## SUPERIOR COURT OF THE DISTRICT OF COLUMBIA CIVIL DIVISION

CENTER FOR INQUIRY, INC., individually and on behalf of consumers and the general public, 1012 14<sup>th</sup> Street NW, Suite 205, Washington, DC 20005,

Case No.:

Plaintiff,

v.

BOIRON, INC., a Pennsylvania corporation, 4 Campus Boulevard Newtown Square, PA 19073,

Defendant.

# COMPLAINT FOR VIOLATIONS OF THE CONSUMER PROTECTION PROCEDURES ACT

On behalf of itself, consumers and the general public of the District of Columbia, Plaintiff Center for Inquiry, Inc. ("Plaintiff" or "CFI") brings this action against Defendant Boiron, Inc. ("Defendant" or "Boiron") for the unfair and deceptive trade practices it regularly utilizes in the marketing and sale of homeopathic products.

Defendant repeatedly violated, and continues to operate in violation of, the Consumer Protection Procedures Act ("CPPA"). D.C. Code §§ 28-3901, et seq. Through a carefully crafted scheme of misrepresentation, obfuscation, ambiguity, innuendo and falsities, Boiron offloads otherwise worthless products upon the unwitting, the ill-informed and the vulnerable. Upon the investigation of counsel, information and belief, Plaintiff alleges the following in support of its claim:

#### INTRODUCTION

- 1. Homeopathy is Pseudoscience; Quackery; Faux Medicine; Health Fraud.
- 2. Boiron is the self-described world leader in "homeopathic medicines."
- 3. Defendant's entire business is based upon a fiction—a centuries old confidence scheme long past its shelf life. Homeopathy does not heal. Homeopathy does not cure. Homeopathy is wishful thinking, deceptively packaged and sold for a hefty profit, nothing more.
- 4. Equipped with an inventory in excess of one thousand various items, including toxic plants, animal venom, noxious gasses, controlled substances, heavy metals, radioactive materials, bacteria, parasites, virus particles, excretions, and even urethral secretions of persons infected by a sexually transmitted disease, proponents of homeopathy peddle "drugs" they claim will treat all medical conditions.
- 5. Defendant recommends and sells a variety of products, each of which it claims will uniquely and specifically treat a plethora of conditions. Yet each product is materially identical in their contents and effects—each indistinguishable but for the promises Boiron makes to consumers.
- 6. From a child's nosebleed caused by trauma,<sup>1</sup> to hiccups after a large meal<sup>2</sup> or those triggered by stress;<sup>3</sup> whether for shingles with bluish-white vesicles<sup>4</sup> or shingles worsened by touch

<sup>&</sup>lt;sup>1</sup> <u>Trauma</u>, Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/?category=Children& mainsymptom=Nosebleeds&addsymptom=From%20trauma (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>2</sup> <u>Digestive Problems, Hiccups</u>, Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/?category=Digestive%20Problems&mainsymptom=Hiccups&addsymptom=After%20a%20large%20meal (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>3</sup> *Id.*, https://www.boironusa.com/mf/?category=Digestive%20Problems&mainsymptom=Hiccups&addsymptom=Triggered%20by%20stress (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>4</sup> <u>First Aid – Skin, Shingles or Zoster pain,</u> Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/?category=First%20Aid%20%20Skin&mainsymptom=Shingles%20or%20Zoster%20pain&addsymptom=With%20bluish-white%20vesicles (last visited Apr. 13, 2022).

or jolts,<sup>5</sup> Boiron markets, recommends and sells its products with the promise they will remedy myriad ails, illnesses and injuries. In so doing, Defendant cheats consumers.

- 7. Defendant uses deceptive and unfair trade practices. In order to induce consumers to purchase Boiron products, Defendant regularly uses false and misleading statements, omissions, innuendo and ambiguities. It repeatedly misrepresents the uses, benefits, approval, characteristics and ingredients of Boiron's products.
- 8. To consumers, Defendant deceptively holds out its products as medicine.<sup>6</sup> It deceives the sick and injured into believing the "active ingredient" in each Boiron product will directly treat<sup>7</sup> the etiological aspect of their condition. Defendant falsely conveys to consumers that each Boiron product is proven safe and effective.
- 9. Absent Defendant's deception, consumers would not purchase Boiron products; a reasonable consumer would not and does not purchase "medicine" that is not actually medicine.
- 10. Defendant utilizes carefully crafted marketing materials and packaging to convince consumers that Boiron products will treat injuries, reduce muscle stiffness, disappear bruises, assuage poor concentration and irritability due to overwork and even heal surgical wounds. It convinces consumers to buy its goods, at a premium, with no intent to deliver the items as promised.
- 11. Through its statements, acts and omissions; through innuendo and ambiguity, Defendant dupes consumers.

<sup>&</sup>lt;sup>5</sup> <u>First Aid – Skin, Shingles or Zoster pain,</u> https://www.boironusa.com/mf/?category=First%20Aid%20-%20Skin&mainsymptom=Shingles%20or%20Zoster%20pain&addsymptom=Worsened%20by%20touch%20or%20 jolts (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>6</sup> "The science and art of diagnosing and treating disease or injury and maintaining health. The branch of this science encompassing treatment by drugs, diet, exercise, and other nonsurgical means." *Medicine*, The American Heritage® Medical Dictionary (2007).

<sup>&</sup>lt;sup>7</sup> "The use of an agent, procedure, or regimen, such as a drug, surgery, or exercise, in an attempt to cure or mitigate a disease, condition, or injury. The agent, procedure, or regimen so used." *Treatment*, *id*.

- 12. Defendant's deception deprived Plaintiff and the general public of the right to truthful information. It violated and continues to violate the CPPA.
- 13. To hold Boiron accountable and prevent its further wholesale use of unfair trade practices, Plaintiff brings this suit and seeks civil penalties, restitution, injunctive relief and any other relief this Court deems necessary, appropriate and proper.

#### **JURISDICTION AND PARTIES**

- 14. This Court has jurisdiction over the matter pursuant to D.C. Code §§ 11-921 and 28-3905.
- 15. This Court has personal jurisdiction over the parties pursuant to D.C. Code § 13-423.
- 16. The proper venue for this matter is the District of Columbia. Defendant markets, sells and delivers its products to consumers within the District of Columbia ("District"), including Plaintiff, through brick-and-mortal retailers and via the internet. Defendant's unlawful deceptive and unfair trade practices, acts and omissions occurred within the District and caused injury and damages therein.
- 17. Plaintiff, Center for Inquiry, Inc., is a 501(c)(3) nonprofit, public interest organization with a headquarters in the State of New York.
- 18. Plaintiff's Executive Office is located in the District of Columbia at 1012 14th St. NW, Suite 205, Washington, DC 20005. Plaintiff operates an active branch, CFI DC, in the District of Columbia and regularly holds meetings and events in the District for its members and the general public.

- 19. On July 1, 2021, from its office in the District, and after viewing various advertisements and marketing materials, Plaintiff purchased a sampling of four Boiron products offered for sale as follows:
  - i. Boiron Oscillococcinum 0.04 Ounce 6 Doses Homeopathic Medicine for Flu-like Symptoms<sup>8</sup> ("Oscillo"),
  - ii. Boiron Staphysagria 30C, 80 Pellets, Homeopathic Medicine for Surgical Wounds<sup>9</sup> ("Staphysagria"),
  - iii. Boiron Phosphoricum Acidum 30C, 80 Pellets, Homeopathic Medicine for Concentration<sup>10</sup> ("Phosphoricum"); and,
  - iv. Boiron Arnica Montana 30C 3 Tubes (80 Pellets per Tube) Homeopathic Medicine for Pain Relief<sup>11</sup> ("Arnica").
- 20. On July 7, 2021, the purchased products were delivered to Plaintiff's office in the District.
- 21. Plaintiff purchased the Boiron products in order to evaluate and test the items. In particular, as it pertains to the use for personal, household and family purposes, CFI tested and evaluated the qualities, characteristics and contents of the products. CFI utilized an independent advanced materials science and analytical services platform to conduct Fourier transform infrared spectroscopy and scanning electron microscopy and energy dispersive X-ray spectroscopy on each product.
- 22. Plaintiff brings this action pursuant to the Consumer Protection Procedures Act, D.C. Code §§ 28-3905(k)(1)(A), (B), (C) and (D), as a nonprofit and public interest organization and as a consumer.

<sup>&</sup>lt;sup>8</sup> https://www.amazon.com/gp/product/B006H9THXY (last visited Apr. 13, 2022).

<sup>9</sup> https://www.amazon.com/gp/product/B00028O0T2 (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>10</sup> https://www.amazon.com/gp/product/B000FJ2NWO (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>11</sup> https://www.amazon.com/gp/product/B013JKW8Z2 (last visited Apr. 13, 2022).

- 23. The Center for Inquiry is dedicated to making a better world through critical thinking and reason, guided by compassion and respect for the dignity of every individual. It stresses evidence-based inquiry into science, pseudoscience, medicine and health, religion, and ethics. Since its very beginning through the present, CFI regularly investigates, educates, advocates and litigates issues related to all forms of pseudoscience and confidence schemes.
- 24. From regulatory submissions to the Food and Drug Administration<sup>12</sup> and the Federal Trade Commission,<sup>13</sup> to *amicus briefs*,<sup>14</sup> the publication of *Skeptical Inquirer*<sup>15</sup> magazine and *Quackwatch*—an online "guide to quackery, health fraud, and intelligent decisions"<sup>16</sup>—quackery has long been a focus of CFI.
- 25. Quackery, a particularly pernicious form of pseudoscience, by definition includes the fraudulent trade of healthcare-related services and goods, commonly referred to as "snake oil."<sup>17</sup>
- 26. Relevant here, homeopathy is quackery; combating quackery is protecting consumers; Boiron's homeopathic products are one example of the snake oil from which CFI has consistently worked to protect consumers, including those within the District of Columbia.

<sup>&</sup>lt;sup>12</sup> <u>Citizen Petition to Require all OTC Homeopathic Drugs to be Tested for Effectiveness and Labeled Accurately,</u> (submitted Aug. 26, 2011) (available at https://centerforinquiry.org/news/cfi\_and\_csi\_petition\_fda\_to\_take\_action on homeopathic drugs (last visited Apr. 13, 2022)).

The state of the Homeopathic Medicine & Advertising Workshop (Nov. 2015) (available at https://www.ftc.gov/system/files/documents/public\_comments/2015/11/00517-99779.pdf. (last visited Apr. 13, 2022)).

<sup>&</sup>lt;sup>14</sup> Brief for Scientists, Science Educators, Skeptics, the Center for Inquiry, and the Richard Dawkins Foundation for Research and Science as Amicus Curiae, *Whole Woman's Health v. Hellerstedt*, 579 U.S. 582 (2016).

<sup>&</sup>lt;sup>15</sup> An Introduction to Homeopathy, Skeptical Inquirer, Vol. 38, No. 5 (Oct. 2014) (available at https://skepticalinquirer.org/2014/09/an-introduction-to-homeopathy (last visited Apr. 13, 2022)). <sup>16</sup> https://quackwatch.org (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>17</sup> One of the most well-known quacks of the 19<sup>th</sup> and early 20<sup>th</sup> centuries was Clark Stanley. Clark Stanley's Snake Oil Liniment, faux medicine advertised as a powerful painkiller, gave rise to the familiar term "snake oil salesmen."

27. Defendant Boiron, Inc., is a corporation organized under the laws of the Commonwealth of Pennsylvania where it maintains an office in Newton Square, Delaware County. Boiron is registered to and regularly conducts business within the District.

28. By, with and through its branches, affiliates and parent company, Boiron USA, Inc., Defendant manufactures, markets, sells, distributes and delivers homeopathic products to the District. At all times material to this complaint, Defendant marketed, sold, distributed and delivered its products to consumers, including Plaintiff, in Washington, DC and throughout the United States.

#### FACTUAL BACKGROUND

#### Homeopathy: Faux Medicine Founded upon a Flub. 18

29. Homeopathy was conceived of by Christian Samuel Hahnemann beginning in the late 18<sup>th</sup> century, shortly before he was caught employing deceptive trade practices in the sale of his own products.<sup>19</sup>

30. Though he received a degree in medicine, Hahnemann worked as a translator. He was perpetually destitute.<sup>20</sup> Throughout much of his life, whether due to widespread derision of his theories or in the search for a way to support his family, he regularly moved throughout Germany.

31. In 1790, Hahnemann translated a medical book written by the then recently deceased Dr. William Cullen. In his book,<sup>21</sup> Dr. Cullen wrote about cinchona bark,<sup>22</sup> a source of

<sup>&</sup>lt;sup>18</sup> Homeopathy, its origins and tenants, underlie a significant and substantial portion of Plaintiff's claims and Defendant's deceptive conduct. In order to provide the proper context and basis of the claims herein, Plaintiff includes this brief, relevant recitation of homeopathy's development.

<sup>&</sup>lt;sup>19</sup> See, Remarks on the Character and Writings of Hahnemann, 1847 New-York J. Med.

<sup>&</sup>lt;sup>20</sup> See, e.g., Anthony Campbell. Homeopathy in Perspective (2014).

<sup>&</sup>lt;sup>21</sup> William Cullen, A treatise of the materia medica (1789).

<sup>&</sup>lt;sup>22</sup> Also commonly referred to as "Peruvian bark," "Jesuit's bark" and "China bark."

quinine regularly used to effectively treat malaria. Cullen theorized the bark worked due to its "tonic effect" (astringency) because, he believed, medicines worked best in the stomach.

- 32. Hahnemann doubted Cullen's statement since, he thought, if other astringent items did not treat malaria, the curative effect must be some other factor.
- 33. Hahnemann began conducting experiments on himself and consumed cinchona bark. He documented the effects as follows:

I took for several days, as an experiment, four drams of good china daily. My feet and finger tips, etc., at first became cold; I became languid and drowsy; my pulse became hard and quick; an intolerable anxiety and trembling (but without rigor); trembling in all limbs; then pulsation in the head, redness in the cheeks, thirst; briefly, all those symptoms which to me are typical of intermittent fever, such as the stupefaction of the senses, a kind of rigidity of all joints, but above all the numb, disagreeable sensation which seems to have its seat in the periosteum<sup>23</sup> over all the bones of the body—all made their appearance. This paroxysm<sup>24</sup> lasted for two or three hours every time, and recurred when I repeated the dose and not otherwise. I discontinued the medicine and I was once more in good health.<sup>25</sup>

- 34. Hahnemann continued his experiments for another six years, and his reaction to cinchona became the foundation for what would later be called "homeopathy." Put simply, he believed that (a) cinchona cures malaria, (b) cinchona causes malaria symptoms in healthy individuals, therefore (c) items that cause illness in a healthy person will cure a similar illness.<sup>26</sup>
- 35. Notwithstanding the logical fallacy of Hahnemann's conclusion, what he experienced were not symptoms of malaria (nor symptoms of cinchonism, an overdose of the bark). Rather, it is more likely than not Hahnemann experienced an allergic reaction to cinchona—a fact that would explain why <u>nobody</u> was able to replicate the results of his experiments.<sup>27</sup>

<sup>&</sup>lt;sup>23</sup> A membranous tissue covering the outer surface of most bones.

<sup>&</sup>lt;sup>24</sup> Sudden attack or intensification.

<sup>&</sup>lt;sup>25</sup> Campbell, *supra*.

<sup>&</sup>lt;sup>26</sup> See, Irvine Loudon, A Brief History of Homeopathy, 99 J. Royal Soc'y Med. 607-10 (2006).

<sup>&</sup>lt;sup>27</sup> Remarks on the Character and Writings of Hahnemann, supra.

- 36. Nevertheless, in 1796, Hahnemann published his new theory in "Essay on a New Principle for Ascertaining the Curative Power of Drugs" from which came the now commonly used phrase, "law of similars."<sup>28</sup>
- 37. In 1800, for the equivalent of approximately \$90.00, Hahnemann advertised and sold a medicinal product he named "alkali pneum." The Society for the Promotion of Natural Sciences tested Hahnemann's product and discovered it was actually just common borax. The following year, for the same cost, Hahnemann sold what he claimed was a new "infallible preventive of scarlet fever." The product was simply extract of Belladonna, Deadly Nightshade.<sup>29</sup>
- 38. Hahnemann developed additional components of his theory, including the need to conduct "provings." These provings were intended to determine the symptoms an item would elicit in healthy individuals.
- 39. The provings process and cataloguing of the results were neither standardized nor adequately controlled. For example, an early proving of *Arnica montana*—one of the items Plaintiff purchased—lists the following among many more:
  - Sensation of coldness on a small spot on the forehead, as if he were touched there by a cold thumb.
  - The scalp down to the eyebrows lies closely attached to the skull, and is almost immovable (aft. 6 h.).
  - On the side of the forehead pimples, partly filled with pus (aft. 3 d.).
  - Dry heat in the face towards evening to behind the ears, without thirst, with very cold nose (aft. 24 h.).

<sup>&</sup>lt;sup>28</sup> The phrase is often written as either "similia similibus" or "similia similibus curentur." In 1899, the American Institute of Homeopathy "redefined homeopathy's law of similars as 'let like be cured by like,' and made it 'less a law than a guide to therapy." Suzanne White Junod, <u>An Alternative Perspective: Homeopathic Drugs, Royal Copeland, and Federal Drug Regulation</u>, 55 Food Drug L.J. 161-83, 167 (2003).

<sup>&</sup>lt;sup>29</sup> Remarks on the Character and Writings of Hahnemann, *supra*.

- The border of the upper eyelid, where it touches the eyeball internally, is painful when the eyeball is moved, as if it were too dry and somewhat sore.
- After eating a kind of suppressed incomplete hiccup.
- She wants always to drink, and knows not what, because everything is repugnant to her.
- After the (evening) meal she weeps, is peevish, will listen to nobody, and will not hear of anything.
- On reading for a long time he grows giddy and sick.<sup>30</sup>
- 40. Hahnemann relied upon the myriad provings to pick and choose among the myriad reactions to decide the particular uses for an item. For example, *Arnica montana* "is very beneficial in the most severe wounds by bullets and blunt weapons, and also in the pains and other ailments consequent on extracting the teeth, and in other surgical operations whereby sensitive parts have been violently stretched, as also after dislocations of the joints, after setting fractures of the bones, &c" but it should never be used "in purely inflammatory acute diseases, with general heat, chiefly external, nor in diarrheas."<sup>31</sup>
- 41. Hahnemann, aware that the items remained dangerous and "aggravated" symptoms, i.e., were harmful, instead recommended that dilutions should be used. For *Arnica montana*, the best for "internal use is the decillionth [1 part to 99 parts dilutant] development of power." From the heavily diluted substances comes the now common term "law of infinitesimal doses"—a phrase Hahnemann did not himself employ.
- 42. By 1810, Hahnemann compiled his theories into *Organon of the Medical [Healing]*Art, the so-called "bible" of homeopathy in which he used the term for the first time. He published

<sup>&</sup>lt;sup>30</sup> Samuel Hahnemann, Materia Medica Pura (1880), 93-97.

<sup>&</sup>lt;sup>31</sup> *Id.* at 89-90.

<sup>&</sup>lt;sup>32</sup> *Id*.

several more editions, changing and adding to his theories in response to criticism and the inherent failures of the existing theories.

- 43. In the fourth edition, Hahnemann introduced his theory of miasm—that 7/8 of all chronic disease are caused by *psora* (itch) and the remaining by "wart-disease" (syphilis).<sup>33</sup> In the following edition, Hahnemann included for the first time his theory of "dynamization"—that the highly diluted homeopathic ingredients must be able to maintain their "curative effects" as a result of a precise, exacting number of ritual "shakings."
- 44. Homeopathy was conceived of as a particularly individualized approach and was intended to be utilized as such—"[f]rom its beginning homeopathy always began with a long consultation, lasting at least an hour, in which all aspects of the patient's illness and life were discussed…"<sup>34</sup>
- 45. Homeopathy was eventually imported to the United States, where it "underwent considerable modifications at the hands of its most influential adherents."<sup>35</sup> The early 20<sup>th</sup> century saw the rise of "classical homeopathy" that is "not only a considerable modification of Hahnemann's teaching, but it fails to take account of Hahnemann's late ideas which he developed in his Paris years and incorporated in the sixth edition of 'The Organon', published posthumously in 1920."<sup>36</sup>
- 46. At the same time, as standards for medical education were elevated, homeopathy began to languish, and the products "enjoyed only a limited market." As government oversight turned to medicinal drugs, homeopathy was mostly overlooked "under the continuing assumption

<sup>&</sup>lt;sup>33</sup> Remarks on the Character and Writings of Hahnemann, supra.

<sup>&</sup>lt;sup>34</sup> Loudon, *supra*, at 607-09.

<sup>&</sup>lt;sup>35</sup> Anthony Campbell, <u>The Origins of Classical Homoeopathy?</u>, 7 Complementary Therapies Med. 76-82 (1999).

<sup>&</sup>lt;sup>37</sup> Junod, *supra*, at 179.

that homeopathy was a dying specialty."<sup>38</sup> During the 1960s and 70s, homeopathy saw a resurgence.

47. Homeopathy eventually grew into the commercialized, multi-billion-dollars industry of today, albeit without its original individualized nature.

#### Boiron's Pills and Powders: Promised Panacea based on Homeopathic Hokum.

- 48. Defendant manufactures, markets, distributes and sells homeopathic products through retailers and directly to consumers. It utilizes marketing materials, endorsements, product descriptions, mobile apps and websites to convey the same message to consumers: purchase a particular Boiron product to treat and heal a specific health condition.
- 49. Boiron broadly classifies its products as either a "single medicine" or "combination medicine." It further groups its products into categories corresponding to the general injury, medical and health issues it claims the items will treat. The categories include, among others, "First Aid Skin," "Joint and Muscle Pains," "Motion Sickness and Nausea."
- 50. Single medicines are said to contain one "active ingredient," which Boiron promises consumers are "homeopathic relief that's targeted to symptoms," and "do not mask symptoms..."

<sup>&</sup>lt;sup>38</sup> *Id*.

<sup>&</sup>lt;sup>39</sup> https://www.boironusa.com/product-category/all-products/single-medicines (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>40</sup> See, e.g., Chestal® Cold & Cough, "all-in-one day & night formula" to "treat common cold and cough symptoms, including nasal and chest congestion" contains *Dulcamara*, *Ferrum phosphoricum*, *Hydrastis canadensis*, *Kali bichormicum* and *Nux vomica* (https://www.oscillo.com/cough-cold-flu/chestal-cold-cough (last visited Apr. 13, 2022)); Cyclease® PMS, treats "minor aches, lower back pain, bloating, water retention, discomfort, emotional changes, and irritability" contains *Folliculinum*, *Natrum muriaticum* and *Sepia*. (https://www.boironusa.com/product/cyclease-pms (last visited Apr. 13, 2022))).

<sup>&</sup>lt;sup>41</sup> Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf (last visited Apr. 13, 2022).

<sup>42</sup> https://www.boironusa.com/single-medicines (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>43</sup> Boiron, Inc., Easy Guide to Homeopathic Medicines (2021), 2.



51. Defendant sells its single medicines in "Boiron blue tubes." Each tube is adorned with peel-back "Drug Facts" that are materially identical across the entirety of the product line:



On Boiron's website<sup>45</sup>



Same item, purchased by Plaintiff

52. On the front of each product, Defendant informs the consumer of the product's abilities. Boiron promises consumers the effects and results they should expect after use:



Items purchased by Plaintiff.

From top to bottom, Staphysagria ("Relieves promotes healing of surgical wounds", Phosphoricum ("Relieves poor concentration due to overwork"), Arnica ("Relieves muscle pain and stillness, swelling from injuries, discoloration from bruising").

<sup>&</sup>lt;sup>44</sup> <u>Boiron product page for Arnica montana</u>, https://www.boironusa.com/product/arnica-montana (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>45</sup> Boiron product page for Staphysagria, https://www.boironusa.com/product/staphysagria (last visited Apr. 13, 2022).

- 53. Defendant also lists the product's "active ingredient," a homeopathic preparation of one of the various "source items" upon which it is based. Boiron represents to consumers that any beneficial effects of the product are due to the homeopathic preparation of the source item. In turn, Boiron conveys that the source item is also curative.
- 54. For each product, Defendant instructs consumers, irrespective of illness, injury or symptoms, to "dissolve 5 pellets under the tongue 3 times a day until symptoms are relieved or as directed by a doctor."

#### **Defendant's Deception Detailed.**

- 55. Homeopathy, and therefore each Boiron product, is based on two central claims:
  (1) an item that harms will cure similar harms and, (2) the more dilute that item is, the more powerful its curative effects will be. Therefore, for each Boiron product, Defendant represents to consumers, or leaves them to believe, that:
  - (i) the source item is an effective treatment for the injury, illness or condition for which the Boiron product is sold;
  - (ii) the active ingredient, made from the source item, is an effective treatment for the injury, illness or condition for which the Boiron product is sold; and,
  - (iii) the product, that contains the active ingredient, is an effective treatment for the injury, illness or condition for which the Boiron product is sold.
  - 56. Defendant's representations, independently and jointly, are deceptive.
- 57. Consumers are misled, or left with the false impression, that each Boiron product, its active ingredients and source items have the purposes, uses, benefits and effects Defendant represents they do and that each is supported by substantial, credible and reliable scientific evidence. They do not and are not.

- 58. Defendant has not, and cannot, reliably substantiate its representation that the source items are effective for their purported uses.<sup>46</sup> This is not surprising given the faulty basis for the homeopathic belief that "what harms you will cure them."<sup>47</sup> The same, therefore, is true of the active ingredients and the entirety of a Boiron product since both are built on the same faulty foundation.
- 59. Yet, even if there were support that a source item was effective, Boiron products contain ingredients so diluted that <u>no molecules</u> of the item remain.
- 60. Further, despite no material differences among Boiron products, Defendant represents to consumers that each product is specifically and uniquely tailored to effectively treat particular issues. Defendant, in part, achieves the deception through falsities, omission, ambiguity and innuendo.
- 61. Each Boiron product contains a heavily diluted ingredient that is provided in miniscule doses of an active ingredient. Yet Defendant's exacting differentiation for each product, and that each has explicit doses and directions, conveys to consumers that there is, and Boiron has, a legitimate, proven basis for its claims and promises.
- 62. The deception, in part, compels consumers to purchase one or more items when in fact all Boiron products are materially and effectively the same; every amount of doses, whether one pellet or an entire bottle, are materially and effectively the same; all products will achieve the same result; and the self-limiting conditions for which Boiron sells its products will resolve at the same rate without the purchase and use of its products.

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<sup>&</sup>lt;sup>46</sup> See, e.g., Gerald Gartlehner et al., <u>Assessing the Magnitude of Reporting Bias in Trials of Homeopathy: A Cross-Sectional Study and Meta-Analysis</u>, 2022 BMJ Evidence-Based Med. (meta-analysis finding those studies which support homeopathic efficacy are biased and unreliable).

<sup>&</sup>lt;sup>47</sup> See ¶35, supra.

- 63. To a consumer who suffers a stye on the upper eyelid, Boiron recommends and sells the treatment Staphysagria 6C (highly toxic Lice-bane).<sup>48</sup> While to the same consumer with a recurrent stye, Boiron recommends and sells Silicea 6C (silica).<sup>49</sup>
- 64. To a consumer with bleeding gums with a bad taste in the mouth, Boiron recommends and sells the treatment Mercurius solubilis 6C (toxic mercury).<sup>50</sup> While to the consumer with bleeding gums without a bad taste, Boiron recommends and sells Phosphorus 6C (the military incendiary, white phosphorus).<sup>51</sup>
- 65. Boiron recommends and sells Magnesia phosphorica for the treatment of "writers cramp," while the same consumer is directed to Arnica for the treatment of "musician cramps." 53
- 66. Despite no material difference between the items, each time a consumer is offered and purchases a Boiron product, they do so because of Defendant's deception.
- 67. Alternatively, to the extent Defendant does not make specific claims as to an item's uses, purposes and effects, Defendant nevertheless deceives consumers. Neither Defendant nor the Boiron products actually, or event attempt to, effectively dissuade consumers from the belief that the items will do what they are represented to do.

<sup>&</sup>lt;sup>48</sup> Stye, On upper eyelid, Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/?category=Eye% 20care&mainsymptom=Stye&addsymptom=On%20upper%20eyelid (last visited Apr. 13, 2022).

<sup>49 &</sup>lt;u>Stye, Recurrent</u>, Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/?category=Eye% 20care&mainsymptom=Stye&addsymptom=Recurrent (last visited Apr. 13, 2022).

bleeding gums, With a bad taste in the mouth, Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/?category=Oral%20Care&mainsymptom=Bleeding%20gums&addsymptom=With%20a%20bad%20taste%20in%20the%20mouth (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>51</sup> <u>Bleeding gums, Other</u>, Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/?category=Oral% 20Care&mainsymptom=Bleeding%20gums&addsymptom=Other (last visited Apr. 13, 2022).

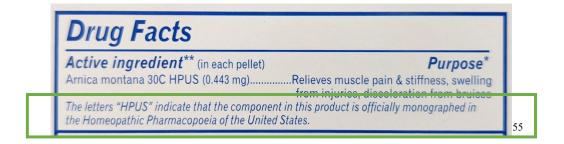
<sup>&</sup>lt;sup>52</sup>Writers cramp, With shooting pain, Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/? category=Joint%20and%20Muscle%20Pains&mainsymptom=Writers%20cramp&addsymptom=With%20shooting %20pain (last visited Apr. 13, 2022).

Musician cramps, Boiron Homeopathic Medicine Finder, https://www.boironusa.com/mf/? category=Joint%20and%20Muscle%20Pains&mainsymptom=Musician%20cramps (last visited Apr. 13, 2022).

- 68. In the event a consumer is left with the impression a product somehow achieved the promised results, Boiron's deception is not lessened. Irrespective of the product or claims, the active ingredient or source item is not the mechanism of any beneficial change.
- 69. Whatever the cause may be—placebo effect, natural healing of the self-limiting conditions for which Boiron recommends its products, increased attention, suggestion, change in harmful or unpleasant external factors or simply a difference in the perception of reality—the purchase and use of a Boiron product was not the cause. A perceived outcome does not erase Boiron's prior deceit since, simply, a Boiron product is neither medicine nor treatment.
- 70. To further its deception, when Defendant lists an active ingredient and the corresponding purpose for which it is sold, Boiron refers to each substance solely in its "Latinized" designation, not its commonly used name.
- 71. Consumers are left with the false impression that the source article is or was transformed into an effective ingredient, able to achieve the purposes Boiron promises it will rather than the ordinary item they would recognize and understand.
- 72. For instance, Boiron sells *Saccharum officinale* for "nervous agitation in children after overindulgence." Consumers would recognize, and fully understand, what *Saccharum officinale* actually is if Defendant did not omit its common name: "table sugar." Aware of the truth, no reasonable consumer would purchase heavily diluted sugar sold by Boiron as a pellet, which itself is entirely made of sugar.
- 73. Along with the active ingredient, on its products and marketing materials, Defendant states that "[t]he letters 'HPUS' indicate that the component in this product is officially monographed in the Homeopathic Pharmacopeia of the United States."

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<sup>&</sup>lt;sup>54</sup> <u>Boiron product page for Saccharum officinale</u>, https://www.boironusa.com/product/saccharumofficinale (last visited Apr. 13, 2022).



- 74. The statement and Defendant's use are deceptive. Defendant represents to consumers, or leaves them to believe, that the ingredient was evaluated and approved by a governmental, regulatory body. In reality, the HPUS is owned by a private organization—the Homœopathic Pharmacopæia Convention of the United States ("HPCUS")—which is left free to operate without oversight.<sup>56</sup>
- 75. Defendant's representation and omission leave consumers with the false and mistaken impression that items in the HPUS are included only after their effectiveness is proven by rigorous scientific examination supported by substantial, compelling and reliable evidence.
- 76. Defendant deceives consumers, through omission, innuendo or ambiguity, into the belief that an HPUS monograph sets out the use, purpose, symptoms, appropriate dosage, and conditions that the ingredient and product are able to treat.
- 77. By representing to consumers that an independent body approved its claims, Defendant lends itself undeserved, unearned credibility. Boiron leverages the fact that consumers recognize and are familiar with FDA OTC monographed medicines—items such as Tylenol and Advil. Mimicking the information these science-backed items are mandated to convey, Boiron

<sup>&</sup>lt;sup>55</sup> Photo of a box of Arnica purchased by Plaintiff. The single products contain a materially similar statement: "The letters 'HPUS' indicate that the component(s) in this product is (are) officially monographed in the Homeopathic Pharmacopoeia of the United States."

<sup>&</sup>lt;sup>56</sup> https://www.hpus.com (last visited Apr. 13, 2022).

compels the mistaken belief that the HPUS monograph also contains all the information found in FDA monographs.<sup>57</sup>

- 78. And while OTC monographed medicines are approved by the FDA because they are safe and effective, an HPUS monograph simply states how a homeopathic items should be prepared, e.g., how much of the purulent secretion from a gonorrhea infected person should be added to distilled water to end up with *Medorrhinum*. Defendant relies on consumers' universal lack of knowledge about the HPUS to induce the purchase of Boiron products.
- 79. As Defendant cultivates and abuses these false impressions, it withholds from consumers a materially significant conflict of interest between HPCUS and Boiron—that is, the chairman of the HPCUS Monograph Review Committee, Mark Land, is Boiron's Vice President of Government and Regulatory Affairs.<sup>58</sup>
- 80. And, should the rare consumer actually search for an ingredient's "official monograph," the consumer will find that the HPUS is not even published in hardcopy, rendering it nearly impossible to learn the truth about the product—a fact Boiron knows or should know given its connection to HPCUS.
- 81. In order to consult the HPUS, a consumer must access an online database. But first, the consumer would be forced to pay HPCUS \$2,000 for the privilege of learning about an \$8.49 Boiron product—something else Defendant knows or should know and that it uses to consumers' detriment.<sup>59</sup>

<sup>&</sup>lt;sup>57</sup> For a list of current FDA OTC Monographs, *see* https://www.accessdata.fda.gov/scripts/cder/omuf/index.cfm

<sup>&</sup>lt;sup>58</sup> HPCUS "Service to Homeopathy Award" Presented to Mark Land, Chain Drug Rev., May 8, 2020 (accessible at https://www.chaindrugreview.com/hpcus-service-to-homeopathy-award-presented-to-mark-land (last visited Apr. 13, 2022)). Land is also the current President of the homeopathy industry trade and lobbying group, American Association of Homeopathic Pharmacists—a partner organization of HPCUS. <u>Board of Directors</u>, https://www.theaahp.org/who-is-aahp/#board (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>59</sup> What is the HPUS Online Database?, https://www.hpus.com/what-is-the-hpus-online-database.php (last visited Apr. 13, 2022). HPCUS states it will allow limited, no cost access to an "educator, student or researcher" but does so at its sole discretion. HPCUS denied CFI's request for access. CFI is currently in litigation against the Department

- 82. Defendant represents to consumers that its products have "no known drug interactions." Boiron deceives consumers regarding the safety of homeopathic ingredients by conveying that they and the products they include are a safe alternative to medicine made by other manufactures. Consumers are led to believe that homeopathic products are risk-free when, in reality, adverse effects can and do occur, <sup>60</sup> and the lack of an FDA monographs means the agency has not confirmed the products are effective and safe.
- 83. On each item, Defendant lists the product's inactive ingredients, in order, as "lactose, sucrose." Defendant informs consumers that its products' "pleasant taste comes from very small amounts of lactose and sucrose inactive ingredients that are essential to the medicine's quality."
- 84. Defendant deceives consumers, through falsity, misrepresentation and ambiguity, about the contents of its products.
- 85. At the outset, homeopathy mandates, or places a premium, on the use of lactose (i.e., milk sugar) to which Boiron does not adhere:

THE PREPARATION OF DRUGS—TRITURATIONS.

Trituration is that process by which the drug particles are still further broken up and isolated. This is accomplished by means of an inert substance, viz., sugar of milk, it being mainly employed in the case of metals, a majority of chemical salts and dried vegetable substances.

86. This is due, in part, to the fact that Boiron products do not contain "very small amounts" of sugar as claimed. Instead, they are mostly, if not entirely, sugar.

of Health and Human Services in an attempt to gain access to the HPUS through the Freedom of Information Act, *Center for Inquiry, Inc. v. HHS, et al.*, Civ. No. 21-3118, (D.D.C. 2022).

<sup>&</sup>lt;sup>60</sup> See, e.g., Trine Stub et al., <u>Adverse Effects of Homeopathy</u>, <u>What Do We Know? A Systematic Review and Meta-Analysis of Randomized Controlled Trials</u>, 26 Complementary Therapies Med. 146-63 (2016) (Meta-analysis of homeopathic trials finding 68% of trials reported adverse effects).

<sup>&</sup>lt;sup>61</sup> Easy Guide to Homeopathic Medicines, supra at 9.

<sup>62</sup> The United States Homœpathic Pharmacopœia (1 ed. 1878), 24, 27.

- 87. Defendant lists lactose in the inactive ingredients section as the first ingredient. Boiron products contain no, or almost no, lactose and the cost and value of lactose is substantially greater than that of sucrose (i.e., table sugar).
- 88. As such, Defendant represents false and deceptive statements to consumers. It relies on consumers' common understanding that products list inactive ingredients in descending order of predominance. Accordingly, consumers believe Boiron products contain more lactose than sucrose.
- 89. However, Defendant deprives consumers of the Boiron product as advertised and instead delivers a lesser item.
- 90. Defendant sells Boiron products in various "dilutions." It represents to consumers, albeit with some inconsistency, that different dilutions will be "right" for a particular condition:

  Compare: with:

WHICH ONE IS RIGHT FOR ME?

6C, 6X, 9C
LOW DILUTIONS =
LOCAL SYMPTOMS
Symptoms that you can point to with
your finger such as bumps, bruises,
sore throats, joint pain, cramps, etc.

12C, 15C, 30C, 30X
HIGH DILUTIONS =
CENERAL + BEHAVIORAL SYMPTOMS
Symptoms such as fever,
apprehension, sleeplessness,
rash, etc.

Here's a quick guide to using homeopathic medicines: Low dilutions, such as 6X or 6C, will relieve local symptoms — a symptom you can point a finger at (e.g., an insect bite or bruise). Medium dilutions, such as 12X, 9C or 12C, will relieve general symptoms — more than one symptom in more than one location (e.g., muscle aches and pains). High dilutions, such as 30X or 30C, will relieve general symptoms — more than one symptom in more than one location with possible behavioral or emotional symptoms (e.g., a very high fever and chills, accompanied by agitation or

(6X or 6C for symptoms "you can point a finger at" and 9C "will relieve general symptoms)<sup>63</sup>

200CK is used by skilled homeopathic practitioners.

(9C for symptoms "you can point to with your finger")<sup>64</sup>

<sup>&</sup>lt;sup>63</sup> What is the difference in dilution levels?, https://www.boironusa.com/faq/what-is-the-difference-in-dilution-levels (last visited Apr. 3, 2022).

<sup>&</sup>lt;sup>64</sup> Boiron product page for Arnica montana, supra.

- 91. Defendant charges consumers a significantly greater monetary amount for the more highly diluted item. For instance, Boiron sells the 30C dilution of Staphysagria for \$8.49 while the 1M dilution costs \$11.99—a 41.225% increase.<sup>65</sup>
- 92. Defendant represents to consumers, or leaves them to believe, that there is a material difference between each dilution. After all, Boiron <u>must</u> have a legitimate reason for the recommendation or it would not have so many options.
- 93. Boiron's explicit recommendations of which product a consumer should use to treat a particular ailment, coupled with the specific differentiations, are used to convince, or leave consumers with the mistaken belief, that each product will actually achieve the promised results. However, the uses and recommendations for each product are arbitrarily chosen by Boiron.
- 94. Defendant also deceptively charges a premium for the higher dilution even though it is in all material aspects identical to the less expensive item. Purchasing and using either product will result in the same outcome—but for its effect on a consumer's bank account—since each dilution contains the same amount of detectible source article (that is, none).
- 95. More so, Defendant markets and sells its products without knowing that the product actually contains the claimed dilution. Boiron represents to consumers that the higher dilution products have a specific ratio of source item to dilutant. As Boiron is confined to the physical realities of the universe, it cannot state with any amount of confidence, let alone certainty, that the promised ratio is correct.<sup>66</sup>

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<sup>&</sup>lt;sup>65</sup> Boiron product page for Staphysagria, *supra*.

<sup>&</sup>lt;sup>66</sup> Oscillo is sold at the 200C dilution—1 part *Anas barbariae* to 99 parts dilutant, the result of which is added as 1 part to 99 parts dilutant and repeated so that there are 200 total sequential dilutions. The final ratio of *Anas barbariae* to dilutant is represented as 1:10<sup>-400</sup> (10 followed by 400 zeros). By comparison, a ratio of one molecule of Oscillo to the entirety of the universe would equate to about a 40C dilution, which is significantly less dilute than the product Boiron sells. *See*, Park, R. L., *Superstition: Belief in the Age of Science*. Princeton University Press, 2008, at 146. *See also*, "Moves toward FDA requirements: Establishing homeopathic finished products specification and shelf life," presentation by Boiron Regulatory Affairs Officer Fanny Guillot at AAHP Summit on Challenges & Solutions in

- 96. Defendant represents that each Boiron product is "medicine." When Boiron uses that word on its products and marketing materials, it does not do so colloquially or metaphorically but explicitly, with deceptive intent and deceptive effect. Boiron does not use the word to convey to consumers what the product "is," but rather to mislead consumers about what the product "does."
- 97. That Defendant puts the term "homeopathic" prior to "medicine" neither lessens nor negates its deception. At the outset, Boiron's use of the term is ambiguous as Boiron makes no effort to elucidate consumers as to its meaning, or what Boiron intends it to mean.<sup>68</sup>
- 98. Defendant also knows, or should know, that even if a consumer is aware of the term "homeopathy," the vast majority do not understand it. Further still, for a significant number of consumers, the term does not even register. Indeed, recent data collected by the homeopathy industry indicates that:
  - Of those who purchased a brand of homeopathic products, <u>85% did not know it</u> was homeopathic;
  - While just 15% of women consumers believed they purchased homeopathic products, 37% actually did—an 84% difference between aware and unaware purchasers; and,
  - Although 91% of purchasers are aware of the term "homeopathic," the same consumers do not know what homeopathy is or how it works.

Quality & Safety of Homeopathic Drug Products (2019), 20. (stating 8X, 4C, dilution is too high to permit detection of homeopathic constituent).

<sup>&</sup>lt;sup>67</sup> "Medicine" is defined as "[t]he science and art of diagnosing and treating disease or injury and maintaining health. The branch of this science encompassing treatment by drugs, diet, exercise, and other nonsurgical means," while "treatment" is defined as "[t]he use of an agent, procedure, or regimen, such as a drug, surgery, or exercise, in an attempt to cure or mitigate a disease, condition, or injury. The agent, procedure, or regimen so used." <u>The American Heritage® Medical Dictionary</u> (2007).

<sup>&</sup>lt;sup>68</sup> See ¶45, supra.

## Awareness is Growing...

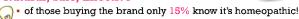


# SHOPPER "BUYING" NATURAL, SAFE, AND EFFECTIVE



• 91% of purchasers are aware of the term *homeopathic* by word of mouth... but they don't know what it is or how it works!

#### Natural, Safe, Effective



- 20% of those buying OTC cold remedies buy BOTH homeopathic & allopathic
   while only 9.2% buy homeopathic only
- = 15% of all women believe they have purchased a homeopathic treatment in the last 24 months...37% DID!  $_{\mbox{\scriptsize (m)}}$



The Emerson Group

\*WSL Survey 3,092 Respondents. \*National Consumer Panel IR Total US All Outlets

- 99. In addition to using consumers' confusion to their detriment, Defendant represents that Boiron products are no different from science-based medicine; clinically proven safe and effective by substantial competent evidence; capable of treating health conditions, illness and injury.
- 100. From the declaration that the product is medicine, to endorsements by medical professionals, to the use of familiar terms from approved, science-based medicines and monographs, Boiron spins a tale intended to mislead and deceive:





<sup>69</sup> The State of Homeopathy, The Emerson Group and American Association of Homeopathic Pharmacists (2020).

Advil Pain Reliever and Fever Reducer, Pain Relief Medicine with Ibuprofen 200mg for Headache, Backaches, Menstrual Pain and Joint Pain Relief, https://www.amazon.com/Advil-Reliever-Reducer-Ibuprofen-Temporary/dp/B0000VLK4O (last visited Apr. 13, 2022).



Neosporin, First Aid Antibiotic Ointment, https://www.walmart.com/ip/Neosporin-Faster-Result-Antibiotic-Original-Ointment-0-5-Oz/125597456 (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>72</sup> Tylenol Cold + Flu Severe Medicine Caplets for Fever, Pain, Cough & Congestion, https://www.amazon.com/TYLENOL-Symptom-Relief-Caplets-Acetaminophen/dp/B009ITR4EY (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>73</sup> https://www.amazon.com/gp/product/B006H9THXY (last visited Apr. 13, 2022).

101. Tucked away on various webpages, marketing materials and products, Defendant utilizes what is generally referred to as the "AAHP Disclaimer:"<sup>74</sup>



"Claims based on traditional homeopathic practice, not accepted medical evidence. Not FDA evaluated"

- 102. Defendant does not utilize this statement as a warning to consumers nor intend it to be one. Instead, Boiron palters and equivocates. The statement is intentionally misleading, replete with omission, innuendo and ambiguity intended to deceive.
- 103. The representation "Not FDA evaluated" is by all accounts true. And while it is unclear whether it refers to Boiron's claims of the product's purposes, uses or to the product in its entirety, the FDA did not evaluate any of the foregoing. So while true, it is not the whole truth and it is deceptive.
- 104. Boiron's products are not evaluated because they <u>are not approved</u>—no Boiron product has passed through the requisite FDA approval process and therefore no Boiron product

<sup>&</sup>lt;sup>74</sup> https://www.theaahp.org/compliance/testing-the-new-aahp-disclaimer-for-effectiveness (last visited Apr. 13, 2022) (AAHP, the American Association of Homeopathic Pharmacists, is an industry trade and lobbying group to which Boiron belongs. The current President of AAHP is Mark Land, Boiron's Vice President of Government and Regulatory Affairs and chairman of the HPCUS Monograph Review Committee).

<sup>&</sup>lt;sup>75</sup> Photo of three Boiron Blue Bottles of Arnica 30C purchased by Plaintiff, arranged so that text that wrapped around the bottles is visible in its entirety.

has been proven safe and effective. Nevertheless, Defendant represents the products as direct replacements for approved OTC products.

- 105. Defendant's partly true statement is intended to obfuscate and avoid the disclosure of relevant, material facts. Defendant leads consumers to believe that it was not required to have each Boiron product evaluated <u>and approved</u> by the FDA and it deprives consumers of the full truth—Boiron products are not proven safe or effective, on their own and relative to products that passed through the New Drug Application ("NDA") process.<sup>76</sup>
- 106. Boiron products contain items defined by federal law as "drugs"<sup>77</sup> and therefore are required to obtain FDA approval through the NDA process.<sup>78</sup>
- 107. An NDA is used, in part, to approve "drugs shown to be safe and effective" and entails the evaluation by the FDA of substantial scientific support.<sup>79</sup> Since Defendant declares on each product that the item was not evaluated by the FDA, Defendant admits, or must admit, that no Boiron product is approved by the FDA.<sup>80</sup>
- 108. This means that the FDA and an expert panel of chemists, statisticians, microbiologists, pharmacologists and medical doctors did not determine Boiron products are safe and effective.
- 109. There was no authoritative confirmation of Boiron products' behavior in the body; no authoritative confirmation that any of the product's labeling is accurate; no authoritative confirmation that any of the product's benefits outweigh the risks of use; no authoritative confirmation that Boiron products are adequately manufactured to maintain strength, quality and

<sup>&</sup>lt;sup>76</sup> See, 21 C.F.R. §§ 314.1, et seq.

<sup>&</sup>lt;sup>77</sup> See, 21 U.S.C. § 321

<sup>&</sup>lt;sup>78</sup> See, 21 C.F.R. §§ 314.1, et seq.

<sup>&</sup>lt;sup>79</sup> 21 C.F.R. § 314.50

<sup>&</sup>lt;sup>80</sup> Whether or not Defendant is in violation of federal law is not at issue. The fact that Boiron products are not evaluated <u>and</u> not approved renders Defendant's statement deceptive.

purity; no authoritative confirmation that any of the products are safe and effective; and, no authoritative confirmation that Boiron's claims are backed by clinical trials supported by substantial, competent evidence.<sup>81</sup>

- 110. Consumers would not knowingly purchase Boiron products, especially while eschewing approved products, if they were aware of the complete truth. Boiron omits the truth while distracting consumers with its deceptive "disclosure."
- 111. Defendant misrepresents that its claims are based on traditional homeopathic practice.

#### 112. Boiron declares,

"With a rigorous scientific approach, Samuel Hahnemann – the doctor behind the advent of homeopathy - precisely defined the various phases in the manufacturing process. Today, the quality of homeopathic medicines still depends on compliance with this unique process, which we master every step of the way." 82

- 113. Defendant attempts to launder its worthless products through the use of the vagaries of the term "homeopathy"—a term that carries little if any meaning to the majority of consumers.<sup>83</sup>
- 114. Still, Boiron products are a far cry from Hahnemann's theories and, to the extent they do actually follow Hahnemann's orthodoxy, Boiron obscures the overwhelming number of fallacies inherent in his theories.
- 115. Nevertheless, by referring to its products as being based on "traditional...practice," Defendant represents that Boiron products are time-tested to be effective. Consumers would not purchase Boiron products if they were made fully aware of what homeopathy really is, how it was created, and that it, and Boiron's claims, are based on unproven theories no different from magic.

<sup>81</sup> See, e.g., 21 C.F.R. §§ 314.1, et seq.

<sup>82</sup> Boiron, Inc., Reliability of Homeopathic Medicine, An Essential Requirement, 5.

<sup>&</sup>lt;sup>83</sup> Footnote 69, *supra*.

- 116. Defendant doubles down on the deception when it states "claims ... not [based on] accepted medical evidence." Boiron's message is not that its products are unproven, pseudoscientific panacea. Rather it represents to consumers that there <u>is</u> scientific evidence of the truthfulness of its claims; it just is not accepted by those who do not adhere to homeopathy's theories.
- 117. More so, Defendant again tells consumers only a part of the truth. AAHP well states the message Boiron intentionally obscures and fails to disclose to consumers:

"the homeopathic product claim was not based on science nor was accepted by modern medical experts." (emphasis added) 84

118. The listing for Boiron Arnica in the National Drug Code Directory<sup>85</sup> further rounds out the truth withheld from consumers,

"This homeopathic product has not been evaluated by the Food and Drug Administration for <u>safety or efficacy</u>. FDA is not aware of <u>scientific evidence</u> to support homeopathy as effective." (emphasis added)<sup>86</sup>

#### Purchased Products Analyses Confirms Defendant's Deceit.

119. Plaintiff purchased four products marketed and sold by Defendant: Oscillo, a trademarked Boiron product; and Staphysagria, Phosphoricum and Arnica, Boiron single medicine products. Two samples of each item were analyzed using Fourier transform infrared spectroscopy ("FTIR") and scanning electron microscopy and energy dispersive X-ray spectroscopy ("SEM-EDS"). The analyses, respectively, were used to determine the organic and inorganic compounds within each sample.

<sup>&</sup>lt;sup>84</sup> <u>Testing the New AAHP Disclaimer for Effectiveness</u>, https://www.theaahp.org/compliance/testing-the-new-aahp-disclaimer-for-effectiveness (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>85</sup> National Drug Code Directory, https://www.fda.gov/drugs/drug-approvals-and-databases/national-drug-code-directory (last visited Apr. 13, 2022).

National Institutes of Health DailyMed, Label: ARNICA- arnica montana pellet, https://dailymed.nlm.nih.gov/dailymed/drugInfo.cfm?setid=1ce3fd1f-24f8-491c-a0ae-087ea3d20040&audience=consumer (last visited Apr. 13, 2022).

- 120. The results of the analyses confirm Defendant's deceptive acts.
- 121. Specifically, the FTIR measurements for each sample, and therefore the samples' components, indicate a greater than 99% match to sucrose, common table sugar.
- 122. No lactose was found in any sample despite Defendant's representation that lactose was an ingredient and, as explained above, <sup>87</sup> would be found in greater quantities than sucrose.
  - 123. Further, no trace of any active ingredient or source item was found.
- 124. In addition, the SEM-EDS results for Arnica indicate the sample contained 24.3% of the chemical element silicon. Therefore, in addition to not containing the promised ingredients, Boiron's product also contained a significant amount of an ingredient it failed to disclose to consumers.

## Deceptive practices particular to Boiron's Oscillococcinum product.<sup>88</sup>

- 125. In addition to the deceptive practices employed in the marketing and sale of its single medicine products, Defendant violated the CPPA in ways particular to Oscillo.
- 126. Boiron markets and sells Oscilliococcinum as an effective treatment for influenza. The listed active ingredient is "Anas barbariae," "200CK HPUS" the purpose of which is "to reduce the duration and severity of flu-like symptoms."
  - 127. The "inactive ingredients" are also listed as "lactose, sucrose."
- 128. As with the single medicines, FTIR and SEM-EDS results show Oscillo did not contain any detectable lactose, any active ingredient or any source item.

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<sup>&</sup>lt;sup>87</sup> See ¶88, supra.

<sup>&</sup>lt;sup>88</sup> "Oscillo is made by mixing one percent Anas Barbariae Hepatis et Cordis Extractum—that is, duck hearts and livers—with 99 percent water, repeating the dilution process 200 times, and then selling the result in pill form. The repeated dilutions render the finished product nothing more than a placebo. Boiron's claim that Oscillo has a therapeutic effect on flu symptoms is thus highly doubtful." *Conrad v. Boiron, Inc.*, 869 F.3d 536, 538 (7th Cir. 2017).

- 129. Defendant charges between \$11.99 for a box of six doses up to \$32.99 for a box of 30 doses.<sup>89</sup> Defendant recommends the product for "everyone ages 2 and up" and directs consumers, irrespective of age, to use one dose per every six hours, up to three times a day.
- 130. On the front of the package, Defendant states Oscillo's doses are "0.04 oz each." The rear of the package states, "each 0.04 oz dose (1 g) contains 1 g of sugar." In the same standard of weight Boiron uses on the front of the package, which it deceptively does not use on the rear of the package, each dose in a six dose box costs \$2.00.
- 131. Each \$2.00 dose of Oscillo contains less than one half of one percent of the advertised active ingredient, 90 a material fact obscured by Defendant.
- 132. Defendant induces consumers to purchase Oscillo by assuring them that it "won't mask symptoms," it "works naturally with [the consumer's] body" to "temporarily relieve fatigue, headache, body aches, chills & fever" and it will "reduce[] both the duration & severity of flu-like symptoms."
- 133. Defendant's claims are grounded neither fact nor competent, reliable scientific evidence. As it does with the single medicine products, Defendant misrepresents the uses and benefits of Oscillo and *Anas barbariae* 200CK HPUS. Defendant affirmatively or through innuendo or ambiguity, misleads consumers about the product dose, directions, purposes and uses of Oscillo as well as the miniscule amount of active ingredient and complete absence of the source item.<sup>93</sup>

<sup>89</sup> Boiron product page for Oscillococcinum®, https://www.boironusa.com/product/oscillo (last visited Apr. 13, 2022).

 $<sup>\</sup>frac{90}{.04}$  oz [dose] = 1.133981 g; 1.133981-1 g [sugar]; .133981 g [active ingredient] = .004726041 oz active ingredient per dose. Each dose is .4158 % active ingredient.

<sup>&</sup>lt;sup>91</sup> About Oscillococcinum®, https://www.oscillo.com/about (last visited Apr. 13, 2022).

https://www.amazon.com/gp/product/B006H9THXY (last visited Apr. 13, 2022).

<sup>&</sup>lt;sup>93</sup> Footnote 65, *supra*.

134. Defendant represents that Oscillo "has been shown in clinical trials to both reduce the severity and shorten the duration of flu-like symptoms.<sup>2,3</sup>" (superscript in original)<sup>94</sup> Boiron asserts consumers that the "medicine works rapidly, with 63 percent of patients showing 'complete resolution' or 'clear improvement' at 48 hours.<sup>†2</sup>" and that in a "double-blind, placebo-controlled clinical trial, the recovery rate within 48 hours of treatment was significantly greater in the group that received Oscillococcinum than in the placebo group.<sup>‡3</sup>" (superscripts in original)<sup>95</sup>



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<sup>&</sup>lt;sup>94</sup> Clinical Studies on Oscillococcinum®, https://www.oscillo.com/about/clinical-studies (last visited Apr. 13, 2022) (superscript 2 cites to, Rosemarie Papp et al., Oscillococcinum® in Patients with Influenza-Like Syndromes: A Placebo-Controlled Double-Blind Evaluation, 87 Brit. Homoeopathic J. 67-76 (1998) ("Papp article"); superscript 3 cites to, JP Ferley et al., A Controlled Evaluation of a Homoeopathic Preparation in the Treatment of Influenza-Like Syndromes., 27 Brit. J. Clinical Pharmacology 329-35 (1989) ("Ferley article.")).

- 135. Defendant's claim that "the recovery rate within 48 hours of treatment was significantly greater in the group that received Oscillococcinum than in the placebo group" is deceptive.
- 136. Defendant misrepresents the significance of the study and leads consumers to believe that Oscillo was scientifically proven to be effective.
- 137. Defendant obscures or fails to state that the "results" from the 1989 Ferely article were based on admittedly unreliable data.<sup>96</sup> In fact, the study <u>did not</u> even contain anyone with a confirmed case of influenza.<sup>97</sup>
- 138. Similarly, Defendant's claim that "63 percent of patients show[] 'complete resolution' or 'clear improvement' at 48 hours' is deceptive.
  - 139. Boiron fails to disclose,
    - that one of the researchers, Philippe Belon, was a <u>Boiron employee</u>;
    - that the article is based on an attempt to replicate the <u>faulty study</u> from the Ferely article;
    - that the study was based out of <u>Boiron's headquarters</u>;
    - that nearly a third of participants in the group using Oscillo <u>also used</u> <u>additional medication</u>; and,
    - that the study declares the results are "<u>not surprising</u> since the disease lasts only 5-10 days even without medication." 98
- 140. Defendant repeats its deception on Oscillo packaging. Boiron declares the product is effective since it "has been shown in clinical studies to help reduce both the duration and the severity of flu-like symptoms."

<sup>&</sup>lt;sup>96</sup> Ferley et al., *supra*, at 334 ("The patients were the main source of information in that they themselves recorded the clinical data twice a day. It might be suggested that physicians would have been more reliable observers.")

<sup>&</sup>lt;sup>97</sup> *Id.* ("Another weakness stems from the choice of criteria for the influenza-like syndrome. The definition was purely clinical and probably lacked specificity.").

<sup>&</sup>lt;sup>98</sup> Papp et al., *supra*.



- 141. Defendant misrepresents the results of clinical studies, fails to state material facts and misleads consumers regarding the existence of competent, reliable scientific evidence of the benefits and effectiveness of Oscillo and *Anas barbariae* 200CK. Boiron's deception is self-evident.
- 142. In *toto*, Defendant's standard business practices are to mislead and deceive. Each deceptive and unfair act stated herein was material or pertained to a material fact and had or would have a material effect on consumers.
- 143. Reasonable consumers, aware of Defendant's deception or the truth it obscures, would not purchase Boiron products.

#### **CAUSE OF ACTION**

# Unfair and Deceptive Trade Practices in Violation of the Consumer Protection Procedures Act

- 144. Plaintiff realleges and incorporates by reference all preceding paragraphs.
- 145. This Count is brought under the Consumer Protection Procedures Act ("CPPA"), D.C. Code §§ 28-3901, *et seq.* The CPPA is a remedial statute that is to be broadly construed.
- 146. The allegations herein are alleged against Defendant pursuant to D.C. Code §§ 28-3905(k)(1)(A), (B), (C) and (D). Plaintiff proceeds as a consumer and as a nonprofit, public interest organization on behalf of itself, consumers and the general public of the District of Columbia.

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<sup>&</sup>lt;sup>99</sup> Photo of Oscillococcinum purchased by Plaintiff.

- 147. Defendant's products are sold for personal, household or family purposes and are consumer goods. D.C. Code § 28-391(a). Defendant offers to and does sell or supply consumer goods and is a merchant.
- 148. It is a violation of the CPPA for any person to engage in deceptive or unfair trade practices, "whether or not any consumer is in fact misled, deceived, or damaged," by, *inter alia*,
  - i. "represent[ing] that goods or services have a source, sponsorship, approval, certification, accessories, characteristics, ingredients, uses, benefits, or quantities that they do not have," D.C. Code § 28-3904(a);
  - ii. "represent[ing] that goods or services are of particular standard, quality, grade, style, or model, if in fact they are of another," D.C. Code § 28-3904(d);
  - iii. "misrepresent[ing] as to a material fact which has a tendency to mislead," D.C. Code § 28-3904(e);
  - iv. "fail[ing] to state a material fact if such failure tends to mislead,"D.C. Code § 28-3904(f);
  - v. "us[ing] innuendo or ambiguity as to a material fact, which has a tendency to mislead," D.C Code § 28-3904(f-1);
  - vi. "advertis[ing] or offer[ing] goods or services without the intent to sell them or without the intent to sell them as advertised or offered," D.C. Code § 28-3904(h);
  - vii. "represent[ing] that the subject of a transaction has been supplied in accordance with a previous representation when it has not," D.C. Code § 28-3904(u).
- 149. As detailed in this Complaint, Defendant's marketing and sale of Boiron products violated the above enumerated provisions of the CPPA.
- 150. Defendant's representations, including that: (i) each Boiron product, each product's active ingredient and each source item upon which an active ingredient is based is effective or

proven effective for the purpose or uses claimed; (ii) each Boiron product contains the amount of active ingredient, source item and inactive ingredient as claimed; (iii) the dosage of and directions for use of each Boiron product is necessary, accurate or substantiated; (iv) each dilution of each Boiron product is uniquely suited to and effective for a particular purpose; (v) each Boiron product is and was proven safe; (vi) each Boiron product is medicine; and, (vii) Oscillococcinum was clinically proven effective—misrepresent as to a material fact which has a tendency to mislead and are representations that goods have a source, sponsorship, approval, certification, accessories, characteristics, ingredients, uses, benefits, or quantities that they do not have, therefore they are deceptive trade practices that violate the CPPA, D.C. Code § 28-3904(e), (a).

- 151. Defendant's representations, including that: (i) each dilution of each Boiron product contains the amount of active ingredient, source item and inactive ingredient as claimed; (ii) each dilution of every Boiron product is uniquely or specifically suited to the claimed uses and purposes; (iii) each dilution of a particular Boiron product is uniquely or specifically suited to the claimed uses and purposes; (iv) each Boiron product is materially different from other Boiron products;, and, (v) each Boiron product contains the claimed dilution—misrepresent as to a material fact which has a tendency to mislead and are representations that goods are of particular standard, quality, grade, style, or model, if in fact they are of another, therefore they are deceptive trade practices that violate the CPPA, D.C. Code § 28-3904(e), (d).
- 152. Defendant's omissions, including Defendant's: (i) failure to disclose, for each Boiron product, that it is an unapproved drug for which the FDA did not confirm its behavior in the body, accuracy of its labeling, that its benefits outweigh the risks of use, that it was manufactured in a way to maintain strength, quality and purity, that it is safe and effective and that the uses and purposes are backed by clinical trials supported by substantial, competent evidence;

- (ii) failure to disclose that the active ingredient, purposes, uses, effects and effectiveness of each Boiron product are not based on science or accepted by modern medical experts; (iii) failure to disclose the actual, accurate amount of active ingredient, source item and inactive ingredient in each Boiron product; (iv) failure to disclose the true nature and source of each active ingredient and source item in each Boiron product; and, (v) failure to disclose Arnica montana contains silicon—are failures to state material facts which tends to mislead and are deceptive trade practices that violate the CPPA, D.C. Code § 28-3094(f).
- 153. Defendant's use of, among others: (i) explicit reference to the HPUS in connection with each active ingredient; (ii) the term "medicine" on each Boiron product; (iii) the term "homeopathic medicine" on each Boiron product; (iv) the "AAHP disclaimer;" (v) the order of the listed inactive ingredients on each Boiron product; (vi) the uncommon name of each active ingredient; (vii) the listed dilution on each Boiron product; (viii) the stated amount of active ingredient on each Boiron product; (ix) results of studies performed on Oscillococcinum; and, (x) the specific purposes, uses and effects for each Boiron product—are innuendo or ambiguity as to a material fact, which has a tendency to mislead and are deceptive trade practices that violate the CPPA, D.C. Code § 28-3094(f-1).
- 154. Defendant marketed each Boiron product knowing that, among others: (i) the product is an unapproved drug that did not pass through the NDA process; (ii) the uses, purposes, effects and dilutions are arbitrarily chosen by Boiron or are chosen without the support of scientific evidence or medical experts; and, (iii) the product does not contain the correct or verifiable amount of active ingredient, source item, dilution or inactive ingredient or the same were not verified by Boiron—thereby advertising or offering goods without the intent to sell them or without the intent to sell them as advertised or offered and representing that the subject of a transaction has been

supplied in accordance with a previous representation when it has not, which are deceptive trade practices that violate the CPPA, D.C. Code § 28-3904(h), (u).

155. Accordingly, pursuant to D.C. Code § 28-3905(k)(2), Plaintiff seeks, individually and on behalf of consumers and the general public of the District of Columbia, and is entitled to all damages available at law, including the greater of treble damages or statutory damages in the amount of \$1,500 per violation, restitution, attorney's fees, injunctive relief from further violations and any other relief this Court deems proper.

#### PRAYER FOR RELIEF

WHEREFORE, Plaintiff Center for Inquiry, Inc., individually and on behalf of consumers and the general public of the District of Columbia, respectfully requests this Court enter a judgment in favor of Plaintiff and grant relief against Defendant as follows:

- (a) Declare Defendant's conduct is in violation of the CPPA;
- (b) Enjoin Defendant from violating the CPPA and order all other appropriate remedial and corrective actions necessary to protect the interests of Plaintiff, consumers and the general public of the District of Columbia;
- (c) Award damages, including the greater of treble damages or statutory damages in the amount of \$1,500 per violation, punitive damages and restitution;
- (d) Award Plaintiff the costs and fees of prosecuting this action, including attorneys' fees;
- (e) Award pre-judgment and post-judgment interest to the extent allowable; and,
- (f) Award any other relief this Court deems proper.

## Respectfully submitted this 14th day of April, 2022.

## /s/ Aaron D. Green

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Counsel for Plaintiff