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## NOTE

# THE SCAMMER AND THE CHARLATAN: REGULATING HEALTH FRAUDSTERS IN THE TIME OF COVID-19

BRITTANY M. RIEHM\*

### I. INTRODUCTION

Arthritis got you down? Or maybe you want an oil that cures cancer? How about a mineral that prevents aging? Oh, you say a novel virus is what troubles you? Well, they have a cure for that. Wherever there is fear, desperation, or uncertainty, bad actors will creep out of the shadows to profit through scam cure-alls that just happen to fix the ailment of the moment.

In this paper, I will discuss the individual and intersecting roles of the Federal Trade Commission (FTC) and the US Food and Drug Administration (FDA) in combatting health fraud. I will begin with an overview of two broad categories of health fraudsters that I have named “the simple scammer” and “the creative charlatan.” I will start with the simple scammer, who operates a low-level scam in which he claims his very basic product is a cure for essentially everything. Next, I will describe the creative charlatan, who runs a more complex scheme in which he appropriates and misapplies scientific research to confuse consumers into believing his treatment is legitimate.

Following that, I will explain how the FDA and FTC work together to regulate healthcare products for safety, effectiveness, and advertising accuracy. I will also discuss the independent and intersecting roles of the agencies in bringing down health fraudsters. From there, I will provide an overview of the recent coronavirus outbreak and discuss where health

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fraudsters are currently operating (in the simple scam arena) and where I predict they will go (to the more complex scheme of the creative charlatan).

I will then walk through some different methods of the simple scammer by introducing individual actors fraudulently selling colloidal silver and essential oils as coronavirus cures. Additionally, I will provide examples of creative charlatans marketing unproven stem cell therapies and discuss how the FDA and FTC are countering these illegal activities. Next, I will explain why I think a creative charlatan coronavirus scheme is on the horizon and what that may mean for consumers. I will finish by arguing that the only true way to protect consumers is proactive and aggressive action by a joint task force of the FDA and FTC designed strictly to combat medical scammers during times of crisis.

## II. OVERVIEW OF SCAMMERS

There are two types of scammers that I will discuss in this paper. My term for the first category of scammers is “the simple scammer.” The simple scammer hawks snake oil. His products have very little or no medicinal value, yet the simple scammer advertises them as some ancient cure-all being kept secret from mainstream society. There is a reason this category of scammers markets the ancientness of its products: the simple scammer is unoriginal. The products do not really change—the peddlers merely add the ailment of the moment to the endless list of what their product allegedly “cures.” The simple scammer takes advantage of consumers’ fears and weaknesses in order to profit. The simple scammer does not get rich off of one individual, so he needs to recruit a loyal base in order to build his empire. Generally, his products defraud individual consumers of hundreds, rather than thousands, of dollars. One of the greatest risks to consumers caught in one of these scams is that they will put off seeking effective medical treatment for an illness because they are sold on the lies of the simple scammer. During a global pandemic, these consumers might also pose a risk to others if they believe they have achieved immunity from the coronavirus and thus refuse to follow the safety guidelines established by the Centers for Disease Control and Prevention.

Simple scams, however, are fairly easy to detect. Because these scammers are just recycling old fraudulent products, there are generally plenty of warnings and discrediting information available to anyone who runs a basic Google search. Additionally, these scammers cast such a wide net when listing ailments that will be “cured” by their product that the breadth of the claims alone will raise a red flag for most moderately savvy consumers.

The simple scam is the category in which many medical scams originate and where low-level scammers remain. The public is currently plagued with a multitude of unscrupulous actors hawking archaic products

(predominantly colloidal silver and essential oils) as faux cures for COVID-19.

The second category of scammer I am going to discuss, I have termed “the creative charlatan.” The creative charlatan is a much more complex evolution of the simple scammer. Creative charlatans appropriate legitimate science and misapply it in order to market unproven treatments to the public with an air of authority. These scams are much harder for consumers to spot because creative charlatans weave valid medical and scientific terms into their scams. The creative charlatan throws budding science into its marketing materials to give consumers false confidence and sprinkles in pseudo-science to confuse consumers. The creative charlatan may also ride on the coattails of legitimate (and respected) medical research institutions in the research trial stage by pointing to them as proof that its similar-sounding treatment is effective.

The creative charlatan can get rich off of far fewer consumers than the simple scammer because the creative charlatan’s products cost individual consumers thousands of dollars. Additionally, the creative charlatan builds his own repeat business model by targeting consumers with illnesses that naturally ebb and flow over time. The charlatan takes credit for the good days and blames the bad on needing another “treatment.” Further, the risks to consumers in this more complex scam are much greater because of the invasive nature of these sketchy “treatments.” Simple scammers generally peddle useless, but fairly benign products; whereas creative charlatans often perform very risky procedures that can themselves have irreversible adverse health effects.

While we have not yet reached the late stages of creative charlatanism with coronavirus scams, I predict that is where we are heading. As legitimate vaccines are being developed, more advanced scams will be rolled out.

### III. ROLES OF THE FDA AND THE FTC IN REGULATING HEALTHCARE CLAIMS

In the United States, the federal government empowers administrative agencies, such as the FDA and the FTC, to combat fraud and protect consumers. The FDA was formed in 1906<sup>1</sup> to, among other things, ensure the safety of drugs intended for human use.<sup>2</sup> Since its humble origins, the FDA’s jurisdiction has expanded to the regulation of vaccines and other biological products,<sup>3</sup> medical devices,<sup>4</sup> and many other products intended

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1. Federal Food and Drug Act of 1906, Pub. L. No. 59-384, 34 Stat. 768, *repealed by* Federal Food, Drug, and Cosmetic Act of 1938, 21 U.S.C. § 301.

2. *What Does FDA Do?*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/fda-basics/what-does-fda-do> (Mar. 28, 2018).

3. FDA General Enforcement Regulations, 21 C.F.R. § 1.78 (2020).

4. 21 C.F.R. § 1.76.

for human or animal use. The FTC was created in 1914,<sup>5</sup> in part, to prevent the use of “unfair or deceptive acts or practices” in commercial advertising.<sup>6</sup> Despite these agencies being put in place for the purpose of protecting consumers, the public continues to “spend billions of dollars a year on fraudulently marketed health-related products and treatments that not only are unproven and often useless, but sometimes also are dangerous.”<sup>7</sup>

#### A. *The Food and Drug Administration’s Role in Combatting Medical Fraud*

There are two relevant FDA regulations at play in the medical scams discussed in this paper: approval for drugs or biologics<sup>8</sup> to enter the market and approval for human studies. Before a new drug or biologic can legally be put on the market, it must be proven safe and effective by the FDA.<sup>9</sup> The FDA determines safety and effectiveness through a pre-market review, wherein it reviews the results of controlled clinical trials completed by a private company that wants to put the new drug or biologic on the market.<sup>10</sup> Most companies seeking FDA market approval for an innovative new drug will have the results of that pre-market review in six months or less.<sup>11</sup> The first category of scams (simple scams) tend to fall under the pre-market approval regulatory umbrella of the FDA.

The FDA review process for experimental medical therapies is aimed at ensuring the safety of participants and upholding scientific rigor of the study to allow the results to be analyzed for safety and effectiveness.<sup>12</sup> Thus, the FDA requires any approved experiments to occur in the form of controlled human studies.<sup>13</sup> In order to gain FDA approval for a human study, the experimenter must first produce sufficient data from animal studies to ensure his product is reasonably safe for use on human participants.<sup>14</sup> The second category of scams (schemes of the creative charlatan) tend to fall under the clinical studies regulation of the FDA because of the invasive nature and complexities involved in the marketed treatment. The creative

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5. 15 U.S.C. § 41.

6. 15 U.S.C. § 45(a)(2).

7. *Miracle Health Claims*, FED. TRADE COMM’N (Nov. 2011), <https://www.consumer.ftc.gov/articles/0167-miracle-health-claims>.

8. FDA Biological Products: General, 21 C.F.R. § 600.3(h) (2020) (A biologic is “a virus, therapeutic serum, toxin, antitoxin, vaccine, blood, blood component or derivative, allergenic product, protein, or analogous product, or arsphenamine or derivative of arsphenamine (or any other trivalent organic arsenic compound), applicable to the prevention, treatment, or cure of a disease or condition of human beings.”).

9. 21 U.S.C. § 355(a).

10. *Id.*

11. *About FDA Product Approval*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/news-events/approvals-fda-regulated-products/about-fda-product-approval> (Dec. 29, 2017).

12. FDA Investigational New Drug Application, 21 C.F.R. § 312.22(a) (2020).

13. *Id.*

14. 21 C.F.R. § 312.22(c).

charlatan often mimics legitimate FDA-approved clinical studies but poses a much greater risk to consumers because he lacks the oversight to ensure safety and scientific rigor.

The FDA has various tools it can use to enforce its regulations. It may issue a warning letter to the violator, informing him of specific violations and requesting the violator respond within a specified period of time with a detailed plan of how he intends to promptly correct any violation.<sup>15</sup> The FDA may also request another government agency take action against a perpetrator. For example, the FDA may recommend the United States bring one or more of the following actions against the perpetrator: injunctive relief,<sup>16</sup> seizure to remove the violative goods from the market,<sup>17</sup> civil penalties,<sup>18</sup> and/or criminal penalties<sup>19</sup> for particularly egregious cases.

### *B. The Federal Trade Commission's Role in Combatting Medical Fraud*

Health fraudsters running a simple scam or creative charlatan scheme both fall under the jurisdiction of the FTC's deceptive advertisement protections. The FTC requires a company to have reliable scientific evidence to support any claims it makes that its product can treat or prevent a disease.<sup>20</sup> Therefore, if someone puts their drug on the market without first obtaining FDA approval, they are also running afoul of the FTC.

The FTC regulates advertisements by stopping companies who make deceptive or fraudulent claims about their products.<sup>21</sup> However, unlike the FDA, the FTC has more enforcement power within its own agency. For example, the Commission can conduct its own hearing and issue a cease and desist order to the business or individual.<sup>22</sup> Further violations after such an order has been entered by the Commission may result in the Attorney General pursuing immediate and permanent injunctive relief and civil penalties of up to \$10,000 for each violation in federal court.<sup>23</sup> Additionally, the FTC may bring its own action in federal court to enjoin the dissemination of an advertisement<sup>24</sup> prior to or during a Commission proceeding intended to address the violative behavior in order to protect consumers in the interim.<sup>25</sup> The FTC may also seek to freeze a violator's assets and get compensation for victims.<sup>26</sup>

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15. 21 U.S.C. § 336.

16. 21 U.S.C. § 332(a).

17. 21 U.S.C. § 334(d)(1).

18. 21 U.S.C. § 333.

19. *Id.*

20. 15 U.S.C. § 52.

21. 15 U.S.C. § 45(a).

22. 15 U.S.C. § 45(b).

23. 15 U.S.C. § 45(l).

24. 15 U.S.C. § 53(b).

25. *Fed. Trade Comm'n v. Thomsen-King & Co.*, 109 F.2d 516, 519 (7th Cir. 1940).

26. 15 U.S.C. § 53(b).

### C. *The Intersection of the FDA and FTC*

Although the FDA and FTC are each a distinct government entity, their regulatory authority often intersects with respect to fraudulent health-care claims. The FDA is charged with regulating the actual products for safety, effectiveness, and accurate labeling, and the FTC regulates advertisement claims for accuracy.

Recognizing the common intersection between the objectives of the FDA and FTC, in 1971 the two agencies entered into a Memorandum of Understanding wherein they agreed to exchange “complete information so that both agencies will be utilized to the maximum effectiveness in the public interest.”<sup>27</sup> Each agency designated a liaison officer to communicate to the other agency about developments in areas of mutual concern.<sup>28</sup> At the end of this article, I will discuss the potential advantages of these agencies taking it a step further and creating a combined task force to combat coronavirus scams.

Next, I will provide an overview of the current coronavirus pandemic and the FDA and FTC’s current role in combatting scam medical treatments being marketed to the public.

## IV. CORONAVIRUS

A novel coronavirus was discovered in early January 2020, following a pneumonia-like illness that had infected over forty citizens of Wuhan, China in late 2019.<sup>29</sup> Within weeks of that discovery, the coronavirus spread to Thailand, Japan, and Korea.<sup>30</sup> The first confirmed case in the United States was reported on January 21, 2020.<sup>31</sup> As of the date of this writing, nearly every country in the world has had confirmed cases of the virus.<sup>32</sup> The World Health Organization declared the coronavirus a global health emergency at the end of January 2020.<sup>33</sup> There are currently many

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27. *Memorandum of Understanding Between the Federal Trade Commission and the Food and Drug Administration*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/about-fda/domestic-mous/mou-225-71-8003> (Dec. 15, 2017).

28. *Id.*

29. *Novel Coronavirus (2019-nCoV) Situation Report - 1*, WORLD HEALTH ORG. 1 (Jan. 21, 2020).

30. *Id.*

31. Roni Rabin, *First Patient with Wuhan Coronavirus Is Identified in the U.S.*, N.Y. TIMES, Jan. 21, 2020; updated May 7, 2020, <https://www.nytimes.com/2020/01/21/health/cdc-coronavirus.html>.

32. *Coronavirus Disease 2019: World Map*, CENTERS FOR DISEASE CONTROL AND PREVENTION, <https://www.cdc.gov/coronavirus/2019-ncov/cases-updates/world-map.html> (June 6, 2020).

33. Sui-Lee Wee et al., *W.H.O. Declares Global Emergency as Wuhan Coronavirus Spreads*, N.Y. TIMES, <https://www.nytimes.com/2020/01/30/health/coronavirus-world-health-organization.html> (Apr. 16, 2020).

potential COVID-19 vaccines in development, but only three which have been authorized for use (and only in certain countries).<sup>34</sup>

While heroes around the globe work tirelessly to implement life-saving measures and to discover medical treatments for this novel virus, a seemingly endless number of unscrupulous actors have crept out of the woodwork proclaiming to hold the cure. Unfortunately, while the coronavirus is new, marketing fraudulent cures and preventative measures to a population of terrified and desperate consumers is a tale as old as time. In fact, many of the fraudulent claims are simply echoes of what have been falsely marketed in the past. Products such as colloidal silver and essential oils have been marketed as cure-alls for decades and are now fraudulently being sold as COVID-19 cures.

The FTC and FDA have joined forces in an attempt to promptly stop fraudsters from making scientifically unsupported claims about their products' ability to prevent and/or treat COVID-19.<sup>35</sup> The agencies are sending joint warning letters to businesses found to be selling fake coronavirus treatments, and are giving violators forty-eight hours to inform the agencies of their plan to promptly correct the violations.<sup>36</sup> If a business fails to take immediate corrective measures, the FDA may recommend criminal prosecution and/or a federal injunction, and the FTC may pursue financial remedies on behalf of consumers.<sup>37</sup>

Both agencies are taking the scams seriously. The FTC Chairman Joe Simons pointed out that the public is already anxious over the COVID-19 pandemic, and said, "What we don't need in this situation are companies preying on consumers by promoting products with fraudulent prevention and treatment claims."<sup>38</sup> According to a March 9, 2020, FDA news release, "The FDA is particularly concerned that products that claim to cure, treat or prevent serious diseases like COVID-19 may cause consumers to delay or stop appropriate medical treatment, leading to serious and life-threatening harm."<sup>39</sup> The FDA has created a task force dedicated solely to the purpose

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34. *Coronavirus Disease (COVID-19): Vaccines*, WORLD HEALTH ORG., [https://www.who.int/news-room/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](https://www.who.int/news-room/q-a-detail/coronavirus-disease-(covid-19)-vaccines) (Oct. 28, 2020).

35. *FTC, FDA Send Warning Letters to Seven Companies About Unsupported Claims That Products Can Treat or Prevent Coronavirus*, FED. TRADE COMM'N (Mar. 9, 2020), <https://www.ftc.gov/news-events/press-releases/2020/03/ftc-fda-send-warning-letters-seven-companies-about-unsupported>.

36. Lesley Fair, *FTC, FDA Warn Companies Making Coronavirus Claims*, FED. TRADE COMM'N (Mar. 9, 2020, 9:56 AM), <https://www.ftc.gov/news-events/blogs/business-blog/2020/03/ftc-fda-warn-companies-making-coronavirus-claims>.

37. *Id.*

38. *Coronavirus Update: FDA and FTC Warn Seven Companies Selling Fraudulent Products That Claim to Treat or Prevent COVID-19*, U.S. FOOD & DRUG ADMIN. (Mar. 9, 2020), <https://www.fda.gov/news-events/press-announcements/coronavirus-update-fda-and-ftc-warn-seven-companies-selling-fraudulent-products-claim-treat-or>.

39. *Id.*



of detecting and stopping “fraudulent products related to COVID-19,”<sup>40</sup> which has successfully removed over one hundred fraudulent listings from the market as of the date of this writing.<sup>41</sup>

## V. THE SIMPLE SCAMMER—WHERE WE ARE NOW

The current COVID-19 scams flooding the market are the low-level simple scams described earlier. As of the date of this writing, the FDA has sent out 145 warning letters,<sup>42</sup> and the FTC has sent out 390 warning letters<sup>43</sup> to individuals or companies marketing fraudulent COVID-19 treatments.<sup>44</sup> The alleged treatments primarily take the form of colloidal silver or essential oils, neither of which have any proven effect in preventing, mitigating, or curing COVID-19, or any other ailment for that matter. In this section, I will offer a brief overview of colloidal silver and essential oils as historic scams. I will then provide details about a small selection of the simple scammers marketing those products who are under scrutiny for alleging to hold the cure for COVID-19.

### A. Colloidal Silver

Unsubstantiated claims that colloidal silver can cure a variety of ailments not only lack originality but have in fact been specifically prohibited by the FDA for over two decades.<sup>45</sup> In order to gain FDA approval, manufacturers of colloidal silver must participate in clinical investigations designed to obtain evidence that the product is “safe and effective for the purpose intended.”<sup>46</sup> This seems like a pretty low bar considering proponents’ claims that it has been a known success for over one hundred years. Colloidal silver manufacturers were even put on notice no later than 1999<sup>47</sup> that the FDA intended to declare colloidal silver as not recognized as safe or effective to treat anything unless scientific evidence was produced to show otherwise. Yet, to date, no studies have been done that prove colloidal silver’s safety and effectiveness. Thus, it remains banned from being advertised as a cure for anything. In fact, animal studies that have been conducted revealed that use of colloidal silver may actually cause seizures and other

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40. *Id.*

41. *Fraudulent Coronavirus Disease 2019 (COVID-19) Products*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/health-fraud-scams/fraudulent-coronavirus-disease-2019-covid-19-products> (last visited Jan. 30, 2021).

42. *Warning Letters*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/compliance-actions-and-activities/warning-letters> (last visited Jan. 30, 2021).

43. *FTC Coronavirus Warning Letters to Companies*, FED. TRADE COMM’N, <https://www.ftc.gov/coronavirus/enforcement/warning-letters> (last visited Jan. 31, 2021).

44. Some of these letters are overlapping.

45. FDA Requirements for Specific New Drugs or Devices, 21 C.F.R. § 310.548 (2020).

46. *Id.*

47. Over-the-Counter Drug Products Containing Colloidal Silver Ingredients or Silver Salts, 64 Fed. Reg. 44653 (Aug. 17, 1999) (codified as 21 C.F.R. § 310.548).

neurological problems, kidney damage, stomach issues, headaches, fatigue, skin irritation, and argyria (a permanent, irreversible condition that turns the skin, organs, deep tissues, nails, and gums a bluish-gray).<sup>48</sup>

The number of companies fraudulently selling colloidal silver as an effective means to prevent, mitigate, and treat COVID-19 is growing rapidly and includes, but is definitely not limited to, Xephyr LLC d/b/a N-Ergetics; The Jim Bakker Show; Gaia's Whole Healing Essentials; JRB Enterprise Group d/b/a Anti Aging Bed; and Colloidal Vitality LLC.<sup>49</sup> The outlandish claims made by these companies go far beyond colloidal silver being sold as a cure-all, although that is the current focus of the FDA and FTC, and each bad actor presents his own unique brand of fraud.

Claims made about the miraculous effects of colloidal silver are not supported by science and run afoul of the FDA's prohibition on the sale of unapproved and misbranded drugs.<sup>50</sup> These claims also violate the FTC's prohibition on advertising that a product can treat a disease without reliable scientific support.<sup>51</sup>

### 1. *Xephyr LLC d/b/a N-Ergetics*

One of the first culprits to receive an FDA-FTC joint warning letter (dated March 6, 2020) for fraudulently selling colloidal silver products as safe and effective at-home treatments for the coronavirus was Xephyr LLC d/b/a N-Ergetics ("N-Ergetics").<sup>52</sup> The unsupported claims made by N-Ergetics include, but are not limited to, the following:

Colloidal Silver is still the only known anti-viral supplement to kill all seven of these Human Coronaviruses.

Preventing The Contraction Of The Novel Coronavirus is Elementary. . . . Even though there are no vaccines available to combat these coronaviruses, there is a home remedy of Colloidal Silver 100 ppm that has worked effectively on coronaviruses successfully for the last 123 years.

Colloidal Silver kills all viruses.<sup>53</sup>

Following the March 6 letter, N-Ergetics scaled back on its unfounded claims and added a disclaimer informing consumers that its products are not scientifically proven to have any medical benefit with respect to the coronavirus. However, these changes have been described by the Depart-

48. BACKGROUNDER, NAT'L CENTER FOR COMPLEMENTARY AND ALTERNATIVE MEDICINE, FACT SHEET D209, at 2 (Dec. 2006).

49. *Warning Letters*, FED. TRADE COMM'N, [https://www.ftc.gov/enforcement/warning-letters?field\\_tags\\_tid%5B0%5D=361](https://www.ftc.gov/enforcement/warning-letters?field_tags_tid%5B0%5D=361) (last visited Dec. 23, 2020).

50. 21 U.S.C. § 355(a); 21 U.S.C. § 352.

51. 15 U.S.C. § 52.

52. Warning Letter from U.S. Food & Drug Admin. and Fed. Trade Comm'n to Xephyr, LLC dba N-Ergetics (Mar. 6, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/xephyr-llc-dba-n-ergetics-604588-03062020>.

53. *Id.*

ment of Justice in a complaint filed in United States District Court as a mere attempt by N-Ergetics and its facilitators “to cloak their claims to prevent liability, while continuing to make the same substantive claims.”<sup>54</sup>

On May 14, 2020, the United States District Court for the Eastern District of Oklahoma issued a Temporary Restraining Order requiring N-Ergetics to, among other things, immediately stop selling any drug, including colloidal silver, and “submit to FDA for its review and approval a recall strategy for [N-Ergetics’] colloidal silver products.”<sup>55</sup> N-Ergetics was further ordered to post a copy of the Temporary Restraining Order on any and all of its websites and in a common area at each of its facilities.<sup>56</sup>

According to the Department of Justice, the operators of N-Ergetics took down their sales site and “posted a message offering refunds to their customers” in response to the lawsuit.<sup>57</sup>

## 2. *Colloidal Vitality LLC*

Colloidal Vitality LLC has been making claims that one or two teaspoons of its Structured Silver Advanced Formula will “[attach] to bacteria, yeast, and viruses rendering them ineffective and boosting your immune system” and that “it’s actually widely acknowledged in both science and the medical industry that ionic silver kills coronaviruses.”<sup>58</sup> The FDA and FTC sent Colloidal Vitality a warning letter on March 6, 2020, to remove the fraudulent statements from its advertising platforms.<sup>59</sup>

As of the date of this writing, while Colloidal Vitality continues to sell colloidal silver, it appears to have removed its unsubstantiated claims with respect to its products’ ability to cure the coronavirus from its website and added FDA-required disclaimers to both its website and Facebook page.

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54. *Court Orders Oklahoma Company to Stop Selling Colloidal Silver as Treatment for COVID-19*, U.S. DEP’T OF JUST. (May 14, 2020), <https://www.justice.gov/opa/pr/court-orders-oklahoma-company-stop-selling-colloidal-silver-treatment-covid-19>.

55. Temporary Restraining Order at 3–4, *United States v. Xephyr*, No. 06:20-CV-00140 (E.D. Okla. May 14, 2020), <https://www.justice.gov/opa/press-release/file/1276661/download>. The court issued a preliminary injunction against N-Ergetics on May 27, 2020, which essentially extended the terms of the temporary order until superseded by a final judgment or dismissal of the court action. Order of Preliminary Injunction, *United States v. Xephyr*, No. 06:20-CV-00140 (E.D. Okla. May 27, 2020), <https://www.docketbird.com/court-documents/United-States-of-America-v-Xephyr-LLC-et-al/ORDER-OF-PRELIMINARY-INJUNCTION-by-Judge-Ronald-A-White-granting-4-United-States-Motion-for-Preliminary-Injunction-tls-Deputy-Clerk/oked-6:2020-cv-00140-00019>.

56. *Id.*

57. *Court Orders Oklahoma Company to Stop Selling Colloidal Silver as Treatment for COVID-19*, U.S. DEP’T OF JUST. (May 14, 2020), <https://www.justice.gov/opa/pr/court-orders-oklahoma-company-stop-selling-colloidal-silver-treatment-covid-19>.

58. Warning Letter from U.S. Food & Drug Admin. and Fed. Trade Comm’n to Colloidal Vitality LLC (Mar. 6, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/colloidal-vitality-llc-vital-silver-604885-03062020>.

59. *Id.*

### 3. *The Jim Bakker Show*

Another recipient of a joint warning letter from the FDA and FTC on March 6, 2020, was the ever-persistent fraudster, Jim Bakker. His current company, The Jim Bakker Show, was determined to be fraudulently selling colloidal silver products as a means of preventing and treating COVID-19 from home.<sup>60</sup> Jim Bakker's twist is that he peddles his fraudulent products under the guise of a religious leader. Jim Bakker is a televangelist who currently specializes in selling "end of the world" products to viewers.<sup>61</sup> The fear and uncertainty surrounding the novel coronavirus outbreak provided Bakker the perfect fuel for his fire of deception.

The FDA and FTC determined that The Jim Bakker Show erroneously claimed that its colloidal silver products have been proven to effectively kill all known viruses and "every pathogen it has ever been tested on," and that its products therefore would be able to kill COVID-19 as well.<sup>62</sup> The "Silver Solution" The Jim Bakker Show advertised was intended to be put in a nebulizer and the steam breathed in, allegedly to kill the virus and "any other infection" in the lungs.<sup>63</sup> Like those from Colloidal Vitality, the fantastic claims made by The Jim Bakker Show were unfounded, violating regulations of both the FDA and FTC.<sup>64</sup>

However, it is worth noting that, unlike Colloidal Vitality's seemingly prompt response to a slap on the wrist for its violations, Jim Bakker is less likely to roll over quietly. While The Jim Bakker Show has, at least temporarily, ceased its colloidal silver sales, this is not the first time Bakker has dabbled in consumer fraud, and seems unlikely to be the last.

Jim Bakker and his previous wife, Tammy Bakker, were among the first televangelists.<sup>65</sup> Together they used telethons to build a multimillion-dollar empire, and in addition to purchasing multiple houses, fancy cars, and other fine things for themselves, the Bakkers used that money to build a religious theme park and resort complex.<sup>66</sup> In 1989, Jim Bakker was convicted of fraud and conspiracy<sup>67</sup> for a scheme in which he bilked his religious followers out of over \$1.5 million by overselling shares for timeshare-

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60. Warning Letter from U.S. Food & Drug Admin. and Fed. Trade Comm'n to The Jim Bakker Show (Mar. 6, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jim-bakker-show-604820-03062020>.

61. Lauren Effron, Andrew Paparella & Jeca Taudte, *The Scandals That Brought Down the Bakkers, Once Among US's Most Famous Televangelists*, ABC NEWS (Dec. 20, 2019), <https://abcnews.go.com/US/scandals-brought-bakkers-uss-famous-televangelists/story?id=60389342>.

62. *Id.*

63. *Id.*

64. *Id.*

65. Effron et al., *supra* note 61.

66. *Id.*

67. Kristin Jensen, *Televangelist Bakker, Companies Warned by FDA, FTC on Fraudulent Coronavirus Claims*, BIOPHARMA DIVE (Mar. 11, 2020), <https://www.biopharmadive.com/news/fda-ftc-coronavirus-marketing-warning-fraudulent-claims/573948>.

like lodging at the resort and diverting that money to support his own extravagant lifestyle.<sup>68</sup>

Although Bakker successfully played the part of a remorseful wrongdoer who had learned the errors of his ways when his original forty-five-year sentence was up for reconsideration following Bakker's appeal in 1991, it appears the twenty-seven-year reduction<sup>69</sup> he managed to finagle was at least partly the result of Bakker's skillful manipulation. Bakker managed to shorten his sentence only to return unrehabilitated and to resume scamming the American public. Following his release from prison, Bakker started The Jim Bakker Show with his new wife, Lori Bakker, and he resumed his televangelical scheme. This time, instead of over-selling shares in a theme park, Bakker began preaching about the end of civilization and selling "freeze-dried food by the five-gallon bucket load and survival gear" to viewers.<sup>70</sup> When the coronavirus outbreak hit, Bakker took advantage of the panic and began marketing his colloidal silver product "Silver Solution" as a treatment for COVID-19.<sup>71</sup>

Jim Bakker's recent colloidal silver scheme has caught the eye of more than the FDA and FTC; both the Missouri and New York Attorneys General are taking separate actions to stop his scams.<sup>72</sup> The Missouri Attorney General filed a lawsuit against Jim Bakker seeking a "permanent injunction ordering Bakker to stop selling Silver Solution as a treatment for coronavirus."<sup>73</sup> The Missouri Attorney General gave consumers the following warning through a March 10, 2020, news release: "Anyone who has bought 'Silver Solution' from the Jim Bakker Show should know that it cannot cure or treat coronavirus."<sup>74</sup> The New York Attorney General's office sent Bakker a cease and desist notice on March 3, 2020.<sup>75</sup> The New York Attorney General's office warned its citizens through a March 10, 2020, press release that "scammers commonly exploit real public health concerns and use heightened public fear to prey on consumers and profit

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68. *Jim Bakker Given Reduced Sentence*, WASH. POST, <https://www.washingtonpost.com/archive/lifestyle/1991/08/24/jim-bakker-given-reduced-sentence/e99c6e27-0b7e-4c0f-848b-5cf262cb67a0> (last visited Feb. 7, 2021).

69. *Id.*

70. Effron et al., *supra* note 61.

71. Warning Letter to Jim Bakker Show, *supra* note 60.

72. Ivan Pereira, *NY, Missouri Attorneys General Order Companies to Stop Promoting Alleged Coronavirus Cures*, ABC NEWS (Mar. 11, 2020), <https://abcnews.go.com/US/ny-attorney-general-orders-televangelist-jim-bakker-stop/story?id=69472032>.

73. Erich Schmitt, *AG Schmitt Files Suit Against Jim Bakker for Selling Fake "Coronavirus Cure"*, OFF. MO. ATT'Y GEN. (Mar. 10, 2020), <https://ago.mo.gov/home/news/2020/03/10/ag-schmitt-files-suit-against-jim-bakker-for-selling-fake-coronavirus-cure>.

74. *Id.*

75. Cease and Desist Notification from State of New York Office of the Attorney General to James Bakker (Mar. 3, 2020), [https://www.ozarksfirst.com/wp-content/uploads/sites/65/2020/03/bakker\\_cease\\_and\\_desist\\_letter\\_notification.pdf](https://www.ozarksfirst.com/wp-content/uploads/sites/65/2020/03/bakker_cease_and_desist_letter_notification.pdf).

from frauds related to those health fears” and reminded the public that there was no FDA-approved vaccine or cure for COVID-19 at that time.<sup>76</sup>

Since the efforts of the FDA, FTC, and Missouri and New York Attorneys General to stop Jim Bakker’s colloidal silver hawking, it has been reported that he has suffered from a stroke.<sup>77</sup> The bright side for Bakker is that, since being forced to stop selling colloidal silver, he should be fully stocked with his magical potion to treat any ailments from home.

#### 4. *Gaia’s Whole Healing Essentials LLC*

Another perpetrator in the colloidal silver scam called out by the FDA and FTC was Gaia’s Whole Healing Essentials LLC (“Gaia”).<sup>78</sup> The FDA and FTC sent a joint warning letter to Gaia on April 1, 2020.<sup>79</sup> As is typical of the simple scammer, Gaia’s claims are outrageous and easily disproven, such as its bold statement that colloidal silver is “the key to protecting yourself” from the novel coronavirus and COVID-19.<sup>80</sup> The company also alleged its colloidal silver is an effective treatment for “all types of infections and diseases,” including lung disease.<sup>81</sup>

While the focus of the agencies’ warning letter was Gaia’s erroneous claim that its colloidal silver products can prevent and fight COVID-19, the company’s outlandish sales gimmicks do not stop there. After receipt of the warning letter, Gaia continued to sell 16 ounces of colloidal silver for \$111.11 and claimed it was an effective treatment for, not only COVID-19, but also the common cold, cancer, ulcers, yeast infections, tuberculosis, Lyme’s disease, bubonic plague, pneumonia, leprosy, gonorrhea, syphilis, scarlet fever, malaria, HIV/AIDS, shingles, diabetes, arthritis, lupus, leukemia, gum disease, and many more diseases.<sup>82</sup> It also claimed use during pregnancy would “aid the baby’s growth and health as well as the mother’s delivery and recovery.”<sup>83</sup> Gaia has since replaced these specific health claims related to colloidal silver with its bold general claim that its products

76. *AG James: Price Gouging Will Not Be Tolerated*, N.Y. ST. ATT’Y GEN. (Mar. 10, 2020), <https://ag.ny.gov/press-release/2020/ag-james-price-gouging-will-not-be-tolerated>.

77. Joe Marusak, *TV Pastor Jim Bakker Suffers Stroke, Wife and Son Confirm. ‘Jim will be back!’*, CHARLOTTE OBSERVER (May 8, 2020), <https://www.charlotteobserver.com/news/local/article242596441.html>.

78. Warning Letter from U.S. Food & Drug Admin. and Fed. Trade Comm’n to Gaia’s Whole Healing Essentials, LLC (Apr. 1, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gaias-whole-healing-essentials-llc-605893-04012020>.

79. *Id.*

80. *Id.*

81. *Id.*

82. GAIAS’ WHOLE HEALING ESSENTIALS, <https://gaiaswholehealingessentials.org/Gaias-Colloidal-Silver-16oz-p137163079> (last visited Apr. 27, 2020) (statements have been removed from website).

83. *Id.*

“heal any and all diseases, ailments, energetic imbalances and more.”<sup>84</sup> It continues to sell its colloidal silver as a “magical colloidal elixir” at the increased price of \$122.21.<sup>85</sup>

And although Gaia has since removed its explicit claims that its products can prevent and treat the coronavirus, its other erroneous claims remain. Apparently, for just over \$100, Gaia’s magic solution will basically cure anything. Of course, the problem with Gaia’s business model is that it relies solely on the word of Gaia and its promoters. Gaia has failed to provide a shred of evidence to back up its claims. And while the company admits to “the lack of research done” on the effects of its products, it alleges this is due to some conspiracy.<sup>86</sup> Specifically, Gaia alleges:

The lack of research comes from knowing how beneficial Colloidal silver is for the human body and not wanting this medical secret to be released as it will solve a vast majority of diseases and issues humanity is experiencing, harming the profitability of pharmaceuticals. . . . The truth about Colloidal silver is deeply hidden from society as it is much cheaper than the medical remedies recommended for the aforementioned diseases. This is an ancient treatment that has been used for many millennia. When used properly with the correct dose and intentions, you will see that Colloidal silver will heal your body in ways you could not even fathom possible.<sup>87</sup>

These are odd allegations considering Gaia itself is the one responsible for conducting the research and providing the scientific evidence to support its claims. The FDA does not conduct independent testing, it evaluates the totality of scientific evidence based on the procedures used and results obtained from testing conducted by or on behalf of companies.<sup>88</sup> And if a company has satisfied the FDA’s requirements by supporting its claims that a product can prevent or treat a disease with sound evidence, it will have no issue with the FTC.<sup>89</sup>

Among Gaia’s bold but easily disproved claims is that “colloidal silver is completely natural and therefore cannot harm you.”<sup>90</sup> The logic of that statement is plainly faulty. Many things found in nature are harmful and even deadly. For example, aconite is a plant native to Europe that, if swallowed, is known to cause death by asphyxiation.<sup>91</sup> Mere skin contact with

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84. *Gaia’s Colloidal Silver*, GAIA’S WHOLE HEALING ESSENTIALS, <https://gaiaswholehealingessentials.org/gaias-colloidal-silver-p261887055> (last visited Dec. 23, 2020).

85. *Id.*

86. *Id.*

87. *Id.*

88. U.S. FOOD & DRUG ADMIN., FDA-2007-D-0371, GUIDANCE FOR INDUSTRY: EVIDENCE-BASED REVIEW SYSTEM FOR THE SCIENTIFIC EVALUATION OF HEALTH CLAIMS (2009).

89. Fair, *supra* note 36.

90. GAIA’S WHOLE HEALING ESSENTIALS, *supra* note 82.

91. AMY STEWART, WICKED PLANTS 2 (2009).

the plant can cause cardiac symptoms.<sup>92</sup> “Aconite is so powerful that Nazi scientists found it useful as an ingredient for poisoned bullets.”<sup>93</sup> Consumption of three or four castor bean seeds (a plant native to Eastern Africa and Western Asia) is enough to kill a person.<sup>94</sup> Asbestos (a naturally occurring fibrous mineral once used for making fireproof materials) was banned by the EPA in 1989 because it caused lung disease from contact or inhalation.<sup>95</sup> Other examples of natural poisons include arsenic, mercury, formaldehyde, and anthrax, to name a few.<sup>96</sup> Clearly, natural is not synonymous with being safe.

### 5. *JRB Enterprise Group d/b/a Anti Aging Bed*

Yet another bad actor anxious to get in on profiting off the pandemic is JRB Enterprise Group d/b/a Anti Aging Bed (“Anti Aging Bed”). As its name suggests, the company sells mattresses and accessories, but apparently could not resist the urge to get in on the COVID-19 panic and began selling colloidal silver products as alleged protection against the coronavirus. Anti Aging Bed claimed inhaling colloidal silver through a nebulizer “provides a real prevention regiment for a number of maladies – including the Corona Virus [*sic*] known as COVID19.”<sup>97</sup> As is common with the simple scammer, a consumer should quickly become suspicious by looking at the scam on its face. A company that sells mattresses and then randomly throws in a magic “treatment” for a novel virus should immediately raise a red flag. Most consumers do not expect to receive medical treatments from a specialty mattress business.

Anti Aging Bed was selling its “Colloidal Silver CoronaVirus Convenience Package” for \$150 (on sale from \$300).<sup>98</sup> The company asserted, without support, that “numerous tests at major universities and commercial labs . . . have proven the effectiveness of silver.”<sup>99</sup>

Perhaps in response to the warning letter sent to Anti Aging Bed on March 20, 2020,<sup>100</sup> by the FDA and FTC, the company’s website temporarily included the following disclaimer: “These statements have not been

92. *Id.*

93. *Id.*

94. *Id.* at 15–16.

95. Sarah Zielinski, *Ten Natural Products That Kill*, SMITHSONIAN MAG. (Nov. 9, 2010), <https://www.smithsonianmag.com/science-nature/ten-natural-products-that-kill-38268113>.

96. *Id.*

97. Warning Letter from U.S. Food & Drug Admin. and Fed. Trade Comm’n to JRB Enterprise Group Inc. DBA Anti Aging Bed (Mar. 30, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/jrb-enterprise-group-inc-dba-anti-aging-bed-605892-03302020>.

98. ANTI AGING BED, [https://antiagingbed.com/products/colloidal-silver-coronavirus-convenience-package?\\_pos=1&\\_sid=58ad3396c&\\_ss=r#](https://antiagingbed.com/products/colloidal-silver-coronavirus-convenience-package?_pos=1&_sid=58ad3396c&_ss=r#) (last visited Feb. 7, 2021) (statements and product have been removed from website).

99. *Id.*

100. Warning Letter to JRB Enterprise Group, *supra* note 97.



evaluated by the Food and Drug Administration. This product is not intended to diagnose, treat, cure or prevent any disease.”<sup>101</sup> Anti Aging Bed stated the disclaimer was “posted under protest” and that the FDA’s requirement to include the disclaimer is a violation of the company’s First Amendment rights.<sup>102</sup> And while corporations do have legal rights in the United States, in order for commercial speech to receive protection it “must concern lawful activity and not be misleading.”<sup>103</sup> It is well-established that inaccurate commercial speech is not protected and may be banned where it is “more likely to deceive the public than to inform it.”<sup>104</sup>

In approximately mid-April, Anti Aging Bed removed its colloidal silver products and the above-mentioned disclaimer and accompanying protest from its website. Apparently, for the time being, the company decided to stick to mattress sales.

### B. *Essential Oils*

Colloidal silver scammers are not the only ones quick to get in the game of turning fake cures for a profit. Many businesses are pushing essential oils as an effective way to prevent, mitigate, and treat COVID-19. Like colloidal silver, essential oils have been sold as a cure-all, without any support for such claims, for quite some time.

The deceptive practice of companies advertising their essential oil products as anti-viral is not a special gimmick thought up for the coronavirus. These companies have routinely popped up to claim, without supporting evidence, that their essential oil products cure virtually every illness under the sun, including whatever the ailment of the hour might be. For example, Young Living was sent a warning letter from the FDA on September 22, 2014, requiring it to correct its inaccurate claims that its products could cure Ebola.<sup>105</sup> Young Living made claims such as: “Viruses (including Ebola) are no match for Young Living Essential Oils” and “Ebola Virus can not [*sic*] live in the presence of cinnamon bark (this is in Thieves) nor Oregano.”<sup>106</sup> Additionally, Young Living’s consultants were advertising its oils as treatments for “Parkinson’s disease, autism, diabetes, hypertension, cancer, insomnia, heart disease, post-traumatic stress disorder (PTSD), dementia, and multiple sclerosis,” among other conditions “that

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101. ANTI AGING BED, *supra* note 98 (internal quotations omitted) (statements and product have been removed from website).

102. *Id.*

103. *Thompson v. W. States Med. Ctr.*, 535 U.S. 357, 357 (2002).

104. *Cent. Hudson Gas & Elec. Corp. v. Pub. Serv. Comm’n of New York*, 447 U.S. 557, 563 (1980).

105. Warning Letter from U.S. Food & Drug Admin. to Young Living (Sept. 22, 2014), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/young-living-09222014>.

106. *Id.*

are not amenable to self-diagnosis and treatment by individuals who are not medical practitioners.”<sup>107</sup>

With the recent coronavirus outbreak, peddlers of essential oils have another ailment to add to their list of what their products allegedly cure.

### 1. *Quinessence Aromatherapy*

The FDA and FTC sent a joint warning letter to Quinessence Aromatherapy Ltd. (“Quinessence”) on March 6, 2020, requiring it to correct fraudulent claims made in its advertisements.<sup>108</sup> Quinessence was advertising “Essential Oils to Protect Against Coronavirus” and made unsupported claims such as “there are a wide range of essential oils that have been clinically proven to possess antiviral properties.”<sup>109</sup> Quinessence went on to promote twenty of its essential oil products as “the most powerful” protection against the coronavirus.<sup>110</sup>

Sometime following receipt of that warning letter, Quinessence removed its direct claims that its essential oils could protect consumers against the coronavirus, but indirect claims remain. A few examples of Quinessence’s many current claims include, but are not limited to, that its Star Anise Essential Oil “has powerful antimicrobial properties, and when vaporised, it has a clearing action on the respiratory system,” that its Bay Leaf Essential Oil is “antiseptic and antibacterial” and vaporizing it “is helpful with a wide range of respiratory conditions,” and that its Bergamot Essential Oil “is an effective antiseptic that helps guard against infection.”<sup>111</sup> Only time will tell if the FDA and FTC will let Quinessence get away with these thinly veiled coronavirus cure claims. As of the date of this writing, public records do not indicate that any further action has been taken against Quinessence.

### 2. *Guru Nanda LLC*

Guru Nanda LLC was also sent a warning letter by the FDA and FTC on March 6, 2020, requesting the company to correct its fraudulent statements that its essential oils would prevent and treat COVID-19.<sup>112</sup> Guru Nanda claimed “municipalities of Wuhan have declared that people should use Pure essential oils as a preventative therapy” for the coronavirus and

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107. *Id.*

108. Warning Letter from U.S. Food & Drug Admin. and Fed. Trade Comm’n to Quinessence Aromatherapy Ltd (Mar. 6, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/quinessence-aromatherapy-ltd-605013-03062020>.

109. *Id.*

110. *Id.*

111. *Essential Oils A - B*, QUINESSENCE, <https://www.quinessence.com/essential-oils/oils/a-b> (last visited Jan. 30, 2021).

112. Warning Letter from U.S. Food & Drug Admin. and Fed. Trade Comm’n to GuruNanda LLC (Mar. 6, 2020), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/gurunanda-llc-604930-03062020>.

that “essential oils are effective against a diverse range of pathogens.”<sup>113</sup> Additionally, according to the *Orange County Register*, Guru Nanda advertised a 50 percent discount to consumers who entered the code “CORONA” at checkout.<sup>114</sup>

Sometime after receipt of the warning letter, Guru Nanda removed the direct claims that its essential oils could prevent COVID-19. However, like Quinessence, Guru Nanda continued to make deceptive claims to consumers about its products’ ability to treat ailments. For example, while Guru Nanda removed its explicit COVID-19 claims from its webpage for its “Whole Body Essential Oils Set,” it continued to display a picture of the box which stated the following:

Guru Nanda’s natural Whole Body Benefit Pack, is a complete at home FARM-ACY that will help maintain optimal well-being from head to feet. Our in-house certified aromatherapist worked hundreds of hours to bring the most effective synergy blends to support your daily health needs all year long.<sup>115</sup>

The Whole Body Essential Oils Set included a product Guru Nanda labeled “Immunity.”<sup>116</sup> Viewed as a whole, clearly this advertisement was intended to mislead consumers into believing its products aid your body’s ability to ward off various health ailments without specifically naming the coronavirus. Guru Nanda has since removed its advertisements for its “Whole Body Essential Oils Set,” and has largely cleaned up its deceptive claims, although it continues to sell “Immunity” and has added a product labeled “Breathe Easy.”<sup>117</sup> Public records do not currently indicate that the FDA or FTC have taken further action against Guru Nanda, and the company appears to have largely cleaned up its act in recent months.

### 3. *Health Mastery Systems d/b/a Pure Plant Essentials*

On April 1, 2020, the FDA and FTC sent a joint letter to Health Mastery Systems d/b/a Pure Plant Essentials (“Pure Plant”) warning it to correct its fraudulent advertisements claiming its essential oils could prevent and mitigate the symptoms of COVID-19.<sup>118</sup>

113. *Id.*

114. Jonathan Lansner, *Coronavirus Warning: Buena Park Firm Told to Stop Pitching Oils as Cures*, ORANGE CNTY. REG. (Mar. 10, 2020), <https://www.ocregister.com/2020/03/10/feds-warn-buena-park-firm-warn-about-pitching-coronavirus-cures>.

115. GURU NANDA, <https://www.gurunanda.com/products/whole-body-essential-oils-set> (last visited Feb. 7, 2021) (statements and product have been removed from website).

116. *Id.*

117. *Guru Nanda 100% Pure Essential Oil Blends - Set of 6, 10 ml Each*, GURU NANDA, <https://gurunanda.com/top-6-blends-set-of-6-essential-oil-blends> (last visited Dec. 23, 2020).

118. Warning Letter from U.S. Food & Drug Admin. and Fed. Trade Comm’n to Health Mastery Systems DBA Pure Plant Essentials (Apr. 1, 2020), [https://www.ftc.gov/system/files/warning-letters/fda-covid-19-letter-health\\_mastery\\_systems\\_dba\\_pure\\_plant.pdf](https://www.ftc.gov/system/files/warning-letters/fda-covid-19-letter-health_mastery_systems_dba_pure_plant.pdf).

Like the earlier-described essential oil companies, Pure Plant appears to have removed its direct claims about being able to fight COVID-19, but it continues to boast its products as a cure-all without specifically mentioning the coronavirus. For example, Pure Plant is selling a book called “Essential Oils for Immunity” that purportedly describes the eighteen “best pure essential oils to use for antimicrobial properties” and includes “research studies proving effectiveness.”<sup>119</sup> Pure Plant claims essential oils are “potent antimicrobial agents” that “have a regulating effect on the body’s [immune] responses to keep them in balance, [and help] when they’ve gotten out of balance as in the case of illness.”<sup>120</sup> Public records do not indicate any further action has been taken by the FDA or FTC against Pure Plant at this time.

## VI. THE CREATIVE CHARLATAN—WHERE WE ARE HEADED

Next, I am going to discuss the second category of fraudsters that I have named the creative charlatans. Creative charlatans run much more complex scams than those of the simple scammer. These schemes are much harder to detect because their creators appropriate and misapply legitimate science. Use of valid medical and scientific terms gives the scams an air of validity and confuses consumers who do not have the in-depth knowledge required to evaluate the claims.

It is virtually inevitable that as vaccines and treatments for the coronavirus begin to be developed and valid clinical studies are underway, creative charlatans will jump in to profit by appropriating some of the valid research being conducted and claiming the government is interfering with allowing providers to perform effective treatments. If it sounds complicated, it is because it is supposed to be. The creative charlatan’s recipe is a dash of science and a cup of confusion.

### A. *Exaggeration of Scientific Advancements—Stem Cell Therapies*

To understand where we are heading with coronavirus scams, it is important to evaluate where we have been. The trending complex scheme prior to the pandemic was fraudulent stem cell treatments. These faux treatments are an example of what we can anticipate creative charlatans will flood the market with, in response to the current pandemic, if the opportunity remains for them to reap any financial gain from doing so.

Legitimate stem cell treatments consist of an extraction of tissue from a specimen, either the patient or a donor, and then intravenous administra-

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119. *Essential Oils for Immunity*, PURE PLANT ESSENTIALS, <https://www.pureplantessentials.com/products/essential-oils-for-immunity-the-18-best-antimicrobial-oils-by-kg-stiles> (last visited Jan. 30, 2021).

120. *Id.*

tion into the patient.<sup>121</sup> All stem cell treatments on humans are required to take certain registration, manufacturing, and reporting steps to prevent the introduction, transmission, and spread of communicable disease.<sup>122</sup> Many such treatments are considered biological products by the FDA and thus also require pre-market approval prior to being administered on a human.<sup>123</sup> Because of the invasive nature of the treatments, manufacturers are required to first demonstrate through animal studies that proposed treatments are safe and effective.<sup>124</sup> Next, manufacturers are required to conduct FDA-approved clinical studies.<sup>125</sup> The clinical studies must be designed to ensure the safety of participants.<sup>126</sup> Once the manufacturer has satisfied the requirements of this stage, it can request pre-market approval from the FDA, which will be granted so long as the prior studies have shown the treatments are both safe and effective.<sup>127</sup>

The rationale for these FDA regulations is to prevent providers from making unfounded promises to vulnerable patients “while continuing to encourage innovation so that the medical industry can properly harness the potential of stem cell products.”<sup>128</sup> The FDA warns consumers about unapproved stem cell therapies. “Researchers hope stem cells will one day be effective in the treatment of many medical conditions and diseases. But unproven stem cell treatments can be unsafe.”<sup>129</sup> Some risks include blindness (when stem cells are injected into the eye), growth of tumors, administration site reactions, the ability of cells to move from placement sites and change into inappropriate cell types or multiply, failure of cells to work as expected, and contamination of cells prior to injection (in cases where cells are manipulated after extraction).<sup>130</sup> These risks are present even if the stem cells used are taken from and injected back into the same patient.<sup>131</sup>

Currently, the only FDA-approved stem cell treatment is the use of blood-forming stem cells derived from umbilical cord blood to treat patients with certain blood disorders.<sup>132</sup> However, there are many experimental stem cell treatments that are currently undergoing FDA-approved clinical stud-

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121. Arezu Sarvestani, *Stem Cell Therapy: What's Real and What's Not at California's For-Profit Clinics*, U.C.S.F. (Nov. 1, 2019), <https://www.ucsf.edu/news/2019/11/415811/stem-cell-therapy-whats-real-and-whats-not-californias-profit-clinics>.

122. FDA Human Cells, Tissues, and Cellular and Tissue-Based Products, 21 C.F.R. § 1271.10.

123. *Id.*

124. *FDA Warns About Stem Cell Therapies*, U.S. FOOD & DRUG ADMIN., (Sept. 3, 2019), <https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies>.

125. *Id.*

126. *Id.*

127. *Id.*

128. *Id.*

129. *Id.*

130. *FDA Warns About Stem Cell Therapies*, U.S. FOOD & DRUG ADMIN., <https://www.fda.gov/consumers/consumer-updates/fda-warns-about-stem-cell-therapies> (Sep. 3, 2019).

131. *Id.*

132. *Id.*

ies.<sup>133</sup> For example, the Mayo Clinic in Rochester, Minnesota, is conducting a study related to treating multiple system atrophy.<sup>134</sup> The University of Texas Health Science Center in Houston, Texas, is conducting a study related to Parkinson's disease.<sup>135</sup> TCA Cellular Therapy LLC in Covington, Louisiana,<sup>136</sup> and Jewish Hospital in Louisville, Kentucky,<sup>137</sup> are conducting separate studies related to the treatment of coronary disease. The University of Minnesota in Minneapolis, Minnesota, is conducting a study related to patients experiencing heart failure who are undergoing a ventricular assist device placement.<sup>138</sup> The University Hospital Cleveland Medical Center in Cleveland, Ohio,<sup>139</sup> and McConnell Spine, Sport, and Joint Physicians in Columbus, Ohio,<sup>140</sup> are conducting separate studies related to treatments of knee osteoarthritis. The Medical University of South Carolina is conducting a study related to the treatment of Type 1 diabetes.<sup>141</sup> This is only a small selection of the FDA-approved clinical stem cell studies currently being conducted in the United States. These legitimate studies are narrowly tailored and subject to scientific rigor.<sup>142</sup>

Clearly, promising research is underway which explores the potential applications for stem cells in treating a wide array of ailments. However, research takes time and resources, and some "unscrupulous actors . . . have seized on the clinical promise of regenerative medicine, while exploiting the uncertainty, in order to make deceptive, and sometimes corrupt, assurances to patients based on unproven, and in some cases, dangerously dubious products."<sup>143</sup> These bad actors promote "unproven, clearly illegal, and

133. *Id.*

134. Mesenchymal Stem Cell Therapy in Multiple System Atrophy, U.S. NAT'L LIBR. MED., ClinicalTrials.gov (search condition or disease field for "NCT02315027").

135. Allogeneic Bone Marrow-Derived Mesenchymal Stem Cell Therapy for Idiopathic Parkinson's Disease, U.S. NAT'L LIBR. MED., ClinicalTrials.gov (search condition or disease field for "NCT02611167").

136. Combination Stem Cell Therapy for the Treatment of Severe Coronary Ischemia, U.S. NAT'L LIBR. MED., ClinicalTrials.gov (search condition or disease field for "NCT00643981").

137. Cardiac Stem Cell Infusion in Patients with Ischemic Cardiomyopathy, U.S. NAT'L LIBR. MED., ClinicalTrials.gov (search condition or disease field for "NCT00474461").

138. Stem Cell Therapy in Patients with Severe Heart Failure & Undergoing Left Ventricular Assist Device Placement, U.S. NAT'L LIBR. MED., ClinicalTrials.gov (search condition or disease field for "NCT00869024").

139. Impact of Mesenchymal Stem Cells in Knee Osteoarthritis, U.S. NAT'L LIBR. MED., ClinicalTrials.gov (search condition or disease field for "NCT03477942").

140. Investigation of Mesenchymal Stem Cell Therapy for the Treatment of Osteoarthritis of the Knee, U.S. NAT'L LIBR. MED., ClinicalTrials.gov (search condition or disease field for "NCT02958267").

141. Cellular Therapy for Type 1 Diabetes Using Mesenchymal Stem Cells, U.S. NAT'L LIBR. MED., ClinicalTrials.gov (search condition or disease field for "NCT04061746").

142. Noro Psikiyatrs Ars, *How to Conduct Scientific Research?*, NCBI 54(2), 97–98 (June 1, 2017), <https://www.ncbi.nlm.nih.gov/pmc/articles/PMC5491675>.

143. *Statement From FDA Commissioner Scott Gottlieb, M.D. on the FDA's New Policy Steps and Enforcement Efforts to Ensure Proper Oversight of Stem Cell Therapies and Regenerative Medicine*, U.S. FOOD & DRUG ADMIN., (Mar. 27, 2018), <https://www.fda.gov/news-events/press->

often expensive treatments that offer little hope, and, even worse, may pose significant risks to the health and safety of vulnerable patients.”<sup>144</sup>

One complexity of the creative charlatan that makes his scam difficult for consumers to detect is that he claims to treat conditions that “normally improve or fluctuate over time, such as joint pain, low back pain, arthritis, or multiple sclerosis.”<sup>145</sup> In the case of fraudulent stem cell treatments, the creative charlatan boasts they will regrow lost tissue, despite there being “no solid evidence” to back up such claims.<sup>146</sup> Patients who feel better after the treatments may believe it is because of these fraudulent treatments, but the truth is that they would likely have felt better anyway due to the natural fluctuation of the ailment suffered. Then when the symptoms flair up again, these fraudsters can lure the consumer back in for another treatment.

The FDA stated in a 2017 news release: “We will take a firm stance against those that prey on the medical promise of regenerative cell therapies to market treatments potentially unsafe or unproven so-called cures.”<sup>147</sup> As promised, the FDA has been calling out bad actors selling unproven stem cell treatments to consumers across the country.

### 1. *Liveyon Labs Inc. and Liveyon LLC*

The FDA issued a warning letter on December 5, 2019, to Liveyon Labs Inc. and Liveyon LLC (“Liveyon”) following the agency’s inspection of the labs.<sup>148</sup> Therein, the FDA noted Liveyon was in violation of FDA regulations requiring the business to have either pre-market approval or be operating an FDA-approved clinical study to legally manufacture umbilical cord blood for distribution to stem cell therapy centers for eventual injection into humans.<sup>149</sup> Additionally, the FDA alerted Liveyon of many “significant deviations from current good manufacturing practice . . . and current good tissue practice.”<sup>150</sup> The FDA informed Liveyon that its “deficient donor eligibility practices, inadequate aseptic practices, and deficient environmental monitoring . . . pose a significant risk that [its] products may be contaminated with microorganisms or have other serious product quality

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announcements/statement-fda-commissioner-scott-gottlieb-md-fdas-new-policy-steps-and-enforcement-efforts-ensure.

144. *Id.*

145. Sarvestani, *supra* note 121.

146. Liz Szabo, *Why Expensive, Unproven Stem Cell Treatments Are a New Health Care Trend*, KAISER HEALTH NEWS (Apr. 4, 2019, 8:00 AM), <https://www.pbs.org/newshour/tag/stem-cells>.

147. FDA Warns US Stem Cell Clinic of Significant Deviations, U.S. Food & Drug Admin., (Mar. 27, 2018), <https://www.fda.gov/news-events/press-announcements/fda-warns-us-stem-cell-clinic-significant-deviations>.

148. Warning Letter from U.S. Food & Drug Admin. to Liveyon Labs Inc., FDA (Dec. 5, 2019), <https://www.fda.gov/inspections-compliance-enforcement-and-criminal-investigations/warning-letters/liveyon-labs-inc-588399-12052019>.

149. *Id.*

150. *Id.*

defects.”<sup>151</sup> More specifically, during its inspection, the FDA observed a failure of Liveyon to review donor medical records or to use FDA-approved donor screening tests to detect risk factors, such as the presence of a communicable disease.<sup>152</sup> Liveyon also failed to establish and follow sterilization procedures to prevent contamination of its product.<sup>153</sup> Further, Liveyon was found to have failed to investigate issues or implement corrective or preventative actions, including instances where umbilical cord blood arrived from donors who tested positive for Zika virus, Hepatitis B, syphilis, and instances where batches of the product were contaminated and then distributed to providers.<sup>154</sup>

## 2. *Regenerative Medical Group and Telehealth Medical Group*

In addition to the actions taken by the FDA, the FTC is also on the watch for creative charlatans making claims that are not supported by scientific evidence. Fairly recently, the FTC succeeded in a suit for deceptive advertisement against Dr. Bryan Henderson and the two companies he owned and operated: Regenerative Medical Group and Telehealth Medical Group.<sup>155</sup> Henderson claimed that the stem cell therapies offered through his companies could treat and cure a variety of serious illnesses, including Parkinson’s disease, autism, dementia, depression, multiple sclerosis, cerebral palsy, traumatic brain injury, heart disease, macular degeneration, chronic kidney disease, osteoarthritis, and stroke.<sup>156</sup> Henderson charged consumers between \$9,500 and \$15,000 for initial stem cell injections and then an additional \$5,000 to \$8,000 for each follow up “booster” treatment.<sup>157</sup>

The FTC succeeded in its suit against Henderson and was granted permanent injunctive relief requiring Henderson and both of his companies to “stop claiming its stem cell therapy treats or cures any disease or health condition and to stop claiming that its stem cell therapy is comparable or superior to conventional medical treatments in curing, mitigating, or treat-

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151. *Id.*

152. *Id.*

153. *Id.*

154. Warning Letter from U.S. Food & Drug Admin. to Liveyon Labs Inc., *supra* note 148.

155. *FTC Returns Almost \$515,000 to Consumers Who Bought Deceptively Marketed “Amniotic Stem Cell Therapy” Between 2014 and 2017*, FED. TRADE COMM’N (Apr. 30, 2019), <https://www.ftc.gov/news-events/press-releases/2019/04/ftc-returns-almost-515000-consumers-who-bought-deceptively>.

156. Colleen Tressler, *FTC Takes Aim at Deceptive Stem Cell Therapy Claims*, FED. TRADE COMM’N (Oct. 18, 2018), <https://www.consumer.ftc.gov/blog/2018/10/ftc-takes-aim-deceptive-stem-cell-therapy-claims>.

157. *FTC Stops Deceptive Health Claims by a Stem Cell Therapy Clinic*, FED. TRADE COMM’N (Oct. 18, 2018), <https://www.ftc.gov/news-events/press-releases/2018/10/ftc-stops-deceptive-health-claims-stem-cell-therapy-clinic>.



ing any disease or health condition.” The court also awarded \$3.31 million to the FTC to provide refunds to affected customers.<sup>158</sup>

Combatting creative charlatans has proved a difficult task in an age of seamless mobility and online platforms. Prior to the coronavirus outbreak, these scammers were already widespread and hard to nail down. Where we sit today, in the heart of a global pandemic, it is necessary to take a proactive, rather than a reactive, approach to consumer protection.

## VII. CONCLUSION

The World Health Organization (WHO) has brought experts together from around the world in an attempt to discover an effective treatment for the novel coronavirus.<sup>159</sup> These researchers have collaborated to identify animal models that mirror human reactions to the virus, which has allowed them to complete animal studies applicable to controlled clinical trials on humans.<sup>160</sup> But real science takes time. Currently, no COVID-19 vaccine has received WHO approval, although three have been authorized for use by certain national authorities.<sup>161</sup> Since the original coronavirus outbreak, two variants have been detected, one in the UK and one in South Africa.<sup>162</sup> A lot of uncertainty remains with respect to this virus, and that is unlikely to change for some time. Unfortunately, all of the unknowns create the perfect breeding ground for the ploys of the creative charlatan.

Creative charlatans will undoubtedly exploit budding research now that valid clinical studies are underway and vaccines are beginning to roll out. As of this writing, the demand for vaccination far exceeds the supply available.<sup>163</sup> Creative charlatans will surely be quick to meet that demand with pseudo-treatments. And because many people who contract the coronavirus are asymptomatic and many will recover naturally, it is all too easy for bad actors to sell nonsense products and to attribute any natural recovery or lack of symptoms to their effects. With no comprehensive contact tracing in effect, in the context of the coronavirus, the lives that will be lost if such scams are not prevented will be incalculable. Individuals operating under the false belief that they have some sort of immunity toward the

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158. *FTC Returns Almost \$515,000*, *supra* note 155.

159. *R&D Blueprint and COVID-19*, WORLD HEALTH ORG., <https://www.who.int/teams/blueprint/covid-19> (last visited Jan. 30, 2021).

160. *Id.*

161. *Coronavirus Disease (COVID-19): Vaccines*, WORLD HEALTH ORG., [https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-\(covid-19\)-vaccines](https://www.who.int/emergencies/diseases/novel-coronavirus-2019/question-and-answers-hub/q-a-detail/coronavirus-disease-(covid-19)-vaccines) (last visited Jan. 30, 2021).

162. *WHO's Science in 5 on COVID-19: Variants and Vaccines*, WORLD HEALTH ORG. (Jan. 8, 2021), <https://www.who.int/emergencies/diseases/novel-coronavirus-2019/media-resources/science-in-5/episode-20---covid-19---variants-vaccines>.

163. Caitlin Owens, *Demand for Coronavirus Vaccines Is Outstripping Supply*, AXIOS (Jan. 19, 2021), <https://www.axios.com/demand-coronavirus-vaccines-outstripping-supply-7314861f-d8f0-4ee8-8480-85fea99846f8.html>.

virus put everyone they come in contact with, and the subsequent contact chain of those thereafter, at substantial risk of contracting a deadly virus with no known cure.

The current climate puts consumers at great risk for falling for the gimmicks of the creative charlatan. Consumers do not want to be afraid. They do not want to accept that there are no good answers, that they have to be patient while scientists and medical professionals around the world scramble to come up with a safe and effective means of combatting the virus, and that in the interim, everyone's health is in danger. It is much more comforting to believe those crying conspiracy or to accept the gimmicks of a creative charlatan who claims to have it all figured out than it is to sit with the reality of the situation.

Protecting consumers from the preying hands of the creative charlatan is more crucial now than ever. And while I have no doubt that minds much greater than mine are thinking up ways to combat this inevitable problem, I am going to share my proposed solution: strict liability for any individual or business that makes a coronavirus treatment, prevention, or cure claim without preapproval from the FDA, with an automatic \$500,000 fine for each such claim. No warning letters. No slap on the wrist. No opportunity to defend dangerous claims. I would propose these claims be addressed by a joint task force between the FTC and FDA, that new regulations be enacted as necessary, and that these new regulations be enforced by the US Attorney General.

Because these scammers are profit motivated, such schemes need to be chopped off at the knees before any profit can be realized. Creative charlatans are not stupid, and if there is proper deterrence in place which shows them that rolling out fake coronavirus products is going to lose them money, most will be deterred from doing so, and those who are not will promptly find themselves in an inoperable business model.

While my proposal is intentionally harsher than the current FDA-FTC enforcement models, it is not an entirely radical idea. The FTC is already authorized to issue cease and desist orders against individual offenders engaging in unfair or deceptive advertising.<sup>164</sup> Once such an order is issued, the US Attorney General may bring a suit against the named offender for a civil penalty of up to \$10,000 for each violation of the Commission's order.<sup>165</sup> What I am proposing is that the FTC issue a blanket order, rather than chasing down individual actors after the fact, that no individual or company shall make any claim that its product can treat or prevent COVID-19 without prior FDA approval. An FDA-FTC pandemic task force would be created to detect violators, who would face a \$500,000 penalty for each violation of the FTC's general order.

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164. 15 U.S.C. § 45(b).

165. 15 U.S.C. § 45(l).

The cost of human lives paid for the coronavirus is already much too high. We must be proactive in preventing creative charlatans from profiting off society's fear and making an already bad problem much worse.