1 2 3 4 5 6 7 8 9 10 11 12	Jonathan Weissglass (SBN 185008) Law Office of Jonathan Weissglass 1939 Harrison Street, Suite 150-B Oakland, CA 94612 Telephone: 510-836-4200 E-Mail: jonathan@weissglass.com Daniel N. Abrahamson (SBN 158668) Law Office of Daniel N. Abrahamson 1912 Bonita Avenue Berkeley, CA 94704 Telephone: 510-326-0224 E-Mail: dnahealthlaw@gmail.com Attorneys for Plaintiff Roots Community Health Center	ELECTRONICALLY FILED   Superior Court of California   O1/11/2024   Chad Finke, Executive Officer / Clerk of the Court   By:   D. Drew   Deputy		
13	SUPERIOR COURT OF CALIFORNIA			
14	COUNTY OF ALAMEDA			
15				
16	ROOTS COMMUNITY HEALTH CENTER,	Case No. 23CV051017		
17 18	Plaintiff, v.	ASSIGNED FOR ALL PURPOSES TO: JUDGE REBEKAH EVENSON DEPARTMENT 24		
19 20	CVS PHARMACY, INC.; WALGREEN CO.;	FIRST AMENDED COMPLAINT		
20 21	COMPASS HEALTH BRANDS CORPORATION; VERIDIAN HEALTHCARE,	Unlimited Civil Case		
21	LLC; CONTEC MEDICAL SYSTEMS USA INC.; EINSTEIN ASSOCIATES LLC; GURIN	Action Filed: November 13, 2023		
22	PRODUCTS LLC; CHOICEMMED AMERICA CORPORATION; ZEWA, INC.; MASIMO	Trial Date: None Set		
23	CORPORATION; MEDTRONIC, INC;			
25	COVIDIEN SALES LLC; GE HEALTHCARE TECHNOLOGIES INC.; and DOES 2-50,			
26	Defendants.			
27				
28				
	FIRST AMENDED COMPLAINT			

1	INTRODUCTION			
2	1. Plaintiff Roots Community Health Center is a non-profit organization that as part			
3	of its mission provides medical care to low-income patients, primarily people of color. Roots			
4	seeks to remedy a widespread threat to the health of people who have darker skin pigmentation.			
5	2. A diagnostic tool known as a pulse oximeter is often used on individuals suffering			
6	from or at risk of medical conditions that affect the cardiopulmonary system. People use pulse			
7	oximeters to monitor from home their blood oxygen levels to determine whether, when, and what			
8	type of medical intervention may be needed. Emergency medical technicians use pulse			
9	oximeters to decide who should be brought to a medical facility. Nurses and doctors use pulse			
10	oximeters to determine patients' appropriate level of care.			
11	3. But pulse oximeters frequently do not properly measure oxygen levels in people			
12	with darker skin. This is true both of pulse oximeters that are cleared by the federal Food and			
13	Drug Administration ("FDA") for use in medical settings and those that are not and are marketed			
14	for consumer use – both of which are at issue in this lawsuit. Moreover, the inaccuracy of pulse			
15	oximeters presents not as a symmetric or random differential but as a bias: Pulse oximeters often			
16	provide readings that <i>overestimate</i> the amount of oxygen in the blood for people with darker			
17	skin. That is, people with darker skin are at risk of seeming to be healthier than they actually are			
18	due to inaccurate pulse oximeter readings.			
19	4. The overestimation of oxygen levels that pulse oximeters frequently give when			
20	used by persons with darker skin can have catastrophic health consequences. By suggesting that			
21	people are healthier than they really are, inaccurate pulse oximeter readings can result in a failure			
22	to provide important, even life-saving, treatment.			
23	5. This critical flaw in pulse oximeters is an example of a historical indifference			
24	towards people with darker skin in health care treatment in the United States. Presumably, no			
25	one purposefully set out to develop a device that could lead to poor health care outcomes for			
26	people with darker skin. But lighter skin or "whiteness" was the default for which pulse			

27 oximeters were designed and tested. To the extent that medical device testing and approval for

# 28 pulse oximeters were conditioned on the device being tested on people with darker skin, such a

1 requirement was an afterthought, with no serious attention paid to the appropriate size of that 2 group of subjects, or the objective measurement of pigmentation of subjects. It would therefore 3 be a mistake to perceive the flaw in pulse oximeters as a mere "glitch," as it results from the 4 systematic and sustained exclusion of darker skinned people from the technical and ethical scope 5 of vision of those responsible for the engineering, adoption, approval, regulation, and use of the 6 technology.

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6. The Covid-19 pandemic laid bare racial disparities in health care treatment and outcomes – disparities that go well beyond Covid-19 and the current moment.

9 7. Covid-19 can manifest as a minor illness or a life-threatening and ultimately 10 deadly one. The lower the level of oxygen in a person afflicted with Covid-19, the more dire a 11 patient's situation. As Covid-19 patients overwhelmed the capacity of emergency departments 12 and primary care facilities to treat them – and even taxed the ability of first responders to reach 13 them – pulse oximeters became a ubiquitous tool for determining the level of care.

- 14 8. In treating Covid-19, front-line health care practitioners have seen first-hand -15 and been surprised by – the blatant disparities between how acutely sick their patients with 16 darker skin presented and seemingly normal readings those patients' pulse oximeters provided. 17 9. Given the stakes for persons who may contract Covid-19 or be afflicted with any 18 other medical condition that affects the cardiopulmonary system, pulse oximeters should be 19 required to measure people with both lighter and darker skin accurately. In the absence of a 20 technological fix, the manufacturers, distributors, and sellers of pulse oximeters that cannot 21 provide accurate readings regardless of a person's skin color should plainly state this critical 22
- 23

#### PARTIES

failing for users and purchasers of their devices. Roots brings this action to obtain such relief.

24 10. Plaintiff Roots Community Health Center is a non-profit organization recognized 25 by the Internal Revenue Service as tax exempt under §501(c)(3) of the Internal Revenue Code. 26 Roots seeks to uplift those impacted by systemic inequities and poverty through medical and 27 behavioral health care, health navigation, workforce enterprises, housing, outreach, and 28 advocacy. Roots was founded in 2008 and currently provides medical care to thousands of

1 people every year. Roots is based in the City of Oakland in the County of Alameda and provides 2 medical and other services there as well as in other parts of California. Roots is committed to 3 delivering comprehensive care to those who have been most marginalized and to providing a 4 medical home for those who have never engaged meaningfully in medical care. The vast 5 majority of the patients Roots treats are Black. Roots also treats other patients with darker skin. 6 11. Defendant CVS Pharmacy, Inc., is headquartered in Woonsocket, Rhode Island. 7 CVS sells pulse oximeters that are not cleared by the FDA in both stores in California and on the 8 Internet to people in California. 9 12. Defendant Walgreen Co. is based in Deerfield, Illinois, and operates Walgreens 10 drugstores. Walgreen sells pulse oximeters that are not cleared by the FDA in both Walgreens 11 stores in California and on the Internet to people in California. 12 13. Compass Health Brands Corporation is headquartered in Middleburg Heights, 13 Ohio. Compass Health distributes pulse oximeters that are not cleared by the FDA and that are 14 sold in California. 14. 15 Defendant Veridian Healthcare, LLC, is based in Gurnee, Illinois. Veridian 16 Healthcare imports and distributes pulse oximeters, including at least some that are not cleared 17 by the FDA. Veridian Healthcare's pulse oximeters are sold to people in California.

18 15. Defendant Contec Medical Systems USA Inc. is based in Elk Grove Village,
19 Illinois. Contec sells pulse oximeters, including at least some that are not cleared by the FDA, to
20 people in California.

21 16. Defendant Einstein Associates LLC is based in Stafford, Texas. Einstein
22 Associates distributes Zacurate pulse oximeters, including at least some that are not cleared by
23 the FDA. Einstein Associates' Zacurate pulse oximeters are sold to people in California.

24 17. Defendant Gurin Products LLC is based in Tustin, California. Gurin distributes
25 SantaMedical pulse oximeters, including at least some that are not cleared by the FDA.

26 18. Defendant ChoiceMMed America Corporation is based in Bristol, Pennsylvania.
27 ChoiceMMed America distributes pulse oximeters that are both cleared and not cleared by the
28 FDA. ChoiceMMed America's pulse oximeters are sold in California.

1	19. Defendant Zewa, Inc., is based in Fort Myers, Florida. Zewa distributes and sells			
2	pulse oximeters that are cleared by the FDA. Zewa's pulse oximeters are sold in California.			
3	20. Defendant Masimo Corporation is based in Irvine, California. Masimo develops			
4	and produces pulse oximeters that are cleared by the FDA.			
5	21. Defendant Medtronic, Inc., is substituted for Doe 1, and has operational			
6	headquarters in Minneapolis, Minnesota. Defendant Covidien Sales LLC is a subsidiary of			
7	Medtronic based in Mansfield, Massachusetts. Through Covidien Sales LLC, Medtronic sells			
8	pulse oximeters under the Nellcor brand that are cleared by the FDA, including into California.			
9	22. Defendant GE HealthCare Technologies Inc. is based in Chicago, Illinois. GE			
10	HealthCare develops, manufactures, and sells patient monitoring systems that include pulse			
11	oximeter technology cleared by the FDA, including to entities in California.			
12	23. Defendants Does 2-50 are sued pursuant to Code of Civil Procedure §474. Does			
13	2-50 manufacture, distribute, or sell pulse oximeters or are otherwise responsible for the			
14	occurrences or harm alleged in this Complaint. The true names and capacities of Does 1-50 are			
15	unknown to Roots, which therefore sues them under these fictitious names. Roots will amend			
16	this Complaint to add their true names and capacities when they become known.			
17	JURISDICTION AND VENUE			
18	24. This Court has jurisdiction over this action pursuant to the California			
19	Constitution, Article VI, §10, because jurisdiction is not given to other courts.			
20	25. Venue is proper in this Court under Code of Civil Procedure §395.5 because the			
21	obligation or liability of Defendants with respect to Roots arises in the County of Alameda,			
22	where Roots is based and suffered injury.			
23	FACTUAL ALLEGATIONS			
24	Hypoxia and Silent Hypoxia			
25	26. Hypoxia is one of the strongest predictors of mortality in Covid-19. "Silent			
26	hypoxia," which occurs when a person does not appear to be short of breath but has abnormally			
27	low oxygen levels, is a major danger of Covid-19 as the hypoxia may go unassessed and/or			
28	undiagnosed. Hypoxia can irreparably damage vital organs if not timely detected.			
	5 FIRST AMENDED COMPLAINT			
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27. 1 Several medical conditions can give rise to silent hypoxia, including asthma, 2 pneumonia, chronic obstructive pulmonary disease, and heart problems. Widespread public 3 awareness of silent hypoxia occurred with the Covid-19 pandemic when it quickly became 4 apparent that hypoxia is one of the early indications as well as one of the greatest dangers of 5 Covid-19, which can cause precipitous drops in oxygen saturation levels. During much of 2020, 6 people around the world were transfixed by stories and pictures of oxygen-deprived persons 7 struggling to reach medical facilities for treatment, and of health workers administering oxygen 8 to weakened patients.

- 9 Pulse Oximeters
- 10

28. The primary way to diagnose hypoxia is a pulse oximeter.

29. 11 The most popular pulse oximeter is a device that is clipped over a finger to 12 measure the saturation of oxygen in the blood. Devices can also clip over a toe or ear lobe. 13 Pulse oximeters emit small beams of light through the skin and, based on how the blood absorbs 14 the light, estimate the percentage of oxygen in the blood. Blood that is highly saturated by 15 oxygen yields a reading of 95 to 98 percent in most healthy individuals. Oxygen saturation that 16 dips below 90 percent is considered hypoxic, which means there is a lower level of oxygen than 17 is needed in the blood. Depleted oxygen can lead to lightheadedness, fainting, coughing, 18 wheezing, and even death.

30. There are two categories of pulse oximeters: (1) devices that the FDA clears for
medical use, and (2) devices that the FDA does not clear, which are marketed to consumers.
Some of Defendants' pulse oximeters have been cleared by the FDA and some have not.

31. Medical professionals use pulse oximeters at hospitals and medical clinics,
including at intake as part of measuring "vital signs." First responders use pulse oximeters to
assess the seriousness of health conditions. Much like blood pressure cuffs and stethoscopes,
pulse oximeters are ubiquitous throughout healthcare settings.

32. Individuals outside of medical settings also use pulse oximeters. For people
suffering from a health condition – or who are at risk of contracting a disease such as Covid-19 –

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that can affect one's oxygen levels, pulse oximeters are commonly dispensed, prescribed,
 ordered, or recommended by health care professionals for use at home.

3 33. People who use pulse oximeters outside of the clinical setting often do so to
determine whether and when to seek professional medical intervention and what intervention to
pursue. Based on the oxygen levels reported by a pulse oximeter, individuals may decide to
administer oxygen to themselves, increase the flow of oxygen already being administered,
contact their health care provider for medical advice, transport themselves to a medical facility
for treatment, or summon emergency medical assistance.

9 34. The U.S. Centers for Disease Control and Prevention ("CDC") advises healthcare
10 workers that they must regularly monitor oxygen levels of Covid-19 patients and can use a pulse
11 oximeter to do so. CDC advises healthcare workers to start oxygen therapy if a Covid-19 patient
12 has an oxygen saturation below 90 percent.

13 35. The use of pulse oximeters to measure oxygen levels in people with Covid-19 has
14 been widely reported – so much so that demand for pulse oximeters outstripped supply for part
15 of 2020. Defendants were aware or should have been aware that pulse oximeters are used to
16 measure oxygen levels in Covid-19 patients by sometime in 2020.

## 17 || <u>The Problem</u>

18 36. Studies have found that pulse oximeters are inaccurate in people with darker skin. 19 A study reported in the December 17, 2020 New England Journal of Medicine compared actual 20 levels of oxygen to the levels shown by pulse oximeters and found Black patients were far more 21 likely than white patients to have pulse oximeters overestimate oxygen levels. The study 22 compared instances where actual oxygen saturation was less than 88 percent with pulse oximeter 23 readings in the range of 92 to 96 percent. For Black patients who had oxygen saturation of 92 to 24 96 percent on pulse oximeters, the actual oxygen saturation was less than 88 percent 25 approximately 11.5 percent of the time. For white patients who had oxygen saturation of 92 to 26 96 percent on pulse oximeters, the actual oxygen saturation was less than 88 percent only 3.6 27 percent of the time. That is, Black patients were approximately three times as likely as white 28 patients to obtain the inaccurate pulse oximeter oxygen reading of less than 88 percent.

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1	37. As these figures suggest, the pulse oximeter's inaccuracy for people with darker			
2	skin is not symmetric or random. The pigmentation-derived inaccuracies of pulse oximeter			
3	readings in people with darker skin consistently skew – or are biased – in one dangerous			
4	direction: showing that their blood is more oxygenated than it is in reality.			
5	38. In exaggerating the blood oxygen levels of darker-skinned persons, pulse			
6	oximeters jeopardize the well-being of these persons by concealing the medical risks they face,			
7	and thus masking the need for timely, perhaps life-saving treatment. Even small average			
8	differences in pulse oximeter accuracy between people with darker and lighter skin can result in			
9	significant health consequences.			
10	39. The difference between an oxygen level of 88 percent and 96 percent – or even 92			
11	percent – can be the difference between rushing to the hospital versus staying at home and			
12	between receiving medically necessary oxygen treatment or not.			
13	40. The study in the New England Journal of Medicine was widely covered in the			
14	media, including in the New York Times. Defendants were aware or should have been aware of			
15	the study by the end of 2020.			
16	41. The American College of Emergency Physicians has concluded: "There is a large			
17	body of evidence suggesting that pulse oximeters are less accurate in individuals with darker skin			
18	pigmentation, thus complicating the ability of emergency physicians to deliver the same level of			
19	care for darker-skinned patients with hypoxia as their lighter-skinned counterparts."			
20	42. The American Academy of Pediatrics has likewise stated: "There is strong			
21	evidence that pulse oximeters are less accurate in individuals with darker skin pigmentation."			
22	43. The disparate reliability of pulse oximeter readings based on differentiating			
23	darkness of skin pigmentation is not limited to Covid-19, but the pandemic surfaced this medical			
24	disparity in dramatic, irrefutable, and deadly terms.			
25	44. People with darker skin have been disproportionately affected by Covid-19. For			
26	instance, the CDC has found that the percentage of Latino, Black, and American Indian or			
27	Alaska Native people who have died from Covid-19 is higher than their percentage of the U.S.			
28	population.			

45. Covid-19's disproportional adverse effect on people with darker skin, including
 higher death rates, has been widely reported in the media. Defendants were aware or should
 have been aware of this at least by the end of 2020.

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46. The American College of Emergency Physicians has stated: "The documented limitations and inaccuracies in pulse oximeters are slowing or preventing some patients with darker skin pigmentation from receiving lifesaving interventions and contributing to racial disparities in health care we see today."

8 47. That a pulse oximeter has been cleared by the FDA does not mean that it is 9 accurate in people with darker skin. The FDA's current guidance for pulse oximeter approval 10 recommends – but does not require – that a "study should have subjects with a range of skin 11 pigmentations, including at least 2 darkly pigmented subjects or 15% of your subject pool, 12 whichever is larger." Even assuming pulse oximeter manufacturers follow this non-binding 13 guidance, manufacturers use various subjective measurements of skin pigmentation. Both the 14 subjective nature of these measurements and the different methods employed to measure skin 15 pigmentation undercut the reliability of studies. Further, the sample size of persons with darker 16 skin pigmentation used by testers is generally too small, meaning a device might appear to be 17 accurate even if it was inaccurate in people with darker skin so long as the device reported 18 accurate readings in a larger number of people with lighter skin. Even were a study conducted 19 on an appropriate number of people with darker skin and using objective and standard 20 measurements of skin pigmentation, that would not show that the pulse oximeter provides 21 reliably accurate readings in real world settings (as opposed to a controlled laboratory) - for 22 example, with unwell patients or with patients with low perfusion (blood flow) or other 23 conditions that combine with darker skin to cause or exacerbate inaccurate measurements.

48. The same issues with respect to testing are true for devices that have not beencleared by the FDA.

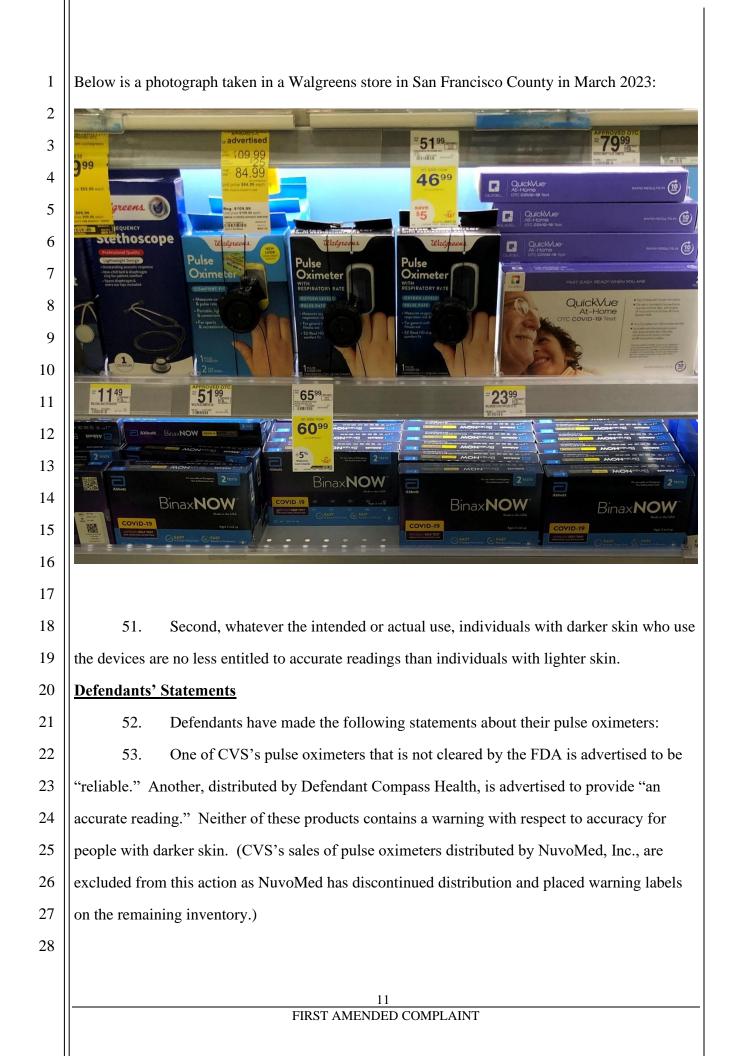
49. With respect to perfusion, a laboratory study on healthy people conducted in 2020
and 2021 found that for individuals with darkly pigmented skin and low perfusion, a Masimo
pulse oximeter registered oxygen saturation of 92 percent or above when actual oxygen

saturation was less than 88 percent in approximately 30 percent of the readings and a Nellcor
 pulse oximeter did so in approximately 8 percent of the readings. Low perfusion amplifies the
 bias of pulse oximeters in real world situations.

4 50. It is irrelevant that a pulse oximeter that is not cleared by the FDA is marketed as 5 not for medical use for at least two reasons. First, many people – including many front-line 6 health care professionals, even physicians – believe the devices are intended for medical use and 7 use them in that manner for themselves as well as their patients – and Defendants are well-aware 8 of that common use. Indeed, CVS and Walgreens stores have placed pulse oximeters in close 9 proximity to Covid-19 supplies, thereby demonstrating the reality that people are using the 10 devices for medical reasons. Below is a photograph taken in a CVS store in Alameda County in March 2023 that shows the placement: 11

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13 14 15 CVSHealth. 16 Portable 17 Pulse ximeter 18 2 TESTS 19 20 At-Home OTC COVID-19 Test 21 22 23 **1** OXIMETER (10 2 AAA BATTERIES, USER MANUAL 24 25 CVS PULSE OXIMETER 49.99 QUICKVUE COVID TST 2CT 26 \$23.99 27 28 10 FIRST AMENDED COMPLAINT



54. Walgreen sells one of Defendant ChoiceMMed America's pulse oximeters that is
 not cleared by the FDA and is advertised as follows: "Dependable oxygen level and pulse rate
 measurements." Walgreen also sells a pulse oximeter distributed by Defendant Veridian
 Healthcare that is not cleared by the FDA and advertised as follows: "Accurately measures
 oxygen saturation." None of these products contain a warning with respect to accuracy for
 people with darker skin.

55. Defendant Compass Health advertises that at least two of its pulse oximeters that
are not cleared by the FDA are "Accurate." Neither of these products contains a warning with
respect to accuracy for people with darker skin.

10 56. Defendant Veridian Healthcare advertises as follows for at least some of its pulse
11 oximeters that are not cleared by the FDA: "Accurately measures oxygen saturation." None of
12 the products that are so advertised contain a warning with respect to accuracy for people with
13 darker skin.

At least one of Defendant Contec's pulse oximeters that is not cleared by the FDA
is claimed to have "High accuracy" and at least one other is advertised as follows: "accurately
determines your SpO2 (blood oxygen saturation levels)." Neither of these products contains a
warning with respect to accuracy for people with darker skin.

18 58. At least one of Defendant Einstein Associates' Zacurate pulse oximeters that is
19 not cleared by the FDA is claimed to be "highly precise and reliable" and at least one other is
20 advertised as follows: "Accurately determines your SpO2 (blood oxygen saturation levels)."
21 Neither of these products contains a warning with respect to accuracy for people with darker
22 skin.

23 59. At least one of Defendant Gurin's SantaMedical pulse oximeters that is not
24 cleared by the FDA is claimed to be "VERY ACCURATE" and at least one other is advertised
25 as "precise." Neither of these products contains a warning with respect to accuracy for people
26 with darker skin.

27 60. Defendant ChoiceMMed America claims that at least one of its pulse oximeters
28 that is not cleared by the FDA will "accurately determine your SpO2" and that at least one other

is "Dependable." ChoiceMMed America does not provide a warning with respect to accuracy
 for people with darker skin for pulse oximeters that are not cleared by the FDA.

61. At least one of ChoiceMMed America's pulse oximeters that is cleared by the
FDA lists in the manual that accompanies the pulse oximeter various reasons for inaccurate
measurements but does not include darker skin pigmentation. ChoiceMMed America does not
provide a warning with respect to accuracy for people with darker skin for pulse oximeters that
are cleared by the FDA.

8 62. At least one of Defendant Zewa's pulse oximeters that is cleared by the FDA is
9 claimed as follows: "Accurately measures SpO2." At least one of Zewa's pulse oximeters that is
10 cleared by the FDA lists in the manual that accompanies the pulse oximeter various reasons for
11 inaccurate measurements but does not include darker skin pigmentation. Zewa does not provide
12 a warning with respect to accuracy of pulse oximeters for people with darker skin.

63. At least one of Defendant Masimo's pulse oximeters that is cleared by the FDA
has accuracy claims in the manual that accompanies the pulse oximeter as to healthy adults "with
light to dark skin pigmentation" and separately as to individuals with low perfusion. The manual
does not explain that measurements in people with darker skin are skewed towards showing that
people with darker skin have more oxygen than they do in reality, nor that dark skin

18 pigmentation can interact with other conditions to cause or exacerbate inaccurate measurements.

19 64. At least one of Medtronic/Covidien's pulse oximeters that is cleared by the FDA
20 notes in the manual that accompanies the pulse oximeter that dark skin pigment can cause
21 inaccurate measurements. The manual does not explain that measurements in people with darker
22 skin are skewed towards showing that people with darker skin have more oxygen than they do in
23 reality, nor that dark skin pigmentation can interact with other conditions to cause or exacerbate
24 inaccurate measurements.

65. At least some of GE HealthCare's patient monitoring systems offer three different
types of pulse oximeter technology cleared by the FDA: Defendant Masimo's, Defendant
Medtronic's, and Defendant GE HealthCare's own in-house TruSignal. The manual that
accompanies at least one such patient monitoring system notes for all three technologies that

1	darkly pigmented skin can cause inaccurate measurements. The manual does not explain that			
2	measurements in people with darker skin are skewed towards showing that people with darker			
3	skin have more oxygen than they do in reality, nor that dark skin pigmentation can interact with			
4	other conditions to cause or exacerbate inaccurate measurements.			
5	66. Despite the above statements, Defendants manufacture, distribute, and sell pulse			
6	oximeters that are less accurate for people with darker skin than for people with lighter skin, at			
7	least in situations where individuals are unwell or have low perfusion.			
8	FIRST CAUSE OF ACTION			
9	(Violations of California Business and Professions Code §17200, et seq.)			
10	67. Roots realleges and incorporates by reference the allegations contained in the			
11	above paragraphs.			
12	68. California Business and Professions Code §17200 provides that "unfair			
13	competition shall mean and include any unlawful, unfair or fraudulent business act or practice."			
14	69. For pulse oximeters that have been cleared by the FDA, Defendants ChoiceMMed			
15	America, Zewa, Masimo, Medtronic/Covidien, and GE HealthCare committed unlawful business			
16	acts and practices within the meaning of California Business and Professions Code §17200			
17	because:			
18	(a) It is unlawful "to manufacture, sell, deliver, hold, or offer for sale any			
19	drug or device that is misbranded" under California Health and Safety Code §111440, "to			
20	misbrand any drug or device" under §111445, and "to receive in commerce any drug or device			
21	that is misbranded or to deliver or proffer for delivery any drug or device" under §111450.			
22	(b) Pulse oximeters that have been cleared by the FDA are "devices" under			
23	California Health and Safety Code §109920.			
24	(c) A "device is misbranded if its labeling is false or misleading in any			
25	particular" under California Health and Safety Code §111330. "Labeling" is defined in §109960			
26	to be "any label or other written, printed, or graphic matter upon a food, drug, device, or			
27	cosmetic or upon its container or wrapper, or that accompanies any food, drug, device, or			
28	cosmetic."			
	14			

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- (d) Defendants ChoiceMMed America, Zewa, Masimo, Medtronic/Covidien,
   and GE HealthCare manufacture, sell, deliver, hold, or offer for sale devices that are misbranded
   in that the labeling is false or misleading; misbrand devices; receive in commerce devices that
   are misbranded; or deliver or proffer for delivery devices that are misbranded.
- 5 70. For pulse oximeters that have not been cleared by the FDA, all Defendants except
  6 Zewa, Masimo, Medtronic/Covidien, and GE HealthCare committed unfair business acts and
  7 practices within the meaning of California Business and Professions Code §17200 by:
- 8 (a) Engaging in conduct that is immoral, unethical, oppressive, unscrupulous,
  9 or substantially injurious to Roots and the patients it serves as well as to consumers, including by
  10 (i) manufacturing, distributing, or selling pulse oximeters that are inaccurate as to people with
  11 darker skin and (ii) failing to provide an adequate warning of the inaccuracy.

12 (b) Engaging in conduct that is (i) the cause of substantial injury to Roots and 13 the patients it serves as well as to consumers, including because Defendants obtain substantial 14 profit from people who buy pulse oximeters while Roots must spend time and money to raise 15 awareness about the inaccuracies of pulse oximeters; (ii) not outweighed by any countervailing 16 benefits, including because the benefit of pulse oximeters for those who obtain an accurate 17 reading can be maintained while either redesigning the product to be more accurate for those 18 who do not or providing a warning; and (iii) not reasonably avoided, including because the injury 19 flows from a consumer transaction in the absence of full information (and Roots' response to fill 20 the information gap).

(c) Engaging in conduct that violates or undermines legislatively declared
policy, including a multicultural health statute that requires the State of California to develop
"plans for implementation of goals and objectives to close the gaps in health status and access to
care among the state's diverse racial and ethnic communities" (Health and Safety Code §152)
and California policy to address racial and ethnic disparities in health care (A.B. 241, 2019-20
Sess., ch. 471, §1, 2019 Cal. Stat.).

27 [71. Roots has suffered injury in fact and lost money and property as required by
28 [California Business and Professions Code §17204 as a result of Defendants' unlawful and unfair

1 business acts and practices, including because of the following: Roots has spent time and money 2 independent of that incurred in litigation or preparation for litigation in investigating and 3 publicizing the deficiencies of pulse oximeters for people with darker skin. For instance, the 4 Chief Executive Officer of Roots, Dr. Noha Aboelata, co-authored and expended time on helping 5 design and oversee the research, data review, drafting, and publication of an article in the 6 American Journal of Epidemiology entitled "Racial Disparities in Pulse Oximetry Device 7 Inaccuracy and Estimated Clinical Impact on COVID-19." That article described the results of a 8 study on the accuracy of pulse oximeters in Black patients and was independent of litigation or 9 preparation for litigation. Dr. Aboelata communicated with media representatives in conjunction 10 with that article and regarding pulse oximeters that were independent of litigation or preparation for litigation. Dr. Aboelata spoke at a summit at the White House on Covid-19 equity and with a 11 12 White House representative independent of litigation or preparation for litigation, including 13 about pulse oximeters, expending both her time and Roots' money. Dr. Aboelata spent time 14 speaking at a forum on pulse oximeters sponsored by the University of California San Francisco. 15 Dr. Aboelata raised issues about pulse oximeters with people responsible for medical treatment 16 as well as with patients she treated. Roots spent time and money with respect to pulse oximeters 17 as a result of the acts and practices challenged in this lawsuit. That time and money could have 18 been spent in other ways that would benefit Roots and the people it serves. 19 72. California Business and Professions Code §17203 provides for injunctive and

19 72. California Business and Professions Code §17203 provides for injunctive and
20 other equitable relief to remedy "unfair competition," including both "unlawful" and "unfair"
21 business acts and practices. Injunctive relief is necessary to prevent Defendants from engaging
22 in the unlawful and unfair business acts and practices alleged above; unless enjoined by the
23 Court, Defendants will continue to engage in these acts and practices.

24

## SECOND CAUSE OF ACTION

(Violations of California Business and Professions Code §17500, et seq.)
 73. Roots realleges and incorporates by reference the allegations contained in the
 above paragraphs.

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74. California Business and Professions Code §17500 prohibits making or
 disseminating "untrue or misleading" statements.

3 75. As set forth above, certain of Defendants' statements with respect to pulse
4 oximeters that have not been cleared by the FDA are untrue or misleading and have deceived and
5 are likely to deceive consumers.

6 76. Defendants other than Zewa, Masimo, Medtronic/Covidien, and GE HealthCare
7 knew or should have known that statements as set forth above with respect to pulse oximeters
8 that have not been cleared by the FDA are untrue or misleading and would deceive or would be
9 likely to deceive consumers.

10 77. Roots spent the time and money it has in investigating and publicizing the
11 deficiencies of pulse oximeters for people with darker skin as a result of statements with respect
12 to pulse oximeters that have not been cleared by the FDA that are untrue or misleading and have
13 deceived or are likely to deceive consumers.

- 14 78. California Business and Professions Code §17535 provides for injunctive and
  15 other equitable relief to remedy violations of §17500. Injunctive relief is necessary to prevent
  16 Defendants from engaging in the acts and practices alleged above; unless enjoined by the Court,
  17 Defendants will continue to engage in these acts and practices.
- 18

#### **PRAYER FOR RELIEF**

19 WHEREFORE, Plaintiff Roots Community Health Center prays for the following relief: 20 1. An injunction (a) prohibiting any further sales of the pulse oximeters at issue into 21 California unless and until they provide accurate readings for people with darker skin or, in the 22 alternative, unless and until an adequate warning about the inaccuracies for people with darker 23 skin is provided; (b) prohibiting Defendants from engaging in the acts and practices complained 24 of above in California; and (c) requiring Defendants to distribute information about the 25 inaccuracies for people with darker skin to those who have purchased the pulse oximeters at 26 issue and any other affected persons in California and to any such persons outside of California 27 with respect to pulse oximeters manufactured, distributed, or sold by a California company. 28 2. A declaration that Defendants have violated the law as described above.

# FIRST AMENDED COMPLAINT

1	3. Attorneys' fees pursuant to Code of Civil Procedure §1021.5 and any other			
2	applicable statute or doctrine that entitles Plaintiff to an award of fees.			
3	4.	4. Costs of suit.		
4	5.	5. Such other and further relief as this Court may deem just and proper.		
5	Dated: Janua	ary 11, 2024	Jonathan Weissglass Law Office of Jonathan Weissglass	
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7			Daniel N. Abrahamson Law Office of Daniel N. Abrahamson	
8			By: <u>/s/ Jonathan Weissglass</u>	
9			Jonathan Weissglass	
10			Attorneys for Plaintiff Roots Community Health Center	
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