UNITED STATES DISTRICT COURT

DISTRICT OF MASSACHUSETTS

THE UNITED STATES OF AMERICA, the STATES of CALIFORNIA, COLORADO, CONNECTICUT, DELAWARE, FLORIDA, GEORGIA, HAWAII, ILLINOIS, INDIANA, IOWA, LOUISIANA, MARYLAND, MICHIGAN, MINNESOTA, MONTANA, NEVADA, NEW JERSEY, NEW MEXICO, NEW YORK, NORTH CAROLINA, OKLAHOMA, RHODE ISLAND, TENNESSEE, TEXAS, VERMONT, and WASHINGTON; the COMMONWEALTHS of MASSACHUSETTS, and VIRGINIA; *ex rel.* JOHN DOE 1, JOHN DOE 2, JOHN DOE 3, and JOHN DOE 4,

Plaintiff-Relators,

v.

QOL MEDICAL, LLC, ONE PATIENT SERVICES, LLC, FREDERICK E. COOPER, METABOLIC SOLUTIONS, LLC, TRUSTEE of the FREDERICK E. COOPER JR. IRREVOCABLE TRUST, and TRUSTEE of the JOHNSON JOSEPH COOPER, IRREVOCABLE TRUST,

Defendants.

CIVIL ACTION NO.:

1:20-cv-11243-AK

FILED UNDER SEAL PURSUANT TO 31 U.S.C. § 3730(b)(2)

JURY TRIAL DEMANDED

LEAVE TO FILE GRANTED

ON JULY 22, 2024

SECOND AMENDED COMPLAINT

1. Pursuant to the Federal False Claims Act, 31 U.S.C. § 3729, *et seq.*, as well as the various state analog statutes referenced herein, Relators John Does 1 through 4 (collectively, "Relators"), hereby bring this action against QOL Medical, LLC, One

Patient Services, LLC, Frederick E. Cooper, Metabolic Solutions, LLC, the Trustee of the Frederick E. Cooper Jr. Irrevocable Trust, and the Trustee of the Johnson Joseph Cooper Irrevocable Trust ("Defendants"). As grounds for this Second Amended Complaint, Relators state as follows:

2. QOL manufactures and sells an enzyme replacement therapy (ERT) made from bakers' yeast to treat CSID, a rare genetic disorder manifesting early in life in a few hundred children. For two decades sales have been modest. In pursuit of outsized profit, QOL has pivoted to a far larger, imaginary, undiagnosed adult population. In 2018, QOL introduced the unvalidated and unreliable "FREE, at-home13C-Sucrose Breath Test" and, with an expanding contract sales force, has blanketed the country with free tests kits that are misbranded. For CSID, the only reliable thing about the test kits is their fallibility—giving false positives for that condition roughly 80% of the time. Accordingly, doctors and patients are misled into trying Sucraid. QOL knows and expects high discontinuation rates among these "undiagnosed" adults but it doesn't matter because every prescription is worth $8,000 a month in revenue. Churning through short-lived prescriptions is very profitable. Sales in 2010 were $16 million. In 2020 sales are on track to be more than $250 million. Medicare, like many private insurers, is paying the price. Since 2018, Medicare spending on Sucraid has increased nearly 500%. QOL is conducting a *de facto,* unapproved clinical trial on an unwitting and aging population—the vast majority of whom will fail to improve with Sucraid. It is often said that success is built on failure—that is especially true for QOL Medical, LLC, One Patient Services, LLC and Frederick E. Cooper, Jr., who are bankrolling their

success by gouging Medicare and Medicaid for treatment failures that predictably result from inappropriate and off-label use.

I. PARTIES

3. John Doe ("Relator 1") is a former employee of QOL Medical, LLC.

4. John Doe ("Relator 2") is a former employee of QOL Medical, LLC.

5. John Doe ("Relator 3") is a former employee of QOL Medical, LLC.

6. John Doe ("Relator 4") is a former employee of QOL Medical, LLC.

7. QOL Medical, LLC ("QOL") is a Delaware corporation registered with file number 3499205. QOL's principal business address is 3405 Ocean Drive, Vero Beach, FL 32963.

8. One Patient Services, LLC ("One Patient Services") is a Florida corporation registered with number 9183455159CC and is a wholly owned subsidiary of QOL. One Patient Services' principal business address is 3405 Ocean Drive, Vero Beach, FL 32963.

9. Frederick ("Derick") E. Cooper ("Cooper") is an individual residing in Vero Beach, Florida. Cooper is CEO of QOL and an authorized representative of One Patient Services. On information and belief, Cooper also holds an ownership interest in both companies, either directly or indirectly.

10. Metabolic Solutions, LLC ("Metabolic Solutions") is a New Hampshire corporation registered with number 329408 and whose principal place of business is 460 Amherst Street, Nashua, New Hampshire 03063.

11. The Trustee of the Frederick E. Cooper Jr. Irrevocable Trust a/k/a the Frederick E. Cooper Jr. Irrevocable Funded Trust (FEIN 58-6280024) ("Trustee 1") is an individual in whom, on information and belief, title to a 47% share in QOL, LLC is vested and whose mailing address is Regional Center, 2630 Centennial Place, Tallahassee, Florida.

12. The Trustee of the Johnson Joseph Cooper Irrevocable Trust, a/k/a the Johnson Joseph Cooper Irrevocable Funded Trust (FEIN 58-6280023) ("Trustee 2") is an individual in whom, on information and belief, title to a 30% share in QOL, LLC is vested and whose mailing address is Regional Center, 2630 Centennial Place, Tallahassee, Florida.

II. JURISDICTION AND VENUE

13. Pursuant to 28 U.S.C. § 1331, this Court has original jurisdiction over the subject matter of this civil action because it arises under the laws of the United States, in particular the False Claims Act, 31 U.S.C. § 3729, *et seq.* ("FCA"). In addition, the FCA specifically confers jurisdiction upon this Court pursuant to 31 U.S.C. § 3732(b).

14. This Court has personal jurisdiction over Defendants pursuant to 31 U.S.C. § 3732(a) because the FCA authorizes nationwide service of process and Defendants have sufficient minimum contacts with the United States of America.

15. Venue is proper in this Court pursuant to 31 U.S.C. § 3732(a) because Defendants reside in and/or transact business in this judicial district.

16. Relators are unaware of any public disclosure of the information or allegations that are the basis of the original Complaint or this Amended Complaint. In the event that there has been a public disclosure, Relators are the original source of the information and allegations contained in this Complaint. Prior to the filing of this action, Relators voluntarily provided information to the United States Government regarding the false claims that are the subject of this action. Relators sent notice to the United States of the false claims alleged in this Complaint on or about June 22, 2020. Relators allege that Defendants' unlawful acts, as described below were, at all times, material to the United States' decision and the named State Plaintiffs' to reimburse the false claims alleged herein.

III. THE FALSE CLAIMS ACT

17. Since 2006, the Medicare program has purchased prescription drugs for those persons eligible for Medicare Part D coverage. Medicare not only covers individuals over age 65, but it also provides medical coverage for many individuals who are permanently disabled under the Social Security Act.

18. The United States also purchases prescription drugs through a number of other programs, including the Department of Veterans Affairs, the Department of Defense's TRICARE program, and the Federal Employees Health Benefit Plan (these governmental health care insurance programs will collectively be referred to as "Government Healthcare Programs").

19. The Government Healthcare Programs identified above spend billions of dollars each year on prescription drugs. Not surprisingly, in order to prevent waste, fraud, and abuse, and to protect the health of patients, the federal and state programs restrict the types and uses of drugs which may be paid for with government funds. These regulatory schemes are designed to ensure that the federal and state programs only pay for drugs which are found to be safe and effective for their prescribed uses.

20. The False Claims Act, 31 U.S.C. § 3729(a)(1)(A), makes "knowingly" presenting or causing to be presented to the United States any false or fraudulent claim for payment or approval a violation of federal law for which the United States may recover three times the amount of the damages the government sustains and a civil monetary penalty of between $11,665 and $23,331 per claim.

21. The False Claims Act makes "knowingly" making, using, or causing to be used or made, a false record or statement material to a false or fraudulent claim, a violation of federal law for which the United States may recover three times the amount of the damages the Government sustains and a civil monetary penalty of between $13,946 and $27,894 per claim.

22. The False Claims Act makes any person who conspires to commit a violation of the FCA liable for three times the amount of the damages the Government sustains and a civil monetary penalty of between $13,946 and $27,894 per claim.

23. The False Claims Act defines a "claim" to include any request or demand, whether under a contract or otherwise, for money or property which is made to a contractor, grantee, or other recipient if the United States Government provides any

portion of the money or property which is requested or demanded, or if the Government will reimburse such contractor, grantee, or other recipient. Any claim submitted by a Medicare or a Medicaid provider for a payment constitutes a claim under the False Claims Act. Any claim submitted by a provider for payment by a federal insurance plan, such as Tricare, is also a "claim" for purposes of the False Claims Act.

24. In 2009, the scope of the FCA was widened to included statements made to private nongovernmental entities in connection with a request for funds to which the United States has no title and which are not expended on the Government's behalf may nevertheless implicate FCA liability if the funds were meant to advance a federal program or interest. Under the amended statutory language, a "claim" now includes:

> *any request or demand, whether under a contract or otherwise, for money or property which 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 which is requested, or demanded,; or if the Government (II) will reimburse such contractor, grantee, or other recipient for any portion of the money or property which is requested or demanded; and (B) does not include requests or demands for money or property that the Government has paid to an individual as compensation for Federal employment or as an income subsidy with no restrictions on that individual's use of the money or property.*

FERA, Pub. L. No. 111-21, § 4 (May 20, 2009).

IV. FEDERAL ANTI-KICKBACK LAWS

25. The Medicare and Medicaid Patient Protection Act, also known as "the Anti-Kickback Statute," 42 U.S.C. § 1320a-7b(b), arose out of congressional concern that the

remuneration and gifts given to those who can influence health care decisions corrupt medical decision-making and can result in the provision of goods and services that are more expensive and/or medically unnecessary or even harmful to a vulnerable patient population. To protect the integrity of Government Health Care Programs, Congress enacted a prohibition against the payment of kickbacks in any form. The Anti-Kickback Statute was enacted in 1972 "to provide penalties for certain practices which have long been regarded by professional organizations as unethical, as well as unlawful . . . and which contribute appreciably to the cost of the Medicare and Medicaid programs." H.R. Rep. No. 92-231, 92d Cong., 1st Sess. 108 (1971), reprinted in 1972 U.S.C.C.A.N. 4989, 5093.

26. In 1977, Congress amended the Anti-Kickback Statute to prohibit receiving or paying "any remuneration" to induce referrals and increased the crime's severity from a misdemeanor to a felony with a penalty of $25,000 and/or five years in jail. *See* Social Security Amendment of 1972, Pub. L. No. 92-603, 241(b) and (c); 42 U.S.C. § 1320a-7b. In doing so, Congress noted that the purpose of the Anti-Kickback Statute was to combat fraud and abuse in medical settings that "cheat[] taxpayers who must ultimately bear the financial burden of misuse of funds . . . [that] divert[] from those most in need, the nation's elderly and poor, scarce program dollars that were intended to provide vitally needed quality health services . . . [and that] erode[] the financial stability of those state and local governments whose budgets are already overextended and who must commit an ever-increasing portion of their financial resources to fulfill

the obligations of their medical assistance programs." H.R. Rep. No. 95–393, pt. 2, at 37, reprinted in 1977 U.S.C.C.A.N. 3039, 3047.[1]

27. In 1987, Congress again strengthened the Anti-Kickback Statute to ensure that kickbacks masquerading as legitimate transactions did not evade its reach. *See* Medicare-Medicaid Antifraud and Abuse Amendments, Pub. L. No. 95-142, Medicare and Medicaid Patient and Program Protection Act of 1987, Pub. L. No. 100-93.

28. The Anti-Kickback Statute prohibits any person or entity from knowingly and willfully offering to pay or paying any remuneration to another person to induce that person to purchase, order, or recommend any good, service, or item for which payment may be made in whole or in part by a Government Health Care Program, which includes any state health program funded in part by the federal government. 42 U.S.C. §§ 1320a-7b(b), 1320a-7b(f).

29. The Anti-Kickback Statute provides, in pertinent part:

> (b) Illegal remunerations
>
> * * *
>
> (2) Whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person –
>
> (A) To refer an individual to a person for the furnishing or arranging for the furnishing of any item or service

[1] Through the amendments Congress sought to "give a clear, loud signal to the thieves and the crooks and the abusers that we [Congress] mean to call a halt to their exploitation of the public and the public purse." 123 Cong. Rec. S31767 (daily ed. Sept 30, 1997) (statement of Sen. Talmadge).

> for which payment may be made in whole or in part under Federal health care program, or
>
> (B) To purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> Shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.

42 U.S.C. § 1320a-7b(b).

30. A transaction may violate the Anti-Kickback Statute even when a payor's unlawful intent is not its exclusive intent. It is enough that "*any one purpose* of the remuneration may be to induce or reward the referral or recommendation of business payable in whole or in part by a Federal health care program." OIG Compliance Program Guidance for Pharmaceutical Manufacturers, 68 Fed. Reg. 23731 (May 3, 2003) (emphasis added). In other words, even "a lawful purpose will not legitimize a payment that also has an unlawful purpose."

31. In addition to criminal penalties, a violation of the Anti-Kickback Statute can also subject the perpetrator to exclusion from participation in Government Health Care Programs (42 U.S.C. § 1320a-7(b)(7)), civil monetary penalties of $50,000 per violation (42 U.S.C. § 1320a-7a(a)(7)), and three times the amount of remuneration paid, regardless of whether any part of the remuneration is for a legitimate purpose, 42 U.S.C. § 1320a-7a(a).

32. The Anti-Kickback Statute not only prohibits outright bribes and rebate schemes, but also prohibits any payment, gift, or other remuneration by a company to a physician or other person which has as one of its purposes the inducement of the physician to use the company's products or the inducement of the physician to influence or recommend the use of the product.

33. Compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under Government Health Care Programs, including Medicare. Moreover, compliance with the Anti-Kickback Statute is a *condition of payment* for any claims for which Medicare reimbursement is sought. Every provider who enters into a contract with Medicare specifically acknowledges in its provider contract that the provider understands "that payment of a claim by Medicare is conditioned upon the claim and the underlying transaction complying with such laws, regulations and program instructions (including, but not limited to, the Federal anti-kickback statute and the Stark law), and on the [provider]'s compliance with all applicable conditions of participation in Medicare."

34. Medicare claims for reimbursement of any goods or services that were the subject of a kickback constitute false claims (see False Claims Act discussion, *infra*). This is because compliance with the Anti-Kickback Statute is a precondition to participation as a health care provider under Government Health Care Programs, including Medicare. Moreover, compliance with the Anti-Kickback Statute is a condition of payment for any goods or services reimbursed by Medicare, including medical devices and related medical procedures using those devices.

35. Furthermore, the Anti-Kickback Statute was amended, effective March 23, 2010, to expressly provide that: "In addition to the penalties provided for in this section or section 1320a-7a of this title, a claim that includes items or services resulting from a violation of this section constitutes a false or fraudulent claim for purposes of [the False Claims Act]." Consequently, any kickbacks paid on or after March 23, 2010, that caused reimbursement claims to be presented to the government for payment would result in actionable false claims regardless of the provisions of any provider agreement.

V. FEDERAL STARK LAW

36. Enacted in the 1980s in an attempt to contain health care costs and reduce conflicts of interests, the Stark Law, Pub. L. No. 101-239, § 6204, 103 Stat. 2106 (1989), generally prohibits physicians from referring their Medicare patients to business entities, such as hospitals or laboratories, with which the physicians or their immediate family members have a "financial relationship." 42 U.S.C. § 1395nn(a)(1). Subsequent amendments later extended certain aspects of the Stark Law to Medicaid patients. *See* 42 U.S.C. § 1396b(s). Applicable regulations reiterate this basic restriction and provide guidance regarding the kinds of financial relationships that trigger the ban on physician referrals. See generally 42 C.F.R. §§ 411.350 - .389 ("Subpart J – Financial Relationships Between Physicians and Entities Furnishing Designated Services").

37. Although HHS has promulgated regulations interpreting the Stark Law in three major phases: the Phase I rules, 66 Fed. Reg. 856 (2001); the Phase II rules, 69 Fed.

Reg. 16054 (2004); and the Phase III rules, 72 Fed. Reg. 51012 (2007), HHS intended for these three phases to be read as a unified whole. *See* 72 Fed. Reg. 51013.

38. The Stark Law and its regulations: (a) prohibit any entity from submitting a Medicare claim for services rendered pursuant to a prohibited referral, *see* 42 U.S.C. § 1395nn(a)(1)(B); 42 C.F.R. § 411.353(b); (b) prohibit Medicare from paying any such claims, *see* 42 U.S.C. § 1395nn(g)(1); 42 C.F.R. § 411.353(c); and require an entity that receives payment for such a claim to reimburse such funds to the United States, *see* 42 C.F.R. § 411.353(d).

39. The Stark Law defines a "financial relationship" to include a "compensation arrangement," 42 U.S.C. § 1395nn(a)(2), which means "any arrangement involving any remuneration between a physician (or an immediate family member of such physician) and an entity," 42 U.S.C. § 1395nn(h)(1)(A). In turn, "remuneration" is broadly defined to include "any remuneration, directly or indirectly, overtly or covertly, in cash or in kind." 42 U.S.C. 1395nn(h)(1)(B). *See* 42 C.F.R. § 411.351 ("Remuneration means any payment or other benefit made directly or indirectly, overtly or covertly, in cash or in kind"). However, the statute excludes certain kinds of payments from the definition of remuneration, including "the provision of items, devices or supplies that are used ***solely*** to (I) collect, transport, process or store specimens ***for the entity providing the item, device or supply***, or (II) order or communicate the results of tests or procedures for such entity." 42 U.S.C. § 1395nn(h)(1)(C)(ii) (emphasis added). The regulations reiterate this statutory carve-out. *See* 42 C.F.R. § 411.351.

VI. MISBRANDING

40. Accord to Section 201(h) of the Food, Drug, and Cosmetic Act ("FDCA"), a medical device is defined to include any "instrument, apparatus, implement, machine, contrivance, implant, in vitro reagent, or other similar or related article, including a component part, or accessory which is…intended for use in the diagnosis of disease or other conditions, or in the cure, mitigation, treatment, or prevention of disease, in man or other animals…"

41. Under the FDCA, 21 U.S.C. §§ 301 *et seq.*, the FDA regulates whether devices may be sold and promoted for particular purposes. *See* 21 U.S.C. §§ 301 *et seq*.

42. The FDCA restricts manufacturers from marketing or promoting off label uses. Thus, 21 U.S.C. § 331 prohibits, "[t]he introduction or delivery for introduction into interstate commerce of any . . . device . . . that is adulterated or misbranded." S*ee also* 21 C.F.R. § 814.80 ("A device may not be manufactured, packaged, stored, labeled, distributed, or advertised in a manner that is inconsistent with any conditions to approval specified in the PMA approval order for the device.").

43. The FDCA classifies such medical devices into three categories, with corresponding levels of regulatory review. 21 U.S.C. § 360c(a)(1).

44. Class III devices include those that present an unreasonable risk of illness or injury. *Id.* § 360c(a)(1)(C). They are subject to a rigorous premarket approval ("PMA") process. It requires the manufacturer to submit valid scientific evidence demonstrating that there is reasonable assurance that the device is safe and effective for its intended use. *Id.* §§ 360c(a)(1)(C), 360e(a), (c), (d); 21 C.F.R. pt. 814. After the PMA process is

complete, Class III devices may be granted premarketing clearance, thereby allowing their sale. 42 C.F.R. § 405.201(b).

45. If a Class III device is without PMA approval, it may be deemed "adulterated," and cannot be offered for sale. *See* 21 U.S.C. § 351(f)(1)(B)(ii) ("A . . . device shall be deemed to be adulterated . . . if it is a class III device . . . which . . . is required to have in effect an approved application for premarket approval . . . and . . . which has an application which has been suspended or is otherwise not in effect.").

46. In general, Class II devices may be marketed and sold once they receive "§ 510(k)" clearance. That clearance may be granted when a device is shown to be "substantially equivalent" to another legally marketed device that has FDA clearance, or meets other criteria. *See* 21 U.S.C. § 360c(i). Section 510(k) clearance is not equivalent to FDA "approval" of a device. 21 C.F.R. § 807.97. Instead, the FDA only clears such devices for the limited uses identified by the manufacturer in the § 510(k) application: the intended use. See 21 C.F.R. § 801.5. When a medical device has been cleared, or granted PMA approval, for a certain use, that use must be disclosed on its label. The marketing or promotion for any other use other than the stated intended use requires a separate approval or clearance.

47. Class I devices present the lowest level of risk. However, Class I devices are still subject to general controls to ensure safety and efficacy, including establishment registration and device listing; premarket notification, if the device is non-exempt; prohibitions against adulteration and misbranding; records and reports; and good

manufacturing practices. *See* Section 513(a)(1)(A) of the FD&C Act (21 U.S.C. § 360c(a)(1)(A)).

VII. ORPHAN DRUGS

48. In certain limited instances, the FDA permits sponsors to bypass the normal approval routes, which can be expensive and time-consuming, and come to market with drug whose testing is not sufficiently robust but is acceptable given the nature of certain diseases for which there would not otherwise be sufficient market incentives for drug development. One the most prominent such pathways is the FDA's orphan drug program. This FDA program exists to incentivize innovation for rarer diseases where there are fewer than 200,000 patients in the United States. These are called "orphan" diseases.

49. "Orphan" drugs, which are submitted for approval for one of these rare conditions, receive a variety of benefits not available for other drugs. First and foremost, orphan drugs can more easily and cheaply gain FDA approval, avoiding the need to obtain the same level of rigorous evidence of safety and efficacy as non-orphan drugs. A clinical trial may only have one or two dozen patients, whereas typically one or two hundred would be required. Second, there are various financial incentives, including federal research grants, tax credits, extended marketing exclusivity and waiver of the FDA's user fees. Third, because "orphan diseases" are usually severe and often life-threatening if untreated, drug companies are often able to command much higher prices. A recent study by America's Health Insurance Plans (AHIP) found that

the average annual cost for orphan drugs is $123,543, which is 25 times more expensive than traditional drugs.

50. This "out-of-control" pricing—quoting AHIP—represents a 26-fold increase in two decades. And while the intent of the FDA's orphan drug program was to incentivize sponsors with modest profits, sponsors have inverted the profitability, now commanding gross profit margin of more than 80%, while the rest of the pharmaceutical industry posts an average gross profit margin of 16%.

51. And while Orphan Medical may not have intended to exploit the FDA's orphan drug program when it submitted its NDA, there is clear evidence that such exploiting is precisely the intent of QOL, which acquired Sucraid for a token payment and has never had to fund a clinical trial.

VIII. FACTUAL ALLEGATIONS

A. What is Congenital Sucrase-Isomaltase Deficiency ("CSID")

52. Congenital sucrase-isomaltase deficiency (CSID) is a rare genetic disorder that affects a person's ability to digest sucrose and maltose due to absent or low activity of two digestive enzymes, sucrase and isomaltase. People with this condition cannot break down the sugars sucrose and maltose, and other compounds made from simple sugar molecules (carbohydrates), which can cause gastrointestinal symptoms such as diarrhea, gas, bloating, abdominal pain.

53. Sucrose—a sugar found in fruits and commonly known as table sugar—and maltose—the sugar found in grains—are called disaccharides because they are made of

two simple sugars. Disaccharides are broken down into simple sugars during digestion. Sucrose is broken down into glucose and fructose, another simple sugar. Maltose is broken down into two glucose molecules. A percentage of the absorbed glucose and fructose is quickly oxidized and exhaled as CO_2 and the remainder is metabolized or stored.

54. Traditionally, patients with CSID were placed on a sucrose-free diet. Compliance with such a diet, which strictly excludes ice cream, cakes, cookie, candy, breakfast cereals, fruit, hot dogs, ham and other cold cuts, jams, honey, and some vegetables, is difficult. Thus there was a rationale for enzyme replacement therapy that, theoretically, would allow patients to have a more normal diet.

B. SUCRAID (Sacrosidase)

55. In 1987, researchers published the results of a pilot study in eight children with CSID which showed that a small amount of baker's yeast (*saccharomyces cervisiae, or s. cervisiae*) eliminated or lessened the symptoms of diarrhea, cramps, and bloating, and lowered breath hydrogen excretion when administered with a sucrose load. *Saccharomyces cerevisiae* is a single-celled eukaryote that is frequently used in scientific research. *S. cerevisiae* is an attractive model organism due to the fact that its genome has been sequenced, its genetics are easily manipulated, and it is very easy to maintain in the lab.

56. Sucraid (sacrosidase) is a liquid enzyme preparation from *saccharomyces cervisiae.* It provides replacement for the missing endogenous sucrase with an exogenous sucrase that retains enzymatic activity when given orally. Sucraid does not,

however, provide replacement for isomaltase deficiency. Thus, while Sucraid may allow some patients to consume sucrose that they otherwise needed to avoid, treated patients may still need to avoid certain starches, such as breads, pastas, and potatoes.

C. FDA designates Sucraid as an Orphan Drug

57. On May 6, 1997, Orphan Medical, Inc. submitted a New Drug Application (NDA) for Sucraid to treat genetically determined sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency. As part of the NDA, Orphan Medical submitted the results from two double-blind, randomized, controlled trials for safety and efficacy, S-1 and S-2, as well as a third open-label trial for long-term safety, S-3. Orphan Medical claimed no patents as part of its NDA.

58. On November 6, 1997, Orphan Medical, Inc. received an "approvable" letter from the FDA. The FDA stated that "CSID is characterized by a complete or almost complete lack of sucrase activity, a very marked reduction in isomaltase activity, and a moderate decrease in maltase activity." The FDA also noted that the definitive test for diagnosis of CSID is the measurement of intestinal disaccharidases following small bowel biopsy. The FDA observed, however, the condition could also be diagnosed with a hydrogen breath test (BHT) so long as the test was administered (i) after an oral challenge with sucrose; (ii) after a negative oral challenge with lactose ; and (iii) in addition to a stool pH of less than 6. Prior to the advent of the BHT, the FDA noted that oral sucrose tolerance tests were utilized as a non-invasive diagnostic alternative to biopsy. The FDA did not endorse those tests, however, due to the "high incidence of false-positive tests using sucrose challenge…"

59. The FDA approved Sucraid primarily in reliance on data from the S-2 study, which was the larger of the two efficacy studies but only had [28] patients. S-1's results were inconsistent. Approval would require that Orphan Medical address a number of deficiencies, including chemistry, manufacturing, and control deficiencies.

60. On February 17, 1998, Orphan Medical wrote to the FDA to explain the company's "planned post-approval surveillance system to ensure that any adverse experiences are appropriately reported to FDA." In that letter Orphan Medical stated that CSID "is a rare disease in the United States. Our market projections currently estimate in the order of 100 to possible as high as five hundred patients with severe enough etiology to require replacement enzyme therapy." Orphan Medical specifically stated that Dr. William Treem, an expert in the field of CSID and of whom every doctor with a CSID patient has heard, had only been approached for 100 referrals in the last five years. Orphan Medical also stated optimistically that it would try to find as many patients as possible to keep the cost reasonable for the health care system.

61. On April 9, 1998, the FDA approved Orphan Medical, Inc.'s NDA for Sucraid. The approved indication is an enzyme replacement therapy for the treatment of genetically determined sucrase deficiency, ***which is part of congenital sucrase-isomaltase deficiency (CSID)***." (emphasis added). The FDA also obligated Orphan Medical to follow through on various "Phase 4 commitments." Although the commitments were redacted from the approval letter, it is clear they involved further studies. Sucraid has not been tested to see if it works in patients with secondary (acquired) sucrase deficiency.

62. QOL's subsequent promotion of Sucraid is based on false and misleading statements including scientific falsehoods or half-truths. Contrary to the marketing claims, the safety or efficacy of Sucraid has never been studied in a long-term controlled study. QOL possesses no scientific data that supports the use of Sucraid in a newly-diagnosed adult population.

63. In fact, there is no evidence that QOL has conducted any clinical trials. QOL has only registered one clinical trial, which was withdrawn before completion. And no trials have been presented to the FDA beyond the original studies submitted with the NDA, which themselves were limited in size and equivocal in results.

64. The FDA has only reviewed three studies (S1, S2, and S3), which had relevant or reviewable data. There were few if any adult patients who were studied for efficacy and no studies have ever demonstrated efficacy in adults.

65. The S1 trial was a small study with poor design, poor documentation, and poor results. That study, which only screened 16 patients, showed some reduction in hydrogen breath test results, but there was no symptomatic superiority of Sucraid treatment over placebo. The mean age of study patients was 8.2 years old. The final publication discloses only 14 patients and states that only 12 actually completed. This suggests that the published results are more favorable than what was submitted to the FDA and may be misleading. Of the 14 patients in the published study, only 3 were adults. Half of the reported patients were younger than 4 years old. Two were 18 years old, and one was 29 years old. The study publication notes: "Older patients given high sucrose loads continued to experience some symptoms even with [Sucraid]

administration." The study notes that all but one patient had undergone a small bowel biopsy.

66. The S2 study was slightly larger and had better design and reporting. For the S2 trial, 40 patients were screened, but only 28 entered dose phase. Two patients failed to complete. The study enrolled only infants and children. There were no adults. The mean age was 4 years old. All patients had undergone a small bowel biopsy. The results of the S2 study were generally favorable, and on the basis of this study alone, the FDA approved Sucraid as an orphan drug.

67. The S3 study was an open-label study for patients in the S1 and S2 studies who volunteered to remain on the drug. A total of 34 agreed to remain on treatment, which ranged from 2 months to 54 months. This study did not support a finding of long-term safety or efficacy.

68. QOL falsely claims the existence of clinical trial data to support its various marketing claims, including: that clinical trials have confirmed the safety and efficacy of Sucraid in an adult population (including naïve elderly patients); that 81% patients became asymptomatic in a long-term clinical trial; that the C13 Breath Test provides a reliable diagnosis of CSID; and that the experimental use of Sucraid itself can be used to "confirm" a diagnosis. None of these statements are true. Not only does QOL not possess such data, but it has not completed its own clinical trials to determine the truthfulness of these statements.

D. QOL's Acquisition of Sucraid

69. In 2003, Orphan Medical, Inc. divested itself of Sucraid, selling the rights to the drug to QOL for a $1.5 million upfront payment and royalties based on future revenues. On information and belief, the royalty payments were small in the initial years. For example, in a 10-Q filed by Orphan Medical in in 2005,[2] the company reported royalty payments of $100,000 for the first quarter of 2005, suggesting that annual royalties for the entire year were less than $0.5 million.

E. Clinical Presentation

70. Congenital sucrase-isomaltase deficiency usually becomes apparent after an infant is weaned and starts to consume fruits, juices, and grains and often is diagnosed under the age of 18 months. Many infants and very young children develop frequent diarrhea, accompanied by severe diaper rash. Untreated, CSID can lead to failure to gain weight and grow at the expected rate and malnutrition. Most affected children are better able to tolerate sucrose and maltose as they get older. CSID may sometimes be diagnosed in older children or adults, but it is a condition which is commonly detected at an early age.

[2] The 10-Q was issued in connection with Orphan Medical's acquisition by Jazz Pharmaceutical in 2005 for $122.6 million. Shortly after the acquisition, an employee named Alfred Caronia established a speakers bureau for Orphan Medical whereby he enlisted physicians to talk to other doctors about off-label uses of Xyrem. Mr. Caronia was caught on audiotape twice discussing unapproved uses of Xyrem as well as its unapproved use in minors (under the age of 16 years) with a physician who was a government informant. He also discussed how to use different billing codes for insurance purposes, indicating it should be delineated as prescribed for an approved use even when the drug was prescribed for off-label uses. This physician met with other prescribers and discussed the off-label benefits of using the medication.

71. The typical presentation is distinguishable from common, temporary, gastrointestinal symptoms. A patient with CSID who has ingested sucrose or maltose will typically experience watery diarrhea, bloating, excess gas production, abdominal pain ("stomach ache"), and malabsorption of other nutrients. Other symptoms may include nausea, vomiting, or reflux-like symptoms, watery diarrhea, bloating, abdominal pain, and flatulence. A small number of severely affected patients require hospitalization for diarrhea, dehydration, malnutrition, muscle wasting, and weakness. The diarrhea, bloating, and gas production result from the malabsorbed carbohydrate which acts as an osmotic laxative drawing water and electrolytes into the intestines. Bacterial metabolism of the undigested carbohydrates produce the gas which distends the colon. CSID symptoms may be mistakenly attributed to a different disorder or cause, such as a functional GI disorder like irritable bowel syndrome with diarrhea (IBS-D) or dyspepsia.

F. Prevalence and causes of CSID

72. CSID is a rare genetic disorder. When Orphan Medical submitted its NDA to gain approval for Sucraid as an orphan drug, it estimated that between 100 and 500 patients would be in need of enzyme replacement therapy due to CSID. While the precise prevalence of CSID is unknown, QOL—who acquire the drug from Orphan Medical for a mere $1.5 million plus future royalty payments—has attempted to create the belief that prevalence is much larger than the evidence suggests. Estimates of prevalence in people of European descent generally range from 1 in 500 to 1 in 2,000, and fewer African Americans are thought to be affected. The condition is much more

prevalent in the indigenous populations of Greenland, Alaska, and Canada, where as many as 1 in 10 to 1 in 30 people may be affected. Nevertheless, QOL touts more recent studies to support a claim that CSID is more common than currently estimated, often using opaque references to "Data on File" as support for these expansive claims. QOL also speculates that it is possible that some people remain undiagnosed and that the incidence is actually higher, although this claim is unlikely given the striking symptomology of CSID experienced in infancy.

73. Mutations in a gene (the SI gene) cause congenital sucrase-isomaltase deficiency. The SI gene provides instructions for producing the enzyme sucrase-isomaltase. This enzyme is found in the small intestine and is involved in the digestion of sugar and starch. It is responsible for breaking down sucrose and maltose into their simple sugar components. These simple sugars are then absorbed by the small intestine. In addition to genetic variations, other factors including dietary, gut motility, and nutritional interactions can affect the severity of symptoms.

74. CSID is characterized by severe symptoms. According to an internal presentation of Defendant QOL Medical, these severe symptoms include "Chronic, frequent loose bowel movements. (5, 7, 10 per day) often as diarrhea. May be described as, at times, 'explosive'."

75. For this reason, patients are generally diagnosed early in life, most commonly upon or shortly after infants are weaned and table sugar is introduced into their diets. These infants immediately suffer multiple bouts of diarrhea per day, so

much so that many develop a severe diaper rash that is itself one of the hallmarks of the disorder.

76. Thus it is rare and unlikely that a patient with CSID would be undiagnosed in adulthood. Further, patients with CSID are not cured, and thus they will have to remain on therapy for the rest of their life or have a return of symptoms. Adherence to the Sucraid regimen (which is ingested at every meal) is known as being "sticky," that is to say a true CSID patient adheres to the medicine because they cannot do without it. On the other hand, patients who have been identified through a false positive test do not adhere to the medicine because it does nothing for them. Accordingly, and according to company data, patients identified in adulthood tend to be less "sticky" because they do not actually have CSID. In the words of the "Sucraid First" brochure, "Patients who do not respond to Sucraid do not have CSID."

G. QOL Medical, LLC

77. Currently, QOL manufactures, sells and distributes Sucraid. In 2010, when Frederick Cooper took over a controlling interest in QOL, Relator 1 recalls that there were just 188 patients taking Sucraid, generating an annual turnover of approximately $16 million. By contrast, an analysis of internal company documents suggests that in 2020 sales of Sucraid will exceed $250 million.

78. These massive sales are only feasible because QOL has steadily shifted focus away from patients with CSID and towards the adult patient population with symptoms that are similar to CSID but lack either a positive genetic diagnosis or a positive biopsy. Overwhelmingly, these patients ultimately discontinue Sucraid

because it does nothing to ease their suffering. In the meantime, QOL reaps months of prescription payments (at roughly $8000 a month) from this transient population.

79. The lucrative cash cow is the large, unsatisfied market for people with IBS and/or varying degrees of food intolerance of unknown or unspecific etiology. This adult population, targeted now with extensive advertising through social media, are unlikely to have undiagnosed CSID.

80. In order to expand the use of Sucraid to the off-label conditions like IBS, QOL had to shed the pediatric emphasis and created the illusion of a large sea of patients who supposedly went through life with mild symptoms and were thus undiagnosed. This shift, beginning in 2016, is best exemplified by the following sales "script." It is thought the script was developed by former Trainer and Senior Director of Sales Rob Scott:

> Originally, it was thought if a patient had a sucrase-isomaltase deficiency both parents would have the same recessive gene and the baby would be born without the ability to break down and digest ANY sugar at all. It is very rare and that child would be diagnosed in infancy. ***What research is now showing is that patients can be a carrier of the gene or have a genetic variant and be symptomatic but not so symptomatic that it gets diagnosed in childhood***. These patients can break down and digest some sugar but once they reach a certain threshold then they will have symptoms of abdominal pain, diarrhea, gas or bloating after eating. These patients often go undiagnosed or get misdiagnosed and continue to have chronic and persistent symptoms after eating. They end up in your adult GI practice. ***These patients might fall under the umbrella of IBS but nothing that normally works for IBS patients seems to help, i.e. - diet, anti-diarrheals, anti-spasmatics, etc. and so they continue to have chronic and persistent symptoms after they eat.*** You may hear these patients say, "I think I have

> celiac" but you know they don't. They may say other things like they have a sugar allergy, or that they have had these symptoms for as long as they can remember but no one can figure out why. In these patients, you have ruled everything out and you really don't know where to go next. ***These patients are the perfect patient to test for a sucrase-isomaltase deficiency.*** We offer a free take home breath test to test for a sucrase deficiency. Do you currently do any breath testing in your office? (Yes or No) Do you currently look for carbohydrate malabsorption? (Yes or No – if they do look for it, ask how do they test for it?) Do you have patients that look like this in your practice?"

(emphasis added).

81. The references to "research" are fraudulent, as there is no research supporting QOL's claims for expansive use or greater prevalence that appears in the literature. Indeed, QOL admits internally that this lack of research is its *Achilles heel*: "What is lacking is submission/acceptance to peer-reviewed journals of existing research. The push-back from the medical society at-large is the lack of published data." Instead, QOL touts its unverified claims of existing scientific research and unfulfilled "upcoming research," which are "imperative to building the foundation to restructure the view of CSID and build confidence around its diagnosis." QOL recognizes that "Changing what is the gold standard is not likely to occur." Instead the Defendants have focused on replacing the gold standard with an unreliable breath test favoring sales over science.

H. Diagnosis of CSID

82. The FDA-approved label requires that patients have "genetically determined" CSID. Genetic testing is widely available from multiple independent

sources (*e.g.* Fulgent Genetics, Temple City, CA; Blueprint Genetics, Seattle, WA) and offers detection of variants in the SI gene will be detected with >99% sensitivity.

83. According to Relator 1, this also results in the identification of a low number of patients as true CSID patients. The "hit rate" with the genetic test is just 7.7% of those tested in what is already an enriched population of symptomatic patients.

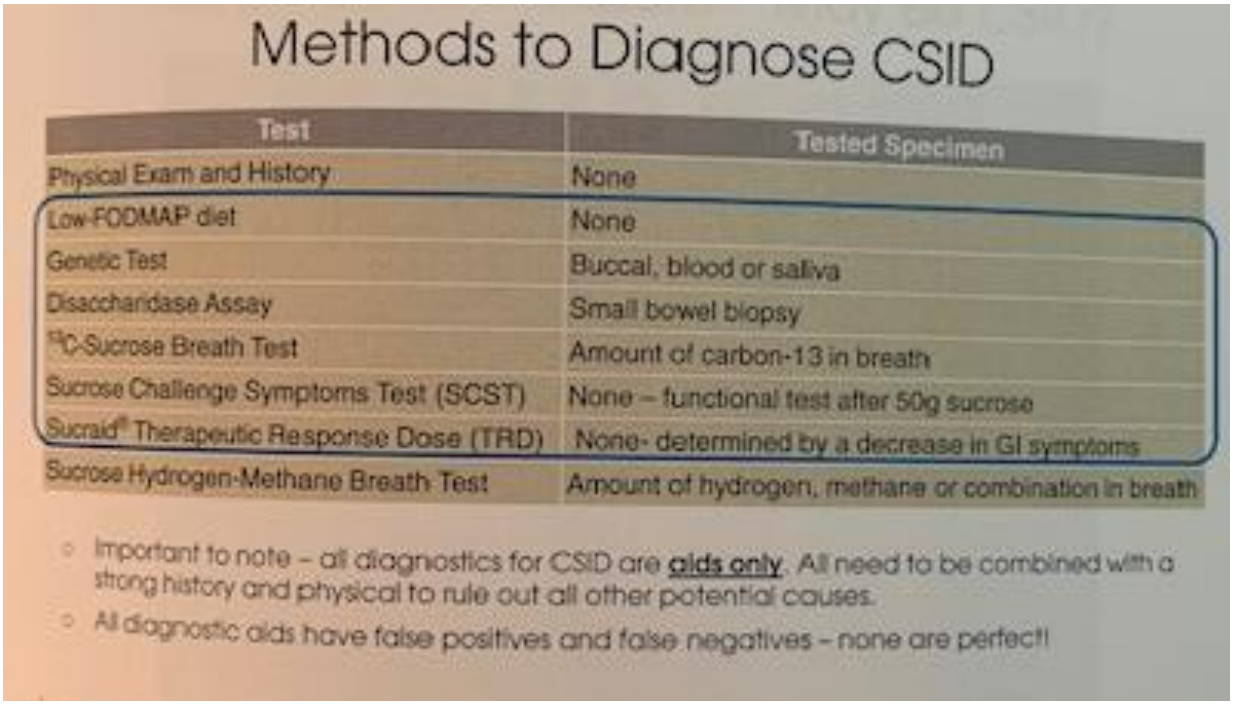
84. As far as Defendants are concerned, they would prefer that the genetic test did not even exist. Indeed, in answer to the question "How is CSID diagnosed?", the 2020 "Sucraid First" brochure completely omits any reference to the genetic test as a method of diagnosis. Instead the first answer given is [with] "The simple, FREE 13C-Sucrose Breath Test." The second answer is the confusingly-named "Disaccharidase Assay" (biopsy). The genetic test is not mentioned.

85. In fact, the biopsy is a standard method of confirming a clinical diagnosis of suspected CSID is with an endoscopic biopsy, where a tissue sample taken from the small intestine is sent for laboratory analysis. Specifically, disaccharidase activity is measured, with low to absent sucrase activity detected by enzyme assay suggesting CSID. The FDA-approved label states that method provides the "definitive diagnosis" and warns that "[o]ther tests used alone may be inaccurate: for example, the breath hydrogen test (high incidence of false negatives) or oral sucrose tolerance test (high incidence of false positives)."

86. Hydrogen breath testing is also possible in theory, but such tests are more susceptible to error and can provoke GI symptoms due to the amount of sucrose that must be ingested to perform the study. In its marketing and promotion, QOL has

abandoned the biopsy and hydrogen breath tests, as both inhibit the off-label use of Sucraid. Biopsies yield definitive diagnoses and are costly and less likely to be ordered for borderline or equivocal patients. Hydrogen breath tests, though easier, produce false negatives, which makes it unattractive as a tool for sales expansion. For these reasons, QOL promotes the use of a carbon-13 (^{13}C-sucrose)[3] breath test (the "C13 Breath Test"), described below. QOL falsely claims that this noninvasive test has a high degree of accuracy and avoids provoking symptoms. QOL also actively discourages genetic testing by either ignoring it or dismissing it as simply another "alternative." QOL discounts genetic testing and biopsy as mere "aids only" and misleadingly suggests that all diagnostic methods produce false positives and false negatives, and therefore "none are perfect!," as seen in the following excerpt from the "Selling Sucraid in 2020" national sales meeting training materials:

[3] Carbon-13 (^{13}C) is a natural, stable isotope of carbon with a nucleus containing six protons and seven neutrons. As one of the environmental isotopes, it makes up about 1.1% of all natural carbon on Earth.

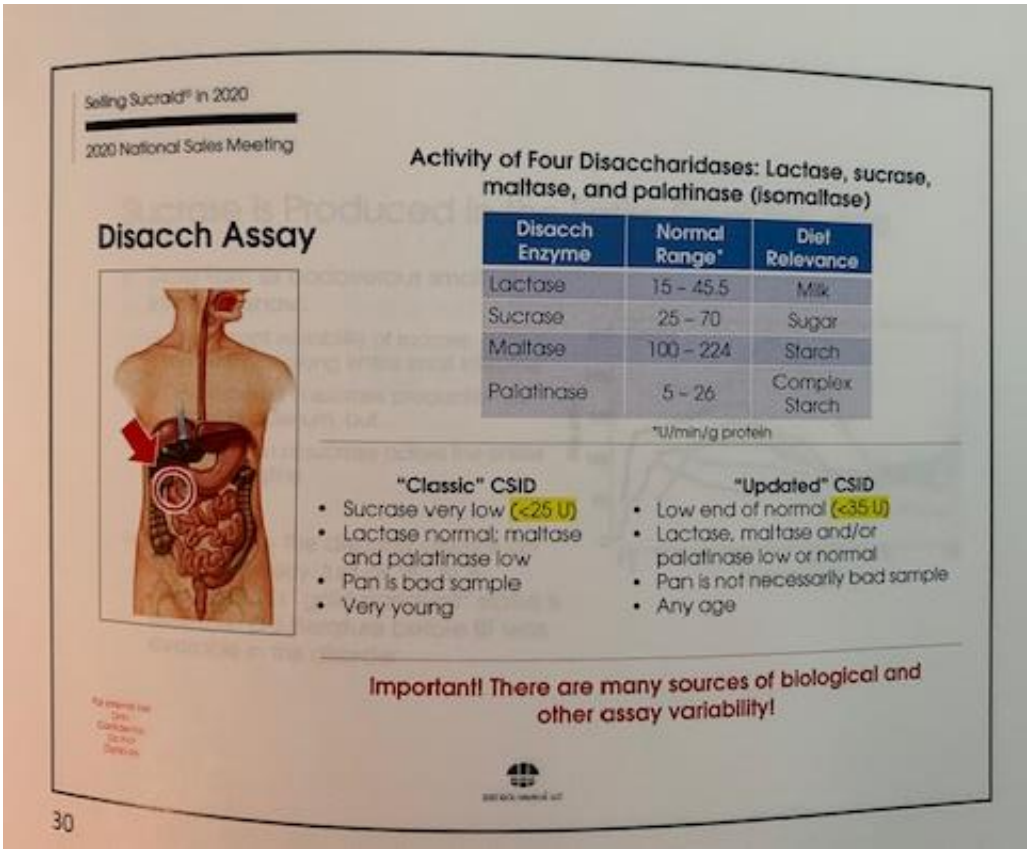


Methods to Diagnose CSID

Test	Tested Specimen
Physical Exam and History	None
Low-FODMAP diet	None
Genetic Test	Buccal, blood or saliva
Disaccharidase Assay	Small bowel biopsy
^{13}C-Sucrose Breath Test	Amount of carbon-13 in breath
Sucrose Challenge Symptoms Test (SCST)	None – functional test after 50g sucrose
Sucraid® Therapeutic Response Dose (TRD)	None- determined by a decrease in GI symptoms
Sucrose Hydrogen-Methane Breath Test	Amount of hydrogen, methane or combination in breath

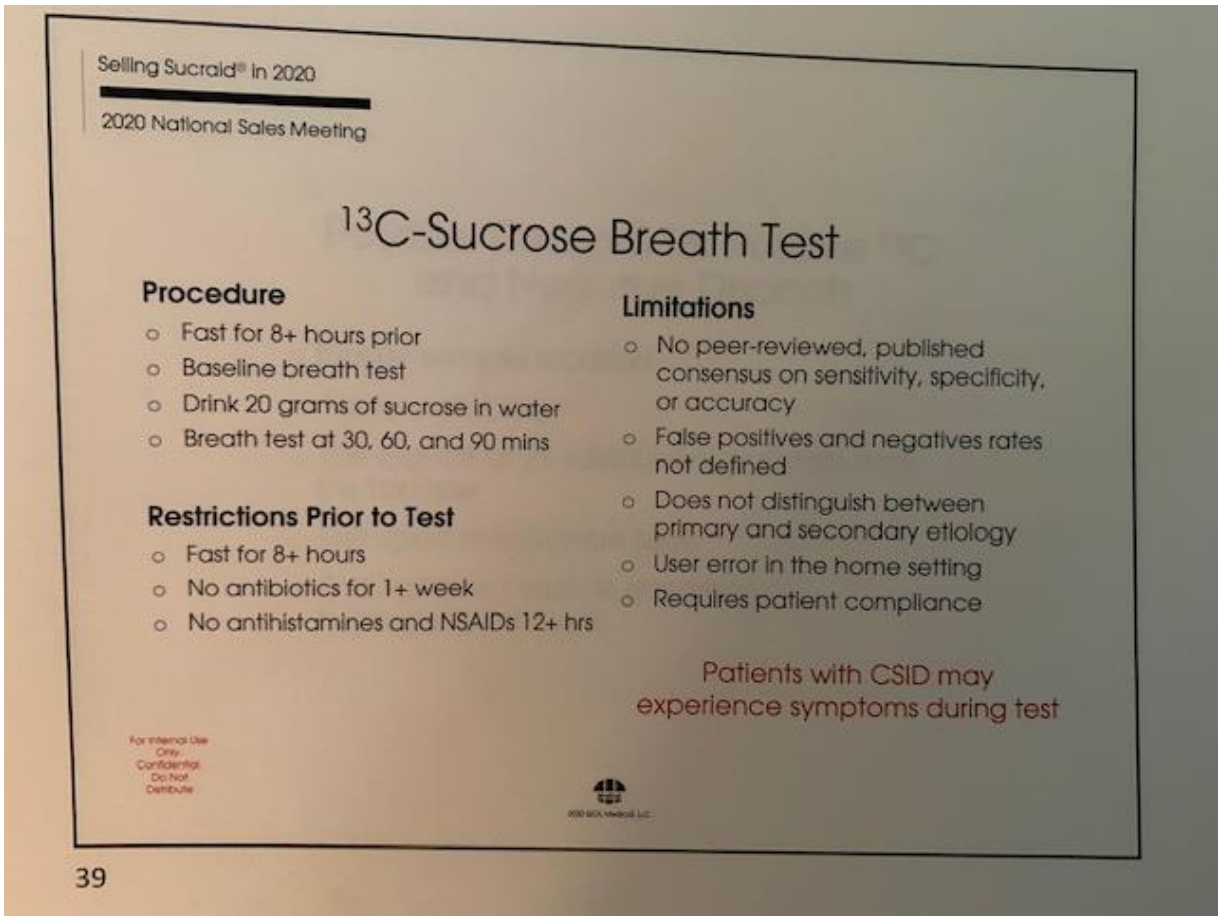
- Important to note – all diagnostics for CSID are **aids only**. All need to be combined with a strong history and physical to rule out all other potential causes.
- All diagnostic aids have false positives and false negatives – none are perfect!

87. Further, QOL has also moved the goal posts by broadening the definition of CSID to target patients with less severe symptoms, patients suspected of mere sucrose intolerance, and patients with generalized sucrase-isomaltase deficiency. Indeed, QOL has unilaterally created an "updated CSID" which includes patients of any age with "low to normal" sucrase enzyme:



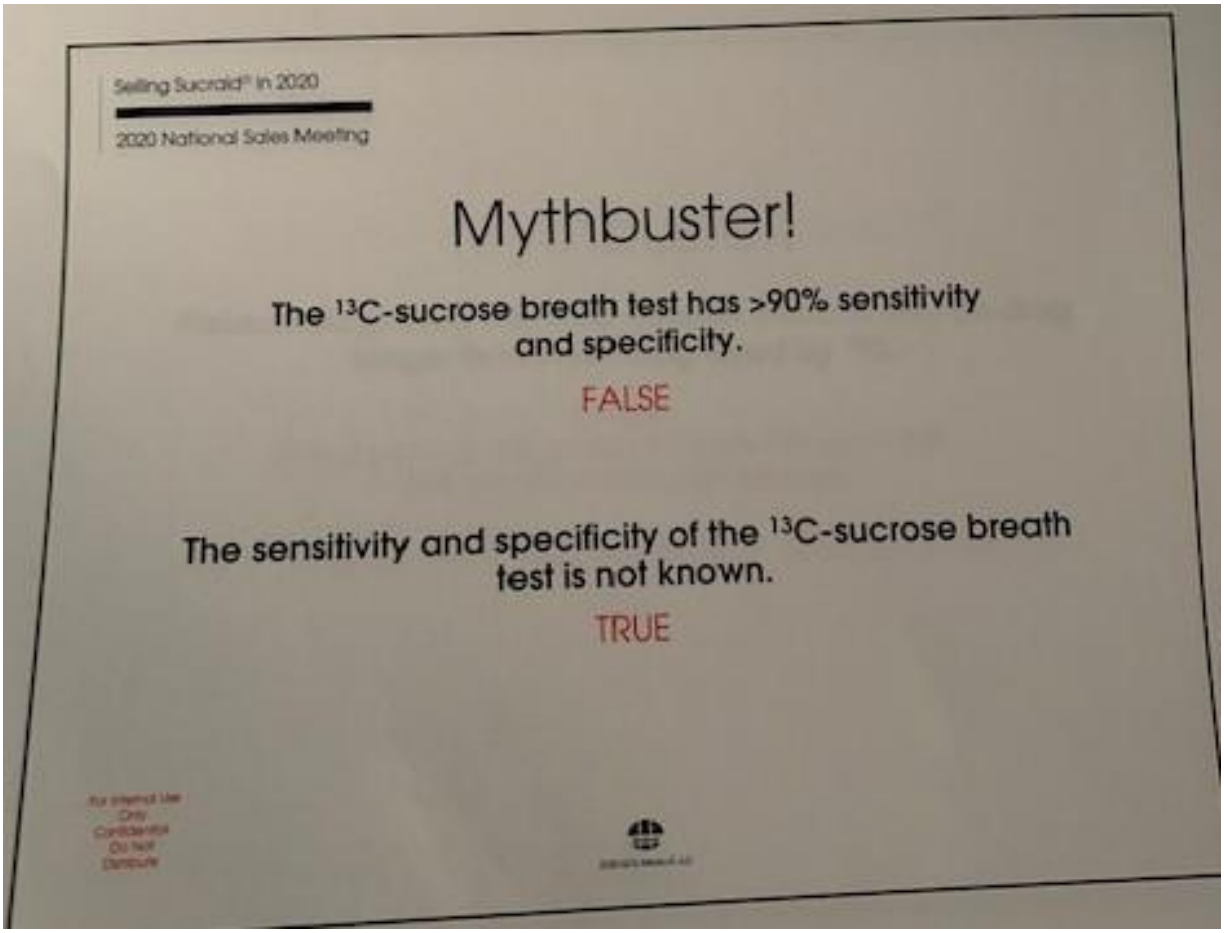
88. The C13 Breath Test, which was first introduced in 2018, purports to be a diagnostic tool for detecting CSID. The device, however, has never received a PMA, a 510(k) clearance, or even an establishment registration for this intended use. Yet, it does have one great advantage for QOL, it has a very favorable "hit" rate. According to an email of January 30, 2018, the national "hit rate" for the C13 Breath Test was 31%. In another email of March 26, 2018, that rate was 29%.

89. This financially favorable hit rate is not something which the company publicly acknowledges. If doctors asked about the reliability of the Breath Test, Relators were instructed to "make something up" or "change the subject" rather than get drawn into an awkward conversation. Internally, however, company documents acknowledged that the Breath Test has its "limits."



In other words, QOL knew that since "false positive and false negative rates [were] not defined" breath test results are meaningless.

90. QOL trained its sales representatives to falsely tout 99% specificity and even 100% validation in order to create a false public perception that the Breath Test had a greater than 90% sensitivity, but according to an internal company document (bearing the warning "For internal use only. Confidential. Do not distribute") this was also a "myth." In reality, all that QOL knew is that the C13 Breath Test was not reliable and that the extent of its reliability was unknown:



91. Despite this internal knowledge of the unreliability of breath testing, Defendants never discontinued the C13 Breath Test and continue to deluge doctors' offices with *free* test kits as a more convenient means of identifying patients. It even directly markets the test to doctors through direct promotion.

92. Currently, One Patient Services (a subsidiary of QOL) obtains the Breath Test from Metabolic Solutions (www.metsol.com) a New Hampshire based company specializing in Hydrogen/Methane breath tests. One Patient Services assembles the test kits and then distributes them to doctors, patients as well as sales representatives. The patient takes the Breath Test home and mails the breath sample to Metabolic Solutions who then sends a "Sucrose Breath Test Report" directly to the doctor which will report

either "Normal Sucrose Activity" or "Low Sucrose Activity." Reports of Low Sucrose Activity frequently result in prescriptions for Sucraid even though QOL knows the results are unreliable. According to Relators 2 and 3, when a doctor orders both a small bowel biopsy and a breath test, the results of the two tests only agree 1 in 6 times. In other words, more than 80% of the time the C13 Breath Test produces a result that is contrary to the diagnostic technique which the FDA states provides the "definitive diagnosis."

93. Further, the C13 Breath Test is neither approved, nor cleared, nor even registered for any intended use in connection with the diagnosis of CSID. The C13 Breath Tests that QOL distributes to doctors are therefore adulterated and misbranded, and cannot be introduced into interstate commerce for any purpose, including the diagnosis of CSID.

94. The effort to expand the patient population for Sucraid beyond CSID is clearly evidenced in QOL's use of the Sucrose Intolerance branded website (https://www.sucroseintolerance.com/), which equates "decreased sucrase activity" and "reduced ability to digest sucrose" with CSID. The conflation between reduced or decreased ability to handle sugar and CSID is inappropriate, as reactions to sucrose vary across the entire population. Some people can handle more sucrose in the diet than others. But not everyone with sucrose difficulties or limitations has CSID.

95. QOL also markets the "4-4-4 Sugar Challenge" as a "simple" way that adult patients can determine if they somehow have undiagnosed CSID. This marketing is off-label, misleading, and potentially dangerous, as it is not a diagnostic test, has never

been validated or approved by the FDA, and puts patients with metabolic conditions like diabetes at risk. Further, the challenge is a cynical way to exploit the fact that most people have problems with large amounts of sucrose or a diet high in sugar.

I. The Distribution of the C13 Breath Test as a Kickback and Stark Violation

96. Metabolic Solutions generally sells its breath tests for $145 to $165 per kit. Under the Defendants' scheme, One Patient Services sources and assembles the C13 Breath Test kit and pays Metabolic Solutions $40 for the subsequent laboratory analysis. Once One Patient Services assembles the kits, it distributes them on behalf of QOL for free to doctors and patients. Metabolic Solutions sends physicians the results.

97. Every time a doctor receives a kit, that doctor is receiving roughly $145 in value from Defendants. According to the Relators, some doctors were incredulous that the company was simply giving test kits away for free. Doctors were also suspicious that they were not permitted to charge patients for the tests. QOL's motivation for the free tests is clear. The convenience of the test, and its diagnostic imprecision, steers patients away from genetic testing or biopsies which would reveal that the majority of patients do not have CSID, and by virtue of the high error rate leads to many more prescriptions than would otherwise result. The breath test is thus the lynchpin of Defendants' scheme, and QOL gladly buy the kits at cost and distributes them for free to illegally boost Sucraid sales.

98. However, in addition to unlawfully inflating sales of Sucraid, QOL knows engenders good will in the doctors' offices. This is classic quid-pro-quo. Only doctors likely to prescribe Sucraid receive the test kits. And the free kits are meant to induce

prescriptions. According to Relator 2, other sales representatives were also wrongfully encouraging doctors to administer the breath test in the office and then bill for those services.

99. Internal company documents coach sales representatives to divert prescribers' attention away from the absence of any scientific data supporting the test. Instead emphasize that the fact that the test kit was a valuable gift. An internal company "script" also emphasizes the point:

> **What is the sensitivity and specificity of the complimentary 13C-sucrose breath test?** Doctor, as you and I both know, breath testing is a widely used diagnostic aid. We do not have published specific sensitivity and specificity to share just as other breath tests commonly used do not. However, when used as a tool with other diagnostic aids and patient assessments, it can be very valuable, and it's FREE.

100. The distribution of free test kits is also a Stark violation, which causes false claims and reverse false claims. Defendants established a "financial relationship" between and among themselves and the physicians prescribing Sucraid by means of the provision to physicians and patients of free tests. The provision of free tests constitutes a "compensation arrangement" for "remuneration" that is not otherwise exempted under the Stark Law.

101. By providing physicians with valuable test kits for free, Defendants have created exactly the sort of intertwined financial relationships in the health care system that the Stark Law and the Anti-Kickback Statute are designed to prohibit.

102. Under this arrangement, QOL provides C13 Breath Tests free of charge so long as doctors understand that they are: (1) not to bill any insurer (including the

federal government) for the tests, and (2) the C13 Breath Tests are only used in connection with the diagnosis of patients being targeted by QOL for Sucraid treatment. The purpose and effect of this arrangement was to give doctors a significant financial incentive to direct patients using the C13 Breath Test to a QOL product (Sucraid) rather than a different company that markets a different treatment. That is precisely the sort of inducement that the Stark Law and the AKS forbid.

103. Defendant QOL Medical Services, the entity that has received such payments, has failed to reimburse such funds to the United States, in violation of 42 C.F.R. § 411.353(d). This failure constitutes a "reverse false claim" under 31 U.S.C. § (a)(1)(G).

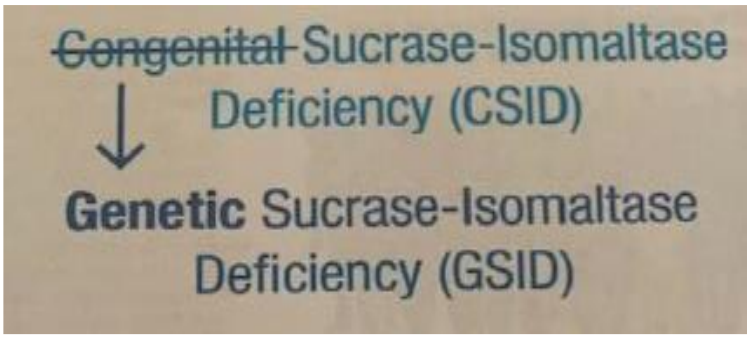
104. In addition to the C13 Breath Tests, Defendants have implemented a new scheme to funnel cash payments to doctors in the form of an honorarium for listening to a sales pitch. The proposal, rolled out to the discomfort of Relators and the salesforce in general, pays $400 to any doctor for "no more than" (and frequently much less than) one hour of their time. The scheme ostensibly solicits "feedback" on a draft promotional piece and culminates in question 15 with a classic sales pitch: "On a scale from 1 to 10 (where 1 is 'not motivated' and 10 is 'very motivated'), how motivated are you ***to now test your patients for CSID*** and treat the positives with Sucraid?" (emphasis added). According to Relators 2 and 3, the "draft" promotional piece had already been mass produced, so the doctors' insights were irrelevant. It is apparent that the only real feedback sought, in return for the $400 payment, is simply a new prescription for Sucraid.

J. OFF LABEL MARKETING

105. According to Sucraid's official FDA approved label the drug is indicated as "oral replacement therapy of the *genetically determined* sucrase deficiency, which is part of congenital sucrase-isomaltase deficiency." (emphasis added) Technically, any prescription which is precipitated in anyway except through genetic testing would be an off label prescription since the condition had not been "genetically determined" and could include a host of conditions similar to but crucially not CSID. According to one Relator, QOL misinformed sales representatives that genetic testing was simply unavailable for CSID.

106. Further, the company used web-based advertisements aimed at persuading potential patients that their allergies to Gluten, Irritable Bowel Syndrome ("IBS"), Small Intestine Bacterial Overgrowth ("SIBO") or bloating was "Sucrose Intolerance" (a generalized, unscientific reference to CSID).

107. Other internal documents illustrate the attempted rebranding of the condition graphically:



108. Relator 2 observed that QOL would obtain drug distribution data ("DDD") and identify prescribers of medications approved for IBS for example Rifaximin (Xifaxan). In this way, QOL was able to identify more recipients for its free C13 Breath Test and turbo charge sales through false positive test results.

109. Indeed, as referenced above, QOL has an entire stand-alone website dedicated to the newly-minted condition of sucrose intolerance (www.sucroseintolerance.com), which equates sucrose intolerance with CSID. *See* https://www.sucroseintolerance.com/symptoms/ Internal company documents show that in 2019, the website has 1,750,000 visitors, up 531% from 2018.

110. The Defendants' strategy to expand the patient population into the supposedly undiagnosed adult market has worked. According to a company analysis, by October 2018, data shows that of breath tests ordered by physicians, only 7% came from pediatric gastroenterologists.

111. Relator 1 had frequently attempted to correct the company's course and, in particular, to persuade Defendant Cooper that they should focus on the pediatric

population, not least because when correctly diagnosed in childhood, the patients stay on drug for the rest of their lives. Cooper was uninterested in the medical argument, preferring instead business-oriented approach. In an email of September 27, 2017, Cooper wrote,

> "Turns out, we shouldn't jerk the car to the pediatric side of the road completely. I was amazed at the following data. I took the total duration of the relationship with each doc (very first TRx ever to last TRx) and divided that into the total prescriptions over that duration times $7k per Rx. This is an estimate of the 'value per day' of a relationship with each physician. It's nearly exactly the same (frighteningly so) between peds and adults! ***Adults find a lot more new patients, but they don't keep them for very long.*** The only difference in value to QOL is in the incentive comp, which would be a lot higher for an adult relationship due to all the NRx rather than renewals."

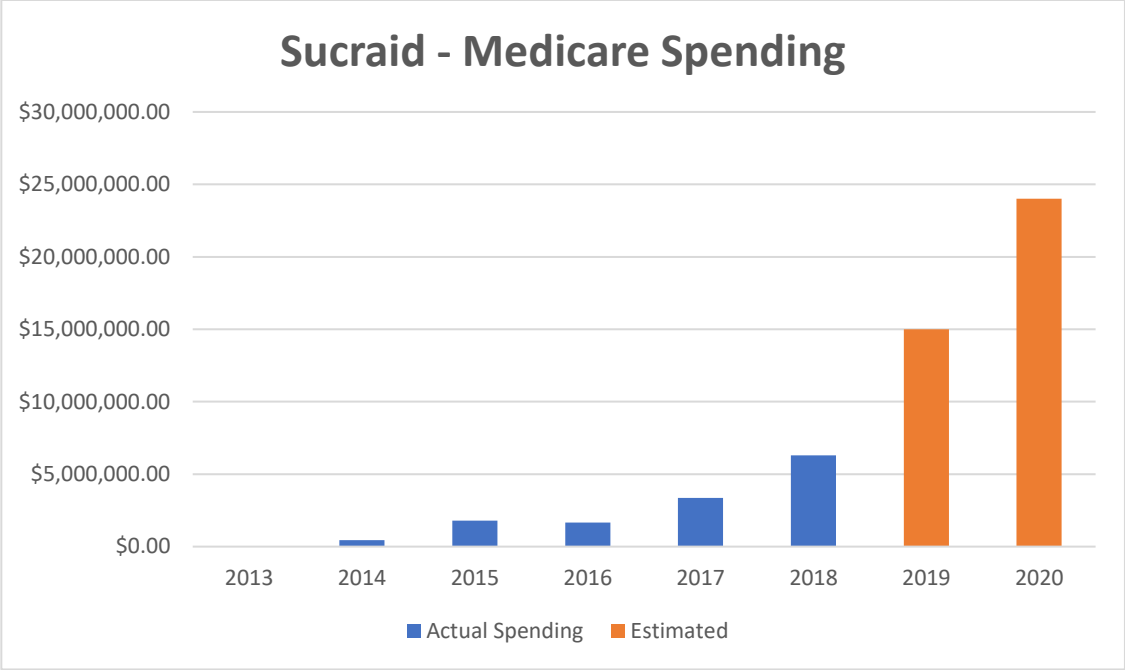
(emphasis added). Cooper then laid out the numbers to put an end to the debate:

	Total Value of Relationship Per Day		New Patients Per Month	
	Ped	Adult	Ped	Adult
Highest Doc	$ 1,311	$ 1,306	0.28	2.06
Top 5	820	826	0.35	1.08
Top 10	634	644	0.37	0.73
Top 15	548	540	0.31	0.60
Top 20	460	458	0.28	0.52

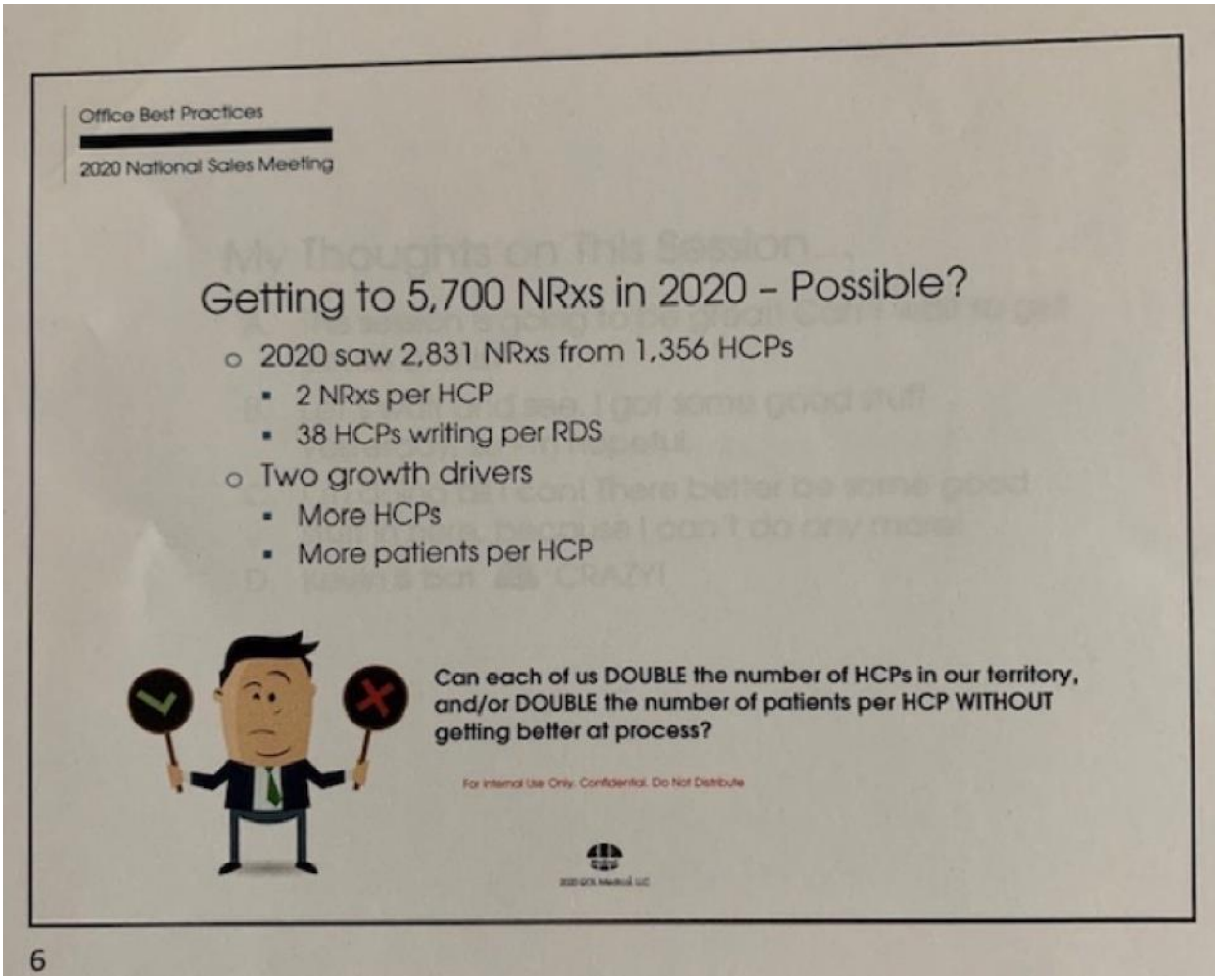
Thus, by Cooper's metric, it doesn't matter that the adults drop off the medication rapidly (*i.e.* don't have CSID) because there are always more adults that can be fooled into *drinking the Sucraid*.

IX. DAMAGES

112. According to estimates based on internal company documents, Medicare spending has grown dramatically since 2017:



113. Long gone are the days of 2010 when Defendants were content with an on-label population of 188 patients. The goals of 2020 are far more ambitious: 5,700 *new* prescriptions (NRxs):



114. Defendants' focus on expanding the, albeit, transient patient population suggests that management intends to achieve "blockbuster" status for this humble extract of bakers' yeast.

X. COUNTS

FIRST CAUSE OF ACTION
DEFENDANTS' VIOLATION OF 31 U.S.C. § 3729 (a)(1)(A)

115. Relators repeat and reallege the allegations set forth above as though set forth herein.

116. As described above, Defendants have knowingly presented, or caused the presentation of numerous false or fraudulent claims to the United States through the Medicare and other Government Healthcare Programs for reimbursement of prescriptions of Sucraid caused by off-label marketing for unapproved and inappropriate uses, payment of kickbacks, and by promoting the use of an unreliable and misbranded test.

117. At all times, Defendants knew (or acted with reckless disregard or with deliberate ignorance) that the scheme described herein would cause Medicare, Tricare, and other Government Healthcare Programs to pay for unapproved uses of Sucraid. If Medicare, Tricare, and the other Government Healthcare Programs had known of Defendants' unlawful actions, the United States would not have reimbursed such false claims.

118. By reason of the above-described actions and the presentment of false or fraudulent claims, the United States has suffered significant losses in an amount to be determined.

SECOND CAUSE OF ACTION

DEFENDANTS' VIOLATION OF 31 U.S.C. § 3729 (a)(1)(B)

119. Relators repeat and reallege the allegations set forth above as though set forth herein.

120. As described above, Defendants knowingly have made, used, or caused to be made or used, false records or statements material to false or fraudulent claims submitted to Medicare and other Government Healthcare Programs for reimbursement

of prescriptions of Sucraid caused by off-label marketing for unapproved and inappropriate uses, payment of kickbacks, and by promoting the use of an unreliable and misbranded test.

121. At all times, Defendants knew (or acted with reckless disregard or with deliberate ignorance) that the scheme described herein would cause Medicare, Tricare, and other Government Healthcare Programs to pay for unapproved uses of Sucraid. If Medicare, Tricare, and the other Government Healthcare Programs had known of Defendants' unlawful actions, the United States would not have reimbursed such false claims.

122. By reason of the above-described actions and the use of false records or statements material to false or fraudulent claims submitted to Medicare, the United States has suffered significant losses in an amount to be determined.

THIRD CAUSE OF ACTION

DEFENDANTS' VIOLATION OF 31 U.S.C. § 3729 (a)(1)(C)

123. Relators repeat and reallege the allegations set forth above as though set forth herein.

124. As described above, and with respect to the reimbursement of prescriptions of Sucraid caused by off-label marketing for unapproved and inappropriate uses, payment of kickbacks, and by promoting the use of an unreliable and misbranded test, Defendants knowingly conspired to: (a) present, or cause to be presented, false or fraudulent claims to Medicare and other Government Healthcare Programs for payment or approval; and (b) make, use, or cause to be made or used, false records or

statements material to a false or fraudulent claim to Medicare and other Government Healthcare Programs.

125. At all times, Defendants knew (or acted with reckless disregard or with deliberate ignorance) that the scheme described herein would cause Medicare, Tricare, and other Government Healthcare Programs to pay for unapproved uses of Sucraid. If Medicare, Tricare, and the other Government Healthcare Programs had known of Defendants' unlawful actions, the United States would not have reimbursed such false claims.

126. By reason of the above-described conspiracy, the United States has suffered significant losses in an amount to be determined.

FOURTH CAUSE OF ACTION

DEFENDANTS' VIOLATION OF 42 U.S.C. § 1320a-7b(b)

127. Relators repeat and reallege the allegations set forth above as though set forth herein.

128. As described above, on or after March 23, 2010, Defendants have submitted or caused to have been submitted claims for reimbursement for off-label prescriptions of Sucraid caused by or that includes items or services resulting from kickbacks.

129. Consequently, all such kickbacks which caused reimbursement claims for off-label prescriptions of Sucraid to be presented to the government for payment are actionable false claims.

130. Further, the cost of Sucraid to Medicare and other Government Healthcare Programs includes the gratuitous provision of free tests that are kickbacks and thus is inflated to the extent of the kickbacks paid.

131. Consequently, all prescriptions of Sucraid reimbursed by Medicare, Tricare, and other Government Healthcare Programs include amounts that are inflated by kickbacks and not allowed for reimbursement.

132. By reason of the above-described kickbacks, the United States has suffered significant losses in an amount to be determined.

FIFTH CAUSE OF ACTION

DEFENDANTS' VIOLATION OF STARK LAW AND REVERSE FALSE CLAIMS
(42 U.S.C. § 1395nn(a)(1)(B); 42 U.S.C. § 1395nn(g)(1); 42 C.F.R. § 411.353(b); 42 C.F.R. § 411.353(c); 42 C.F.R. § 411.353(d); and 31 U.S.C. § (a)(1)(G))

133. Relators repeat and reallege the allegations set forth above as though set forth herein.

134. Defendants established a "financial relationship" between and among themselves and the physicians prescribing Sucraid by means of the provision to physicians and patients of free tests. The provision of free tests constitutes a "compensation arrangement" for "remuneration" that is not otherwise exempted under the Stark Law.

135. In violation of the Stark Law, Defendants have submitting or caused to be submitted to Medicare and other Government Healthcare Programs claims for Sucraid prescriptions pursuant to a prohibited referrals.

136. In violation of the Stark Law, Medicare and other Government Healthcare Programs have paid millions of dollars for such claims, in violation of 42 U.S.C. § 1395nn(g)(1) and 42 C.F.R. § 411.353(c).

137. Defendant QOL Medical Services, the entity that has received such payments, has failed to reimburse such funds to the United States, in violation of 42 C.F.R. § 411.353(d). This failure constitutes a "reverse false claim" under 31 U.S.C. § (a)(1)(G).

138. By reason of the above-described Stark Law violations and reverse false claims, the United States has suffered significant losses in an amount to be determined.

139. Consequently, all prescriptions of Sucraid reimbursed by Medicare, Tricare, and other Government Healthcare Programs caused by these illegal compensation arrangements must be disgorged by the Defendants.

140. By reason of the above-described Stark Law violations and reverse false claims, the United States has suffered significant losses in an amount to be determined.

SIXTH CAUSE OF ACTION
California False Claims Act
Cal. Gov't. Code §§ 12650 *et seq.*

141. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

142. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer or employee of

the State of California or of any political subdivision thereof, a false claim for payment or approval, in violation of Cal. Gov't Code § 12651(a)(1).

143. By reason of Defendants' acts, the State of California has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

144. Pursuant to Cal. Gov't Code § 12651(a), the State of California is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SEVENTH CAUSE OF ACTION
Colorado Medicaid False Claims Act
CRS §§ 25.5-4-304 *et seq.*

145. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

146. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer or employee of a Colorado agency a false claim for payment or approval, in violation of CRS §25.5-4-305(a).

147. By reason of Defendants' acts, the State of Colorado has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

148. Pursuant to CRS §25.5-4-305(a), the State of Colorado is entitled to three times actual damages plus the maximum penalty for each and every false or fraudulent

claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTH CAUSE OF ACTION
Connecticut General Statutes, §17b-301a *et seq.*
Connecticut False Claims Act

149. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

150. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer or employee of a Connecticut agency a false claim for payment or approval, in violation of Conn. Gen. Stat. § 17b-301b(a)(1).

151. By reason of Defendants' acts, the State of Connecticut has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

152. Pursuant to Conn. Gen. Stat. § 17b-301b(a), the State of Connecticut is entitled to three times actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

NINTH CAUSE OF ACTION
Delaware False Claims And Reporting Act
6 Del. C. §§ 1201 *et seq.*

153. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

154. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented, directly or indirectly, to an officer or employee of Delaware a false or fraudulent claim for payment or approval, in violation of 6 Del. C. § 1201(a)(1).

155. By reason of Defendants' acts, the State of Delaware has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

156. Pursuant to 6 Del. C. § 1201(a), the State of Delaware is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TENTH CAUSE OF ACTION
Florida False Claims Act
Fla. Stat. §§ 68.081 *et seq.*

157. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

158. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer or employee of a Florida agency a false claim for payment or approval, in violation of Fla. Stat. § 68.082(2)(a).

159. By reason of Defendants' acts, the State of Florida has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

160. Pursuant to Fla. Stat. § 68.082(2)(g), the State of Florida is entitled to three times actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

ELEVENTH CAUSE OF ACTION
Georgia State False Medicaid Claims Act
O.C.G.A. § 49-4-168

161. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

162. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer, employee, fiscal intermediary grantee or contractor of the Georgia Medicaid Program a false claim for payment or approval, in violation of O.G.C.A. § 49-4-168.1(a)(1).

163. By reason of Defendants' acts, the State of Georgia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

164. Pursuant to O.G.C.A. § 49-4-168.1(a), the State of Georgia is entitled to three times actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used or caused to be made or used by Defendants.

TWELFTH CAUSE OF ACTION
Hawaii False Claims Act
Haw. Rev. Stat. §§ 661-21 *et seq.*

165. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

166. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented, to an officer or employee of the State of Hawaii a false or fraudulent claim for payment or approval, in violation of Haw. Rev. Stat. § 661-21(a)(1).

167. By reason of Defendants' acts, the State of Hawaii has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

168. Pursuant to Haw. Rev. Stat. § 66l-21(a)(8) the State of Hawaii is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTEENTH CAUSE OF ACTION
Illinois Whistleblower Reward And Protection Act
740 Ill. Comp. Stat. §§ 175/1 *et seq.*

169. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

170. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented, to an officer or employee of the State of Illinois a false or fraudulent claim for payment or approval in violation of 740 Ill. Comp. Stat. § 175/3(a)(1).

171. By reason of Defendants' acts, the State of Illinois has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

172. Pursuant to 740 Ill. Comp. Stat. § 175/3(a)(7), the State of Illinois is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FOURTEENTH CAUSE OF ACTION
Indiana False Claims and Whistleblower Protection Act
Ind. Code. §§ 5-11-5.5 *et seq.*

173. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

174. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented, to an officer or employee of the State of Indiana a false or fraudulent claim for payment or approval in violation of Ind. Code §§ 5-11-5.5-2(b)(1) and (8).

175. By reason of Defendants' acts, the State of Indiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

176. Pursuant to § 5-11-5.5-2(b), the State of Indiana is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

FIFTEENTH CAUSE OF ACTION
Iowa Medicaid False Claims Act
Iowa Code §685 *et seq.*

177. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

178. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer or employee of a Iowa agency a false claim for payment or approval, in violation of Iowa Code §685.2.1.a.

179. By reason of Defendants' acts, the State of Iowa has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

180. Pursuant to Iowa Code 685.2.1, the State of Iowa is entitled to three times actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SIXTEENTH CAUSE OF ACTION
Louisiana False Claims Act/Medical Assistance Programs Integrity Law
46 La. Rev. Stat. Ch. 3 §§ 437.1 *et seq.*

181. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

182. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test,

Defendants knowingly presented or caused to be presented to Louisiana false or fraudulent claims, in violation of 46 La. Rev. Stat. Ch. 3 §438.3(A).

183. By reason of Defendants' acts, the State of Louisiana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

184. Pursuant to 46 La. Rev. Stat. Ch. 3 § 438.5 and § 438.6, the State of Louisiana is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

SEVENTEENTH CAUSE OF ACTION
Maryland False Health Claims Act
Md. Code Ann., Health-Gen §2-601 *et seq.*

185. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

186. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer or employee of a Maryland agency a false claim for payment or approval, in violation of Md. Code Ann., Health-Gen §2-602(a)(1).

187. By reason of Defendants' acts, the State of Maryland has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

188. Pursuant to Md. Code Ann., Health-Gen §2-602(b), the State of Maryland is entitled to three times actual damages plus the maximum penalty for each and every

false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

EIGHTEENTH CAUSE OF ACTION
Massachusetts False Claims Law
Mass. Gen. Laws Ch. 12 §§ 5A *et seq.*

189. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

190. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented to the Commonwealth of Massachusetts, a false or fraudulent claim for payment or approval, in violation of M.G.L. c. 12 § 5B(l).

191. By reason of Defendants' acts, the Commonwealth of Massachusetts has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

192. Pursuant to M.G.L. c. 12 § 5B(9), the Commonwealth of Massachusetts is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

NINETEENTH CAUSE OF ACTION
Michigan Medicaid False Claim Act
M.C.L. §§ 400.601 *et seq.*

193. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

194. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly caused to be presented to Michigan, a false statement or false representation of a material fact in an application for Medicaid benefits, in violation of M.C.L. § 400.603(l).

195. By reason of Defendants' acts, the State of Michigan has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

196. Pursuant to M.C.L. § 400.612, the State of Michigan is entitled to three times the amount of actual damages, forfeiture of all amounts received by Defendants and the maximum penalty for each and every false or fraudulent claim made, used, presented or caused to be made, used or presented by Defendants.

TWENTIETH CAUSE OF ACTION

Minnesota False Claims Act
M.S.A. § 15C.01 et seq.

197. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

198. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer or employee of a Minnesota agency a false claim for payment or approval, in violation of M.S.A. § 15C.02(a)(1).

199. By reason of Defendants' acts, the State of Minnesota has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

200. Pursuant to M.S.A. § 15C.02(a), the State of Minnesota is entitled to three times actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-FIRST CAUSE OF ACTION

Montana False Claims Act

Mont. Code Ann. §§17-8-401 et. seq.

201. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

202. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented to an officer or employee of a Montana governmental entity, a false or fraudulent claim for payment or approval, in violation of Mont. Code Ann. § 17-8-403(l)(a).

203. By reason of Defendants' acts, the State of Montana has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

204. Pursuant to Mont. Code Ann. § 17-8-403(2), the State of Montana is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-SECOND CAUSE OF ACTION

Nevada False Claims Act

Nev. Rev. Stat. §§ 357.010 et seq.

205. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

206. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to Nevada a false claim for payment or approval, in violation of Nev. Rev. Stat. §357.040(1)(a).

207. By reason of Defendants' acts, the State of Nevada has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

208. Pursuant to Nev. Rev. Stat. § 357.040(1), the State of Nevada is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-THIRD CAUSE OF ACTION

New Jersey False Claims Act

N.J. Stat. Ann. §§ 2A:32C-1 et seq.

209. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

210. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented to an employee, officer or

agent of New Jersey or any contractor, grantee or recipient of New Jersey state funds, a false or fraudulent claim for payment or approval, in violation of N.J. Stat. Ann. § 2A:32-C3a.

211. By reason of Defendants' acts, the State of New Jersey has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

212. Pursuant to N.J. Stat. Ann. § 2A:32-C3, the State of New Jersey is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-FOURTH CAUSE OF ACTION
New Mexico False Claims Act
N.M.S.A §§ 27-14-1 *et seq.*

213. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

214. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants presented, or caused to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent, in violation of N.M.S.A. § 27-14-4(A).

215. By reason of Defendants' acts, the State of New Mexico has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

216. Pursuant to N.M.S.A. § 27-14-4, the State of New Mexico is entitled to three times the amount of actual damages plus the maximum penalty which may be

applicable for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-FIFTH CAUSE OF ACTION
New York False Claims Act
N.Y. Fin. Law §§ 187 et seq.

217. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

218. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented, to employees, officers or agents of New York or New York local governments, false or fraudulent claims for payment or approval, in violation of N.Y. Fin. Law § 189.1(a).

219. By reason of Defendants' acts, the State of New York has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

220. Pursuant to N.Y. Fin. Law § 189.1(g), the State of New York is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-SIXTH CAUSE OF ACTION
North Carolina False Claims Act
N.C.G.S. §1-605 et seq.

221. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

222. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to an officer or employee of a North Carolina agency a false claim for payment or approval, in violation of N.C.G.S. § 1-607(a)(1).

223. By reason of Defendants' acts, the State of North Carolina has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

224. Pursuant to N.C.G.S. § 1-607(a), the State of North Carolina is entitled to three times actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-SEVENTH CAUSE OF ACTION
Oklahoma Medicaid False Claims Act
Okla. Stat. §63-5053 et seq.

225. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

226. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to Officers or employees of the State of Oklahoma a false claim for payment or approval, in violation of Okla. Stat. §63-5053.1B1.

227. By reason of Defendants' acts, the State of Oklahoma has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

228. Pursuant to Okla. Stat. §63-5053.1B, the State of Oklahoma is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-EIGHTH CAUSE OF ACTION
Rhode Island False Claims Act
R.I. Gen. Laws §§ 9-1.1 et seq.

229. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

230. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented to officers or employees of Rhode Island false claims for payment or approval, in violation of R.I. Gen. Laws §§ 9-1.1-3(a)(1).

231. By reason of Defendants' acts, the State of Rhode Island has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

232. Pursuant to R.I. Gen. Laws §§ 9-1.1-3(a), the State of Rhode Island is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

TWENTY-NINTH CAUSE OF ACTION
Tennessee Medicaid False Claims Act
Tenn. Code §§ 71-5-181 et seq.

233. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

234. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants presented, or caused to be presented, to the state a claim for payment under the Medicaid program knowing such claim is false or fraudulent, in violation of Tenn. Code § 71-5-182(a)(l)(A).

235. By reason of Defendants' acts, the State of Tennessee has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

236. Pursuant to Tenn. Code § 71-5-182(a)(1), the State of Tennessee is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTIETH CAUSE OF ACTION
Texas Medicaid Fraud Prevention Law
Tex. Hum. Res. Code §§ 36.001 *et seq.*

237. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

238. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented or caused to be presented false or fraudulent claims to

the State of Texas for payment or approval, in violation of Tex. Hum. Res. Code § 36.002.

239. By reason of Defendants' acts, the State of Texas has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

240. Pursuant to Tex. Hum. Res. Code § 36.052, the State of Texas is entitled to two times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTY-FIRST CAUSE OF ACTION
Vermont False Claims Act,
32 V.S.A. Chapter 7, Subchapter 8, §631(a)(1)

241. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

242. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented, to an officer or employee of the State of Vermont a false or fraudulent claim for payment or approval," in violation of the Vermont False Claims Act, 32 V.S.A. Chapter 7, Subchapter 8, §631(a)(1).

243. By reason of Defendants' acts, the State of Vermont has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

244. Pursuant to the Vermont False Claims Act, 32 V.S.A. Chapter 7, Subchapter 8, the State of Vermont is entitled to two times the amount of actual damages plus the

maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTY-SECOND CAUSE OF ACTION
Virginia Fraud Against Taxpayers Act
Va. Code §§ 8.01-216.1 *et seq.*

245. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

246. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants kknowingly presented, or caused to be presented, a false or fraudulent claim for payment or approval in violation of the Virginia Fraud Against Taxpayers Act, Va. Code § 8.01-216.3(A).

247. By reason of Defendants' acts, the Commonwealth of Virginia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

248. Pursuant to Va. Code § 8.01-216.3(A), the Commonwealth of Virginia is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTHY-THIRD CAUSE OF ACTION
Washington Medicaid Fraud False Claims Act
Wash. Rev. Code §§ 74.66.020 *et seq.*

249. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

250. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented, a false or fraudulent claim for payment or approval in violation of the Washington Medicaid Fraud False Claims Act, Wash. Rev. Code §§ 74.66.020 (1).

251. By reason of Defendants' acts, the State of Washington has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

252. Pursuant to Wash. Rev. Code §§ 74.66.020 (1), the State of Washington is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

THIRTY-FOURTH CAUSE OF ACTION
District of Columbia False Claims Act
D.C. Code §§ 2-308.03 *et seq.*

253. Relator repeats and realleges the allegations set forth in above as though set forth fully herein.

254. By virtue of the off-label marketing of unapproved and inappropriate uses, the payment of kickbacks, and the promotion of an unreliable and misbranded test, Defendants knowingly presented, or caused to be presented, to an officer or employee of the District of Columbia a false claim for payment or approval, in violation of D.C. Code § 2-308.14(a)(1).

255. By reason of Defendants' acts, the District of Columbia has been damaged, and continues to be damaged, in a substantial amount to be determined at trial.

256. Pursuant to D.C. Code § 2-308.14(a), the District of Columbia is entitled to three times the amount of actual damages plus the maximum penalty for each and every false or fraudulent claim, record or statement made, used, presented or caused to be made, used or presented by Defendants.

CONCLUSION

WHEREFORE, the Relators, on behalf of the United States, the States (or Commonwealths) hereby pray that this Court:

1. Enter judgment against Defendants holding them liable for civil penalties of $27,894 for each violation of the False Claims Act committed by Defendants;
2. Enter judgment against Defendants holding them liable for three times the amount of damages sustained by the United States and the named State Plaintiffs because of the acts of Defendants;
3. Enter judgment against Defendants awarding the Relator a percentage of the proceeds recovered by the United States and the named State Plaintiffs as a result of this action in accordance with 31 U.S.C. § 3730(d);
4. Enter judgment against Defendants awarding the Relator his costs and reasonable attorneys' fees for prosecuting this action in accordance with 31 U.S.C. § 3730(d); and
5. Enter judgment against Defendants awarding any and all other relief that the Court finds to be just and equitable.

PLAINTIFFS/RELATORS DEMAND A TRIAL BY JURY ON ALL COUNTS

Respectfully submitted,

PLAINTIFF–RELATORS,
By their Attorneys,

Dated: July 22, 2024

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