UNITED STATES DISTRICT COURT
WESTERN DISTRICT OF MICHIGAN
SOUTHERN DIVISION

UNITED STATES OF AMERICA,

Plaintiff,

v.

THE PROMETHEUS GROUP OF NEW HAMPSHIRE LIMITED; and RICHARD D. POORE,

Defendants.
_____/

Case No.

Hon.
U.S. District Judge

COMPLAINT

The United States of America files this Complaint against the Defendants and alleges as follows:

I. INTRODUCTION

1. The Medicare Program does not spend taxpayer dollars on procedures that are not reasonable and necessary for diagnosis or treatment, including, as in this case, invasive anal procedures performed with equipment—improperly reused on multiple patients—that unnecessarily exposed vulnerable Medicare beneficiaries to risks of serious bacterial, fungal, and viral infections, including HIV, herpes, gonorrhea, chlamydia, HPV, E. Coli, and salmonella infections.

2. For years, Defendants flouted their own FDA clearances by training healthcare providers across the United States to dangerously reuse rectal pressure

sensors—single-*user* devices—by repeatedly inserting the same sensor into the rectums of multiple patients.

3. For years, Defendants ignored the risks of contamination and encouraged and trained healthcare providers to dangerously reuse a competitor's anorectal manometry catheter—a single-*use* device—in multiple patients' rectums during diagnostic procedures.

4. Defendants trained healthcare providers to perform these hazardous practices, even over concerns about possible contamination, knowing that the providers would submit false claims to Medicare for therapeutic and diagnostic procedures that were not reasonable and necessary and that subjected beneficiaries to needless risks of potentially life-threatening infections.

5. Defendants' dangerous training practices were fueled by a desire to gain a marketing advantage over their competitors, and they caused healthcare providers across the United States to submit millions of dollars in false claims to Medicare in violation of the False Claims Act, 31 U.S.C. § 3729, *et seq*.

II. JURISDICTION AND VENUE

6. The Court has subject matter jurisdiction over this action pursuant to 28 U.S.C. §§ 1331, 1345, 1355(a), and 1367(a). The Court may exercise personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a).

7. Venue is proper in the Western District of Michigan pursuant to 31 U.S.C. § 3732(a) and 28 U.S.C. § 1391(b) because a substantial part of the events or

omissions giving rise to this claim occurred in this District and because Defendants committed acts in violation of 31 U.S.C. § 3729 within this District.

III. THE PARTIES

8. The United States brings this action on behalf of the United States Department of Health & Human Services ("HHS"), including its component, the Centers for Medicare and Medicaid Services ("CMS"), which administers the Medicare Program.

9. Defendant ***The Prometheus Group of New Hampshire Limited*** ("Prometheus") is a medical device manufacturer located in Dover, New Hampshire. Prometheus is a domestic profit corporation with a principal office address at 1 Washington Street, Ste. 3137, Dover, New Hampshire 03820.

10. Defendant ***Richard D. Poore*** ("Richard Poore"), is a resident of the State of New Hampshire. Mr. Poore is the President, Secretary, Treasurer, sole Director, and sole shareholder of Prometheus.

IV. THE MEDICARE PROGRAM

11. In 1965, Congress enacted the Health Insurance for the Aged and Disabled Act, known as the Medicare Program, to pay for the costs of certain healthcare items and services. 42 U.S.C. § 1395, *et seq*. Entitlement to Medicare benefits is based on age, disability, or affliction with end-stage renal disease. *See* 42 U.S.C. §§ 426 to 426-1. As a result, Medicare covers healthcare costs for a particularly vulnerable patient population, including the elderly.

12. HHS is responsible for the administration and supervision of the Medicare Program. CMS is an agency of HHS and is directly responsible for the administration of the Medicare Program.

13. The Medicare Program is divided into several parts, including, as relevant to this action, Medicare Part B.

A. Medicare Part B

14. Medicare Part B is a federally subsidized, voluntary insurance program that covers a percentage of the fee schedule for a variety of outpatient "medical and other services," including certain physical therapy and diagnostic services. *See* 42 U.S.C. §§ 1395j–1395w-5.

15. The United States provides reimbursement for Medicare Part B claims from the Medicare Trust Fund through CMS. To assist in the administration of the Medicare Part B program, CMS contracts with Medicare Administrative Contractors ("MACs"). 42 U.S.C. § 1395u. MACs are responsible for processing the payment of Medicare Part B claims to providers on behalf of CMS. For example, Wisconsin Physicians Service Government Health Administrators ("WPS"), is the MAC that currently processes claims under Medicare Part B on behalf of CMS for the State of Michigan.

16. Medicare reimburses only those items and services furnished to beneficiaries that are "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)(l)(A).

17. How a service was provided—regardless of whether that service had a diagnostic or therapeutic benefit—is material to Medicare's determination of whether that service is "reasonable and necessary."

18. Providers of outpatient physical therapy or diagnostic services submit claims to the Medicare Part B program for reimbursement of services provided to Medicare beneficiaries.

19. Medicare regulations require providers to certify that they meet, and will continue to meet, the requirements of the Medicare statutes and regulations. 42 C.F.R. § 424.516(a)(1).

20. To obtain Medicare reimbursement for certain outpatient items or services, providers submit a claim form known as the CMS 1500 form ("CMS 1500") or its electronic equivalent, known as the 837P format. Among the information the providers include on a CMS 1500 or through the 837P format are certain five-digit codes, including Current Procedural Terminology Codes ("CPT Codes") and Healthcare Common Procedure Coding System ("HCPCS") Level II codes, that identify the services rendered and for which reimbursement is sought.

21. When submitting claims to Medicare, providers certify on the CMS 1500, *inter alia*, that (a) the services rendered are medically indicated and necessary for the health of the patient; (b) the information on the claim form is "true, accurate, and complete"; and (c) the provider understands that "payment and satisfaction of this claim will be from Federal and State funds, and that any false claims, statements, or documents, or concealment of material fact, may be prosecuted under

applicable Federal and State laws." After a February 2012 revision to the CMS 1500, providers further certify that their claims comply "with all applicable Medicare . . . laws, regulations, and program instructions for payment." CMS 1500 also requires providers to acknowledge that: "Any person who knowingly files a statement of claim containing any misrepresentation or any false, incomplete or misleading information may be guilty of a criminal act punishable under law and may be subject to civil penalties."

22. Similarly, when enrolling to submit claims electronically, providers certify that they will submit claims that are "accurate, complete, and truthful," and they "acknowledge that all claims will be paid from Federal funds, that the submission of such claims is a claim for payment under the Medicare . . . program, and that anyone who misrepresents or falsifies or causes to be misrepresented or falsified any record or other information relating to that claim that is required pursuant to this Agreement may, upon conviction, be subject to a fine and/or imprisonment under applicable Federal law." CMS, Electronic Data Interchange (EDI) Enrollment Form, *available at* https://www.cms.gov/Medicare/CMS-Forms/CMS-Forms/Downloads/CMS10164B.pdf.

B. Medicare Coverage of Pelvic Muscle Rehabilitation & Anorectal Manometry

23. Pelvic muscle rehabilitation ("PMR") is a non-surgical therapy to eliminate or reduce symptoms of pelvic floor disorders, including urinary and fecal incontinence. PMR therapy incorporates a variety of treatment techniques including bladder/bowel training, pelvic muscle exercises, electromyography and rectal

pressure therapy, and electrical stimulation therapy. Rectal pressure therapy measures the resting and squeeze pressures of the anal sphincter muscles to evaluate strength gains as part of PMR therapy.

24. PMR therapy is often performed on elderly, female patients who are seeking relief from fecal incontinence (i.e., the lack of ability to control bowel movements, resulting in stool leaking from the rectum) or urinary incontinence (i.e., the involuntary leaking of urine). Many of these patients reside in nursing homes or long-term care facilities.

25. As part of the rectal pressure therapy portion of PMR, healthcare providers often insert rectal pressure sensors—typically thin, plastic or silicone-based cylinders with an internal balloon on the tip—into the patients' rectums to measure rectal pressure, including during therapy.

26. Under certain criteria, Medicare Part B covers rectal pressure therapy using rectal pressure sensors as part of PMR therapy for beneficiaries with certain pelvic floor disorders.

27. Anorectal manometry is a diagnostic test that measures the anal sphincter pressures and provides an assessment of rectal sensation, rectoanal reflexes, and rectal compliance.

28. As part of anorectal manometry, healthcare providers insert an anorectal manometry catheter—typically a set of thin plastic tubes with one or more balloons at the end—into a patient's rectum, and the anorectal manometry catheter sends pressure signals back to a computer for diagnostic review.

29. Under certain criteria, Medicare Part B covers anorectal manometry using anorectal manometry catheters during an initial diagnostic evaluation to help diagnose the cause of fecal or urinary incontinence.

V. THE FALSE CLAIMS ACT

30. The False Claims Act ("FCA"), 31 U.S.C. §§ 3729-3733, provides for the award of treble damages and civil penalties for, among other things, knowingly causing the submission of false or fraudulent claims for payment to the United States Government.

31. The FCA provides, in pertinent part:

> (a) LIABILITY FOR CERTAIN ACTS.—
>
> (1) IN GENERAL.—Subject to paragraph (2), any person who—
>
> (A) 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.
>
> * * *
>
> (b) DEFINITIONS.—For purposes of this section—
>
> (1) the terms "knowing" and "knowingly"—
>
> (A) 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; and
>
> (B) require no proof of specific intent to defraud . . . .

31 U.S.C. § 3729.

32. The FCA reflects Congress's objective to "enhance the Government's ability to recover losses as a result of fraud against the Government." S. Rep. No. 99-345, at 1 (1986), *available at* 1986 U.S.C.C.A.N. 5266.

33. A defendant violates the FCA when the defendant "knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval." 31 U.S.C. § 3729(a)(1)(A). Under the FCA, a claim includes a request for money. *Id.* § 3729(b)(2). Further, a claim is "false or fraudulent" under the FCA if the entity or person submitting the claim was not entitled to payment.

34. A defendant also violates the FCA when the defendant "knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim." 31 U.S.C. § 3729(a)(1)(B).

VI. FACTS

A. Prometheus's Rectal Pressure Sensor

35. Prometheus is a medical device manufacturer located in Dover, New Hampshire.

36. Prometheus is a privately held business that specializes in the design, development, manufacture, and sale of electromyography, manometry, stimulation,

urodynamic/uroflowmetry, and ultrasound medical devices used by colorectal surgeons, therapists, urogynecologists, and urologists.

37. Richard Poore started Prometheus in the late 1980s, and he serves as the company's President, Secretary, Treasurer, sole Director, and sole shareholder.

38. As part of its offerings in the PMR therapy and anorectal manometry fields, Prometheus markets certain systems and machines. These include the Pathway CTS 2000 Pelvic Floor Training System (designed for use in PMR therapy) and the Morpheus System (a multi-faceted system, which includes both PMR therapy and anorectal manometry). Both machines are computer-based systems that require the use of component parts, such as sensors, electrodes, and tubes. These components are disposable items. Healthcare providers must purchase these disposable items for use in patients with the Pathway and Morpheus machines.

39. Among other medical devices, Prometheus manufactures and distributes one of its disposables, the Pathway® Rectal Silicon Pressure Sensor, Part No. 6425 ("Rectal Pressure Sensor") (featured below in Figure 1). The Rectal Pressure Sensor is a perineometer sensor designed to provide detection and biofeedback of the muscle contraction activity of the pelvic musculature for the purpose of rehabilitation of weak pelvic muscles and restoration of neuromuscular control. The silicone head of the Rectal Pressure Sensor is inserted into the patient's rectum, while the tubing is connected to the Pathway or Morpheus machines.

Figure 1: The Pathway® Rectal Silicon Pressure Sensor

40. In or around May 2000, Prometheus submitted a mandatory premarket notification (also known as a 510(k) submission) for the Pathway CTS 2000 Pelvic Floor Training System to the Federal Food and Drug Administration ("FDA") for clearance to introduce the device into interstate commerce. As part of that submission, Prometheus included the Rectal Pressure Sensor as a component part and proposed instructions for use for the Rectal Pressure Sensor. On July 31, 2000, the FDA cleared Prometheus's Pathway CTS 2000 Pelvic Floor Training System, including the Rectal Pressure Sensor as a component part, as a class II medical device under 510(k) #K001515.

41. The FDA cleared the Rectal Pressure Sensor as a single-user device.

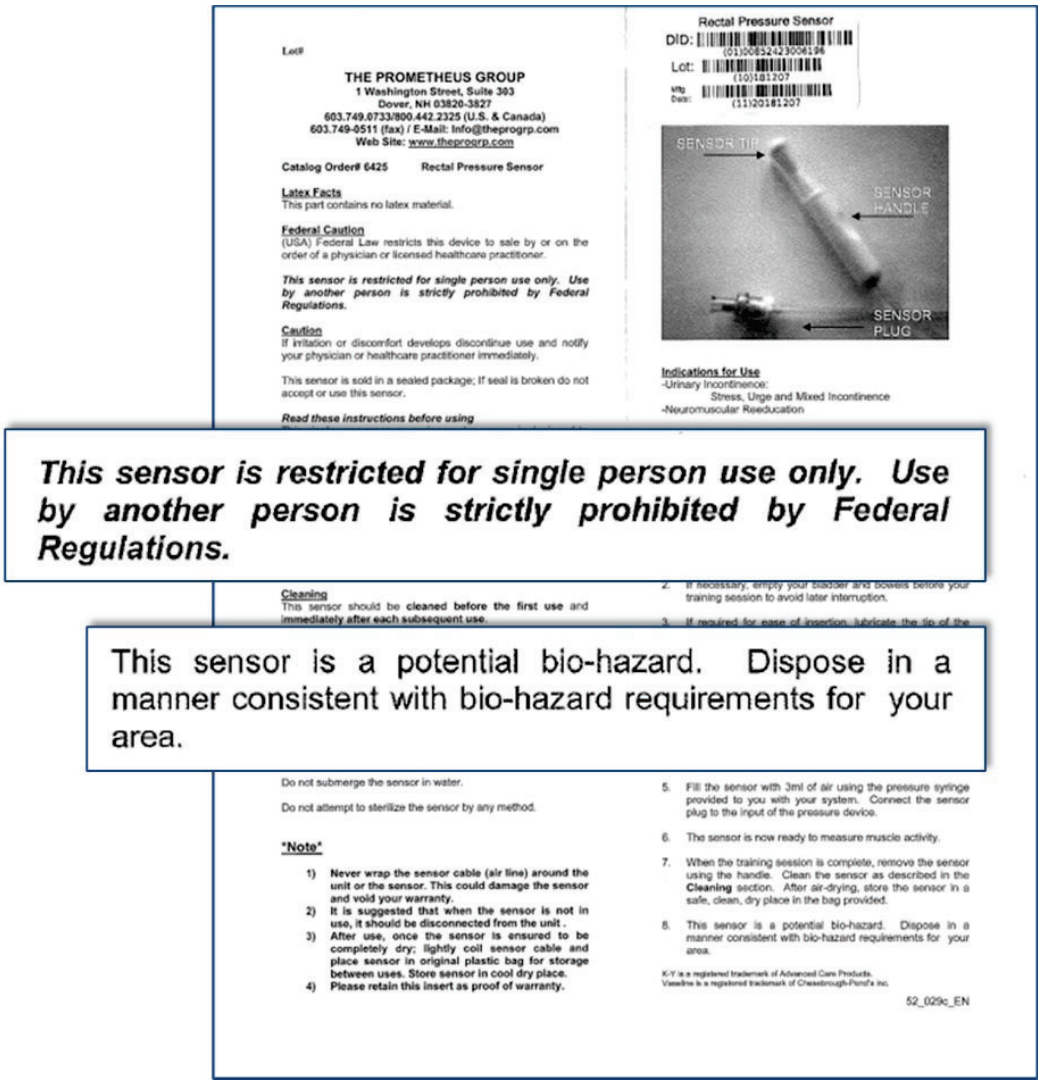
42. Consistent with the FDA's clearance, the FDA-cleared instructions for use, which Prometheus drafted and submitted, for the Rectal Pressure Sensor warned that the Rectal Pressure Sensor is restricted to use on a single patient: "This sensor is restricted for single person use only. Use by another person is strictly prohibited by Federal Regulations."

43. The instructions for use further made clear that the Rectal Pressure Sensor was a "single-user pressure perineometer sensor designed to provide accurate detection and biofeedback of the muscle contraction activity of the pelvic musculature for the purpose of rehabilitation of weak pelvic muscles and/or restoration of neuromuscular control."

44. The instructions for use directed that the sensor be cleaned with soap and water between any subsequent use on a single patient, and it warned against attempting to "sterilize the sensor by any method."

45. The instructions for use further warned that the Rectal Pressure Sensor is a "potential bio-hazard" and must be disposed of "in a manner consistent with bio-hazard requirements for your area."

46. The instructions for use with these restrictions and warnings (featured with magnified callouts below as Figure 2) were included in the packaging for each Rectal Pressure Sensor.



Lot#

THE PROMETHEUS GROUP
1 Washington Street, Suite 303
Dover, NH 03820-3827
603.749.0733/800.442.2325 (U.S. & Canada)
603.749-0511 (fax) / E-Mail: Info@theprogrp.com
Web Site: www.theprogrp.com

Catalog Order# 6425 Rectal Pressure Sensor

Latex Facts
This part contains no latex material.

Federal Caution
(USA) Federal Law restricts this device to sale by or on the order of a physician or licensed healthcare practitioner.

This sensor is restricted for single person use only. Use by another person is strictly prohibited by Federal Regulations.

Caution
If irritation or discomfort develops discontinue use and notify your physician or healthcare practitioner immediately.

This sensor is sold in a sealed package; If seal is broken do not accept or use this sensor.

Read these instructions before using

Rectal Pressure Sensor
DID: (01)00852423006196
Lot: (10)181207
Mfg Date: (11)120181207

Indications for Use
-Urinary Incontinence:
Stress, Urge and Mixed Incontinence
-Neuromuscular Reeducation

This sensor is restricted for single person use only. Use by another person is strictly prohibited by Federal Regulations.

Cleaning
This sensor should be **cleaned before the first use** and **immediately after each subsequent use.**

2. If necessary, empty your bladder and bowels before your training session to avoid later interruption.
3. If required for ease of insertion, lubricate the tip of the

This sensor is a potential bio-hazard. Dispose in a manner consistent with bio-hazard requirements for your area.

Do not submerge the sensor in water.

Do not attempt to sterilize the sensor by any method.

Note

1) **Never wrap the sensor cable (air line) around the unit or the sensor. This could damage the sensor and void your warranty.**
2) **It is suggested that when the sensor is not in use, it should be disconnected from the unit .**
3) **After use, once the sensor is ensured to be completely dry; lightly coil sensor cable and place sensor in original plastic bag for storage between uses. Store sensor in cool dry place.**
4) **Please retain this insert as proof of warranty.**

5. Fill the sensor with 3ml of air using the pressure syringe provided to you with your system. Connect the sensor plug to the input of the pressure device.
6. The sensor is now ready to measure muscle activity.
7. When the training session is complete, remove the sensor using the handle. Clean the sensor as described in the **Cleaning** section. After air-drying, store the sensor in a safe, clean, dry place in the bag provided.
8. This sensor is a potential bio-hazard. Dispose in a manner consistent with bio-hazard requirements for your area.

K-Y is a registered trademark of Advanced Care Products.
Vaseline is a registered trademark of Chesebrough-Pond's Inc.

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Figure 2: Rectal Pressure Sensor Instructions for Use

47. Prometheus markets its devices, including the Rectal Pressure Sensor, for use in PMR therapy and, specifically, for measuring rectal pressure.

48. Practitioners use the Rectal Pressure Sensor during PMR therapy by inserting it into the patient's rectum while connected to one of Prometheus's pelvic floor training system devices, such as the Pathway System or its newer Morpheus System.

B. Prometheus and Its Competitor's ARM Catheter

49. Prometheus's Morpheus System is a multi-faceted platform that allows certain diagnostic testing, including anorectal manometry, and PMR therapy. On or around 2011, Prometheus began marketing the Morpheus System, eventually adding the anorectal manometry technology to this device. Lacking an adequate anorectal manometry catheter of its own, Prometheus encouraged its customers to use an anorectal manometry catheter known as the T-DOC Air-Charged Anorectal Manometry Catheter ("ARM Catheter") manufactured by its competitor, Laborie Medical Technologies, Corp. ("Laborie"), with Prometheus's Morpheus System, and even supplied its customers with ARM Catheters.

50. On or around June 5, 1997, the FDA cleared the ARM Catheter (featured in Figure 3 below) for introduction into interstate commerce under 510(k) number K963064. The FDA cleared the ARM Catheter as a class II device for the intended use of quantifying anorectal pressures. As used with Prometheus equipment, the balloon end of the ARM Catheter is inserted through the rectum and utilizes multiple pressure-sensing balloons, inflated in the rectum, to assess internal pressures, which are measured through the internal tubes that run from the balloons in the patient's rectum and back to the Morpheus machine.

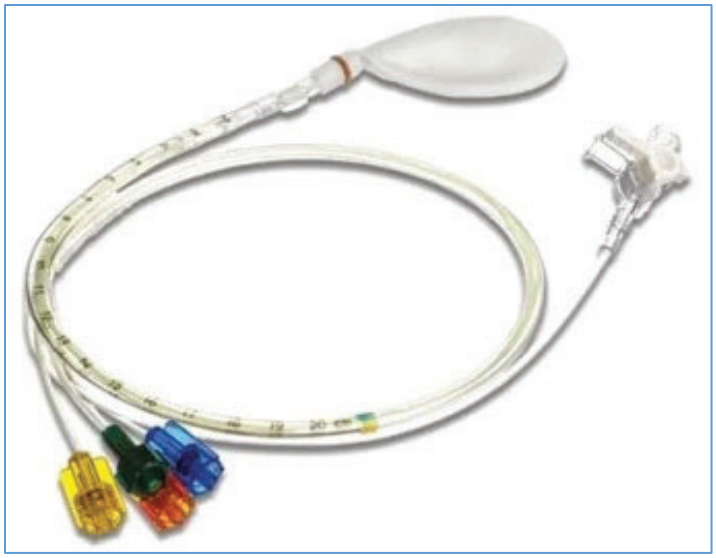

Figure 3: T-DOC Air-Charged Anorectal Manometry Catheter

51. The ARM Catheter is a single-use, disposable device.

52. The ARM Catheter's outer package (featured in Figure 4 below) states that the catheter is "disposable," and warns: "Do not re-use." The ARM Catheter's packaging also includes the "Universal Prohibited" symbol making clear that the disposable device cannot be used more than once. The FDA-cleared instructions for use also explain that the ARM Catheter is "a disposable pressure catheter." The instructions for use direct practitioners, after use of the ARM Catheter, to "[d]ispose of catheter according to hospital protocol and local environmental regulations."

Figure 4: T-DOC Air-Charged Anorectal Manometry Catheter Packaging

C. Defendants Caused Healthcare Providers Across the United States to Reuse Rectal Pressure Sensors on Multiple Patients to Gain a Competitive Edge and Drive Profits.

53. Prometheus's machines, including the Pathway System and the Morpheus System, are some of the primary, more-expensive capital pieces in Prometheus's sales portfolio and the focus of its sales efforts. A disposable, like the Rectal Pressure Sensor, is not a sales focus, but it is a necessary component for its customers to purchase to continue using the machines.

54. Customers often complained to Prometheus about the costs of disposables. Because these disposables were not significant revenue generators—but

were essential if a healthcare provider purchased and used the Pathway System or Morpheus System—Prometheus and Richard Poore told these providers that they could reuse the single-user Rectal Pressure Sensor, which typically cost about $50.00, on multiple patients. Making the purchase of these disposables seem like a one-time cost, the Defendants sought to boost the sales of their more expensive machines.

55. Defendants trained their customers to place the finger of a rubber glove or a condom on the Rectal Pressure Sensor prior to inserting it into a patient's rectum, and then to replace the glove or condom with a new one when using the Rectal Pressure Sensor on the next patient.

56. Defendants never evaluated or studied the safety of these practices, which were inconsistent with the FDA clearance and violated Prometheus's own instructions for use. In fact, these practices were dangerous and unsafe.

57. Prometheus did not seek new approval or clearance from the FDA to market the Rectal Pressure Sensor for use on multiple patients.

58. Prometheus never performed any validation studies to determine whether the Rectal Pressure Sensor was still therapeutically or diagnostically effective—i.e., that it accurately detected and provided biofeedback of the muscle contraction activity—when covered with *anything*, including a piece of rubber glove or condom.

59. For at least fourteen years, from at least 2005 through 2019, Prometheus encouraged and trained healthcare providers across the United States to reuse the Rectal Pressure Sensor on multiple patients. During that time, it had

no safety studies or clinical approvals supporting this training and encouragement. This conduct was systemic throughout Prometheus, including Richard Poore, the Director of Clinical Services, the company's sales team, and the company's contracted clinical trainers.

60. At national conferences, Prometheus told healthcare providers that they could reuse the Rectal Pressure Sensor on multiple patients. Through its contract clinical trainers and Director of Clinical Services, Prometheus also provided customers with in-service training, which often included training—sometimes on live patients—on what Prometheus called "gloving" to reuse the Rectal Pressure Sensor on multiple patients.

61. Additionally, Richard Poore and Prometheus's sales representatives marketed Prometheus machines and the Rectal Pressure Sensor, instructing healthcare providers that they could "glove" and reuse the Rectal Pressure Sensor on multiple patients.

62. In 2013, for example, independent contract trainers working on behalf of Prometheus presented to the Society of Urological Nurses & Associates on PMR therapy and nursing guidelines for practice. Part of the presentation focused on the anorectal manometry portion of PMR therapy and showcased the Rectal Pressure Sensor (slide excerpt in Figure 5 below). The speaker notes for that particular slide indicate that the independent contractor verbally advised practitioners to "[c]over [the] rectal probe with finger of glove, lubricate and gently advance into anus."

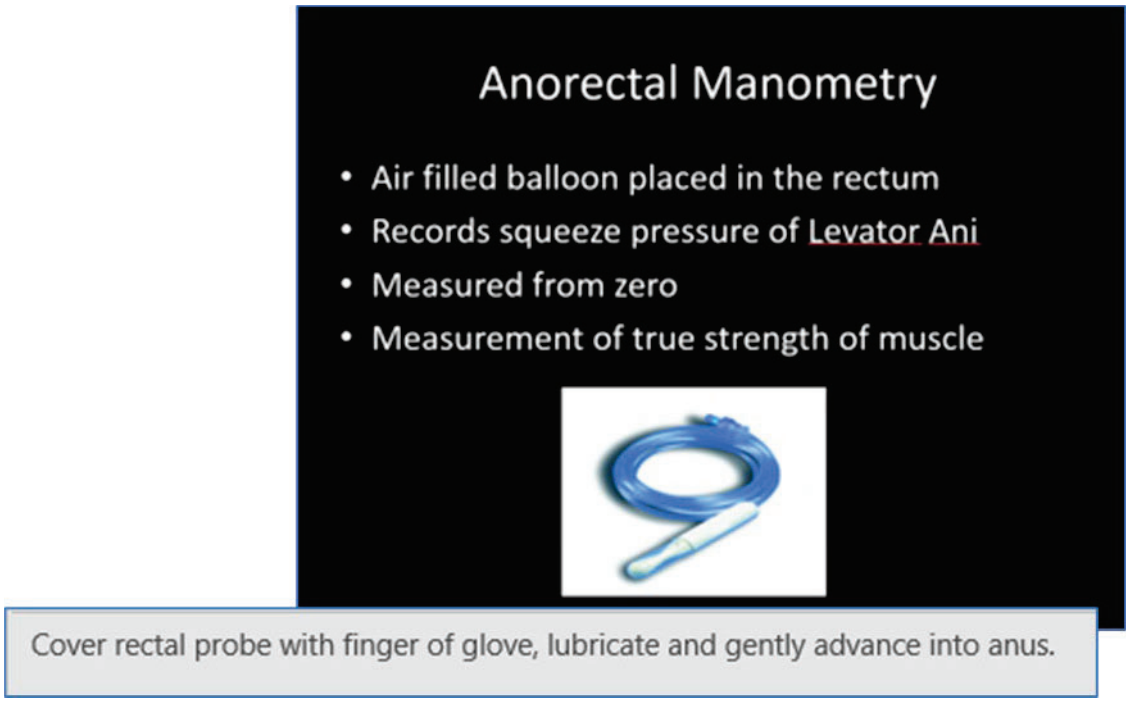

Figure 5: Slide and Speaker Note from 2013 Presentation

63. In response to a customer inquiry as to whether the Rectal Pressure Sensor was for "one time use or can [] be reused with the ***same patient***" (emphasis added), Richard Poore responded via email on January 22, 2014: "While FDA approved for single patient use, I find that many clinics will use a sheath (a glove or condom) over this sensor in order to use it with ***multiple patients***. Obviously, the sheath would be removed and discarded after each session" (emphasis added).

64. In response to a customer question about the costs of disposables, a Prometheus Regional Sales Manager responded via email on January 30, 2014, explaining that the "pressure balloon sensors [i.e., the Rectal Pressure Sensors] are $50.00 each. These are gloved from patient to patient. These will last several months each."

65. When a customer wrote asking about pricing and how many Rectal Pressure Sensors her practice should purchase in addition to the four provided in the starter package, Richard Poore responded via email on April 22, 2014: "I would not purchase additional Rectal Pressure Sensors. You are able to fit a glove or condom over the pressure bulb and use the sensor on multiple patients by simply discarding the glove or condom."

66. In a July 16, 2014 email providing healthcare providers with a "quote," a Prometheus Regional Sales Manager wrote: "The rectal pressure sensor is typically covered or 'gloved' and can thus [sic] reusable between patients."

67. In response to a customer who had three Rectal Pressure Sensors in stock inquiring about whether she had enough disposables, the Prometheus Director of Clinical Services responded via email on June 6, 2016: "The #6425 [Rectal Pressure Sensor] amount that you have is fine. They are reusable."

68. In an exchange with a potential customer who was concerned about the costs of disposables, Richard Poore responded via email on November 10, 2017, with some ideas for minimizing the costs of disposables: "The 6425 [Rectal Pressure Sensor] can be gloved with a finger clot, sterile glove, or probe cover and used for multiple patients. To minimize consumable costs I would recommend the following: . . . Glove the 6425 [Rectal Pressure] sensor."

D. Defendants Encouraged Healthcare Providers to Reuse the Single-Use ARM Catheter on Multiple Patients.

69. In or around 2011, shortly after bringing the Morpheus System to market with its anorectal manometry feature, Prometheus began to include

approximately four of the single-use ARM Catheters in startup packages when customers purchased the Morpheus System.

70. Prometheus, however, was unable to distribute the ARM Catheter, which belonged to a competitor, so the company paid a doctor in Michigan to purchase these ARM Catheters at Prometheus's request, and then send them to Prometheus. Prometheus provided these ARM Catheters as part of its Morpheus System startup package for customers who purchased the anorectal manometry feature.

71. Because these ARM Catheters were for single-use only, cost approximately $60.00, and were not available for purchase from Prometheus, the company began to encourage customers to reuse the ARM Catheter on multiple patients as a cost-saving measure to provide a competitive edge in selling the Morpheus System.

72. Similar to the training provided for the reuse of the Rectal Pressure Sensor, Prometheus trained its customers to cover the ARM Catheter with a condom during procedures where the ARM Catheter was inserted in a patient's rectum, and then reuse the ARM Catheter with a new condom on multiple patients. Prometheus representatives, including the Director of Clinical Services, provided customers with in-service training, which often included training—sometimes on live patients—on reusing the ARM Catheter on multiple patients.

73. Additionally, Richard Poore and Prometheus's sales representatives also marketed the Morpheus System, instructing their customers that they could cover and reuse the ARM Catheter on multiple patients.

74. Defendants never evaluated or studied the safety of these practices, which were inconsistent with the ARM Catheter's FDA clearance and instructions for use. In fact, these practices were dangerous and unsafe.

75. Prometheus did not seek new approval or clearance from the FDA to market the ARM Catheter alongside the Morpheus System for use on multiple patients.

76. Prometheus never performed any validation studies to determine whether the ARM Catheter was still diagnostically effective—i.e., that it accurately quantified anorectal pressure—when used more than once or when covered with *anything*, including a condom.

77. For at least eight years, from at least 2011 through 2019, Defendants encouraged and trained healthcare providers across the United States to reuse the ARM Catheter on multiple patients. During that time, it had no safety studies or clinical approvals supporting this training and encouragement. This conduct was systemic throughout Prometheus, including Richard Poore, the Director of Clinical Services, the company's sales team, and the company's contracted clinical trainers.

78. On June 11, 2014, for example, a healthcare provider wrote to a Prometheus Regional Sales Manager about "issues re-using the ARM probes (***as we discussed***- I am able to reuse after disinfecting). ***I have had 2 balloons break/tear (one breaking inside the pts rectum upon balloon expulsion***.)" (emphases added). That same day, the Regional Sales Manager responded to the provider: "The

catheter is considered disposable, ***how many time [sic] did you reuse the catheter before the baloon [sic] failed?***" (emphasis added).

79. In response to a healthcare provider question about the cost of ARM Catheters, another Prometheus Regional Sales Manager responded via email on June 11, 2014: "ARM catheters from TDOC, I tell people to glove the catheters with a condom to reuse."

80. In a November 14, 2014 email to a healthcare provider, Prometheus's Director of Clinical Services wrote about training the provider to reuse the ARM Catheter: "If you can get some condoms, I will be able to show you how you can get several uses out of these air-charged catheters. They are expensive, but I have a couple of doctors that have reused them successfully by placing a thin condom over the catheter."

81. In a March 23, 2015 email exchange, the Director of Clinical Services asked one of the company's contract clinical trainers about whether she had trained a healthcare provider to reuse the ARM Catheter: "By the way, did you tell them you could re-use the catheter if they placed the condom on it and was that ok with everyone?" The contract trainer wrote back: "Yes to the reuse..we [sic] did the patient with a condom on the ARM catheter."

82. In response to a healthcare provider question about how to know if an ARM Catheter has been reused too long to provide proper measurements, the Director of Clinical Services responded in a May 9, 2015 email: "Following every patient, the catheter should be wiped down with a saniwipe and the four small

pressure balloons should be squeezed so that no air remains in them . . . . ***If taken care of properly, I have seen them reused as much as 10-12 times***" (emphasis added).

83. On June 4, 2016, a Prometheus Regional Sales Manager emailed a healthcare provider a spreadsheet (excerpt featured with modified callouts in Figure 6 below) of Annual Revenue Projections, estimating how much that provider could make based on reimbursement for procedures and the costs of the Morpheus System and disposables. These projections were based, in part, on reusing the ARM Catheter on multiple patients.

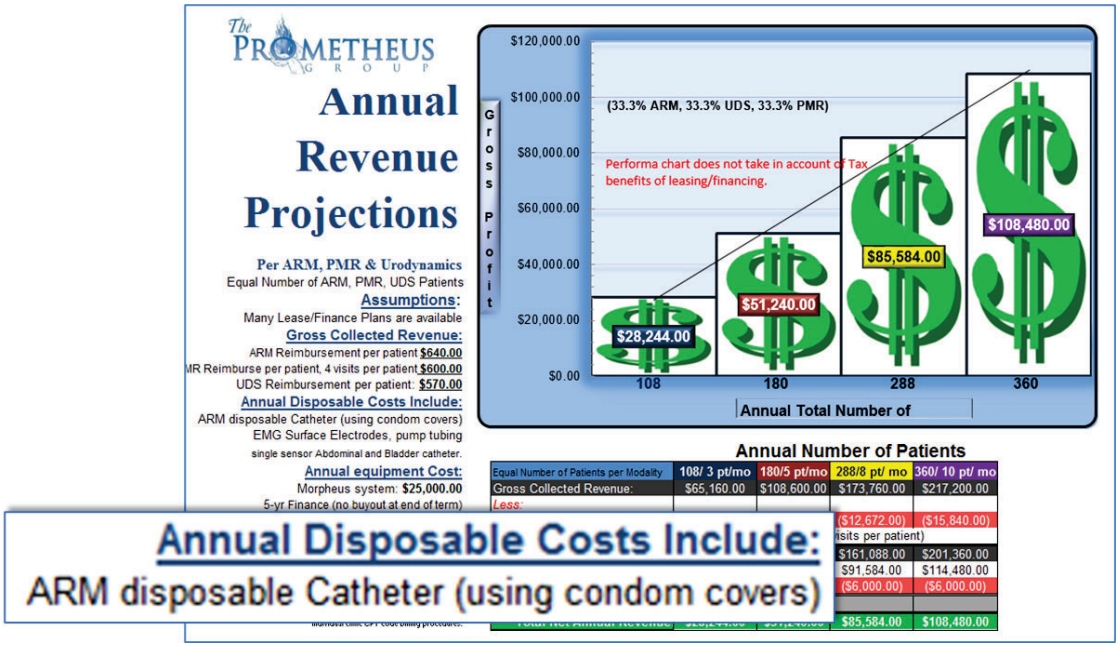

Figure 6: June 4, 2016 Annual Revenue Projection by Prometheus Regional Sales Manager

84. In a December 22, 2016 email exchange between Richard Poore and one of the Regional Sales Managers about providing a pricing quote for a healthcare provider, Richard Poore wrote: "If he wants to get away from Laborie we can provide

him the water perfused UDS catheters (that's the plan) and the air-charged ARM catheters using Denise's trick of gloving the catheter for reuse." The Regional Sales Manager responded: "We discussed gloving the TDOC ARM catheter at our meeting, ***they do not want to do that because of possible contamination***" (emphasis added).

85. In a May 22, 2018 email to a healthcare provider asking about pricing of catheters, a Prometheus Regional Sales Manager wrote: "We use the air-charged catheters for ARM, however, some offices use probe covers or condoms to cover the catheter to be able to use the catheter from patient to patient to reduce the cost per study. For secondary sterilization, you are able to soak the catheter in Cidex. Being able to cover the catheter is dependent on your protocol or rules with your hospital and/or practice."

E. The Defendants' Practices Resulted in Healthcare Providers Performing Invasive Procedures That Exposed Patients to Unnecessary and Unreasonable Risks of Infectious Diseases.

86. The Rectal Pressure Sensor and the ARM Catheter were designed—and cleared by FDA—as single-user and single-use devices respectively for a critical reason: to protect against patient harm. These devices are inserted into anal cavities where they are exposed to feces, blood, and other matter that can carry diseases, such as bacterial, viral, and fungal infections. As one Prometheus customer pointed out, reusing these devices exposed patients to "possible contamination" and, by extension, potentially life-threatening infections.

87. More specifically, when healthcare practitioners use the Rectal Pressure Sensor or the ARM Catheter, they insert the device into the patient's rectum. As such, the device comes into physical contact with the gastrointestinal (or "GI") tract. The GI tract contains a high concentration of microbes, which are used to break down food products, resulting in a large concentration of these microbes in fecal matter in and around the rectum.

88. These microbes in the rectum are small and not visible to the human eye. A bacterial microbe found in the rectum is as small as one micron (i.e., one-thousandth of a millimeter). A virus microbe found in the rectum is even smaller—on the order of 0.05 to 0.1 micron.

89. When the Rectal Pressure Sensor or the ARM Catheter is placed in a patient's rectum, these bacterial and viral microbes can transfer from the patient's rectum and onto the device. When the device is subsequently placed into another patient's rectum, cross-contamination of these diseases and infections can occur by transferring the microbes into the subsequent patient's rectum. By way of example with a different, but similar, device, an outbreak of a highly vancomycin-resistant strain of *Enterococcus* (a severe bacterial infection resistant to antibiotics) in an intensive care unit was traced back to the transmission of the infectious agent through the use of contaminated electronic rectal thermometers that were used on multiple patients. Livornese et al., *Hospital-acquired Infection with Vancomycin-resistant* Enterococcus faecium *Transmitted by Electronic Thermometers*, 117 Annals Internal Med. 112 (1992).

90. Covering the Rectal Pressure Sensor or the ARM Catheter with a glove or condom does not remove the risk of transfer and cross-contamination. Even when used properly, medical gloves and condoms have known failure rates. *See, e.g.*, Duerr et al., *Assessing Male Condom Failure and Incorrect Use*, 38 Sexually Transmitted Diseases 580 (2011); Patel et al., *A Preliminary Report on the Incidence of Pre-Existing Pinhole Defects in Nitrile Dental Gloves*, 195 Brit. Dental J. 509 (2003). Gloves or condoms can also develop miniscule holes, including when they are placed over the sensor or catheter, through which infectious microbes can transfer onto the devices. *See, e.g.*, Masood et al., *Condom Perforation During Transrectal Ultrasound Guided (TRUS) Prostrate Biopsies: A Potential Infection* Risk, 39 Int'l Urology & Nephrology 1121 (2007) (demonstrating a significant condom perforation rate among patients undergoing biopsies where condom was placed over rectal probe and raising issues of hygiene and cross infection). Holes or leaks in the next set of gloves or condoms can result in transfer of these infectious microbes into the rectum and GI tract of a subsequent patient.

91. Additionally, cross-contamination can occur when the glove or condom is being removed from the Rectal Pressure Sensor or ARM Catheter or through what is known as "touch contamination" through which even a portion of the device (such as the lead tubes) that is not inserted into the patient's rectum (i.e., the parts of the device that are not covered by a glove or condom) can still become contaminated and transfer infectious microbes onto the portion of the device that is placed in the patient's rectum.

92. There is also a risk that a viral infection can absorb through untorn latex material with no detectable leaks. *See, e.g.*, Lytyle et al., *A Simple Method to Test Condoms for Penetration by Viruses*, 58 Applied & Envtl. Microbiology 3180 (1992).

93. Prometheus's Rectal Pressure Sensor—made, in part, with silicone and plastic—is inherently resistant to sterilization or high-level disinfection.

94. Thus, Prometheus's FDA-cleared instructions for the use of the Rectal Pressure Sensor warn: "Do not attempt to sterilize the sensor by any method." Instead, the instructions for use direct that the sensor be cleaned with soap and water between uses *with the same person*.

95. The ARM Catheter, manufactured with plastic tubing and balloons, is similarly resistant to sterilization or high-level disinfection. The FDA-cleared instructions for use therefore direct practitioners to "[d]ispose of catheter according to hospital protocol and local environmental regulations" after one use.

96. Covering the Rectal Pressure Sensor and ARM Catheter with gloves or condoms and then reusing the devices on multiple patients did not remove the risk of cross-contamination of bacterial, viral, and fungal infections. These coverings were not designed to be used on hard device surfaces or over balloons, nor were the devices designed—or tested for safety and efficacy—to be used with these coverings.

97. As a result of Prometheus's encouragement and training, healthcare providers reused the Rectal Pressure Sensor and the ARM Catheter on multiple patients during unsafe therapeutic and diagnostic procedures that were billed to Medicare. These therapeutic and diagnostic procedures involving reused equipment

needlessly subjected patients to the risk of cross-contamination of infectious diseases such as HIV, Gonorrhea, Chlamydia, Herpes, HPV, Clostridium difficile, Escherichia coli (or E. coli), and Salmonella.

F. Medicare Would Not Have Paid for These Procedures If It Had Known That the Rectal Pressure Senor or ARM Catheter Had Been Previously Used on a Different Patient.

98. Medicare does not cover services that are not "reasonable and necessary." 42 U.S.C. § 1395y(a)(1)(A).

99. How a procedure is performed—regardless of whether that service had a diagnostic or therapeutic benefit—is material to Medicare's determination of whether that service was "reasonable and necessary."

100. Services utilizing the single-user Rectal Pressure Sensor or the single-use ARM Catheter after they had previously been used on one or more patients were not "reasonable and necessary," including for the following reasons:

a. Acting on the training and advice of Prometheus, healthcare providers reused these devices on multiple patients despite contraindicated warnings on the labeling of the Rectal Pressure Sensor and the ARM Catheter that these devices should not be reused on multiple patients.

b. The reuse of the Rectal Pressure Sensor and the ARM Catheter on patients—including Medicare beneficiaries—exposed those patients to the risk of infection of various bacterial and viral diseases through cross-contamination. These diseases included HIV, Gonorrhea, Chlamydia, Herpes, HPV, Clostridium difficile, E. coli, and Salmonella.

c. This risk of infection through cross-contamination was a wholly unnecessary risk created by the healthcare providers' desire to save money—a desire Prometheus exploited in order to sell its more lucrative devices, such as the Pathway System and Morpheus System.

d. The Medicare beneficiaries—many of whom likely had little to no idea that these devices were being reused on multiple patients—were not made aware of the risks of infection through cross-contamination, and they never consented to these risks.

101. For all these reasons, the delivery of these services was not reasonable and necessary, and Medicare would not have paid for these services if it had known that the Rectal Pressure Sensor or the ARM Catheter were being reused.

102. Defendants knew that these services were not reasonable and necessary—including because healthcare providers told them about "possible contamination" and intra-rectal breakage events—and their training practices caused the submission of claims to Medicare for services that were not reasonable and necessary.

G. Defendants Knowingly Caused Healthcare Providers to Bill Medicare for Services That Were Not Reasonable or Necessary.

103. In addition to providing its customers with training on the reuse of the Rectal Pressure Sensor and the ARM Catheter, the Defendants knew that healthcare providers were submitting claims to Medicare for these services.

104. In fact, Prometheus provided its customers with billing information and advice, such as information about billing these therapeutic and diagnostic services to

Medicare, including, specifically, PMR therapy and anorectal manometry. Prometheus's Director of Clinical Services routinely provided customers with information on coding and submitting claims for reimbursement to Medicare for PMR therapy and anorectal manometry.

105. Additionally, healthcare providers routinely asked Prometheus questions about submitting claims for reimbursement for PMR therapy and anorectal manometry to Medicare.

106. For example, during a September 29-30, 2005 seminar in New York City hosted by Prometheus and its contract clinical trainers, Prometheus trained the participants on how to reuse the Rectal Pressure Sensor by "gloving" it so it could be reused on multiple patients. During that seminar, Prometheus also provided the healthcare providers with materials and training on seeking reimbursement for PMR therapy services. This material and training contained information and suggestions on obtaining Medicare reimbursement, including a warning to the attendees that "Medicare is Not your Friend" (see presentation slide excerpt in Figure 7 below).

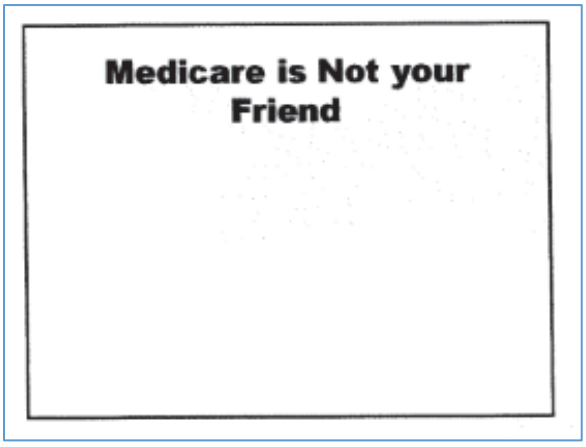

Figure 7: Excerpt from September 29-30, 2005 Seminar Training Slides

107. By way of further example, in a July 16, 2014 email, a Regional Sales Manager not only encouraged healthcare providers to reuse the Rectal Pressure Sensor, he also provided them with a reimbursement guide that listed average Medicare payments for PMR and anorectal manometry procedures.

108. Additionally, in a March 24, 2015 email from a practice in Michigan that Prometheus trained to reuse both the Rectal Pressure Sensor and the ARM Catheter, the practice asked the Prometheus Director of Clinical Services about Prometheus's suggestions on billing to Medicare.

109. Richard Poore was also aware that Prometheus was providing Medicare reimbursement advice to Prometheus customers. For example, he was copied on a January 6, 2017 email from a Prometheus employee that forwarded an email from the Director of Clinical Services about reimbursement and discussing and attaching "a guide that is used for Medicare patients."

H. Defendants Caused Healthcare Providers Throughout the Country, Including in the Western District of Michigan, To Submit False Claims to Medicare.

110. As discussed more fully above, Defendants spent years encouraging and training healthcare providers to dangerously reuse the Rectal Pressure Sensor and ARM Catheter on multiple patients, including Medicare beneficiaries. As a result, these providers submitted false claims to Medicare for services that were not reasonable and necessary and that needlessly placed these beneficiaries at risk of cross-contamination of bacterial, viral, and fungal infections.

111. The following are examples of specific false claims presented to Medicare in the Western District of Michigan, though similarly false claims were presented throughout the United States:

1. Restoring Your Balance in Norton Shores, Michigan

112. One of Prometheus's customers was a physical therapy practice, Restoring Your Balance, LLC, located in Norton Shores, Michigan. Restoring Your Balance and its owner provided physical therapy services at Woman Care Ob/Gyn, PLC ("Woman Care"), an obstetrician-gynecology practice located in Norton Shores, Michigan. Woman Care submitted claims to Medicare for these physical therapy services that were billed under the national practitioner identifier number of one of Woman Care's physicians.

113. Restoring Your Balance provided patients, including Medicare beneficiaries, with PMR therapy.

114. Starting in 2006, Restoring Your Balance began to use Prometheus equipment in PMR therapy. Prometheus representatives also provided Restoring Your Balance with in-person training on the use of the Prometheus equipment, including the Rectal Pressure Sensor.

115. During that training, a trainer contracted by Prometheus taught the staff at Restoring Your Balance to use a latex condom to cover the Rectal Pressure Sensor so that it could be reused on future patients. Part of that training also included a manual, which provided the following instructions on treating a female patient using the Rectal Pressure Sensor: "Cover the anorectal manometry sensor

with a glove or condom. Apply lubricant, and insert into the rectum." The trainer never informed the Restoring Your Balance staff that the Rectal Pressure Sensor was meant for single-patient use only.

116. As a result, Restoring Your Balance reused the Rectal Pressure Sensor on multiple patients, initially covering it with a condom and later with a sheath. Between uses, Restoring Your Balance would also rub or swab the Rectal Pressure Sensor with rubbing alcohol.

117. In March 2011, Prometheus's Director of Clinical Services provided Restoring Your Balance staff with additional training, including live training on three patients. Consistent with the training from 2006, the Director of Clinical Services trained the practice staff on how to reuse the Rectal Pressure Sensor by covering it with a latex condom, placing gel on the end of it for insertion comfort into the rectum, discarding the condom afterwards, and then wiping the Rectal Pressure Sensor with an alcohol wipe or swab.

118. During this time, Prometheus also provided Restoring Your Balance with guidance on billing these services to Medicare. For example, on February 13, 2014, Prometheus's Director of Clinical Services emailed the physical therapist at Restoring Your Balance with information and guidance on Medicare reimbursement.

119. For thirteen years, from 2006 through 2019, Restoring Your Balance followed Prometheus's advice on reusing the Rectal Pressure Sensor, covering it with a condom or sheath between uses on multiple patients. During that time period, Restoring Your Balance only replaced the Rectal Pressure Sensor once.

120. As a result of the reuse of the Rectal Pressure Sensor, Medicare beneficiaries treated at Restoring Your Balance were needlessly placed at risk of serious bacterial, viral, and fungal infections. Woman Care then submitted false claims to Medicare for those unsafe services that were not reasonable or necessary, including the following:

a. On September 4, 2012, Restoring Your Balance provided PMR therapy to beneficiary K.P.[1] As part of the PMR therapy, staff reused the practice's single Rectal Pressure Sensor, inserting it into K.P.'s rectum. Woman Care then submitted a claim (#681112257086760) to Medicare. The providers at Woman Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $383.11, which included $171.54 specifically for an anorectal pressure study. Based on the foregoing allegations including those at paragraphs 112 through 119, Defendants caused the submission of this false claim.

b. On September 10, 2012, Restoring Your Balance provided PMR therapy to beneficiary B.R. As part of the PMR therapy, staff reused the practice's single Rectal Pressure Sensor, inserting it into B.R.'s rectum.

[1] Throughout this Complaint, the names of Medicare beneficiaries have been reduced to their initials in order to protect the privacy, including healthcare information, of these beneficiaries. The United States is prepared to supply these names to the Defendants under a protective order.

Woman Care then submitted a claim (#681812258046000) to Medicare. The providers at Woman Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $383.11, which included $171.54 specifically for an anorectal pressure study. Based on the foregoing allegations including those at paragraphs 112 through 119, Defendants caused the submission of this false claim.

c. On September 11, 2012, Restoring Your Balance provided an initial evaluation to beneficiary C.B. As part of this evaluation, staff reused the practice's single Rectal Pressure Sensor, inserting it into C.B.'s rectum. Woman Care then submitted a claim (#681812258045470) to Medicare. The providers at Woman Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $393.78, which included $171.54 specifically for an anorectal pressure study. Based on the foregoing allegations including those at paragraphs 112 through 119, Defendants caused the submission of this false claim.

d. On October 3, 2012, Restoring Your Balance provided PMR therapy to beneficiary B.R. As part of the PMR therapy, staff reused the practice's single Rectal Pressure Sensor, inserting it into B.R.'s rectum. Woman Care then submitted a claim (#681112285074730) to Medicare. The providers at Woman Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $383.11, which included $171.54 specifically for an anorectal pressure study. Based on the foregoing allegations including those at paragraphs 112 through 119, Defendants caused the submission of this false claim.

e. Also on October 3, 2012, Restoring Your Balance provided PMR therapy to beneficiary C.B. As part of the PMR therapy, staff reused the practice's single Rectal Pressure Sensor, inserting it into C.B.'s rectum. Woman Care then submitted a claim (#681112285074830) to Medicare. The providers at Woman Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $383.11, which included $171.54 specifically for an anorectal pressure study. Based on the foregoing allegations including

those at paragraphs 112 through 119, Defendants caused the submission of this false claim.

f. On October 17, 2012, Restoring Your Balance provided PMR therapy to beneficiary K.P. As part of the PMR therapy, staff reused the practice's single Rectal Pressure Sensor, inserting it into K.P.'s rectum. Woman Care then submitted a claim (#681112293105710) to Medicare. The providers at Woman Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $383.11, which included $171.54 specifically for an anorectal pressure study. Based on the foregoing allegations including those at paragraphs 112 through 119, Defendants caused the submission of this false claim.

g. On April 14, 2015, Restoring Your Balance provided PMR therapy to beneficiary M.S. As part of the PMR therapy, staff reused the practice's single Rectal Pressure Sensor, inserting it into M.S.'s rectum. Woman Care then submitted a claim (#681915114401720) to Medicare. The providers at Woman Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $304.01, which included $107.43 specifically for an anorectal pressure

study. Based on the foregoing allegations including those at paragraphs 112 through 119, Defendants caused the submission of this false claim.

2. Urological Solutions of Michigan and Women's Health Care Specialists

121. Another set of Prometheus customers that reused both the Rectal Pressure Sensor and the ARM Catheter on their patients, including Medicare beneficiaries, were two practices under common ownership. Urological Solutions of Michigan ("Urological Solutions") was a West Michigan-based mobile medical practice providing PMR therapy to patients in their homes and assisted living facilities in the greater Traverse City, Grand Rapids, and Kalamazoo areas. Women's Health Care Specialists ("Women's Health Care") was a gynecology practice located in Kalamazoo.

122. In 2005, a staff member from Woman's Health Care received training on PMR therapy and use of the Prometheus equipment at a conference run by contract Prometheus trainers. During this conference, the trainer instructed the staff member and other participants to "glove" the Rectal Pressure Sensor by placing a rubber barrier over the end of the sensor prior to placing it inside a patient's rectum. The trainer instructed the staff member to have one or two extra Rectal Pressure Sensors in inventory at a practice because the Rectal Pressure Sensors could break after use on several patients. The trainer also taught the staff member to clean the Rectal Pressure Sensor between uses on patients by wiping it with a sanitation wipe.

123. For fourteen years, from at least 2005 through 2019, Urological Solutions and Women's Health Care reused the Rectal Pressure Sensor on multiple

patients. For example, at Women's Health Care, it was typical for a Rectal Pressure Sensor to be used over ***one hundred times*** before being replaced.

124. During this time, Prometheus also provided Urological Solutions and Women's Health Care with guidance on billing these services to Medicare. For example, on January 26, 2015, Prometheus's Director of Clinical Services emailed the manager of Urological Solutions with information on Medicare coverage for PMR therapy. Similarly, on May 28, 2018, Prometheus's Director of Clinical Services emailed staff at Women's Health Care coding and reimbursement information for PMR therapy for Medicare in an email with the subject line: "Coding for PFT - Medicare."

125. As a result of this reuse, Medicare beneficiaries treated by Urological Solutions were needlessly at risk of cross-contamination of bacterial, viral, and fungal infections. Urological Solutions then submitted false claims to Medicare for those unsafe services that were not medically reasonable or necessary, including the following:

a. On May 31, 2018, Urological Solutions provided PMR therapy to beneficiary M.R. As part of the PMR therapy, staff reused a Rectal Pressure Sensor that had previously been used on other patients, inserting it into M.R.'s rectum. Urological Solutions then submitted a claim (#681918159271140) to Medicare. The providers at Urological Solutions agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet

they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $266.81, which included $56.10 specifically for a biofeedback session. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

b. Also on May 31, 2018, Urological Solutions provided PMR therapy to beneficiary M.S. As part of the PMR therapy, staff reused a Rectal Pressure Sensor that had previously been used on other patients, inserting it into M.S.'s rectum. Urological Solutions then submitted a claim (#681918159271150) to Medicare. The providers at Urological Solutions agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $266.81, which included $56.10 specifically for a biofeedback session. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

c. Also on May 31, 2018, Urological Solutions provided PMR therapy to beneficiary M.W. As part of the PMR therapy, staff reused a Rectal Pressure Sensor that had previously been used on other patients, inserting it into M.W.'s rectum. Urological Solutions then submitted a claim (#681918159271160) to Medicare. The providers at Urological

Solutions agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $177.18, which included $56.10 specifically for a biofeedback session. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

d. On June 7, 2018, Urological Solutions provided PMR therapy to beneficiary M.S. As part of the PMR therapy, staff reused a Rectal Pressure Sensor that had previously been used on other patients, inserting it into M.S.'s rectum. Urological Solutions then submitted a claim (#681818169655510) to Medicare. The providers at Urological Solutions agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $177.18, which included $56.10 specifically for a biofeedback session. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

e. Also on June 7, 2018, Urological Solutions provided PMR therapy to beneficiary M.W. As part of the PMR therapy, staff reused a Rectal Pressure Sensor that had previously been used on other patients,

inserting it into M.W.'s rectum. Urological Solutions then submitted a claim (#681818169655920) to Medicare. The providers at Urological Solutions agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $177.18, which included $56.10 specifically for a biofeedback session. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

f. On February 21, 2018, Urological Solutions provided PMR therapy to beneficiary M.R. As part of the PMR therapy, staff reused a Rectal Pressure Sensor that had previously been used on other patients, inserting it into M.R.'s rectum. A picture of the Rectal Pressure Sensor obtained from Urological Solutions staff immediately following the PMR therapy session with M.R. is included below as Figure 8.

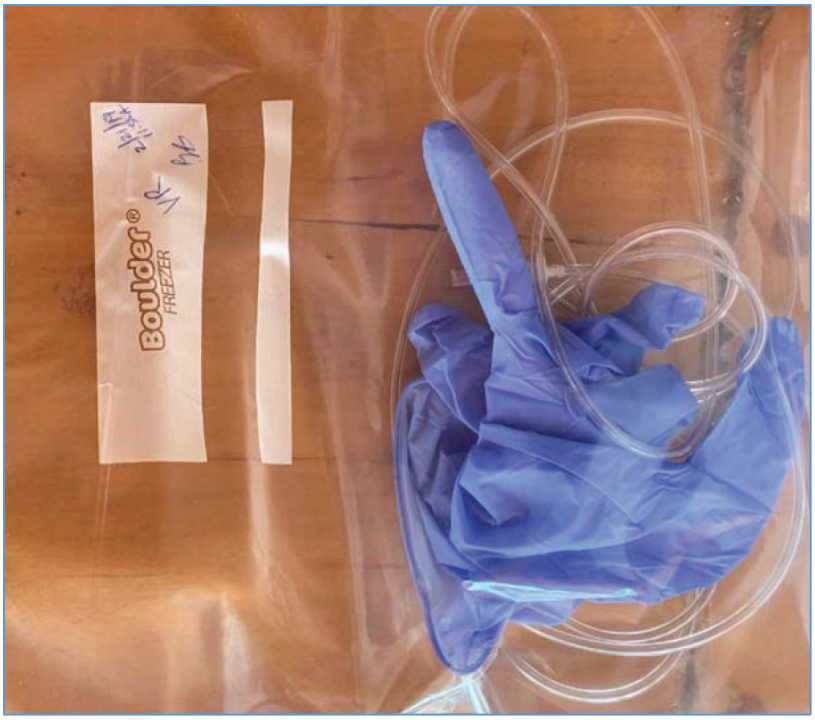

Figure 8: Rectal Pressure Sensor Used By Urological Solutions Staff on M.R. on February 21, 2019

Urological Solutions then submitted a claim (#681819057343470) to Medicare. The providers at Urological Solutions agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $264.03, which included $56.39 specifically for a biofeedback session. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

126. Similarly, Medicare beneficiaries treated by Women's Health Care were needlessly placed at risk of cross-contamination of bacterial, viral, and fungal

infections by this reuse. Women's Health Care then submitted false claims to Medicare for those unsafe services that were not medically reasonable or necessary, including the following:

a. On June 17, 2015, Women's Health Care provided PMR therapy to beneficiary L.C. As part of the PMR therapy, staff used one of the clinic's Rectal Pressure Sensors that was shared between multiple patients, inserting it into L.C.'s rectum. Women's Health Care then submitted a claim (#681915173401120) to Medicare. The providers at Women's Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $362.19, which included $166.08 specifically for an anorectal pressure study. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

b. On June 24, 2015, Women's Health Care provided PMR therapy to beneficiary L.C. As part of the PMR therapy, staff used one of the clinic's Rectal Pressure Sensors that was shared between multiple patients, inserting it into L.C.'s rectum. Women's Health Care then submitted a claim (#681815177548130) to Medicare. The providers at Women's Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet

they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $220.48, which included $166.08 specifically for an anorectal pressure study. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

c. On June 15, 2016, Women's Health Care provided PMR therapy to beneficiary B.S. As part of the PMR therapy, staff used one of the clinic's Rectal Pressure Sensors that was shared between multiple patients, inserting it into B.S.'s rectum. Women's Health Care then submitted a claim (#681916169167390) to Medicare. The providers at Women's Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $127.12, which included $61.99 specifically for a biofeedback session. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

d. On June 23, 2016, Women's Health Care provided PMR therapy to beneficiary B.S. As part of the PMR therapy, staff used one of the clinic's Rectal Pressure Sensors that was shared between multiple patients, inserting it into B.S.'s rectum. Women's Health Care then submitted a claim (#681916179155440) to Medicare. The providers at Women's

> Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $127.12, which included $61.99 specifically for a biofeedback session. Based on the foregoing allegations including those at paragraphs 121 through 124, Defendants caused the submission of this false claim.

127. Additionally, by at least May 2015, Prometheus also trained the staff at Women's Health Care to reuse the ARM Catheter on multiple patients. Specifically, Prometheus's Director of Clinical Services visited Women's Health Care before May 2015 and trained the staff how to reuse the ARM Catheter by covering it with a condom, advising Women's Health Care staff that it was possible to reuse the ARM Catheter. That training is reflected in a May 9, 2015 email written by the Director of Clinical Services in response to a question from the office manager for Women's Health Care who asked: "Can you tell me (maybe call me if easier) about how we should know if ARM caths have been re-used enough/gone bad?" The Director of Clinical Services responded: "[R]eally the way to know if the catheter has gone bad is just what you described. . . . Following every patient, the catheter should be wiped down with a saniwipe and the four small pressure balloons should be squeezed so that no air remains in them. . . . If taken care properly, I have seen them reused as much as 10-12 times)."

128. For four years, from at least 2015 through February 2019, Women's Health Care reused the ARM Catheter on multiple patients.

129. As a result of this reuse, Medicare beneficiaries treated by Women's Health Care were needlessly placed at risk of cross-contamination of bacterial, viral, and fungal infections. Women's Health Care then submitted false claims to Medicare for those unsafe services that were not medically reasonable or necessary, including the following:

a. On April 28, 2016, Women's Health Care performed an anorectal manometry study on beneficiary N.K. As part of the anorectal manometry study, staff used one of the clinic's ARM Catheters that was shared between multiple patients, inserting it into N.K.'s rectum. Women's Health Care then submitted a claim (#681916123231510) to Medicare. The providers at Women's Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $446.59. Based on the foregoing allegations including those at paragraphs 127 through 128, Defendants caused the submission of this false claim.

b. On May 3, 2016, Women's Health Care performed an anorectal manometry study on beneficiary E.F. As part of the anorectal manometry study, staff used one of the clinic's ARM Catheters that was

shared between multiple patients, inserting it into E.F.'s rectum. Women's Health Care then submitted a claim (#681816126621690) to Medicare. The providers at Women's Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $446.59. Based on the foregoing allegations including those at paragraphs 127 through 128, Defendants caused the submission of this false claim.

c. On May 23, 2016, Women's Health Care performed an anorectal manometry study on beneficiary M.B. As part of the anorectal manometry study, staff used one of the clinic's ARM Catheters that was shared between multiple patients, inserting it into M.B.'s rectum. Women's Health Care then submitted a claim (#681916146104630) to Medicare. The providers at Women's Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $446.59. Based on the foregoing allegations including those at paragraphs 127 through 128, Defendants caused the submission of this false claim.

d. On July 7, 2016, Women's Health Care performed an anorectal manometry study on beneficiary B.S. As part of the anorectal manometry study, staff used one of the clinic's ARM Catheters that was shared between multiple patients, inserting it into B.S.'s rectum. Women's Health Care then submitted a claim (#681816194197290) to Medicare. The providers at Women's Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $305.41. Based on the foregoing allegations including those at paragraphs 127 through 128, Defendants caused the submission of this false claim.

e. On September 13, 2016, Women's Health Care performed an anorectal manometry study on beneficiary M.B. As part of the anorectal manometry study, staff used one of the clinic's ARM Catheters that was shared between multiple patients, inserting it into M.B.'s rectum. Women's Health Care then submitted a claim (#681816260244480) to Medicare. The providers at Women's Health Care agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $305.41. Based on the foregoing

allegations including those at paragraphs 127 through 128, Defendants caused the submission of this false claim.

3. Center for Women's Healthcare in Carson City, Michigan

130. Center for Women's Healthcare was a Prometheus customer located in Carson City, Michigan. The Center for Women's Healthcare provided PMR therapy services, including to Medicare beneficiaries.

131. On or about September 13, 2017, Prometheus's Director of Clinical Services provided clinical training to staff members at the Center for Women's Healthcare for PMR therapy using Prometheus equipment, including the Rectal Pressure Sensor.

132. As part of the PMR training, the Director of Clinical Services addressed the practice's use of the Rectal Pressure Sensor. As a result of training the Center for Women's Healthcare previously received from other Prometheus representatives, the practice routinely reused the Rectal Pressure Sensor on multiple patients by covering it with the finger of a surgical glove. During the September 2017 training, Prometheus's Director of Clinical Services confirmed that the practice could reuse the Rectal Pressure Sensor on multiple patients by covering it with a glove.

133. Based on this training, the Center for Women's Healthcare continued to reuse the Rectal Pressure Sensor on multiple patients from September 13, 2017, through in or about May 2019.

134. As a result of this reuse, Medicare beneficiaries treated by the Center for Women's Healthcare were needlessly placed at risk of cross-contamination of

bacterial, viral, and fungal infections. The Center for Women's Healthcare then submitted false claims to Medicare for those unsafe services that were not medically reasonable or necessary, including the following:

a. On March 8, 2017, the Center for Women's Healthcare provided PMR therapy to beneficiary J.M. As part of the PMR therapy, staff reused one of the clinic's Rectal Pressure Sensors that was shared between multiple patients, inserting it into J.M.'s rectum. The Center for Women's Healthcare then submitted a claim (#681817109420240) to Medicare. The providers at the Center for Women's Healthcare agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $63.98 for biofeedback training. Based on the foregoing allegations including those at paragraphs 130 through 133, Defendants caused the submission of this false claim.

b. On August 24, 2017, the Center for Women's Healthcare provided PMR therapy to beneficiary J.H. As part of the PMR therapy, staff reused one of the clinic's Rectal Pressure Sensors that was shared between multiple patients, inserting it into J.H.'s rectum. The Center for Women's Healthcare then submitted a claim (#681917268141300) to Medicare. The providers at the Center for Women's Healthcare agreed to comply

with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $63.98 for biofeedback training. Based on the foregoing allegations including those at paragraphs 130 through 133, Defendants caused the submission of this false claim.

c. Also on August 24, 2017, the Center for Women's Healthcare provided PMR therapy to beneficiary M.R. As part of the PMR therapy, staff reused one of the clinic's Rectal Pressure Sensors that was shared between multiple patients, inserting it into M.R.'s rectum. The Center for Women's Healthcare then submitted a claim (#681917255208460) to Medicare. The providers at the Center for Women's Healthcare agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $63.98 for biofeedback training. Based on the foregoing allegations including those at paragraphs 130 through 133, Defendants caused the submission of this false claim.

d. On February 14, 2018, the Center for Women's Healthcare provided PMR therapy to beneficiary F.S. As part of the PMR therapy, staff reused one of the clinic's Rectal Pressure Sensors that was shared

between multiple patients, inserting it into F.S.'s rectum. The Center for Women's Healthcare then submitted a claim (#681818053551290) to Medicare. The providers at the Center for Women's Healthcare agreed to comply with all applicable Medicare statutes and regulations in the provision of services and submission of claims, yet they knowingly submitted this claim that was not reasonable and necessary. As a result of this false claim, Medicare paid a total of $64.02 for biofeedback training. Based on the foregoing allegations including those at paragraphs 130 through 133, Defendants caused the submission of this false claim.

135. The United States alleges that Defendants caused the submission of the preceding exemplar false claims, as well as other false claims to be identified through discovery and proven at trial, to the Medicare Program.

136. In addition to the allegations set forth above, the United States may prove other relevant facts and additional false claims at trial.

COUNT I –
PRESENTATION OF FALSE OR FRAUDULENT CLAIMS
(False Claims Act, 31 U.S.C. § 3729(a)(1)(A))

137. The United States realleges and incorporates by reference the allegations of all of the preceding paragraphs of the Complaint.

138. As discussed more fully above, Defendants knowingly presented or caused to be presented false or fraudulent claims for payment to the Government.

139. By virtue of these false or fraudulent claims, the Government suffered damages and is therefore entitled to treble damages under the False Claims Act, in an amount to be determined at trial, plus civil penalties of between $11,803 and $23,607 for each violation occurring after November 2, 2015, and between $5,000 and $11,000 for each violation occurring on or before November 2, 2015. 31 U.S.C. § 3729(a); 28 C.F.R. §§ 85.3, 85.5.

COUNT II –
FALSE RECORDS OR STATEMENTS
(False Claims Act, 31 U.S.C. § 3729(a)(1)(B))

140. The United States realleges and incorporates by reference the allegations of all of the preceding paragraphs of the Complaint.

141. As discussed more fully above, Defendants knowingly made, used, or caused to be made or used, materially false records and statements to get false or fraudulent claims paid or approved by the Government.

142. By virtue of these materially false records or statements, the Government suffered damages and is therefore entitled to treble damages under the False Claims Act, in an amount to be determined at trial, plus civil penalties of between $11,803 and $23,607 for each violation occurring after November 2, 2015, and between $5,000 and $11,000 for each violation occurring on or before November 2, 2015. 31 U.S.C. § 3729(a); 28 C.F.R. §§ 85.3, 85.5.

PRAYER FOR RELIEF

The United States demands and prays that judgment be entered in its favor, and against Defendants for the amount of statutory treble damages, and such civil

penalties as are required by law, together with all such further relief as may be just and proper.

DEMAND FOR JURY TRIAL

The United States hereby demands a trial by jury pursuant to Federal Rule of Civil Procedure 38.

Dated: May 17, 2022

Respectfully submitted,

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