-15226422.php>;

<https://www.statnews.com/2020/05/29/cdc-local-transmission-coronavirus-united-states/>.

⁹ <https://www.cnn.com/2020/03/05/health/us-coronavirus-thursday/index.html>

¹⁰ <https://www.mass.gov/news/governor-baker-declares-state-of-emergency-to-support-commonwealths-response-to-coronavirus>.

¹¹ <https://www.nbcnews.com/politics/donald-trump/trump-hold-friday-afternoon-press-conference-coronavirus-n1157981>.

16. As part of the effort to combat the spread of the COVID-19 virus, the CDC recommended hand hygiene measures including frequent hand washing with soap and water, and, if soap and water were not readily available, using a hand sanitizer containing at least 60% alcohol (“alcohol-based hand sanitizer”).¹² The CDC described hand hygiene as “one of the most important steps a person [could] take to avoid getting sick.”¹³

17. The CDC advised the public to wash hands or use an alcohol-based hand sanitizer both before and after taking the following actions: touching a mask; entering and leaving a public space; and touching an item or surface that may be frequently touched by other people, such as door handles, tables, gas pumps, shopping carts, or electronic cashier registers/screens.¹⁴ The CDC emphasized the need to wash hands or reapply alcohol-based hand sanitizer *before* and *after* taking such action.¹⁵

18. By early March, due to the wide and rapid spread of the COVID-19 virus across the United States, alcohol-based hand sanitizer had become difficult to obtain.¹⁶ Governments, private companies, and consumers alike struggled to purchase alcohol-based hand sanitizer.¹⁷

¹² <http://web.archive.org/web/20200124175525/https://www.cdc.gov/coronavirus/2019-ncov/about/prevention-treatment.html> (dated January 23, 2020) (explaining that the “[C]DC always recommends everyday preventive actions to help prevent the spread of respiratory viruses, including: Wash your hands often with soap and water for at least 20 seconds. If soap and water are not available, use an alcohol-based hand sanitizer.”); <http://web.archive.org/web/20200328172009/https://www.cdc.gov/coronavirus/2019-ncov/prevent-getting-sick/prevention.html> (dated March 18, 2020) (listing hand washing with soap and water and, if soap is not available, using an alcohol-based hand sanitizer with at least 60% alcohol under a section specific to COVID-19, titled “Take steps to protect yourself”). According to the CDC, “Alcohol-based hand sanitizers work by killing germs on your hands, while washing your hands with soap and water removes germs from your hands. Handwashing will remove all types of germs from your hands, but hand sanitizers are not able to kill all types of germs or remove harmful chemicals like pesticides and heavy metals.” <https://www.cdc.gov/handwashing/faqs.html#key-times-to-wash>.

¹³ CDC - “Cleaning, Disinfection, and Hand Hygiene in Schools – a Toolkit for School Administrators” <https://www.cdc.gov/coronavirus/2019-ncov/community/schools-childcare/clean-disinfect-hygiene.html>.

¹⁴ <https://www.cdc.gov/handwashing/when-how-handwashing.html>;
<https://web.archive.org/web/20200402235959/https://www.cdc.gov/handwashing/when-how-handwashing.html> (dated April 2, 2020).

¹⁵ *See id.* (advising the public to “wash your hands with soap and water for at least 20 seconds or use a hand sanitizer with at least 60% alcohol to clean hands BEFORE and AFTER” taking the aforementioned action).

¹⁶ <https://www.nytimes.com/2020/02/29/business/coronavirus-hand-sanitizer.html>.

¹⁷ <https://www.bostonglobe.com/2020/03/02/metro/coronavirus-drives-sales-surgical-masks-hand-sanitizer/?p1=Article Inline Text Link>;

From December 2019 to January 2020, demand for alcohol-based hand sanitizer skyrocketed by an eye-popping 1,400%.¹⁸ Stores began rationing product as private consumers engaged in panic-buying.¹⁹

19. As demand for alcohol-based hand sanitizer hit record highs, opportunists saw a chance to capitalize on the fear and panic sowed by the pandemic. Hoping to turn a quick profit at the expense of governments, companies, and consumers, some sought to take advantage of the alcohol-based hand sanitizer shortage.²⁰

II. The FDA Regulatory Framework

20. The FDA is responsible for promoting public health through the control and supervision of various categories of products, including cosmetics, prescription drugs, and non-prescription (“over-the-counter”) drugs. The FDA’s primary focus is enforcement of the Federal Food, Drug, and Cosmetic Act (“FD&C Act”).

21. The FD&C Act defines a product as a drug or a cosmetic depending on that product’s intended use.²¹

22. Under the FD&C Act, cosmetics are defined as “articles intended to be rubbed, poured, sprinkled, or sprayed on, introduced into, or otherwise applied to the human body. . . for cleansing, beautifying, promoting attractiveness, or altering the appearance.”²²

¹⁸ <https://www.cbsnews.com/news/coronavirus-demand-for-household-cleaners-disinfectants-lysol-clorox-purell-sanitizers-2020-03-02/>

¹⁹ <https://www.vox.com/the-goods/2020/3/5/21164673/hand-sanitizer-coronavirus-pocketbac-purell>

²⁰ See, e.g., <https://www.fda.gov/news-events/press-announcements/coronavirus-update-fda-and-ftc-warn-seven-companies-selling-fraudulent-products-claim-treat-or>; <https://www.desmoinesregister.com/story/news/2020/05/11/we-didnt-do-it-says-first-u-s-hand-sanitizer-maker-accused-false-claims-treat-cure-covid-19/3109835001/>; <https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-daily-roundup-may-27-2020>.

²¹ See, e.g., “Is It a Cosmetic, a Drug, or Both? (Or Is It Soap?),” available at

<https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap>.

²² *Id.*; FD&C Act, sec. 201(i)

23. It is violative of the FD&C Act for cosmetic manufacturers or suppliers to make claims that a cosmetic can prevent, treat, or cure any health condition or disease, including such claims that the cosmetic can kill or inactivate pathogens.²³ Such claims would violate § 505(a)²⁴ of the FD&C Act because they would make the product an unapproved new drug.²⁵

24. Under the FD&C Act, drugs are defined as “articles intended for use in the diagnosis, cure, mitigation, treatment, or prevention of disease” and “articles (other than food) intended to affect the structure or any function of the body”²⁶

25. The FDA classifies an over-the-counter drug (“OTC drug”) as any drug that can be obtained by a consumer without the intervention of a health care professional. OTC drugs are regulated by the FDA and must be pre-approved – either through demonstrated conformance with an OTC drug “monograph” or through a new drug application – in order to be marketed and sold to the public.²⁷

26. With minor exceptions, the FDA requires all OTC drugs to include uniform labeling clearly visible on the drug’s packaging (“Drug Facts Label”).²⁸ The Drug Facts Label tells consumers what the OTC drug is supposed to do, who should or should not take it, how to

²³ <https://www.fda.gov/cosmetics/cosmetics-laws-regulations/it-cosmetic-drug-or-both-or-it-soap#Different>

²⁴ This section is also known by its U.S. Code title, 21 U.S.C. § 355(a). *See, e.g.*, <https://www.fda.gov/regulatory-information/federal-food-drug-and-cosmetic-act-fdc-act/fdc-act-chapter-v-drugs-and-devices>.

²⁵ *See, e.g.*, <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/colloidal-vitality-llcvital-silver-604885-03062020>.

²⁶ *Id.*; FD&C Act, sec. 201(g)(1)

²⁷ <https://www.fda.gov/drugs/questions-answers/prescription-drugs-and-over-counter-otc-drugs-questions-and-answers>. An OTC drug monograph is a “rule book” for a given therapeutic category that establishes a set of conditions – such as active ingredients, indicated uses, doses, labeling, and testing – to which a product in the given therapeutic category must conform in order to be legally marketed as an OTC drug. <https://www.fda.gov/drugs/over-counter-otc-drug-monograph-process>.

²⁸ 21 CFR 201.66(c); <https://www.fda.gov/drugs/information-consumers-and-patients-drugs/otc-drug-facts-label>.

use it, and provides a list of its ingredients. Cosmetics are not required to include a Drug Facts Label.²⁹

27. The FDA categorizes hand sanitizers as OTC drugs.³⁰

28. According to the FDA, “[h]and sanitizers using active ingredients other than alcohol (ethanol), isopropyl alcohol, or benzalkonium chloride are not legally marketed, and the FDA recommends that consumers avoid their use.”³¹

III. Theraworx Protect Within the FDA Regulatory Framework

29. Avadim, the manufacturer of Theraworx Protect, voluntarily registered Theraworx Protect as a cosmetic with the FDA.³²

30. This registration does not denote any type of FDA approval of Theraworx Protect.³³ The FDA never approved Theraworx Protect for any purpose, including as a hand sanitizer.

31. According to Avadim, the product’s manufacturer, Theraworx Protect is not a hand sanitizer.

32. Theraworx Protect does not contain ethyl alcohol, isopropyl alcohol, or benzalkonium chloride. Thus, applying FDA guidance, Theraworx Protect is the type of product that cannot be legally marketed as a hand sanitizer and it is “recommend[ed] that consumers avoid [its] use.”³⁴

²⁹ See *id.*; see also 21 C.F.R. § 701 *et seq.* (requiring cosmetic label to include a list of ingredients, net quantity of contents, and the name and place of business of the manufacturer, distributor, or packer);

<https://www.fda.gov/cosmetics/cosmetics-labeling-regulations/cosmetics-labeling-guide#clgi>.

³⁰ <https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19>

³¹ FDA, “Q&A for Consumers | Hand Sanitizers and COVID-19,” available at <https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19>.

³² Avadim Prospectus at p. 32.

³³ *Id.* at p. 35.

³⁴ FDA, “Q&A for Consumers | Hand Sanitizers and COVID-19,” available at <https://www.fda.gov/drugs/information-drug-class/qa-consumers-hand-sanitizers-and-covid-19>.

33. Theraworx Protect contains the following ingredients: “Aqua (Water), Cocamidopropyl Betaine, Aloe Barbadenis Leaf Juice, Colloidal Silver, Tocopheryl Acetate, Glycerin, Allantoin, Beta Glucan, Citrus Paradisi (Grapefruit) Seed Extract, Lauryl Glucoside, Tetrasodium EDTA, PEG/PPG-4/12 Dimethicone, Methylparaben, Propylparaben, and Parfum (Fragrance).”

34. In 1999, the FDA issued a final ruling, titled “Over-the-Counter Drug Products Containing Colloidal Silver Ingredients or Silver Salts” (the “1999 FDA Ruling”), stating, *inter alia*, that “products containing colloidal silver ingredients or silver salts for internal or external use are not generally recognized as safe and effective” and the “FDA is not aware of any substantial scientific evidence that supports the use of OTC colloidal silver ingredients or silver salts for disease conditions. . . .”³⁵ The 1999 FDA Ruling remains in effect.

35. Pursuant to the 1999 FDA Ruling, the FDA promulgated a regulation governing the marketing of OTC drug products containing colloidal silver stating, *inter alia*: “There are serious and complicating aspects to many of the diseases these silver ingredients purport to treat or prevent. Further, there is a lack of adequate data to establish general recognition of the safety and effectiveness of colloidal silver ingredients or silver salts for OTC use in the treatment or prevention of any disease.”³⁶

IV. No Studies Prove That Theraworx Protect Is Effective To Kill Or Inactivate The COVID-19 Virus

36. There is no competent and reliable scientific evidence that Theraworx Protect is effective to kill or inactivate the COVID-19 virus.

37. There are no adequate and well-controlled studies that prove that Theraworx

³⁵ 64 F.R. 44653, 44654 (Aug. 17, 1999), available at <https://www.govinfo.gov/content/pkg/FR-1999-08-17/pdf/99-21253.pdf>.

³⁶ 21 C.F.R. § 310.548(a).

Protect is effective to kill or inactivate the COVID-19 virus.

38. Conversely, there is a 1999 FDA Ruling respecting the use of colloidal silver, one of the ingredients in Theraworx Protect, which confirms, *inter alia*, that there is a lack of adequate data to establish general recognition of the safety and effectiveness of colloidal silver for OTC use in the prevention of any disease.

V. School Health Knew That Its Claims Regarding Theraworx Protect Were False

39. In or about late February and early March, as COVID-19 was rapidly developing into a global pandemic and supplies of alcohol-based hand sanitizer were dwindling, School Health began defrauding the Cities and Towns by marketing and selling Theraworx Protect, a cosmetic product containing no alcohol, as a hand sanitizer capable of inactivating the COVID-19 virus and providing a multi-hour barrier against the COVID-19 virus without the need for reapplication.

40. School Health engaged in these marketing tactics with deliberate ignorance and/or reckless disregard of the truth or falsity of the information in the claims it was making to the Cities and Towns regarding Theraworx Protect. For example, because Theraworx Protect's packaging did not include a Drug Facts Label, as is required for OTC drugs, School Health recklessly disregarded the fact that Theraworx Protect could not have been an OTC drug, and was instead a cosmetic that could not be marketed as capable of inactivating any virus.

41. Other examples illustrating School Health's deliberate ignorance and/or reckless disregard of the truth or falsity of information in the claims it was making to the Cities and Towns regarding Theraworx Protect include:

- a. Shortly before and almost immediately after School Health began to market and sell Theraworx Protect as a hand sanitizer capable of

combatting the spread of COVID-19, its customers and employees began questioning the claims it was making regarding the product's efficacy and complaining about the product's performance and ingredients;

- b. On February 11, Joanne Nicholas ("Nicholas"), a School Health Territory Manager, emailed Greg Evans ("Evans") and Cyrus Severance ("Severance"), also of School Health, alerting them to a customer's complaint that an ingredient in Theraworx Protect, colloidal silver, was unsafe. Nicholas included a quote from the website WebMD.com stating that "[c]olloidal silver is LIKELY UNSAFE when taken by mouth, applied to the skin, or injected intravenously (by IV)." Evans is listed on School Health's website under its "[T]eam of Experts" as a Sales Specialist with responsibilities including "educating the sales and support teams about [product] uses." Severance is School Health's National Sales Manager. After sending her email to Evans and Severance, Nicholas forwarded the same email to five other School Health employees, including Kim Chilingirian ("Chilingirian"), along with the message: "[W]hat are your thoughts on this ingredient [colloidal silver]-it doesn't look safe to me[.]" Chilingirian was a School Health Territory Sales Manager and her sales territory included Massachusetts. Later that same day, February 11, Chilingirian responded to Nicholas' email:

"I had the same exact kick back when I presented Theraworx . . . to the Vermont State School Nurse leader. Needless to say - when she looked at the bottle she saw that

ingredient immediately and said she would not indorse [sic]”;

A simple internet search by School Health would have quickly revealed that the colloidal silver in Theraworx Protect was the subject of the 1999 FDA Ruling and that the FDA considers colloidal silver ineffective for use in the prevention of any disease or condition;

- c. On March 4, Nicholas informed Evans and Stephen Bruns (“Bruns”), School Health’s E-Commerce Manager, that a School Health customer, a New Jersey school district, had complained that Theraworx Protect did not comply with CDC guidance regarding hand sanitizer usage during the COVID-19 pandemic because it did not contain at least 60% alcohol, and that the school district was upset that School Health had promoted the product as a hand sanitizer suitable for the prevention of COVID-19;
- d. On March 18, Severance, School Health’s National Sales Manager, emailed a client, admitting:

“...Unfortunately, since the COVID-19 virus is so new, we do not currently have any completed white papers on [Theraworx Protect’s] efficacy yet....”;

Severance’s March 18 email was a direct acknowledgment by School Health that as of that date, it had no competent or reliable scientific evidence regarding Theraworx Protect’s efficacy against the COVID-19 virus;

- e. On March 29, a Tennessee public school district contacted School Health and pointed out the CDC guidance on alcohol-based hand sanitizers and noted that Theraworx Protect did not comply with those guidelines.

The school district also noted to School Health that there was a lack of adequate studies supporting School Health's claims;

- f. On April 1, Austin Peay State University contacted School Health to advise that it had an issue with School Health's claims that Theraworx Protect was effective to inactivate or kill the COVID-19 virus; and
- g. On April 20, a Customer Solutions Consultant at Fastenal Company emailed School Health to describe a customer's complaint regarding Theraworx Protect, explaining: "I sold several case [sic] of you [sic] Theraworx [Protect] to customers and they are claiming that it is not effective against COVID-19...."

VI. To Induce Sales Of Theraworx Protect To The Cities And Towns, School Health Made False and Fraudulent Claims About The Product's Efficacy Against The COVID-19 Virus

42. With no competent and reliable scientific evidence and no adequate and well-controlled studies in the published literature establishing that Theraworx Protect was effective in killing or inactivating the COVID-19 virus, or that it could serve as a multi-hour barrier against the COVID-19 virus, School Health made repeated false claims to the Cities and Towns regarding the product's efficacy in order to induce sales. School Health's claims that Theraworx Protect provided a multi-hour barrier against the COVID-19 virus were especially egregious because they gave the false impression that users need not rigorously adhere to health measures recommended by the CDC, such as washing hands with soap and water or applying alcohol-based hand sanitizer both before and after touching a surface or object out in public.

Framingham Public Schools

43. Framingham Public Schools (“Framingham”) is the public school district in the city of Framingham, Massachusetts and is a political subdivision for the purposes of the MFCA.

44. In early February, before the rise in COVID-19 cases, Framingham began discussions with Chilingirian, its long-time School Health sales representative, to replace its then-current hand sanitizer with another product.

45. On March 4, because of the rise in COVID-19 cases, Framingham emailed Chilingirian, with the subject “Sanitizer,” asking her to send “some info on the sanitizer we are looking to use instead of purell?”

46. On March 5, in response to Framingham’s request from the prior day, and to convey that there was scientific evidence to support her claim respecting Theraworx Protect’s efficacy as a hand sanitizer, Chilingirian emailed Framingham three studies. All three of the studies were published long before the start of the COVID-19 pandemic and evaluated Theraworx Protect against bacteria or fungi, which are different pathogens than a virus.³⁷ None of the studies evaluated Theraworx Protect’s efficacy against the COVID-19 virus.

47. On or about March 10, Chilingirian attended a meeting with Framingham to pitch Theraworx Protect as a replacement product for the alcohol-based hand sanitizer the district had been using.

³⁷ The first study, published in 2015, evaluated Theraworx Protect’s performance against carbapenem-resistant Enterobacteriaceae (CRE), a bacterium common in hospital and long-term care settings. This first study specifically stated that its results could not be extrapolated to other pathogens. The second study, conducted in 2007, evaluated Theraworx Protect against Methicillin-resistant *Staphylococcus aureus* (MRSA), another bacterium commonly spread in healthcare settings and prisons. The third study, published in 2017, evaluated the performance of a “colloidal silver solution” against three different bacteria and one fungus.

48. During the March 10 meeting, Chilingirian represented the following regarding Theraworx Protect: (1) that it inactivated or killed the COVID-19 virus; (2) that it offered a 4- to 6-hour barrier against all pathogens, including the COVID-19 virus, without the need for re-application; and (3) that it was a superior product to alcohol-based hand sanitizer because it had the same pathogen-inactivating properties as alcohol-based hand sanitizer, but, since it contained no alcohol, conferred the added benefit of preserving the skin's outer layer.

49. All of Chilingirian's March 10 representations to Framingham, set forth in paragraph 48 above, were knowingly false.

50. At the March 10 meeting with Framingham, Chilingirian also presented a number of misleading and deceptive clinical materials and documents regarding Theraworx Protect, including the following:

- a) Four studies³⁸ that predated the COVID-19 pandemic and evaluated Theraworx Protect against bacteria and fungi – pathogens which are unrelated to the COVID-19 virus;
- b) A clinical document titled “Response to Clinical Inquiry/Clinical Summary - Theraworx Protect (Coronavirus),” which, despite the inclusion of “Coronavirus” in its title, did not contain a single study demonstrating Theraworx Protect's efficacy against the COVID-19 virus (the “Theraworx Backgrounder”);
- c) A clinical document titled “COVID-19: Hand and T-Zone Protection - Theraworx Protect” that listed the ways in which

³⁸ Three of the four studies presented by Chilingirian on March 10 were those discussed *supra*, at footnote 37. The fourth study, conducted in 2017, was titled “An Evaluation of One Test Product for Its Antimicrobial Properties When Challenged with Three Microorganisms Using An In-vitro Time-Kill Method” and evaluated Theraworx Protect against *Candida auris*, a fungus.

COVID-19 was believed at the time to spread from person-to-person, but which did not contain any studies demonstrating Theraworx Protect's efficacy against the COVID-19 virus (the "School Health 1 Pager");

- d) A document titled "Theraworx Protect Hand and T-Zone Defense," which noted that "the [WHO] cautions that 'touching your face after touching contaminated surfaces or sick people is one of the ways the coronavirus can be transmitted,'" then stated that "overusing [alcohol-based hand sanitizer] can cause damage to the skin and even compromise the skin's natural barrier and defensive functions," before concluding that "[Theraworx Protect's] non-toxic, no-rinse solution provides advanced hygiene for the hands and face" (the "School Health Theraworx Flyer");
- e) A form letter which stated, *inter alia*: "As the current health crisis continues to escalate, we are working to provide you with the best infection and disease prevention products to ensure the health and safety of you, your students and your staff. Theraworx Protect is one of the few products, indicated to be applied to the hands and face, that meets the recommendations of the CDC to prevent disease transmission."

51. Given the context in which the documents listed in paragraph 50 above were presented by Chilingirian to Framingham on March 10 and their frequent references to COVID-19 or the "Coronavirus," the documents' intended effect was to convey,

without any competent or reliable scientific evidence, that Theraworx Protect was effective against the COVID-19 virus. As such, these documents constituted knowingly false records and/or statements.

52. On May 13, Chilingirian emailed Framingham again and referred to Theraworx Protect as the district's "new hand sanitizer."

53. Chilingirian's characterization of Theraworx Protect as a "hand sanitizer" was knowingly false. Theraworx Protect is a cosmetic product; it is not approved by the FDA as a hand sanitizer.

54. On May 15, Framingham emailed Chilingirian: "Does [Theraworx Protect] kill covid, I am sure it does but I will need to articulate that to all Staff in the District."

55. On May 16, Chilingirian responded to Framingham's query from the previous day: "Attached is documentation on [Theraworx Protect's] effectiveness and specific to COVID... ." She included three attachments to her email.

56. One of the attachments to Chilingirian's May 16 email was the Theraworx Backgrounder. A second attached document, titled "Theraworx Protect: Topical Immune Health System for the Microbiome," did not contain any competent or reliable evidence to support Chilingirian's representation that the product could kill the COVID-19 virus. However, the document's opening paragraph claimed that use of Theraworx Protect would "result[] in maximum protection benefit" and stated that Theraworx Protect has been "[t]ruste[d] by the world's most renowned children's hospitals for immune compromised patients" and is "now available to the general public." It omitted the fact that hospitals were not using the product to combat the spread of COVID-19. Given that the documents were shared in direct response to Framingham's specific request for documentary evidence demonstrating Theraworx Protect's

efficacy against the COVID-19 virus, and that the documents in fact had nothing to do with the COVID-19 virus, the documents were deceptive, misleading, and constituted knowingly false records and/or statements.

57. On May 20, Framingham emailed Chilingirian to inquire why Theraworx Protect costs “four times what we are paying for our foam dispenser already in use.” Chilingirian responded:

“[S]o the difference with [Theraworx Protect] is that it is not alcohol based as we discussed. That is what makes your other products so cheap-as alcohol is cheap-but as you know destructive to the bldgs. and not really great for the skin. They should also use less of the product as it stays on the skin for a minimum of 4 hours as a barrier (unless you wash your hands.) . . .”

58. Chilingirian’s representation in her May 21 email that Theraworx Protect creates a minimum 4-hour protective barrier was knowingly false.

59. In June, in reliance on School Health’s knowingly false claims regarding Theraworx Protect, Framingham ordered a substantial quantity of Theraworx Protect to replace the alcohol-based hand sanitizer it had been using in its school buildings.

60. On July 1, School Health invoiced Framingham for a \$3,223.95 purchase of Theraworx Protect.

61. On July 6, in an email with a subject “the new hand sanitizer,” Framingham emailed Chilingirian:

“Just checking on the new hand sanitizer product we ordered. The [Department of Public Health] issued Handwashing Recommendations last week which state that ...hand sanitizers that are not alcohol based are not recommended... will the product we have purchased suffice? I know you said it is comparable and has demonstrated that it works against COVID. Just want to be sure that we do not have an issue.”

62. On July 7, Chilingirian responded to Framingham's July 6 email:

“You will be fine with the Theraworx product for the purposes of it killing COVID etc. . . . []Theraworx is 100% safe for eyes, ingestions etc. If you need me to forward you the studies again I will be happy to do so.”

63. Chilingirian's representation in her July 7 email to Framingham that Theraworx Protect was “fine” for the “purposes of killing COVID” was knowingly false.

64. On July 15 and August 20, School Health invoiced Framingham respecting purchases of Theraworx Protect for \$79,800 and \$2,432, totaling \$82,232. The grand total of all invoices submitted by School Health to Framingham respecting purchases of Theraworx Protect was \$85,455.95.

65. On November 17, news outlets reported on the filing of an Assurance of Discontinuance between the Massachusetts Attorney General's Office (“AGO”) and Federal Resources Supply Company (“Federal Resources”) resolving the AGO's claims that Federal Resources violated provisions of the MFCA in its sale of Theraworx Protect to the Massachusetts Bay Transportation Authority based on Federal Resources' representations that Theraworx Protect would be effective as a hand sanitizer to combat the COVID-19 virus without adequate evidence or well-controlled and reliable studies to support its claims.³⁹

66. Upon the news of the Federal Resources matter, Framingham, until then unaware that there was a problem with the Theraworx Protect installed in all of its school buildings, scrambled to procure an alcohol-based hand sanitizer. In doing so, Framingham incurred significant expense both due to the high market demand for alcohol-based hand sanitizer and the

³⁹ See, e.g., <https://www.wbur.org/news/2020/11/18/mbta-coronavirus-covid-19-ineffective-sanitizer>

overtime hours personnel were required to spend to remove Theraworx Protect from the school buildings and install the new alcohol-based hand sanitizer.

67. The next day, November 18, Chilingirian emailed Evans, Severance and Steve Tallon, all of School Health, attaching various documents that she had previously presented or sent to Framingham, and admitted:

“This is what I had communicated [to Framingham] and I think the T-Zone is misleading as it’s [sic] says COVID 19.”⁴⁰

68. Later that day, November 18, Chilingirian emailed her assistant, Elena Perrone, a hyperlink to a news story covering the Assurance of Discontinuance between the AGO and Federal Resources regarding sales of Theraworx Protect, along with the message: “Buddy I want to vomit[.]”

Winchester Public Schools

69. Winchester Public Schools (“Winchester”) is the public school district in the town of Winchester, Massachusetts and is a political subdivision for the purposes of the MFCA.

70. In early March, with the COVID-19 pandemic rapidly worsening, Winchester telephoned Chilingirian, its long-time sales representative, and asked whether School Health had any hand sanitizer available to purchase to help combat the spread of the COVID-19 virus.

71. On March 6, in an email with the subject “Sanitizer,” Chilingirian sent Winchester a quote for Theraworx Protect bladders and wall dispensers.

72. Chilingirian’s representations to Winchester that Theraworx Protect was a hand sanitizer were knowingly false.

⁴⁰ Chilingirian’s mention of “the T-Zone” is believed to be a reference to the School Health 1 Pager. That document includes “COVID-19” in its title and references the “T-Zone.”

73. On March 9, relying on Chilingirian's knowingly false representations that Theraworx Protect was a hand sanitizer, Winchester ordered 80 Theraworx Protect bladders and 40 Theraworx Protect wall mount dispensers at a total cost of \$2,865.60.

74. The next day, on March 10, replying to the email chain with the subject "RE: Sanitizer," and again relying on Chilingirian's knowingly false representation that Theraworx Protect was a hand sanitizer, Winchester ordered a further 240 Theraworx Protect bladders and 120 Theraworx Protect dispensers, thereby increasing Winchester's order to 320 Theraworx Protect bladders and 160 Theraworx Protect dispensers. This increased order was meant, in part, to provide the Town of Winchester with hand sanitizer for use in its town offices.

75. On March 10 and March 12, School Health invoiced Winchester again, for a grand total of \$11,463 worth of Theraworx Protect.

76. After the Theraworx Protect arrived from School Health, some of the product was placed in the Town of Winchester office buildings for use as a hand sanitizer.

77. On March 19, the Director of the Town of Winchester's Health Department emailed Winchester to inform it that the Theraworx Protect placed in Winchester Town Hall was in fact not hand sanitizer:

"Thank you for the dispensers – were those from schools? One thing, I believe the liquid is not sanitizer, it may be soap. Perhaps town hall go [sic] the wrong inserts? Were they intended to be soap? If so, we hung them in the wrong spots around town hall!"

78. That same day, March 19, Winchester sent an email to Chilingirian, with a subject "Problem with Order" stating: "Very concerned that the product we received was not hand sanitizer but a no rinse soap. This is not what I requested."

79. Later on March 19, Chilingirian responded via email to Winchester: "I have attached the White Papers for your medical team to review and will be happy to have a

conference call with them and the [Avadim] team to review further. I hope you know I would not sell you something that had not been proven and tested. . . .” Chilingirian made this representation to Winchester despite the fact that the previous day, March 18, School Health’s National Sales Manager admitted there were no “white papers” on Theraworx Protect’s efficacy against the COVID-19 virus because the virus was too new.

80. Chilingirian’s representations to Winchester that Theraworx Protect had been “proven and tested” in regard to COVID-19 were knowingly false.

81. Chilingirian attached nine documents to her March 19 email to Winchester, including the Theraworx Backgrounder and four studies that pre-dated the COVID-19 pandemic and evaluated Theraworx Protect against certain bacteria and fungi and not the COVID-19 virus.

82. On March 24, in an effort to stop Winchester from returning the Theraworx Protect to School Health, Chilingirian emailed Winchester and stated: “Attached is a detailed page on how Theraworx works on COVID 19.” She attached two documents purporting to prove the product’s efficacy against the COVID-19 virus: the Theraworx Backgrounder and the School Health One Pager.

83. Chilingirian’s representation to Winchester in her March 24 email that “Theraworx works on COVID 19” was knowingly false.

School Health’s Claims to Other Cities and Towns

84. In addition to School Health’s false or fraudulent claims to Framingham and Winchester, School Health made numerous false or fraudulent claims regarding Theraworx Protect to other Massachusetts Cities and Towns, including Wachusett Regional School District, New Bedford Public Schools, the City of Malden, Bridgewater-Raynham Regional School District, and Nahant and Swampscott Public Schools.

85. No cosmetic is intended to or is approved by the FDA to prevent any disease or condition, including COVID-19. Despite this, School Health claimed on multiple occasions that Theraworx Protect – a cosmetic – could inactivate and/or kill the COVID-19 virus, and/or was effective against it. For example:

- a) On April 21, in two separate emails with the subject “Infection Control Products Available at School Health,” Jeff Pinney (“Pinney”), a School Health sales representative, pitched both New Bedford Public Schools and Bridgewater-Raynham Regional School District on Theraworx Protect:

“. . . School Health currently has the infection control products in the links below: . . .

“Theraworx Protect - Non-alcohol based hand sanitizer lowers the skins ph level to kill and protect against viruses, bacteria, and fungi for over 3 hours. Additionally, this is effective against the coronavirus and has been shown to be more effective than alcohol based hand-sanitizers. . . .”;

- b) On April 30, Chilingirian, a School Health sales representative, hosted a video call with Nahant Public Schools and Swampscott Public Schools in which she presented Theraworx Protect as an equivalent product to alcohol-based hand sanitizer that would provide a 4- to 6-hour barrier against the COVID-19 virus, as well as other pathogens, and represented that Theraworx Protect “kills any virus that potentially would pass through your nose or mouth

if you applied it to your face around your nose and mouth.”⁴¹

86. School Health claimed that Theraworx Protect provided a time-specific extended barrier which effectively relieved individuals of the need to re-wash hands or re-apply alcohol-based hand sanitizer each time after contacting surfaces or objects in public. No product has been proven to provide a time-specific extended barrier against the COVID-19 virus. The CDC continues to advise the public to wash hands or use an alcohol-based hand sanitizer both before and after entering and leaving a public space and touching an item or surface that may be frequently touched by other people. For example:

- a) On March 2, Pinney emailed the New Bedford Public Schools to pitch products to combat COVID-19, including Theraworx Protect:

“With the spread of the coronavirus there has been an influx of requests for N-95 masks and other infection prevention products. Below is link [sic] to the CDC guidelines for prevention of the spread of coronavirus as well as products to help control the spread. . . . Lastly, below is a link to Theraworx Protect, a fully [sic] body skin sanitizer, skin disinfectant, and skin barrier that is effective for up to 3 hours”

- b) On March 19, in an email with the subject “Theraworx Protect Hand Sanitizer and Barrier,” Pinney emailed Wachusett Regional School District to pitch the product:

“I wanted to . . . let you know that School Health carries a skin sanitizer/barrier system used in hospitals across the US called Theraworx. Theraworx lowers the skins [sic] Ph levels killing and making it inhabitable for bacteria,

⁴¹ On October 13, Swampscott Public Schools sent the following email to Chilingirian to complain about the product: “. . . I was wondering about this Theraworx Protect foam you encouraged us to purchase. You said it kills any virus that potentially would pass through your nose or mouth if you applied it to your face around your nose and mouth. I cannot find anything in the literature about this stuff that says it has a bacterial or viral killing component. It appears to be a glorified hand washing soap. Can you send me something that backs up what you said about it when we all met on a zoom call. I’ve tried looking it up but can’t find anything. . . .”

fungus, and virus's [sic] for up to three hours.”

87. School Health claimed that Theraworx Protect, a product containing absolutely no alcohol, met the CDC's recommendations regarding the COVID-19 virus. For example, on March 25, in an email with the subject “Theraworx COVID-19 Response,” Gina Streepy, another School Health sales representative, emailed the City of Malden's Controller to pitch Theraworx Protect:

“. . . [Theraworx Protect] is a product being used heavily in hospitals and army bases. . . . As the current health crisis continues to escalate, we are working to provide you with the best infection and disease prevention products to ensure the health and safety of you, your students and your staff. Theraworx Protect is one of the few products, indicated to be applied to the hands and face, that meets the recommendations of the CDC to prevent disease transmission. With both hand and face protection through advanced barrier system technology, Theraworx Protect is an ideal addition to your hygiene protocols.”

88. School Health shared numerous marketing and clinical materials with the Cities and Towns in an effort to support its claims that Theraworx Protect could inactivate and/or kill the COVID-19 virus and reduce the spread of COVID-19.⁴²

89. Relying on School Health's false claims regarding Theraworx Protect, the Cities and Towns each purchased quantities of the product and School Health issued the Cities and Towns the following invoices for payment:

⁴² Such marketing and clinical materials shared with the Cities and Towns included, but were not limited to: (a) the Theraworx Backgrounder; (b) the School Health 1 Pager; (c) the School Health Theraworx Flyer; (d) a study, conducted in 2007, which evaluated Theraworx Protect against Methicillin-resistant *Staphylococcus aureus* (MRSA), another bacterium commonly spread in healthcare settings and prisons, discussed supra at footnote 38; and (e) a study, published in 2018, which compared Theraworx Protect's performance to that of chlorhexidine gluconate (CHG), a common antiseptic used in long-term care and hospital settings, by testing the products' reaction against microorganism samples taken from the groin region of human subjects (rather than against a specific pathogen). None of these studies tested Theraworx Protect against COVID-19.

- a) two invoices to Wachusett Regional School District, dated February 28 and September 24, for \$89;
- b) two invoices to the City of Malden, dated March 26 and March 31, for \$6,263;
- c) an invoice to New Bedford School District, dated May 28, for \$898;
- d) an invoice to Bridgewater-Raynham Regional School District, dated June 4, for \$1,170;
- e) two invoices to Nahant Public Schools, dated June 2 and June 5, for \$325; and
- f) an invoice to Swampscott Public Schools, dated July 7, for \$645.

CAUSES OF ACTION

Count I

Violations of the False Claims Act, G.L. c. 12, § 5B(a)(1)

90. The Commonwealth realleges the allegations contained above and incorporates them herein by reference.

91. In connection with its sales of Theraworx Protect, School Health violated G.L. c. 12, §5B(a)(1), by, without limitation, knowingly presenting to the Cities and Towns false or fraudulent claims for payment or approval.

92. The false or fraudulent claims for payment or approval, included, without limitation, invoices submitted by School Health to the Cities and Towns for Theraworx Protect because that product did not have the claimed qualities.

93. School Health's conduct was knowing because it possessed actual knowledge of relevant information, acted with deliberate ignorance of the truth or falsity of information, and/or with reckless disregard of the truth or falsity of the information.

94. School Health's MFCA violations caused damage to the Commonwealth.

Count II

Violations of the False Claims Act, G.L. c. 12, § 5B(a)(2)

95. The Commonwealth realleges the allegations contained above and incorporates them herein by reference.

96. In connection with its sales of Theraworx Protect, School Health violated G.L. c. 12, §5B(a)(2), by, without limitation, knowingly making or using, or causing to be made or used, false records or statements material to its false or fraudulent claims.

97. The false records or statements included, without limitation, School Health's false representations regarding Theraworx Protect's efficacy against the COVID-19 virus and its ability to serve as a multi-hour blocker of the COVID-19 virus, as well as the numerous marketing and clinical materials School Health shared to support its false representations.

98. School Health's conduct was knowing because it possessed actual knowledge of relevant information, acted with deliberate ignorance of the truth or falsity of information, and/or with reckless disregard of the truth or falsity of the information.

99. School Health's MFCA violations caused damage to the Commonwealth.

Count III

Violations of the False Claims Act, G.L. c. 12, § 5B(a)(8)

100. The Commonwealth realleges the allegations contained above and incorporates them herein by reference.

101. School Health violated G.L. c. 12, §5B(a)(8) by, without limitation, entering into an agreement, contract or understanding with the Cities and Towns knowing that information contained therein was false.

102. The false information included, without limitation, representations that Theraworx Protect was a hand sanitizer, that it was effective to kill or inactivate the COVID-19 virus, that it met the CDC's guidance for hand sanitizer usage during the COVID-19 pandemic, and that it provided a multi-hour barrier against the COVID-19 virus.

103. School Health's conduct was knowing because it possessed actual knowledge of relevant information, acted with deliberate ignorance of the truth or falsity of information, and/or with reckless disregard of the truth or falsity of the information.

104. School Health's MFCA violations caused damage to the Commonwealth.

PRAYERS FOR RELIEF

WHEREFORE, the Commonwealth requests that this Court:

As to Counts I through III, enter judgment in favor of the Commonwealth and against School Health and award the Commonwealth:

- a. Three times the amount of damages, including consequential damages, that the Commonwealth and its Cities and Towns sustained because of School Health's conduct, pursuant to G.L. c. 12, § 5B;
- b. An appropriate civil penalty for each violation of G.L. c. 12, § 5B; and
- c. The expenses of this action including, without limitation, the Commonwealth's reasonable attorneys' fees, reasonable expert fees, and the costs of investigation for the Attorney General;
- d. Grant such other relief as the Court deems appropriate.

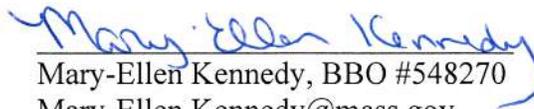
JURY DEMAND

The Commonwealth demands a trial by jury.

Respectfully Submitted,

Commonwealth of Massachusetts

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Date: November 29, 2021