UNITED STATES DISTRICT COURT
DISTRICT OF MASSACHUSETTS

UNITED STATES *ex rel.* Benjamin Scarborough, Plaintiff, v. TACTILE SYSTEMS TECHNOLOGY, INC., Defendant.	Civil Action No. 21-cv-10813 Talwani J. FILED IN CAMERA AND UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2) DO NOT ENTER INTO PACER DO NOT PLACE IN PRESS BOX

FALSE CLAIMS ACT COMPLAINT

Introduction

1. Benjamin Scarborough (the "Relator") brings this action as a *qui tam* relator on behalf of the United States against Tactile Systems Technology, Inc. ("Tactile"), pursuant to the *qui tam* provisions of the False Claims Act, 31 U.S.C. § 3729-33, to recover damages, penalties, attorneys' fees and costs, and other relief. Relator alleges that Tactile directed its sales personnel to fabricate medical documentation necessary to support Medicare reimbursement claims for Tactile's products.

2. Tactile develops, promotes, and distributes two pneumatic compression devices ("PCDs"), the Entre and the Flexitouch, which are used to treat lymphedema. Tactile bills Medicare directly for these PCDs, as well as for the garments that patients wear while using the PCDs. Under relevant Medicare rules, in order to bill Medicare for either of its PCDs, Tactile must have documentation showing that a more "conservative" (i.e., less-costly) mode of therapy did not improve the patient's condition.

3. From March 2020 until February 2021, Relator marketed and sold Tactile's PCDs and garments. His responsibilities included not only convincing healthcare providers to order Tactile PCDs for their patients, but also obtaining documentation to show the medical necessity of the Tactile equipment and then providing that documentation to Tactile headquarters personnel who submitted reimbursement claims to Medicare and other insurers. When Relator explained to his manager the difficulty in obtaining this documentation, the manager connected him with another Tactile employee who explained how to fabricate documentation showing that a more conservative mode of therapy had failed to improve the patient's condition and thus that a Tactile PCD was medically necessary. The Tactile employee also told Relator that he would fill in the clinical information requested in Section B of CMS Form 846 – Certificate of Medical Necessity ("CMN") – a form that must accompany each initial Medicare reimbursement claim for a PCD – even though the form states, in bold print "SECTION B: Information in this Section May Not Be Completed by the Supplier of the Items/Supplies." Relator subsequently learned from other current and former Tactile employees that these fraudulent practices were widespread at Tactile.

4. Tactile's claims to Medicare violated the False Claims Act because they relied on fabricated medical records with forged or copied signatures of healthcare providers, as well as on CMNs with clinical information that had been provided by Tactile personnel rather than by treating providers. Tactile knew that its claims were false, not only because the fraud was blatant, but because the Department of Health and Human Services Office of Inspector General ("HHS-OIG") long ago published program guidance for equipment suppliers warning against "[f]alsifying information on the claim form, CMN, and/or accompanying documentation," and "[c]ompleting portions of CMNs reserved for completion only by the treating physician or other

authorized person." *See* HHS-OIG, Publication of OIG Compliance Program Guidance for the Durable Medical Equipment, Prosthetics, Orthotics and Supply Industry, 64 Fed. Reg. 36368, 36373 (July 6, 1999).

5. Prior to the filing of this Complaint, Relator made substantive disclosures to the government of facts and evidence underlying the allegations in this Complaint, in accordance with the requirements of the False Claims Act, 31 U.S.C. § 3730(b)(2).

6. The Relator is an original source of the information underlying this Complaint and of the information provided to the United States prior to the filing of this Complaint. *See* 31 U.S.C. § 3730(e)(4)(B). To the Relator's knowledge, the information underlying the allegations and transactions in this Complaint has not been publicly disclosed.

7. This action is filed *in camera* and under seal pursuant to the requirements of the False Claims Act. 31 U.S.C. § 3730(b)(2).

Jurisdiction and Venue

8. This action arises under the False Claims Act ("FCA"), as amended, 31 U.S.C. §§ 3729-33. This Court has jurisdiction over this action under 31 U.S.C. § 3732 and 28 U.S.C. §§ 1331 and 1345.

9. Venue is proper in the District of Massachusetts pursuant to 28 U.S.C. § 1391(b) and 31 U.S.C. § 3732(a).

10. This Court may exercise personal jurisdiction over Tactile pursuant to 31 U.S.C. § 3732(a) and because Tactile transacts business in this District.

The Parties

11. Relator Scarborough is a resident of Raymond, Maine, and has over ten years of sales and marketing experience. In March 2020, Relator started as an Associate Product

Specialist at Tactile. Initially, he assisted Jennifer "Natasha" Porras, a Product Specialist at Tactile, in marketing and selling Tactile products in Maine and New Hampshire, and at the Veterans Affairs Medical Center in White River Junction, Vermont. In or about September 2020, Tactile fired Ms. Porras for failing to meet the company's monthly sales quotas, and Relator assumed her responsibilities, although his title did not change. On February 12, 2021, he notified Tactile of his intent to resign his position because of the company's fraudulent conduct. Relator ceased working at Tactile on February 26, 2021.

12. Defendant Tactile is a Delaware corporation headquartered at 3701 Wayzata Blvd, Suite 300, Minneapolis, Minnesota 55416. Tactile markets its Entre and Flexitouch systems as at-home therapies for the treatment of lymphedema and chronic venous insufficiency. According to the NPI Registry, Tactile is registered to submit claims to Medicare for its devices using National Provider Identifiers 1427131424, 1982244380, 1497395800, 1811537228, and 1871065599. To support those claims, or appeals of denials of those claims, Tactile gathers, creates, and maintains medical records and other documents concerning the medical necessity of its products for particular patients.

Lymphedema and Chronic Venous Insufficiency

A. Lymphedema

13. Tactile's 2020 Annual Report explains that the lymphatic system "consists of lymph vessels and lymph organs that protect the body against harmful bacteria and transport lymph fluid from the body's tissues back to the cardiovascular system." Tactile 2020 Annual Report, SEC Form 10-K (Feb. 23, 2021), at 7. The Annual Report further explains that lymphedema "occurs when there is impairment to the lymphatic system, disrupting normal transport of lymph fluid within the body." *Id.* Lymphedema causes "accumulation of fluid in the

tissue." Local Coverage Determination L33829, Pneumatic Compression Devices, at 4. According to Tactile, the swelling "related to lymphedema can present anywhere in the body, including the head, neck, arms, legs, trunk and genitals." Tactile 2020 Annual Report at 8. Tactile further asserts that, while lymphedema "has no known cure . . . [t]he symptoms of lymphedema can be managed." *Id.*

B. Chronic Venous Insufficiency

14. CVI, Tactile explains, "occurs when the venous wall and/or valves in the veins are not working effectively, making it difficult for blood to return to the heart." *Id.* According to the Local Coverage Determination, CVI can cause lymphedema "when fluid leaks into the tissues from the venous system." Tactile asserts that, if CVI is left untreated, ulcers can develop "as swelling interferes with the movement of oxygen and nutrients through tissues." Tactile 2020 Annual Report at 8.

Tactile's Products

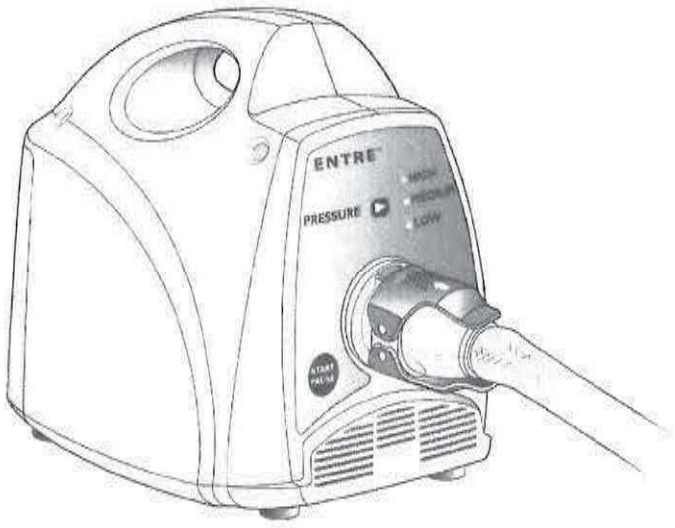
15. Tactile sells two PCD systems: (1) the Entre, which, as its name suggests, is an entry-level PCD, and (2) the Flexitouch, which is a more sophisticated – and much more expensive – PCD. Tactile also sells the garments that a patient must wear during treatment with either of the Tactile PCDs.

A. Entre System

16. Tactile describes its Entre system as "a basic pneumatic compression device used for the at-home treatment of venous disorders including lymphedema and [CVI]." *Id.* at 11. The Entre system consists of a pneumatic "pump with garments covering the arm or leg with eight chambers that inflate in sequence and remain inflated for a preset time period. All chambers deflate at once. [The] Entre system moves fluid from fingers or toes toward areas closer to the

trunk. The system can be programmed to a variety of pressures delivering a prescribed treatment. . . ." *Id.*

17. Tactile's Entre User Guide contains the following images of the Entre and associated leg garments:



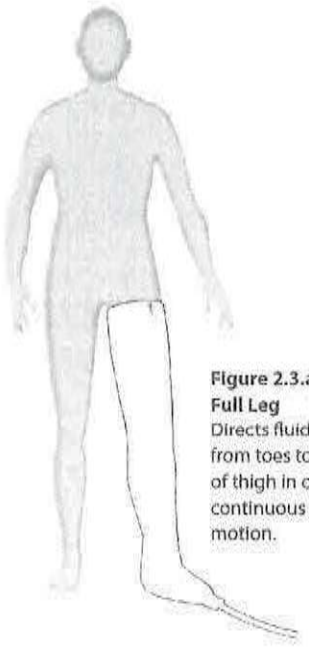


Figure 2.3.a
Full Leg
Directs fluid from toes to top of thigh in one continuous motion.

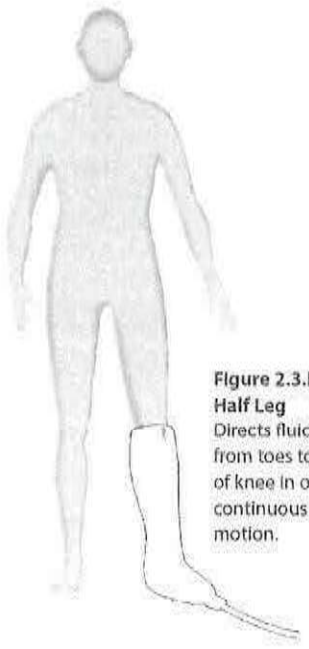


Figure 2.3.b
Half Leg
Directs fluid from toes to top of knee in one continuous motion.

According to the Entre User Guide, the Entre treatment time is 60 minutes per session.

18. According to Tactile, the Entre system controller is reimbursed under HCPCS code E0651. Tactile 2020 Annual Report at 16. As of the fourth quarter of 2020, the Medicare allowable amount for HCPCS code E0651 in Maine, Massachusetts, and New Hampshire was $906.92. *See* Noridian DMEPOS Fee Schedule.

B. Flexitouch System

19. Tactile describes its Flexitouch system as "a fully automated, programmable, advanced pneumatic compression device, or APCD, designed for treatment of lymphedema in the home setting." Tactile 2020 Annual Report at 11. The Flexitouch Plus system (the latest iteration of the Flexitouch line) "consists of an electronic controller unit that offers 17 treatment settings and multiple contoured garment configurations for the trunk, chest, head, neck and the arm or leg. The electronic controller is a pneumatic compressor with four connector outlets. Each connector has eight outflow ports into which the garment hoses are connected. . . . [A]ir passes through the hoses, delivering sequential inflation and deflation to the garments." *Id.*

20. Tactile's Flexitouch Plus User Guide contains the following images of the Flexitouch Plus and a leg garment with trunk accessory:

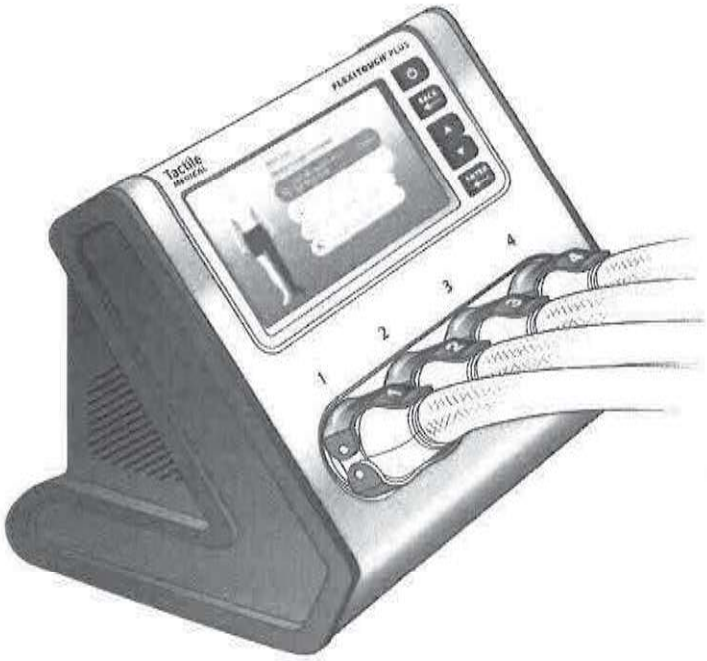


Figure 5.2.b. Fully Applied Full Leg Garment and Trunk Accessory

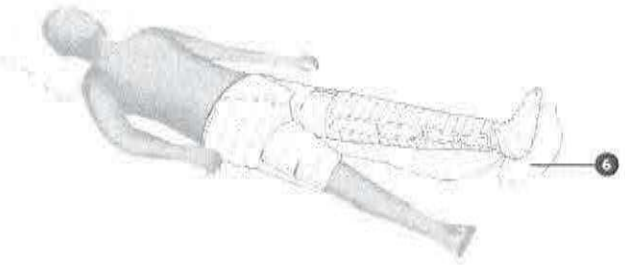
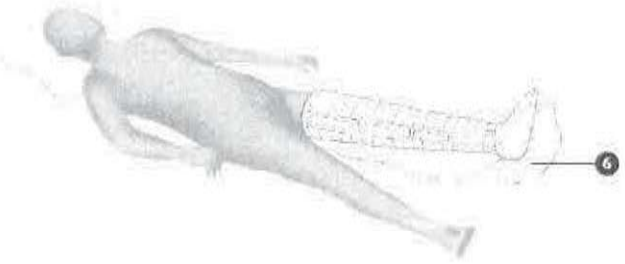


Figure 5.2.c. Fully Applied Full Leg Garment



21. According to Tactile, the Flexitouch system controller is reimbursed under HCPCS code E0652. Tactile 2020 Annual Report at 16. As of the fourth quarter of 2020, the Medicare allowable amount for HCPCS code E0652 in Maine, Massachusetts, and New Hampshire was $6,158.92. *See* Noridian DMEPOS Fee Schedule.

C. Tactile's PCD Garments

22. According to Tactile, the Entre and Flexitouch garments for various parts of the body are reimbursed under HCPCS codes E0667, E0668 and E0669. Tactile 2020 Annual Report at 16. (Tactile's head and neck garments do not currently have billing codes assigned. *See id.*) As of the fourth quarter of 2020, Medicare reimbursement for these HCPCS codes in Maine, Massachusetts, and New Hampshire ranged from $202.20 (E0669) to $513.35 (E0668). *See* Noridian DMEPOS Fee Schedule.

Medicare Coverage Requirements for Tactile's Products

23. Medicare Part B covers 80 percent of the cost of durable medical equipment ("DME") such as Tactile's products. *See* 42 U.S.C. § 1395m. The Centers for Medicare and Medicaid Services ("CMS") contracts with private entities known as Medicare Administrative Contractors ("MACs") to administer, process, and pay Medicare Part B claims for DME. *See* 42 U.S.C. § 1395kk-1(a)(4).

24. Medicare Part B does not reimburse "for any expenses incurred for items or services which . . . are not reasonable and necessary for the diagnosis or treatment of illness or injury or to improve the functioning of a malformed body member." 42 U.S.C. § 1395y(a)(1)(A). While the Medicare statute does not define "reasonable and necessary," Congress empowered CMS to issue National Coverage Determinations ("NCDs") "with respect to whether or not a particular item or service is covered nationally." 42 U.S.C. § 1395ff(f)(1)(B); *see also* 42 C.F.R. § 405.1060(a)(1) ("An NCD is a determination by the Secretary of whether a particular item or service is covered nationally under Medicare.").

25. In addition, Congress empowered MACs to issue Local Coverage Determinations ("LCDs") "respecting whether or not a particular item or service is covered" by that MAC. 42 U.S.C. § 1395ff(f)(2)(B).

A. The NCD for PCDs

26. The NCD for PCDs states that:

> Pneumatic compression devices are covered only when prescribed by a physician and when they are used with appropriate physician oversight, i.e., physician evaluation of the patient's condition to determine medical necessity of the device, assuring suitable instruction in the operation of the machine, a treatment plan defining the pressure to be used and the frequency and duration of use, and ongoing monitoring of use and response to treatment.
>
> The determination by the physician of the medical necessity of a pneumatic compression device must include:
>
> 1. The patient's diagnosis and prognosis;
> 2. Symptoms and objective findings, including measurements which establish the severity of the condition;
> 3. The reason the device is required, including the treatments which have been tried and failed; and
> 4. The clinical response to an initial treatment with the device.
>
> The clinical response includes the change in pre-treatment measurements, ability to tolerate the treatment session and parameters, and ability of the patient (or caregiver) to apply the device for continued use in the home.
> The only time that a segmented, calibrated gradient pneumatic compression device (HCPCs code E0652) [such as Flexitouch] would be covered is when the individual has unique characteristics that prevent them from receiving satisfactory pneumatic compression treatment using a nonsegmented device in conjunction with a segmented appliance or a segmented compression device without manual control of pressure in each chamber.

CMS, Medicare National Coverage Determinations Manual, Ch. 1, § 280.6, NCD for Pneumatic Compression Devices (Jan. 14, 2002). Thus, in order for a Medicare claim for a PCD to satisfy the requirements of the NCD, the underlying medical record must reflect, among other things, measurements that "establish the severity of the condition," measurements from before and after

an initial treatment with the device showing that the PCD improved the patient's condition, and a finding that the patient is able to tolerate the initial treatment session with the device. *See id.*

B. The LCD for PCDs

27. LCD L33829 provides further detail concerning when MACs will cover expenses for a PCD with HCPCS code E0651 or E0652. By its terms, LCD L33829 applies in all 50 states and the District of Columbia.

28. Under LCD L33829, reimbursement for a PCD coded as E0651 is allowed only for Medicare beneficiaries with "chronic and severe lymphedema" and only:

> when all of the following three requirements are met:
> 1. The beneficiary has a diagnosis of lymphedema . . ., and
> 2. The beneficiary has persistence of chronic and severe lymphedema as identified by the documented presence of at least one of the following clinical findings:
>   - Marked hyperkeratosis with hyperplasia and hyperpigmentation,
>   - Papillomatosis cutis lymphostatica,
>   - Deformity of elephantiasis,
>   - Skin breakdown with persisting lymphorrhea,
>   - Detailed measurements over time confirming the persistence of the lymphedema with a history evidencing a likely etiology, and
> 3. In addition to this documented persistence, the lymphedema is then documented to be unresponsive to other clinical treatment over the course of a required four-week trial.

LCD L33829 at 5. According to the LCD, the "four-week trial of conservative therapy" that is a pre-condition to coverage under E0651:

> must include all of the following:
> - Regular and compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
>   - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement, and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
>   - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.

- Regular exercise
- Elevation of the limb

Id. at 6. The LCD stresses that, "[a]t the end of the four-week trial, if there has been improvement, then reimbursement for a PCD is not justified." *Id.* The LCD further explains that "[t]he trial of conservative therapy must be documented in the beneficiary's medical record before prescribing any type of pneumatic compression device." *Id.* at 7.

29. A PCD coded as E0561 may be covered to treat CVI of the lower extremities only if the patient has edema, "one or more venous stasis ulcer(s), and the ulcer(s) have failed to heal after a six-month trial of conservative therapy directed by the treating practitioner." *Id.* PCDs coded as E0562 are not covered to treat CVI. *Id.*

30. Under the LCD, in order for a Medicare beneficiary with lymphedema to receive coverage for a PCD coded as E0652, the beneficiary must have lymphedema that has extended from the extremities "onto the chest, trunk, and/or abdomen," and the "chest, trunk and/or abdominal lymphedema [must have] failed to improve with a four-week trial" that consisted of:

- At least four weeks of regular, daily, multiple-hour home usage of the E0650 or E0651 after careful, in-person fitting, training and supervision by a technician who is skilled in and who regularly and successfully uses the appliance provided
- Compliant use of an appropriate compression bandage system or compression garment to provide adequate graduated compression
  - Adequate compression is defined as (1) sufficient pressure at the lowest pressure point to cause fluid movement and (2) sufficient pressure across the gradient (from highest to lowest pressure point) to move fluid from distal to proximal. The compression used must not create a tourniquet effect at any point.
  - The garment may be prefabricated or custom-fabricated but must provide adequate graduated compression starting with a minimum of 30 mmHg distally.
- Regular exercise
- Elevation where appropriate
- Manual lymphatic drainage (where available) and self-manual lymphatic drainage (MLD) for at least 30 minutes per day
- Evaluation of diet and implementation of any necessary change

- Medications as appropriate (e.g. diuretics and/or other treatment of congestive failure, etc.)
- Correction (where possible) of anemia and/or hypoprotenemia

Id. at 9.

31. The LCD states that coverage is available for the garments used with PCDs "only when the appropriate, related base PCD . . . meets the applicable coverage criteria for that type of PCD." *Id.*

32. The LCD incorporates by reference a separate Policy Article on PCDs. Local Coverage Article: Pneumatic Compression Devices – Policy Article (A52488). The Policy Article specifies that coverage for a PCD coded as E0651 or E0652 is available only when the patient's medical record contains "careful, detailed records of measurements" showing that the relevant trial specified in the LCD failed to reduce the patient's swelling from edema. *Id.* at 5. The Policy Article further requires that:

> A Certificate of Medical Necessity (CMN) which has been completed, signed, and dated by the treating practitioner must be kept on file by the supplier and made available upon request. . . . The CMN for pneumatic compression pumps is CMS Form 846. The initial claim must include an electronic copy of the CMN. In addition to the order information that the treating practitioner enters in Section B, the supplier can use the space in Section C for a written confirmation of other details of the order or the treating practitioner can enter the other details directly.

Id. at 6.

33. The Policy Article refers to a separate article entitled Local Coverage Article: Standard Documentation Requirements for All Claims Submitted to DME MACs (A55426). The Standard Documentation Requirements Article specifies that "[d]ocumentation must be maintained in the supplier's files for seven (7) years" and that "[a]ll signatures must comply with the CMS signature requirements outlined in the Medicare Program Integrity Manual." *Id.* at 7, 17. That Manual explains that "Medicare requires that services provided/ordered/certified be

authenticated by the persons responsible for the care of the beneficiary." Medicare Program Integrity Manual (Pub. 100-08), § 3.3.2.4.

34. Consistent with the LCD requirements, Tactile's website includes a document entitled "Medicare Coverage Criteria for Lymphedema – Pneumatic Compression Devices (E0652)." The document shows that Tactile understood the nature and extent of the medical documentation it needed to have in its files to show that a claim for a PCD was reasonable and necessary.

The False Claims Act

35. The False Claims Act provides, in pertinent part, that any person who:

> knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval; [or]
>
> (B) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;
>
> . . . is liable to the United States Government for a civil penalty of not less than $5,000 and not more than $10,000, as adjusted by the Federal Civil Penalties Inflation Adjustment Act of 1990 (28 U.S.C. 2461 note; Public Law 104-410), plus 3 times the amount of damages which the Government sustains because of the act of that person.

31 U.S.C. § 3729(a)(1).

36. For purposes of the False Claims Act, the terms "knowing" and "knowingly" mean that a person, with respect to information: (i) has actual knowledge of the information; (ii) acts in deliberate ignorance of the truth or falsity of the information; or (iii) acts in reckless disregard of the truth or falsity of the information. No proof of specific intent to defraud is required. 31 U.S.C. § 3729(b)(1).

37. The False Claims Act defines the term "claim," in pertinent part, as

> any request or demand, whether under a contract or otherwise, for money or property and whether or not the United States has title to the money or property,

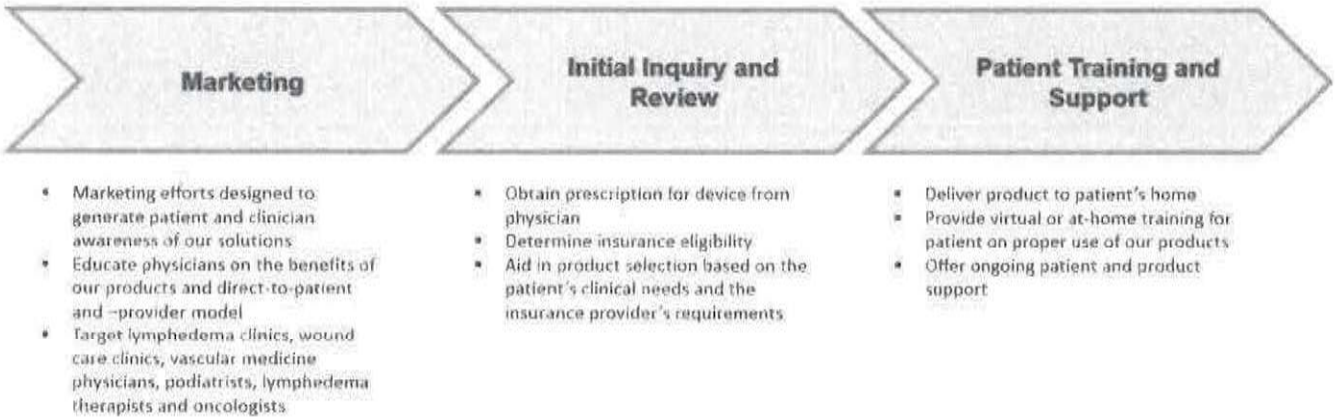
> that (i) is presented to an officer, employee, or agent of the United States; or (ii) is made to a contractor, grantee, or other recipient, if the money or property is to be spent or used on the Government's behalf or to advance a Government program or interest, and if the United States Government--(I) provides or has provided any portion of the money or property requested or demanded; or (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded[.]

31 U.S.C. § 3729(b)(2).

38. For purposes of the False Claims Act, the term "material" means "having a natural tendency to influence, or be capable of influencing, the payment or receipt of money or property." 31 U.S.C. § 3729(b)(4).

Tactile's Marketing, Distribution, and Billing Model

39. According to its Annual Report, Tactile uses "a direct-to-patient and -provider model, through which we obtain patient referrals from clinicians, manage insurance claims on behalf of our patients and their clinicians, deliver our solutions directly to patients and train them on the proper use of our solutions in their homes." Tactile 2020 Annual Report at 5. The Annual Report includes this graphic depiction of Tactile's marketing, sales, and distribution model:



Id. at 15.

40. To effectuate this model, Tactile employs sales representatives, which it calls Product Specialists and Associate Product Specialists. During Relator's tenure with the

company, Tactile divided its sales force into four "Areas" – Central, Northeast, Southern, and West. Each Area had multiple Regions, and each Region had one or more Districts. Relator worked in the New England District of the New England Region in the Northeast Area. From March 2020 until September 2020, Relator reported to Ms. Porras, who was the Product Specialist for Maine, New Hampshire, and the Veterans Affairs Medical Center in White River Junction, Vermont. Ms. Porras reported to Melissa Geraci, who was the District Manager for the New England District and, in January 2021, became the Regional Manager for the New England Region. From September 2020 until February 2021, Relator reported directly to Ms. Geraci. Ms. Geraci reported to Angela Neofotistos, the Director of Sales for the Northeast Area.

41. Tactile's Product Specialists were responsible for soliciting physicians and other healthcare providers to initiate orders of Tactile PCDs for their patients. After a healthcare provider initiated an order for an Entre for a Medicare patient, the Product Specialist's duties included the following:

- Contacting the patient and obtaining written permission from the patient for the healthcare provider to share the patient's medical records with Tactile;
- Obtaining the patient's relevant medical records, including measurements of the affected area prior to and after a four-week trial of conservative therapy;
- Obtaining a signed CMN and prescription from the patient's healthcare provider;
- Submitting the CMN and the patient's relevant medical records to a Medicare Specialist at Tactile headquarters;
- Training the patient on the Entre with an initial treatment, and obtaining measurements of the affected area immediately prior to and after this initial treatment;

- Submitting the measurements from the initial treatment to a Medicare Specialist at Tactile headquarters to complete the order for the Entre.

After the Product Specialist submitted all of the documentation required by the NCD and the LCD to the Tactile Medicare Specialist, Tactile then would submit a claim, including the CMN, to the appropriate MAC for reimbursement.

42. Four weeks or more after a patient received an Entre, Tactile often would encourage its Product Specialists to "convert" the patient to a Flexitouch. The Product Specialists would do this through marketing efforts directed both at the patient and the patient's healthcare provider. Relator recalls, for example, that his manager, Ms. Geraci, instructed him to call patients with Entre systems and to ask whether their conditions were improving or if their wounds had healed. Following Ms. Geraci's instruction, he told these patients that they might qualify for a new pump, the Flexitouch, that would not cost them anything and might improve their treatment. Relator recalls that many patients expressed interest in the product when he presented it to them in this fashion, and the patients then would contact their healthcare providers about getting an upgrade to a Flexitouch. Once a provider initiated an order for a Flexitouch for a Medicare patient, the Product Specialist's duties included obtaining records to show that the Entre did not successfully address the patient's condition and that a Flexitouch was necessary, and then to transmit those records to Tactile headquarters so that the company could submit a reimbursement claim for the Flexitouch to the appropriate MAC.

43. Tactile incentivized sales performance by setting monthly quotas for its sales personnel. In or around December 2020, for example, Relator and Ms. Geraci discussed his potential future promotion to Product Specialist, and she explained that, if he met his sales goals for ten months out of the year and he hit 130 percent of his sales goals for the entire year, he

would earn half his compensation in commission, with total annual pay of somewhere between $140,000 and $150,000. Relator understood that, if his monthly quota for Flexitouch orders shipped were 15, and he met that quota, he would receive a $2,000 bonus, and that he would receive an additional $1,000 bonus for every five additional orders. Conversely, Relator understood that, if he consistently failed to meet his quotas, he still would receive his base salary but Tactile likely would terminate him, as it had terminated Ms. Porras.

Tactile's Fraudulent Conduct

A. Fabricating Documentation of Measurements Before and After a Four-Week Trial of Conservative Therapy Preceding Submission of a Medicare Claim for an Entre System

44. In September 2020, after Tactile fired Ms. Porras, Relator for the first time had responsibility for getting Medicare orders closed, and he quickly found it difficult to obtain the documentation necessary to support the medical necessity of Medicare reimbursement claims for Tactile's PCDs. In particular, while he was generally able to get copies of Medicare patients' relevant medical records, he often found that those records did not reflect measurements of the affected area before and after the four-week trial of conservative therapy that was to precede a Medicare claim for an Entre system. Relator's difficulties were evident on his "Open Order" report, which was available to his manager, Ms. Geraci. In September 2020, Relator's Open Order report showed that orders for patients with Medicare accounted for a substantial portion of all of his orders and that he had a large number of open orders for Medicare patients. After taking over for Ms. Porras, Relator felt pressure to meet his monthly quotas. On several occasions in or around September 2020, Relator and Ms. Geraci discussed his difficulties in obtaining the measurements of patients' affected areas before and after a four-week trial of conservative therapy. Relator told Ms. Geraci that obtaining a completed CMN often posed an

additional hurdle because the healthcare provider ordering the PCD might not know the patient's medical history well enough to complete Section B of the CMN accurately. Relator recalls that, on sales team calls, Ms. Geraci made statements such as "do what you gotta do to get those measurement forms and CMNs finished."

45. On or about September 21, 2020, shortly after one of Relator's conversations with Ms. Geraci about the difficulty of obtaining the documentation necessary for Medicare orders, Relator received a telephone call from Austin Drew, a Tactile Product Specialist in Connecticut. Relator recalls that Mr. Drew began the call by saying words to the effect that "Melissa [Geraci] wanted me to call you and tell you how these Medicare orders are done." Mr. Drew explained that, in order to satisfy Medicare requirements for a given patient, Tactile needed to have two sets of measurements a minimum of thirty days apart. Mr. Drew acknowledged that, given the required length of time between measurements, it was difficult to complete orders quickly enough to hit the monthly goals Tactile set for each Product Specialist. Mr. Drew also noted that, because many patients' healthcare providers were not aware of the need for measurements for Medicare patients, they did not take such measurements or document them in the patients' files.

46. Given these limitations, Mr. Drew explained that it was much easier to generate the required documentation for a PCD order by fabricating a measurement form and making it appear to have been prepared by a healthcare provider. To do this, he told Relator to print a copy of Tactile's "Lower Extremity Volume Tracking and Measurement Chart" form, which was available through the "FlexiNet" app on the iPads that Tactile provided to each of its sales team members. Mr. Drew advised Relator to modify this form for each provider by affixing to it the logo of the provider's clinic or hospital. Mr. Drew described how he would search for a logo on Google Images, print the logo, cut it out, glue it to a measurement form, and then make a copy or

scan of the entire form so that the patching would be less visible. Mr. Drew further explained that he would look through the patient's medical record for an image of the provider's signature and then would employ the same technique to affix the provider's signature to the measurement form. Alternatively, Mr. Drew said, he would just sign the form with the provider's name, making the signature appear as close as possible to the provider's actual signature.

47. Mr. Drew then instructed Relator how to put fabricated measurement data on a form that had been altered to make it appear as if it had come from a healthcare provider. As a first step, Mr. Drew explained, Relator should look through each patient's medical records for any actual measurements that had been taken. If a set of such measurements existed, Mr. Drew advised Relator to transcribe them onto the measurement form and then to add figures for a second set of measurements dated either at least 30 days before or at least 30 days after the date of the actual measurements. Mr. Drew explained that, if Relator was going to make up measurements dated before the actual measurements, then the fabricated measurements should be smaller than the actual measurements so that it would appear that the patient's swelling had increased during the four-week trial of conservative therapy. Alternatively, according to Mr. Drew, if Relator were to date the measurements 30 days after the initial set, then Relator should make up measurements larger than the initial set, again to show that the patient's condition had worsened during the trial. Mr. Drew suggested that Relator should decide whether to date the fabricated measurements 30 days before or 30 days after the actual measurements based on the whether the actual records were new or old. For example, if Tactile received a referral for a new order on October 1, 2020, and the patient's medical records contained a set of actual measurements dated September 30, 2020, Relator understood from Mr. Drew that he should date the fabricated measurements at least 30 days prior to September 30, 2020. Mr. Drew

also told the Relator that, whenever possible, Relator should use a date for the fabricated measurements that matched a date when the patient actually had visited the healthcare provider, thus reducing the chance that a subsequent audit would find an issue with the date of the fabricated measurements.

48. During their call, Mr. Drew and Relator discussed the fact that Medicare patients' records often did not contain any measurement data at all. In such a case, Mr. Drew advised, Relator should fabricate both sets of measurements to make it appear that the patient's swelling had increased during a trial of conservative therapy. Mr. Drew cautioned, however, that Relator should ensure that the measurements did not increase too much lest they attract attention. Mr. Drew advised Relator to make the later-dated measurements a centimeter or less bigger than the earlier-dated measurements. For example, if there were no measurements in the medical record for a Medicare patient, Relator might create initial measurements of 75 centimeters for the right thigh, 45 centimeters for the right calf, and 40 centimeters for the right ankle, and then a later set of measurements of 75.5 centimeters for the right thigh, 46 centimeters for the right calf, and 40.3 centimeters for the right ankle.

49. Mr. Drew also told Relator that it was a common practice among Tactile Product Specialists in the Northeast Area to complete Section B of the CMN for healthcare providers, thus ensuring that the completed form would satisfy Medicare's prerequisites for coverage. Mr. Drew said this notwithstanding that Section B of the CMN explicitly states that it cannot be completed by the supplier. Relator recalls that, on the version of this form available through the FlexiNet app on a Tactile iPad, it said in bright red: "stop, employees cannot fill out this section." Mr. Drew told Relator, however, that if he swiped right on the iPad, he would be able to fill out this section of the form for the provider. Mr. Drew explained that healthcare providers

ordering PCDs often did not know the patient's medical history well enough to complete this section on their own.

50. Mr. Drew did not tell Relator specifically where he got the ideas of fabricating measurement forms and filling out CMNs for providers, but Relator understood that Ms. Geraci trained Mr. Drew and others in the New England Region to engage in this fraudulent behavior. Relator knew that Ms. Geraci had trained Mr. Drew. Relator also inferred from the timing of Mr. Drew's call – immediately after Relator had been talking to Ms. Geraci about the difficulty of getting the measurement data necessary to complete PCD orders for Medicare patients – and from Mr. Drew's statement that Ms. Geraci had directed him to call Relator, that Ms. Geraci had instructed Mr. Drew to tell Relator how to fabricate the measurement forms. Furthermore, when Relator subsequently called Ms. Geraci and told her that he had spoken with Mr. Drew about how to get Medicare orders closed, Ms. Geraci responded with words to the effect of, "yeah, that's why I wanted him to call you."

51. After Relator's calls with Mr. Drew and Ms. Geraci, he examined the open Medicare orders that Ms. Porras had worked on before she was fired, and he observed that the measurement forms in the patient documentation were all in Ms. Porras' handwriting, including the measurements, dates, and provider signatures.

52. Later, on February 12, 2021, after he decided to leave Tactile, Relator spoke with Ms. Porras about the company's fraudulent practices. Ms. Porras told him that, in January 2019, after she started as a Tactile Associate Product Specialist in Connecticut, her manager, Ms. Geraci had trained her to fabricate measurement forms in much the same way Mr. Drew had described. During this conversation, Ms. Porras also suggested that Relator speak to Mike Genova, who had just quit his position as a Tactile Associate Product Specialist in New Jersey.

Ms. Porras explained that Mr. Genova quit for a number of reasons, including that he was not comfortable with the fraudulent practices his supervisor had directed him to employ. Relator understands that Mr. Genova's supervisor was Gianna Marazzito, who became the District Manager for New York and New Jersey in October 2020 and had previously served as a Senior Product Specialist.

53. Later on February 12, 2021, Relator spoke with Mr. Genova, who told Relator that a Senior Product Specialist had instructed him to fabricate measurement forms and to fill out and sign CMNs for healthcare providers. Mr. Genova explained that the managers in his area were careful not to discuss this conduct over text or email and would only discuss it in person.

54. Also on February 12, 2021, Relator spoke again with Mr. Drew, who reiterated that he would copy and paste provider logos and signatures on patient measurement forms. When Relator noted that it was still taking him too long to obtain completed Medicare orders, Mr. Drew told Relator that he saved time by creating several copies of a fabricated measurement form for each provider, so that he would need only to fill in the patient information and measurement numbers on the form before submitting a particular order. Mr. Drew asked Relator not to tell anyone about this practice.

B. Fabricating Documentation of Measurements and Other Information Before and After an Initial Treatment with a Tactile PCD

55. To satisfy the NCD requirement that the provider's determination of medical necessity consider "[t] he clinical response to an initial treatment with the device . . . [including] the change in pre-treatment measurements [and] ability to tolerate the treatment session and parameters," Medicare Coverage Determinations Manual, Ch. 1, § 280.6, Tactile procedures called for prospective PCD patients to receive an equipment demonstration, with measurements

of the affected area taken before and after the demonstration. Relator observed that Tactile sales personnel fabricated these measurements, too.

56. In early 2020, when Relator was interviewing with Ms. Geraci for a position at Tactile, she asked him to participate in a "ride-along" with Lecia DiPietro, a Product Specialist in Tactile's Boston territory. During this ride-along, Relator observed Ms. DiPietro conduct two product demonstrations where she used Tactile Entre systems and garments on patients and taught the patients how to use the products. Prior to each demonstration, Ms. DiPietro took measurements of the patients' limbs, and recorded those figures on a measurement form. Then she had the patient conduct therapy for approximately 15 to 20 minutes (even though the Entre System User Guide specifies a treatment time of 60 minutes). After each brief demonstration, however, Ms. DiPietro did not take a second set of measurements; she simply created new sets of measurements and wrote them down on the forms, making it appear that the initial treatment sessions had decreased the patients' swelling.

57. When Relator asked Ms. DiPietro why they did not conduct a full 60-minute therapy session with the patients, per the product instructions, Ms. DiPietro explained that it would not be an efficient use of time. Relator observed that the abbreviated demonstration times made it impossible to determine whether, consistent with the NCD requirement, the patients showed an "ability to tolerate the treatment session." In fact, Relator later learned that some patients did not tolerate one-hour therapy sessions well, so conducting a full one-hour initial treatment was critical to determining whether the patient could use the product effectively. By reducing the demonstration treatments to just 15-20 minutes, Ms. DiPietro reduced the likelihood that the patients would decline the product due to having issues with the one-hour treatment duration.

58. After Relator was hired at Tactile, Ms. Geraci arranged for him to participate in additional ride-alongs with Ms. DiPietro. During those ride-alongs, she conducted several patient demonstrations of the Entre and the Flexitouch, and, each time, she fabricated the post-treatment measurements, always showing that the volume of the patients' limbs had decreased.

59. Ms. Geraci also arranged for Relator to participate in ride-alongs with T.J. Hayduk, an Associate Product Specialist who worked in the Boston territory with Ms. DiPietro. Relator observed Mr. Hayduk conduct two product demonstrations where he took the patients' measurements before the initial treatment and then fabricated the post-treatment reduction in patient limb volume on the measurement forms while the patients were still receiving treatment. Mr. Hayduk explained to Relator that simply adding a reduction in limb volume to the form was easier than spending time waiting for the treatment session to finish, even though, as with Ms. DiPietro, Mr. Hayduk's demonstration treatments lasted only about 15 minutes.

C. Other Fraudulent Conduct at Tactile

60. During his conversations with Ms. Porras and Mr. Genova, Relator learned about other fraudulent conduct by Tactile sales personnel. Ms. Porras, for example, told Relator that she had once seen Ms. Geraci sign a Tactile PCD prescription electronically on behalf of a physician at a time near the end of a month, when Ms. Geraci was facing a deadline to meet Tactile's monthly sales quota.

61. Meanwhile, Mr. Genova told Relator that he and his colleagues would add "key terms" to the measurement forms to show that use of a PCD was medically necessary. Similarly, Ms. Porras told Relator that Ms. Geraci and Ms. DiPietro used software to add key terms to patients' medical records. Relator understood from Ms. Geraci and from communications he received from Tactile headquarters that, for an Entre order, the key terms might include words

such as "hyperpigmentation," "hyperkeratosis," "hyperplasia," "elephantiasis" or "papilloma" that would help to show a patient needed a PCD. For a Flexitouch order, the key terms might include references to "abdominal swelling," since documentation of swelling beyond the extremities is a precondition of Medicare reimbursement under the LCD.

62. Separately, Relator recalls that, in a webinar "breakout session" during his initial training at Tactile, one of the individuals leading the discussion advised the trainees to prepare a "failure form" for patients the same day that they completed the Entre demonstration. The failure form could be used later to document that a patient did not obtain a therapeutic benefit from using the Entre, thus potentially qualifying the patient for a Flexitouch.

Examples of Fraudulent Documentation

63. During the period from September 2020 through February 2021, during which Relator was responsible for obtaining the documentation necessary to support Medicare claims for Tactile PCDs, Relator followed the instructions he received from Mr. Drew and the examples he saw in the documentation prepared by Ms. Porras: he created measurement forms with copied logos and forged or copied signatures, and he filled those measurement forms with fabricated data. He also regularly completed Section B on CMN forms, even though the forms explicitly warned against doing so. The following describes examples of fraudulent documentation Relator and Ms. Porras created:

A. Patient DP[1]

64. DP, a Medicare beneficiary and Maine resident, received an Entre and two full leg garments from Tactile on October 4, 2020. Below is a redacted excerpt from a measurement form for DP that Relator fabricated, consistent with Tactile's practices:

LOWER EXTREMITY VOLUME TRACKING AND DOCUMENTATION CHART

ST. MARY'S HEALTH SYSTEM
A Member of Covenant Health

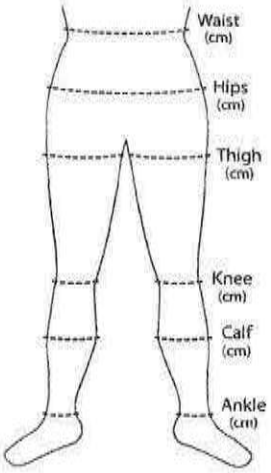
PATIENT INFORMATION

Patient Name: [redacted]

Patient Date of Birth (MM/DD/YYYY): [redacted]

Affected Limb: ☐ Left ☐ Right ☑ Both Height: 5' 5"

Healthcare Provider: Virginia Coleman, ANP-C



AFFECTED AREA MEASUREMENTS BEFORE THERAPY		
DATE: 8-31-20		
Waist	115	
Hips	139	
	LEFT	RIGHT
Thigh	67	69
Knee	48	46.5
Calf	45	46
Ankle	39	41
WEIGHT:		

AFFECTED AREA MEASUREMENTS AFTER THERAPY (measure in cm)					
DATE: 9-29-20		DATE:		DATE:	
Waist	116				
Hips	139				
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh	67.5	70				
Knee	48	47.5				
Calf	45.5	47				
Ankle	39.3	41.5				
WEIGHT:		WEIGHT:		WEIGHT:	

DATE:		DATE:		DATE:	
Waist					
Hips					
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh					
Knee					
Calf					
Ankle					
WEIGHT:		WEIGHT:		WEIGHT:	

COMMENTS

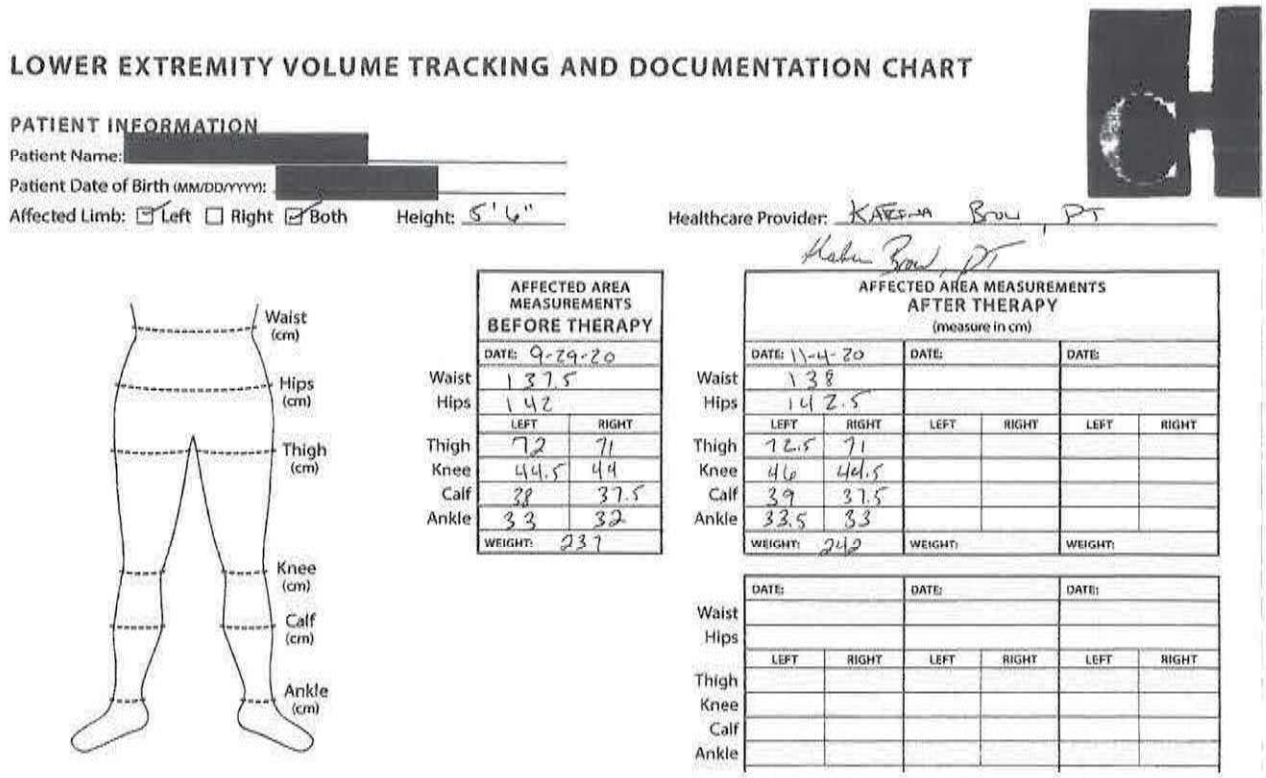
On this form, Relator affixed the logo of St. Mary's Health System, where DP received medical care, and he forged the signature of Virginia Coleman, the nurse practitioner who treated DP. Relator also fabricated all of the measurement data on the form, falsely making it appear that both of DP's legs had swelled during a four-week trial of conservative therapy. Relator

[1] This Complaint references only the patients' initials. Relator has provided the patients' full names to the government, and will provide them to Tactile in discovery pursuant to a proper protective order.

transmitted the fabricated form to Tactile to support a Medicare reimbursement claim for the equipment Tactile provided to DP.

B. Patient DC

65. DC, a Medicare beneficiary and New Hampshire resident, received an Entre and a short leg garment from Tactile in or around late December 2020. Below is a redacted excerpt from a measurement form for DC that Relator fabricated, consistent with Tactile's practices:



LOWER EXTREMITY VOLUME TRACKING AND DOCUMENTATION CHART

PATIENT INFORMATION
Patient Name: [redacted]
Patient Date of Birth (MM/DD/YYYY): [redacted]
Affected Limb: ☑ Left ☐ Right ☑ Both Height: 5'6"
Healthcare Provider: Katrina Brow, PT

Waist (cm)
Hips (cm)
Thigh (cm)
Knee (cm)
Calf (cm)
Ankle (cm)

AFFECTED AREA MEASUREMENTS BEFORE THERAPY		
DATE: 9-29-20		
Waist	137.5	
Hips	142	
	LEFT	RIGHT
Thigh	72	71
Knee	44.5	44
Calf	38	37.5
Ankle	33	32
WEIGHT:	237	

AFFECTED AREA MEASUREMENTS AFTER THERAPY (measure in cm)					
DATE: 11-4-20		DATE:		DATE:	
Waist	138				
Hips	142.5				
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh	72.5	71				
Knee	46	46.5				
Calf	39	37.5				
Ankle	33.5	33				
WEIGHT:	242	WEIGHT:		WEIGHT:	

DATE:		DATE:		DATE:	
Waist					
Hips					
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh					
Knee					
Calf					
Ankle					

On this form, Relator affixed the logo of Concord Hospital, where DC received medical care, and he forged the signature of Katrina Brow, the physical therapist who treated DC. Relator also fabricated all of the measurement data on the form, falsely making it appear that both of DC's legs had swelled during a four-week trial of conservative therapy. Relator transmitted the fabricated form to Tactile to support a Medicare reimbursement claim for the equipment Tactile provided to DC.

66. Separately, Relator completed Section B of the CMN for DC's Tactile equipment. Relator subsequently obtained the signature of DC's healthcare provider on the CMN and transmitted it to Tactile for submission to the MAC along with the Medicare reimbursement claim for the equipment Tactile provided to DC.

C. Patient GM

67. GM, a Medicare beneficiary and New Hampshire resident, received an Entre with two full leg garments from Tactile in on or around late January 2021. Below is a redacted excerpt from a measurement form for GM that Relator fabricated, consistent with Tactile's practices:

LOWER EXTREMITY VOLUME TRACKING AND DOCUMENTATION CHART

Appledore Medical Group
Appledore Family Medicine

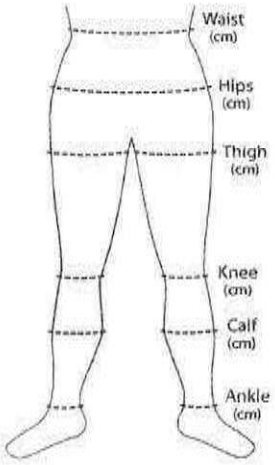
PATIENT INFORMATION

Patient Name: [redacted]

Patient Date of Birth (MM/DD/YYYY): [redacted]

Affected Limb: ☐ Left ☐ Right ☑ Both Height: 5' 7"

Healthcare Provider: Crystal Bonias, APRN 1-6-21



AFFECTED AREA MEASUREMENTS BEFORE THERAPY		
DATE: 12-7-20		
Waist		
Hips		
	LEFT	RIGHT
Thigh	62	59
Knee		
Calf	48	45
Ankle	31	29
WEIGHT: 248		

AFFECTED AREA MEASUREMENTS AFTER THERAPY (measure in cm)					
DATE: 1-6-21		DATE:		DATE:	
Waist					
Hips					
	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh	63	61				
Knee						
Calf	48.5	46				
Ankle	31.7	30.3				
WEIGHT: 251		WEIGHT:		WEIGHT:	

DATE:		DATE:		DATE:	
Waist					
Hips					
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh					
Knee					
Calf					
Ankle					
WEIGHT:		WEIGHT:		WEIGHT:	

On this form, Relator affixed the logo of Appledore Medical Group, which provided medical care to GM, and he wrote the name of Crystal Bonias, the advanced practice registered nurse who treated GM. Relator also fabricated all of the measurement data on the form, falsely making it appear that both of GM's legs had swelled during a four-week trial of conservative therapy.

Relator transmitted the fabricated form to Tactile to support a Medicare reimbursement claim for the equipment Tactile had provided to GM.

68. Separately, Relator completed Section B of the CMN for GM's Tactile equipment. Relator subsequently obtained the signature of GM's healthcare provider on the CMN and transmitted it to Tactile for submission to the MAC along with the Medicare reimbursement claim for the equipment Tactile provided to GM.

D. Patient JA

69. JA, a Medicare patient and Florida resident, received a Flexitouch with two full leg garments and a trunk garment from Tactile in or around late October 2020. Below is a redacted excerpt from a measurement form for JA that Relator fabricated, consistent with Tactile's practices:

LOWER EXTREMITY VOLUME TRACKING AND DOCUMENTATION CHART MaineGeneral Health

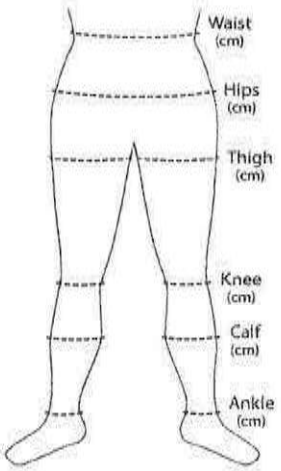
PATIENT INFORMATION

Patient Name: [redacted]

Patient Date of Birth (MM/DD/YYYY): [redacted]

Affected Limb: ☐ Left ☐ Right ☑ Both Height: 6'3"

Healthcare Provider: Lowe Hoffa
Lower - Hoffa



AFFECTED AREA MEASUREMENTS BEFORE THERAPY		
DATE: 8.21.20		
Waist	150	
Hips	130	
	LEFT	RIGHT
Thigh		
Knee		
Calf		
Ankle		
WEIGHT:		

AFFECTED AREA MEASUREMENTS AFTER THERAPY (measure in cm)					
DATE: 10.1.20		DATE:		DATE:	
Waist	151				
Hips	131.7				
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh					
Knee					
Calf					
Ankle					
WEIGHT:		WEIGHT:		WEIGHT:	

DATE:		DATE:		DATE:	
Waist					
Hips					
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh					
Knee					
Calf					
Ankle					
WEIGHT:		WEIGHT:		WEIGHT:	

On this form, Relator affixed the logo of Maine General Health, which provided medical care to JA, and he forged the signature of Lorri Hoffay, the occupational therapist who treated JA. Relator also fabricated all of the measurement data on the form, falsely making it appear that JA's waist and hips had swelled during a four-week trial of conservative therapy. Relator transmitted the fabricated form to Tactile to support a Medicare reimbursement claim for the equipment Tactile provided to JA.

70. Separately, Relator completed Section B of the CMN for JA's Tactile equipment. Relator subsequently obtained the signature of JA's healthcare provider on the CMN and transmitted it to Tactile for submission to the MAC along with the Medicare reimbursement claim for the equipment Tactile provided to JA.

71. On January 13, 2021, the MAC denied Tactile's claims for the equipment it had supplied to JA. An excerpt from that denial notice is below:

CGS - DME MAC JURISDICTION C
P O BOX 20010
NASHVILLE, TN 372020010

Medicare Remittance Notice

TACTILE SYSTEMS TECHNOLOG
PO BOX 855350
MINNEAPOLIS, MN 554855350

PROVIDER #/NPI: 1427131424
PAGE #: 1 of 1
Remittance Date: 01/13/2021
Check Date: 01/13/2021
CHECK/EFT#: [redacted]

PERF PROV	SERV DATE	POS	NOS	PROC	MODS	BILLED	ALLOWED	DEDUCT	COINS/COPAY	GRP/RC-AMT	PROV-PD
NAME: [redacted]			MI: [redacted]			ACNT: [redacted]		ICN [redacted]		ASG Y MOA: MA13 MA01	
1427131424	1021 102120	12	1	E0652	NU	$7,150.00	$0.00	$0.00	$0.00/$0.00	CO-50 $7,150.00	$0.00
1427131424	1021 102120	12	1	E0667	NULT	$825.00	$0.00	$0.00	$0.00/$0.00	CO-50 $825.00	$0.00
1427131424	1021 102120	12	1	E0667	NURT	$825.00	$0.00	$0.00	$0.00/$0.00	CO-50 $825.00	$0.00
REM: M25 N115											
PT RESP $0.00				CLAIM TOTAL		$8,800.00	$0.00	$0.00	$0.00/$0.00	$8,800.00	$0.00
ADJ TO TOTALS: PREV PD				$0.00	INTEREST	$0.00	LATE FILING CHARGE		$0.00	NET	$0.00

TOTALS:	# OF CLAIMS	BILLED AMT	ALLOWED AMT	DEDUCT AMT	COINS AMT	COPAY AMT	TOTAL RC-AMT	PROV PD AMT	CHECK AMT
	1	$8,800.00	$0.00	$0.00	$0.00	$0.00	$8,800.00	$0.00	$54,227.04

GLOSSARY: GROUP, REASON, MOA, REMARK AND REASON CODES

CO-50	These are non-covered services because this is not deemed a 'medical necessity' by the payer. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
M25	The information furnished does not substantiate the need for this level of service. If you believe the service should have been fully covered as billed, or if you did not know and could not reasonably have been expected to know that we would not pay for this level of service, or if you notified the patient in writing in advance that we would not pay for this level of service and he/she agreed in writing to pay, ask us to review your claim within 120 days of the date of this notice. If you do not request an appeal, we will, upon application from the patient, reimburse him/her for the amount you have collected from him/her in excess of any deductible and coinsurance amounts. We will recover the reimbursement from you as an overpayment.
MA01	Alert: If you do not agree with what we approved for these services, you may appeal our decision. To make sure that we are fair to you, we require another individual that did not process your initial claim to conduct the appeal. However, in order to be eligible for an appeal, you must write to us within 120 days of the date you received this notice, unless you have a good reason for being late.
MA13	Alert: You may be subject to penalties if you bill the patient for amounts not reported with the PR (patient responsibility) group code.
N115	This decision was based on a Local Coverage Determination (LCD). An LCD provides a guide to assist in determining whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd, or if you do not have web access, you may contact the contractor to request a copy of the LCD.

The notice shows a denial code of CO-50, which, according to the glossary on the notice, means: "These are non-covered services because this is not deemed a 'medical necessity' by the payer." On information and belief, based on Tactile's typical practice, the company appealed this denial.

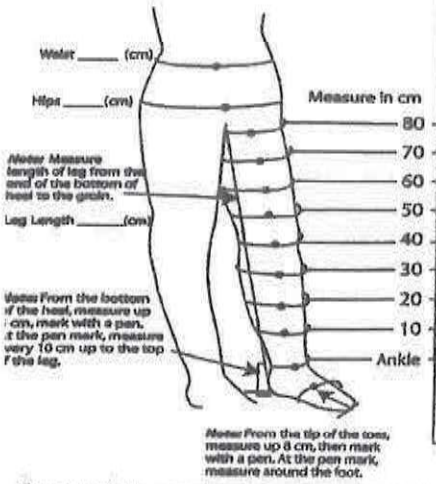
E. Patient JT

72. JT, a Medicare beneficiary and New Hampshire resident, received an Entre with two full leg garments from Tactile in or around early November 2019. JT's medical records

included a measurement form reflecting measurements taken by JT's provider on September 10, 2019, but they did not include a second set of measurements. Below is an excerpt from a second measurement form, with measurements dated September 10, 2019, and October 20, 2019, and showing that JT's legs swelled during that time:

Leg Volume Tracking and Documentation Chart

Patient Name: [redacted]
Patient Date of Birth (mm/dd/yyyy): [redacted]
Diagnosis: [redacted]
Affected Limb: ☐ Left ☐ Right ☒ Both Height: 5'3
Therapist Name: Dana J Catalfo



Measure Both Legs Before Therapy		Measure Affected Leg(s) After Therapy									
Date: 9/10/19		Date: 10/21/19		Date:		Date:		Date:		Date:	
Right	Left	Right	Left	Right	Left	Right	Left	Right	Left	Right	Left
49	46.4	49.6	46.8								
31.6	25.1	25.1	25.5								
Weight:											

Comments:

On information and belief, Ms. Porras fabricated the later set of measurements on the second measurement form. Further on information and belief, Ms. Porras transmitted the fabricated form to Tactile to support a Medicare reimbursement claim for the equipment Tactile provided to JT.

F. Patient MC

73. MC, a Medicare beneficiary and Maine resident, received an Entre and two full leg garments from Tactile in or about early January 2021. Below is a redacted excerpt from a measurement form for MC that Relator fabricated, consistent with Tactile's practices:

LOWER EXTREMITY VOLUME TRACKING AND DOCUMENTATION CHART

PATIENT INFORMATION

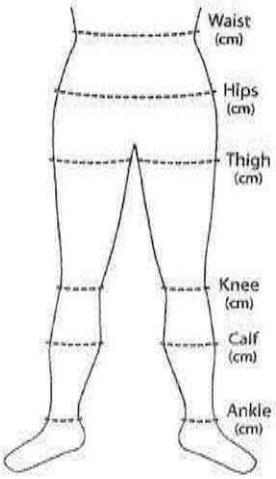
Patient Name: [redacted]

Patient Date of Birth (MM/DD/YYYY): [redacted]

Affected Limb: ☐ Left ☐ Right ☑ Both Height: 5'5"

Healthcare Provider: TARYN Everett

12-14-20 Taryn Everett, DPT, CLT



AFFECTED AREA MEASUREMENTS BEFORE THERAPY		
DATE:		
Waist		
Hips		
	LEFT	RIGHT
Thigh		
Knee		
Calf		
Ankle		
WEIGHT:		

AFFECTED AREA MEASUREMENTS AFTER THERAPY (measure in cm)					
DATE: 10-12-20		DATE: 12-9-20		DATE:	
Waist	142		143		
Hips	159		160		
	LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh	67	59	70	60		
Knee	50	45	53	47		
Calf	48	39	51	40		
Ankle	30	28	32	28.5		
WEIGHT: 208		WEIGHT: 215		WEIGHT:	

DATE:		DATE:		DATE:	
Waist					
Hips					
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh					
Knee					
Calf					
Ankle					
WEIGHT:		WEIGHT:		WEIGHT:	

On this form, Relator forged the signature of Taryn Everett, the physical therapist who treated MC. Relator also fabricated all of the measurement data on the form, falsely making it appear that both of MC's legs had swelled during a trial of conservative therapy. Relator transmitted the fabricated form to Tactile to support a Medicare reimbursement claim for the equipment Tactile provided to MC.

G. Patient NW

74. NW, a Medicare beneficiary and resident of Massachusetts, received an Entre and a full leg garment from Tactile on January 29, 2021. NW's medical records reflected measurements taken by the provider on November 12, 2020, and December 15, 2020. The measurements showed that, over this period, the swelling in NW's lower left leg improved, but the swelling in NW's upper left leg worsened. On January 14, 2021, Relator demonstrated the Entre system to NW. Before the demonstration, he took measurements of NW's left leg, but he did not take any measurements after the demonstration. Nonetheless, after the demonstration, Relator fabricated a measurement form

showing that the initial treatment with the Entre system had reduced the swelling in NW's leg. Below is an excerpt from this fabricated measurement form:

MEASUREMENT AND DEMONSTRATION RESULTS
E0651 PNEUMATIC COMPRESSION DEVICE

PATIENT INFORMATION

NAME	DOB	HEIGHT (INCHES)	WEIGHT (LBS.)
[redacted]	[redacted]	5' 1"	203

PATIENT REQUIRES TREATMENT FOR

☐ Left Arm ☐ Right Arm ☒ Left Leg ☐ Right Leg

DEMONSTRATION REQUESTED BY

CLINICIAN'S NAME	REQUEST TYPE
Martina Shanley PT	☐ On-site ☒ Phone ☐ Email/Fax ☐ Rx

CONTRAINDICATIONS

Does the patient currently have any of the following contraindications listed? ☒ No ☐ Yes (Please indicate below, check all that apply)

- ☐ Heart failure (acute pulmonary edema, decompensated acute heart failure)
- ☐ Acute venous disease (acute thrombophlebitis, acute deep venous thrombosis, acute pulmonary embolism)
- ☐ Severe peripheral artery disease (critical limb ischemia including ischemic rest pain, arterial wounds or gangrene)
- ☐ Active skin or limb infection/inflammatory disease (acute cellulitis, other uncontrolled skin or untreated inflammatory skin disease)
- ☐ Active cancer (cancer that is currently under treatment, but not yet in remission)
- ☐ Any circumstances where increased lymphatic or venous return is undesirable

DATE OF DEMONSTRATION	LOCATION OF DEMONSTRATION	PERFORMED BY (NAME)
1/14/2021	☒ Home ☐ Clinic	Benjamin Scarborough

PRE- AND POST- MEASUREMENTS

ENTER PRE- MEASUREMENTS FOR ALL AFFECTED LIMBS, ENTER PRE- AND POST- MEASUREMENTS FOR LIMB(S) RECEIVING DEMONSTRATION TREATMENT

Upper Extremity Measurements (cm)

Arm Inseam				
	LEFT		RIGHT	
	PRE	POST	PRE	POST
Biceps				
Forearm				
Wrist				
Suggested Configuration	Teal #1 ☐ Teal #2 ☐	Black #1 ☐ Black #2 ☐	Teal #1 ☐ Teal #2 ☐	Black #1 ☐ Black #2 ☐

Lower Extremity Measurements (cm)

Leg Inseam	67		☐ Half Leg Override	
	LEFT		RIGHT	
	PRE	POST	PRE	POST
Thigh	61	60		
Knee	46	45.5		
Calf	43	42		
Ankle	26	25.5		
Suggested Configuration	Teal #1 ☐ Teal #2 ☐	Black #1 ☐ Black #2 ☐	Teal #1 ☐ Teal #2 ☐	Black #1 ☐ Black #2 ☐

CLINICAL RESPONSE TO TREATMENT

Patient is capable of, or has a caregiver who assists with, donning/doffing the garments? ☒ Yes ☐ No

Patient is able to tolerate the treatment session? ☒ Yes ☐ No

Relator transmitted the fabricated form to Tactile to support a Medicare reimbursement claim for the equipment Tactile provided to NW.

75. Separately, Relator completed Section B of the CMN for NW's Tactile equipment. Relator subsequently obtained the signature of NW's healthcare provider on the CMN and

transmitted it to Tactile for submission to the MAC along with the Medicare reimbursement claim for the equipment Tactile provided to NW.

H. Patient SW

76. SW, a Medicare patient and Maine resident, received a Flexitouch and two full leg garments from Tactile in or around mid-December 2020. Below is a redacted excerpt from a measurement form for SW that Relator fabricated, consistent with Tactile's practices:

LOWER EXTREMITY VOLUME TRACKING AND DOCUMENTATION CHART

Northern Light Health

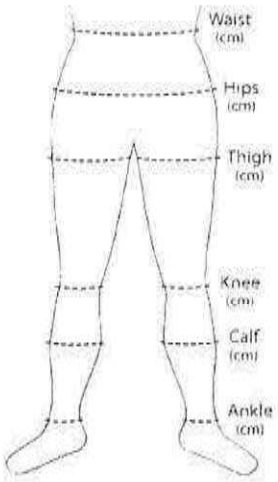
PATIENT INFORMATION

Patient Name: [redacted]

Patient Date of Birth (MM/DD/YYYY): [redacted]

Affected Limb: ☐ Left ☐ Right ☐ Both Height: _____

Healthcare Provider: Renee Richards MS OTR CLT LANA



AFFECTED AREA MEASUREMENTS BEFORE THERAPY		
DATE: 8/10/20		
Waist	160	
Hips	170	
	LEFT	RIGHT
Thigh		
Knee		
Calf		
Ankle		
WEIGHT:		

AFFECTED AREA MEASUREMENTS AFTER THERAPY (measure in cm)					
DATE: 9/23/20		DATE:		DATE:	
Waist	162				
Hips	171.3				
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh					
Knee					
Calf					
Ankle					
WEIGHT:		WEIGHT:		WEIGHT:	

DATE:		DATE:		DATE:	
Waist					
Hips					
LEFT	RIGHT	LEFT	RIGHT	LEFT	RIGHT
Thigh					
Knee					
Calf					
Ankle					
WEIGHT:		WEIGHT:		WEIGHT:	

On this form, Relator affixed the logo of Northern Light Health, which provided medical care to SW, and Relator forged the signature of Renee Richards, the occupational therapist who treated SW. Relator also fabricated all of the measurement data on the form, falsely making it appear that SW's waist and hips had swelled during a trial of conservative therapy. Relator transmitted the fabricated form to Tactile to support a Medicare reimbursement claim for the equipment Tactile provided to SW.

77. On January 12, 2021, the MAC denied Tactile's claims for the equipment it had supplied to SW. An excerpt from that denial notice is below:

NORIDIAN - DMEMAC JURISDICTION A
P O BOX 6780
FARGO, ND 581086780

Medicare Remittance Notice

TACTILE SYSTEMS TECHNOLOG
PO BOX 855350
MINNEAPOLIS, MN 554855350

PROVIDER #/NPI: 1427131424
PAGE #: 1 of 1
Remittance Date: 01/12/2021
Check Date: 01/12/2021
CHECK/EFT#: [redacted]

PERF PROV	SERV DATE	POS	NOS	PROC	MODS	BILLED	ALLOWED	DEDUCT	COINS/COPAY	GRP/RC-AMT	PROV-PD
NAME: [redacted]			MI: [redacted]			ACNT: [redacted]		ICN: [redacted]		ASG Y MOA: MA07 MA13 MA01	
1427131424	1210 121020	12	1	E0652	NU	$7,150.00	$0.00	$0.00	$0.00/$0.00	CO-50 $7,150.00	$0.00
1427131424	1210 121020	12	1	E0667	NULT	$825.00	$0.00	$0.00	$0.00/$0.00	CO-50 $825.00	$0.00
1427131424	1210 121020	12	1	E0667	NURT	$825.00	$0.00	$0.00	$0.00/$0.00	CO-50 $825.00	$0.00
REM: M25 N115											
PT RESP $0.00				CLAIM TOTAL		$8,800.00	$0.00	$0.00	$0.00/$0.00	$8,800.00	$0.00
ADJ TO TOTALS: PREV PD				$0.00	INTEREST	$0.00	LATE FILING CHARGE		$0.00	NET	$0.00

CLAIM INFORMATION FORWARDED TO: MAINECARE

TOTALS:	# OF CLAIMS	BILLED AMT	ALLOWED AMT	DEDUCT AMT	COINS AMT	COPAY AMT	TOTAL RC-AMT	PROV PD AMT	CHECK AMT
	1	$8,800.00	$0.00	$0.00	$0.00	$0.00	$8,800.00	$0.00	$22,886.05

GLOSSARY: GROUP, REASON, MOA, REMARK AND REASON CODES

CO-50	These are non-covered services because this is not deemed a 'medical necessity' by the payer. Note: Refer to the 835 Healthcare Policy Identification Segment (loop 2110 Service Payment Information REF), if present.
M25	The information furnished does not substantiate the need for this level of service. If you believe the service should have been fully covered as billed, or if you did not know and could not reasonably have been expected to know that we would not pay for this level of service, or if you notified the patient in writing in advance that we would not pay for this level of service and he/she agreed in writing to pay, ask us to review your claim within 120 days of the date of this notice. If you do not request an appeal, we will, upon application from the patient, reimburse him/her for the amount you have collected from him/her in excess of any deductible and coinsurance amounts. We will recover the reimbursement from you as an overpayment.
MA01	Alert: If you do not agree with what we approved for these services, you may appeal our decision. To make sure that we are fair to you, we require another individual that did not process your initial claim to conduct the appeal. However, in order to be eligible for an appeal, you must write to us within 120 days of the date you received this notice, unless you have a good reason for being late.
MA07	Alert: The claim information has also been forwarded to Medicaid for review.
MA13	Alert: You may be subject to penalties if you bill the patient for amounts not reported with the PR (patient responsibility) group code.
N115	This decision was based on a Local Coverage Determination (LCD). An LCD provides a guide to assist in determining whether a particular item or service is covered. A copy of this policy is available at www.cms.gov/mcd, or if you do not have web access, you may contact the contractor to request a copy of the LCD.

The notice shows a denial code of CO-50, which, according to the glossary on the notice, means: "These are non-covered services because this is not deemed a 'medical necessity' by the payer." On information and belief, based on Tactile's typical practice, the company appealed this denial.

Count I: False or Fraudulent Claims
(31 U.S.C. § 3729(a)(1)(A))

78. Relator repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

79. Beginning at least as early as 2019 and continuing through 2021, Tactile presented false or fraudulent claims for payment or approval, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(A), specifically, claims for payment to Medicare Part B for unreasonable or unnecessary DME.

80. By virtue of the false or fraudulent claims Tactile presented, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Count II: False Statements
(31 U.S.C. § 3729(a)(1)(B))

81. Relator repeats and realleges each allegation in each of the preceding paragraphs as if fully set forth herein.

82. Beginning at least as early as 2019 and continuing through 2021, Tactile knowingly made, used, or caused to be made or used false records or statements, including fabricated measurement forms and CMNs on which Tactile employees had completed Section B, material to false or fraudulent claims, in violation of the False Claims Act, 31 U.S.C. § 3729(a)(1)(B).

83. By virtue of the false records or statements Tactile made, used, or caused to be made or used, the United States has suffered actual damages and is entitled to recover treble damages plus a civil monetary penalty for each false claim.

Prayer for Relief

WHEREFORE, Relator demands and prays for the following relief:

1. On Counts I and II, that judgment be entered in favor of the United States for the amount of the United States' damages, trebled as required by law, and such civil penalties as are required by law, together with all such further relief as may be just and proper;
2. An award to the Relator of a percentage of the proceeds of the action in accordance with 31 U.S.C. § 3730(d);
3. An award to the Relator of his costs and reasonable attorneys' fees for prosecuting this action; and
4. All other relief as may be required or authorized by law and in the interests of justice.

Demand for Jury Trial

Relator, on behalf of himself and the United States, demands a jury trial on all claims alleged herein.

Dated: May 12 2021

Respectfully submitted,

BENJAMIN SCARBOROUGH

By his attorneys

/s/ Jeffrey Newman

Jeffrey A. Newman (BBO No. 370450)
Gregg Shapiro (BBO No. 642069)
Evan A. Johnson (BBO No. 699582)
Newman and Shapiro
One Story Terrace
Marblehead, MA 01945
Tel: 781-808-6789
jnewman@newmanshapiro.com
gshapiro@newmanshapiro.com
ejohnson@newmanshapiro.com