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PEOPLE OF THE STATE OF CALIFORNIA

[NO FEE - Govt. Code § 6103]

SUPERIOR COURT OF THE STATE OF CALIFORNIA

COUNTY OF LOS ANGELES

THE PEOPLE OF THE STATE OF CALIFORNIA, Plaintiff, v. ROOTMD, INC., a California corporation; and DOES 1 through 10, inclusive, Defendants.	Case No. 20STCV15180 **COMPLAINT FOR PERMANENT INJUNCTION, CIVIL PENALTIES, RESTITUTION, AND OTHER EQUITABLE RELIEF** [VERIFIED ANSWER REQUIRED PURSUANT TO CODE OF CIVIL PROCEDURE SECTION 446]

Plaintiff, the People of the State of California, appearing through their attorney, Michael N. Feuer, City Attorney for the City of Los Angeles, allege the following on information and belief:

INTRODUCTION

1. This civil law enforcement action involves exposure and immunity test kits for the novel coronavirus SARS-CoV-2 ("COVID-19") falsely advertised for sale as "at-home" self-collection kits. There currently are no such Food and Drug Administration ("FDA")-approved "at-home" self-collection test kits. Unless the FDA has approved or otherwise exempted a manufacturer's at-home test kit, it cannot lawfully be sold in California or elsewhere in the United States.

2. On March 4, 2020, the City of Los Angeles, the County of Los Angeles, and the State of California all declared a public health emergency related to COVID-19, to help protect public health from this serious pandemic. The COVID-19 virus can cause symptoms including high fever, sharp cough, and shortness of breath or breathing difficulty. In some cases, the virus quickly progresses to pneumonia, Acute Respiratory Distress Syndrome (ARDS), kidney failure, and other serious life-threatening complications. On March 11, 2020, the World Health Organization recognized the spread of COVID-19 as a global pandemic.

3. To date, the COVID-19 pandemic has been particularly dangerous—even deadly—for the elderly and those with other pre-existing conditions, although all age groups have been impacted.

4. The threat from COVID-19 is growing exponentially throughout the United States, including in Los Angeles and other areas of California.

5. The harms of the COVID-19 pandemic are made worse by the spread of confusion, misinformation, and the proliferation of consumer scams and frauds regarding this novel coronavirus.

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6. Among the chief aids to public health available in the face of this pandemic is accurate, reliable, and widespread testing. Countries with higher relative per capita testing rates have, thus far, had the most relative success in blunting the exponential growth, or "flattening the curve," of COVID-19 cases in their countries.[1]

7. Unfortunately, as this public health emergency initially developed in the United States and California, COVID-19 testing was not initially widely available, and due to the shortages, was tightly restricted and rationed by public health authorities. The City of Los Angeles has recently announced a testing program that is available to all sympotmatic residents in Los Angeles County.[2]

8. In addition to the public health benefit of widespread testing, consumers also have important reasons to seek testing: consumers may have had a contact with someone diagnosed with COVID-19; consumers may have a symptom that could be consistent with COVID-19; or consumers may wish to put their minds at ease (or know to seek treatment). Consumers might also wish to confirm that they do not have COVID-19 in order to better protect more vulnerable members of their families.

9. The FDA has announced guidance to help rapidly increase the type and variety of testing available in this pandemic health emergency through emergency use authorizations and other policies.[3]

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[1] See https://www.nytimes.com/2020/03/23/world/asia/coronavirus-south-korea-flatten-curve.html (accessed April 13, 2020).

[2] https://lacovidprod.service-now.com/rrs (accessed April 11, 2020); see also https://www.latimes.com/california/story/2020-04-07/all-la-residents-can-now-get-coronavirus-tests-heres-where-to-go (accessed April 11, 2020).

[3] *See, e.g.*, https://www.fda.gov/regulatory-information/search-fda-guidance-documents/policy-diagnostic-tests-coronavirus-disease-2019-during-public-health-emergency (accessed April 12, 2020).

10. But to date, the FDA has not approved any COVID-19 exposure and immunity tests for at-home testing, and in fact has warned consumers about the dangers of at-home testing.[4]

11. Because these "at-home" tests have not been validated by the FDA, the reliability of these "at-home" tests have varied wildly and "tests of 'frankly dubious quality' have flooded the American market, leading to false positives and false negatives.[5]

12. In fact, the World Health Organization recently came out and declared that until more validation on serological antibody testing has occurred, it "does not recommend the use of antigen-detecting rapid diagnostic tests for patient care."[6]

13. Nevertheless, the marketplace has seen a rise in the number of companies and individuals making false claims that they have FDA-approved COVID-19 test kits, often, but not always, serological antibody tests. "At-home" testing kits are particularly enticing to consumers in Los Angeles (and many other areas of the United States), who are under various "stay-at-home" or "safer-at-home" orders and guidance from the governor, the mayor, the County, and the federal Center for Disease Control (CDC).

14. Here, the Defendants have widely marketed and sold "at-home" test kits on the internet and across social media platforms.

15. In this public health emergency, consumers require—and under California law are entitled to—accurate, reliable, and truthful information about COVID-19, including its testing, treatments, mitigations, and cures. The health, and even the lives, of California consumers depend on it.

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[4] *See, e.g.*, https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-fda-alerts-consumers-about-unauthorized-fraudulent-covid-19-test-kits (accessed April 12, 2020).

[5] *See, e.g.*, https://www.nytimes.com/2020/04/19/us/coronavirus-antibody-tests.html (accessed April 19, 2020).

[6] *See* https://www.who.int/news-room/commentaries/detail/advice-on-the-use-of-point-of-care-immunodiagnostic-tests-for-covid-19 (accessed April 19, 2020)

PARTIES

16. Plaintiff, the People of the State of California (the "People"), is the sovereign power of the State of California (Gov. Code § 100), authorized to enforce Business and Professions Code section 17200 et seq. ("Unfair Competition Law" or "UCL") and Business and Professions Code section 17500 et seq. ("False Advertising Law" or "FAL") in civil law enforcement actions. The People have an interest in ensuring that the individuals and entities doing business in this state comply with all applicable laws. The People act here by and through Michael N. Feuer, Los Angeles City Attorney, under the authority granted to them by Business and Professions Code sections 17204, 17206, 17508, 17535, and 17536.

17. Defendant RootMD, Inc. ("RootMD"), is a California corporation, headquartered and with its principal place of business in Santa Monica, California. At all relevant times, RootMD has transacted business in California, including Los Angeles City and County. RootMD purports to be a "digital platform for functional medicine, aimed at personalized medicine for chronic gut diseases," but also claims to market an "at home" COVID-19 expsure and immunity test.

18. Defendants sued herein as Does 1 through 10, inclusive, are presently unknown to the People, who therefore sue these unknown Defendants by such fictitious names. When the true names and capacities of any unknown Defendants have been ascertained, the People will ask leave of the Court to amend this Complaint and to insert in lieu of such fictitious names the true names and capacities of any fictitiously named Defendants. The People are informed and believe that Does 1 through 10 participated in, and are responsible for, the wrongful conduct alleged in this Complaint.

19. Each Defendant is a "person" within the meaning of Business and Professions Code sections 17506 and 17201.

20. Whenever this Complaint refers to "Defendants," it includes any and all Defendants named in paragraphs 16 and 17 of this Complaint.

21. At all relevant times, some or all Defendants acted as the agent of the others, and all Defendants acted within the scope of their agency if acting as an agent of another.

22. At all relevant times, Defendants together comprised an "organization of persons" within the meaning of Business and Professions Code section 17201, in that they associated together for the common purpose of engaging in a course of unlawful, unfair, and fraudulent business acts and practices as alleged herein.

23. At all relevant times, each Defendant acted individually and jointly with every other Defendant in committing the acts alleged to have been committed by "Defendants" in this Complaint.

24. At all relevant times, each Defendant acted: (a) as a principal; (b) under express or implied agency; and/or (c) with actual or ostensible authority to perform the acts alleged in this Complaint on behalf of every other Defendant.

25. At all relevant times, each Defendant knew or realized, or should have known or realized, that the other Defendants were engaging in or planned to engage in the violations of law alleged in this Complaint. Knowing or realizing that the other Defendants were engaging in such unlawful conduct, each Defendant nevertheless facilitated the commission of those unlawful acts. Each Defendant intended to and did encourage, facilitate, or assist in the commission of the unlawful acts, and thereby aided and abetted the other Defendants in the unlawful conduct.

26. Defendants have engaged in a conspiracy, common enterprise, and common course of conduct, the purpose of which was and is to engage in the violations of law alleged in this Complaint. The conspiracy, common enterprise, and common course of conduct continue to the present.

JURISDICTION AND VENUE

27. This Court has subject matter jurisdiction over this matter pursuant to Business and Professions Code sections 17203, 17204, 17206, 17500, 17508, 17535, and 17536.

28. This Court has personal jurisdiction over each of the Defendants pursuant to California Constitution, Article VI, section 10, and California Code of Civil Procedure section 410.10 in that each Defendant that is a corporation does substantial business in California; all of

the Defendants have purposely availed themselves of the benefits of doing business in this state; and Defendants' violations of law alleged herein occurred, in whole or in part, in this state.

29. The violations of law alleged in this Complaint occurred in Los Angeles City and County and throughout the State of California. Venue for this matter properly lies within Los Angeles County because the violations of law alleged in this Complaint occurred, in whole or in part, in Los Angeles County.

STATUTORY BACKGROUND

I. THE UNFAIR COMPETITION LAW

30. Business and Professions Code section 17200, ("Unfair Competition Law" or "UCL") provides that "unfair competition shall mean and include unlawful, unfair or fraudulent business practice."

31. Business and Professions Code section 17203 provides that "(a)ny person performing or proposing to perform an act of unfair competition within this state may be enjoined in any court of competent jurisdiction." Section 17203 also permits recovery of any "interest in money or property, real or personal" acquired by a violation of the Unfair Competition Law.

32. Business and Professions Code section 17206, subdivision (a), provides that any person violating section 17200 "shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California . . . by any city attorney of a city having a population in excess of 750,000."

33. Under Business and Professions Code section 17205, these remedies and penalties are "cumulative to each other and to the remedies or penalties available under all other laws of this state."

II. THE FALSE ADVERTISING LAW

34. Business and Professions Code section 17500 ("False Advertising Law" or "FAL") provides that it is unlawful for any person "with the intent directly or indirectly to dispose of real or personal property . . . to make or disseminate or cause to be made . . . any

statement, concerning that real or personal property . . . which is untrue or misleading, and which is known, or which by the exercise of reasonable care should be known, to be untrue or misleading."

35. Business and Professions Code section 17535 authorizes "any city attorney" to seek an injunction to prevent such untrue or misleading statements, and to provide restitution for victims of such statements.

36. Business and Professions Code section 17536 provides that any person violating section 17500 "shall be liable for a civil penalty not to exceed two thousand five hundred dollars ($2,500) for each violation, which shall be assessed and recovered in a civil action brought in the name of the people of the State of California . . . by any . . . city attorney." These civil penalties are cumulative to those obtained under Section 17200.

III. THE SHERMAN FOOD AND DRUG ACT

37. Health and Safety Code section 109875 et seq. (the "Sherman Food, Drug, and Cosmetic Law" or "Sherman Law") regulates the manufacture and sale of medical devices in California (including incorporation of relevant federal standards).

38. Health and Safety Code section 109920 defines "device" as "any instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including any component, part, or accessory, that is . . . (b) Intended for use in the diagnosis of disease or other condition, or in the cure, mitigation, treatment, or prevention of disease in humans or any other animal."

39. Health and Safety Code section 109948.1 defines "home medical device," in relevant part, as "a device intended for use in a home care setting including, but not limited to . . . (4) Respiratory disease management devices . . . (11) Disposable medical supplies [and] (12) In vitro diagnostic tests."[7] (Health & Saf. Code, § 109948.1, subd. (b).)

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[7] An "in vitro" test is test that takes place in a test tube, culture dish, or elsewhere outside a living organism.

40. It is unlawful to sell a home medical device in California that is misbranded (Health & Saf. Code, § 111330), and devices can only be sold if they comply with federal regulations (Health & Saf. Code, § 111550).

THE FDA HAS NOT APPROVED ANY AT-HOME TEST KITS

41. The FDA is responsible for validating and authorizing the safety and effectiveness of drugs and medical devices, such as drug test kits.

42. As a result of the COVID-19 pandemic, the FDA has issued guidelines to accelerate the availability of COVID-19 testing ("Interim Guidelines"), while still retaining standards for reliability and validity of such devices.[8]

43. The Interim Guidelines emphasize the importance of FDA validation of all tests because "[i]n the context of a public health emergency involving pandemic infectious disease, it is critically important that tests are validated as false results can have broad public health impact beyond that to the individual patient."[9]

44. The Interim Guidelines provide guidance in four different areas:

A. Part A is directed to clinical labs developing tests and the process for received Emergency Use Authorization;

B. Part B is directed to States allowing them to set their own validation standards for testing;

C. Part C provides guidance to commercial manufacturers of diagnostic tests that are provided to laboratories or health care providers; and

D. Part D provides guidance to commercial manufacturers of diagnostic tests relying solely on blood;[10]

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[8] https://www.fda.gov/media/135659/download (accessed April 12, 2020).

[9] *Id.* at p. 3.

[10] *Id.*

45. Importantly, none of the Interim Guidelines apply to at-home test kits. Parts C and D, which are directed to commercial manufacturers of Corona test kits, specifically state that "this policy does not apply to at home testing."[11]

46. The FDA has updated its website with a "Frequently Asked Questions" page, where, in response to the question of,"[a]re there any tests that I can purchase to test myself at home for COVID-19?", states: "[a]t this time, the FDA **has not authorized any test** that is available to purchase for testing yourself at home for COVID-19, **including self-collection of a specimen with or without the use of telemedicine**. The FDA sees the public health value in expanding the availability of COVID-19 testing through safe and accurate tests that may include home collection, and we are actively working with test developers in this space."[12]

47. The FDA has also specifically warned that "serological" testing, i.e., blood tests for COVID-19 antibodies—the type of testing at issue in this case—should not be used alone without other tests or diagnostic tools:

> Serological tests measure the amount of antibodies or proteins present in the blood when the body is responding to a specific infection, like COVID-19. In other words, the test detects the body's immune response to the infection caused by the virus rather than detecting the virus itself. In the early days of an infection when the body's immune response is still building, antibodies may not be detected. This limits the test's effectiveness for diagnosing COVID-19 and why it should not be used as the sole basis to diagnose COVID-19.[13]

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[11] *Id.*

[12] https://www.fda.gov/medical-devices/emergency-situations-medical-devices/faqs-diagnostic-testing-sars-cov-2 (emphasis added) (accessed April 12, 2020).

[13] https://www.fda.gov/news-events/press-announcements/coronavirus-covid-19-update-serological-tests (accessed April 11, 2020).

DEFENDANTS' UNLAWFUL BUSINESS PRACTICES

48. Incorporated in 2018, defendant RootMD represents that it is a "a "digital platform for functional medicine, aimed at personalized medicine for chronic gut diseases."[14]

49. Defendant RootMD owns and operates the website "http://rootmd.com" ("RootMD Website").

50. On the RootMD Website, RootMD sold an "at-home" COVID-19 expsoure and immunity test kit ("At-Home COVID-19 Test Kit"). Selling for $249.00, RootMD made the following representations:

i. "At-home Covid-19 exposure and immunity testing"

ii. "COVID-19 Check Blood Testing On Your Terms"

iii. "We are the first to offer at-home collection for this testing allowing all who order the test to easily collect and ship their sample in the convenience and safety of their home."

iv. "Given the tremendous lack of certainty surrounding who has been exposed to COVID-19, we believe this test provides well-needed information and clarity. This test was used extensively by the Chinese CDC to confirm who in their population had been exposed and was now immune."

v. "Is this test FDA approved? While the test has not yet completed the several month investigation periods by the FDA to be labeled as approved, they did issue a statement on March 16th allowing its use under emergency provisions."

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[14] See https://rootmd.com/aboutus (accessed April 17, 2020).

51. The At-Home COVID-19 Test Kit is a "device" and a "home medical device" under Health and Safety Code sections 109920 and 109948.1, because, among other reasons, it is designed for the diagnosis of a disease or other condition, and intended for home use as an in vitro diagnostic test related to a respiratory disease or condition.

52. The People contacted RootMD on April 7, 2020 regarding these allegations, and RootMD represented to the People that they stopped selling At-Home COVID-19 Test Kit directly to consumers as of April 8, 2020.

FIRST CAUSE OF ACTION:

VIOLATIONS OF BUSINESS AND PROFESSIONS CODE SECTION 17500

(UNTRUE OR MISLEADING REPRESENTATIONS)

(Against All Defendants)

53. The People restate and incorporate herein each and every allegation set forth in paragraphs 1–52 above, as though fully alleged herein.

54. Beginning no later than March 2020, and continuing to the present, Defendants, and each of them, with each other or with other unknown persons, have engaged in and continue to engage in, aided and abetted and continue to aid and abet, and conspired to and continue to conspire to violate Business and Professions Code section 17500 by making or disseminating untrue or misleading statements, or causing untrue or misleading statements to be made in the in the City and County of Los Angeles, with the intent to induce the purchase of at-home test kits, when they knew or by the exercise of reasonable care should have known the statements were untrue, misleading, and unsubstantiated. Defendants' untrue or misleading representations include, but are not limited to, the following:

A. Representing with respect to Defendants' testing kits, that the Defendants advertised the At-Home COVID-19 Test Kit as an "At-Home Kit." Such statements are untrue and misleading because the FDA has not authorized the use of any in-home testing kits for COVID-19, including tests kits using self-collection with or without telemedicine.

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B. Representing, with respect to the At-Home COVID-19 Test Kit, that one can "[c]heck Blood Testing [o]n [y]our [t]erms." Such statements are untrue and/or misleading because the FDA has not authorized the direct sale to consumers of any in-home testing kits for COVID-19, including tests kits using self-collection with or without telemedicine.

C. Representing that "[w]e are the first to offer at-home collection for this testing allowing all who order the test to easily collect and ship their sample in the convenience and safety of their home." Such statements are untrue and/or misleading because the FDA has not authorized the use of any in-home testing kits for COVID-19, including tests kits using self-collection with or without telemedicine.

D. Representing that "[g]iven the tremendous lack of certainty surrounding who has been exposed to COVID-19, we believe this test provides well-needed information and clarity. This test was used extensively by the Chinese CDC to confirm who in their population had been exposed and was now immune." Such statements are untrue and/or misleading because the FDA has not validated the accuracy of nor authorized the use of any in-home testing kits for COVID-19, including tests kits using self-collection with or without telemedicine.

E. Representing that "[i]s this test FDA approved? While the test has not yet completed the several month investigation periods by the FDA to be labeled as approved, they did issue a statement on March 16th allowing its use under emergency provisions." Such statements are untrue and/or misleading because the FDA has not authorized the use of any in-home testing kits for COVID-19, including tests kits using self-collection with or without telemedicine.

55. Defendants knew, or by the exercise of reasonable care should have known at the time of making the statements, or causing the statements to be made, that the statements set forth in Paragraph 54.A. through 54.E. were untrue or misleading.

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56. These violations render each Defendant liable to the People for civil remedies of up to $2,500 for each violation under Business and Professions Code section 17536 and provide the basis for other remedies.

57. Defendants' conduct is in continuing violation of the False Advertising Law, beginning on approximately March 2020, and is within four years of the filing of this Complaint.

SEOND CAUSE OF ACTION:

VIOLATION OF BUSINESS AND PROFESSIONS CODE 17200

(UNFAIR COMPETITION)

(Against All Defendants)

58. The People restate and incorporate herein each and every allegation set forth in paragraphs 1 through 57 above, as though fully alleged herein.

59. Beginning no later than March 2020 and continuing to the present, Defendants, and each of them, with each other or other unknown persons, have engaged in and continue to engage in, aided and abetted and continue to aid and abet, and conspired to and continue to conspire to engage in acts or practices that constitute unfair competition as defined by Business and Professions Code section 17200. Such acts or practices include, but are not limited to, the following:

A. Violating Business and Professions Code section 17200, because Defendants' business acts and practices, as described above, as well as similar conduct, are *unlawful* under section 17200;

B. Violating Business and Professions Code section 17200, because Defendants' business acts and practices, as described above, as well as similar conduct, are *unfair* under section 17200;

C. Violating Business and Professions Code section 17200, because Defendants' business acts and practices, as described above, as well as similar conduct, are *fraudulent* under section 17200;

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D. Violating Business and Professions Code section 17200, because Defendants' actions as described above, as well as similar conduct, are unfair, deceptive, untrue, or misleading advertising under section 17200;

E. Violating Business and Professions Code section 17500, by making or disseminating, or causing to be made or disseminated, statements before the public with respect to the effectiveness that Defendants knew were untrue and misleading and which were and are known by Defendants to be untrue and misleading, as described above;

60. By committing the acts alleged above, at all times material to this complaint, each Defendant has engaged in unlawful business practices that constitute unfair competition within the meaning of Business and Professions Code section 17200.

61. By committing the acts alleged above, Defendants are liable to the People for civil penalties of up to $2,500 for each violation.

62. Defendant's unlawful, unfair, and fraudulent business acts or practices, as described above, present a continuing threat to members of the public.

63. Defendants' conduct was in continuing violation of the Unfair Competition Law, beginning at a time unknown to the People but no later than March 2020, and continuing to within four years of the filing of this Complaint.

PRAYER FOR RELIEF

Wherefore, the People pray for judgment as follows:

64. That pursuant to Business and Professions Code sections 17203 and 17204 and the equitable powers of the Court, Defendants, and their successors, agents, representatives, employees, and all persons who act in concert with Defendants be permanently enjoined from engaging in unfair competition as defined in Business and Professions Code section 17200 et seq., including, but not limited to, the acts and practices alleged in this Complaint.

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65. That pursuant to Business and Professions Code section 17206, Defendants be assessed a civil penalty of $2,500 for each violation of Business and Professions Code section 17200 et seq. that they committed, caused, aided and abetted or conspired to commit, as proved at trial.

66. That pursuant to Business and Professions Code section 17535, Defendants, their successors, agents, representatives, employees, and all persons who act in concert with Defendants be permanently enjoined from making any untrue or misleading statements in violation of Business and Professions Code section 17500 et seq., including but not limited to, the untrue or misleading statements alleged in the Complaint.

67. That pursuant to Business and Professions Code section 17536, Defendants be accessed a civil penalty of $2,500 for each violation of Business and Professions Code sections 17500 et seq. that they committed, caused, aided and abetted, or conspired to commit, as proved at trial.

68. That Defendants be ordered to make direct restitution of any money or other property that may have been acquired by the violations of Business and Professions Code section 17200 et seq. and 17500 et seq.

69. That the People recover the costs of this action.

70. Such other relief that the Court deems just and proper.

Dated: April 20, 2020

Respectfully Submitted,

MICHAEL N. FEUER
Los Angeles City Attorney

By: _____
MIGUEL RUIZ
Deputy City Attorney