UNITED STATES DISTRICT COURT
FOR THE WESTERN DISTRICT OF MISSOURI
WESTERN DIVISION

BLUE CROSS AND BLUE SHIELD OF KANSAS CITY, Plaintiff, v. GS LABS LLC, Defendant.	)	Cause No.: 4:21-cv-00525-FJG

SUGGESTIONS IN OPPOSITION TO GS LABS, LLC'S MOTION FOR LEAVE TO FILE FIRST AMENDED COUNTERCLAIMS

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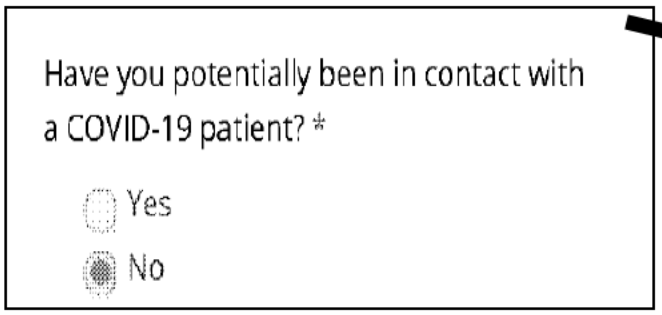
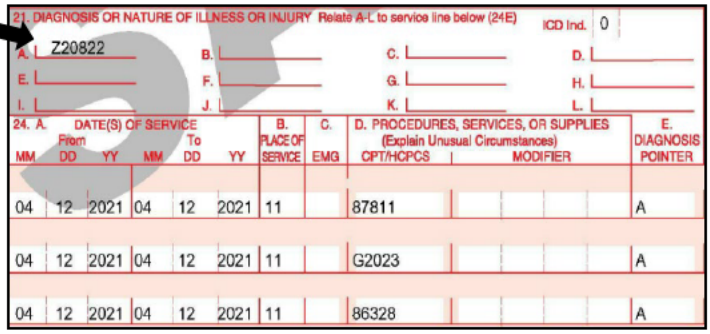
GSL's proposed counterclaims are fatally defective. Its pleading deficiencies, when placed in context of the litigation as a whole, lead to the inevitable conclusion that the additional claims are designed to impede the just, speedy, and inexpensive determination of the litigation.

Blue KC filed suit alleging GSL's COVID-19 testing claims are not payable, because (1) GSL's claims are the product of price gouging and disaster profiteering (2) GSL used a false artifice in connection with its claims, particularly its sham cash price and, (3) the testing GSL claims to have provided was of exceptionally poor quality. At the core of this litigation the parties present a binary dispute – either the claims are not payable (according to Blue KC) or payable (according to GSL). Even GSL described this litigation as "a relatively simple instance of an insurer" not paying the claims of an out of network provider. Doc. No. 37.

Although GSL has evaded depositions so far (*see*, Doc. 93), to date, the evidence collected provides compelling support for Blue KC's position. GSL has produced documents illustrating in stark terms its price gouging. *See* Doc. 43 (GSL demands $380 per test); (**Exhibits A**) (examples of GSL's unit price for test kits); (**Exhibits B**, **C, D, & E**) (substantiating GSL's unreliable, delayed, or otherwise improper testing); (**Exhibit F**) (correspondence from GSL's attorney regarding its failure to collect cash price from uninsured). The Kansas Attorney General ordered GSL to cease and desist and GSL no longer operates in that state. (**Exhibit G**). Although Blue KC propounded requests for production in August of 2021, GSL has only produced approximately one quarter of the patient records regarding the claims submitted to Blue KC. The records that have been produced to date contain unambiguous, jarring evidence of attempted fraud. *See e.g.* (**Exhibits H**) (patient denies

exposure to COVID-19 on Consent and Release Forms, GSL bills Blue KC using a diagnostic code representing an exposure to COVID-19):[1]





To state it mildly, the facts are not breaking for GSL. Instead, discovery is only substantiating serious problems with GSL, its testing, and its claims for reimbursement.

Faced with the prospect of concluding discovery and moving to trial on these facts, GSL now seeks to delay and significantly expand the scope of this litigation by adding six facially deficient counterclaims. These new counterclaims, if permitted, would each be subject to motion to dismiss under Rule 12 and only delay the orderly progression of this litigation. The proposed tortious interference claim is inadequate because GSL has not properly identified a business expectancy and Blue KC is party to any potential business expectancy. The proposed defamation claim fails to identify each purported defamatory statement. And, as for the one specific statement identified, the statement is essentially true, is privileged, and has not damaged GSL. The antitrust claims are also each futile because GSL lacks antitrust standing, GSL has not identified a legally cognizable market, nor has it alleged that Blue KC exercises sufficient market power in the same. For these reasons, GSL's motion for leave to file additional counterclaims should be denied.

[1] The Z20822 code means "Contact with and (suspected) exposure to COVID-19" *See* https://www.cdc.gov/nchs/data/icd/Announcement-New-ICD-code-for-coronavirus-19-508.pdf (last visited 1/27/2022); *see also* https://www.cms.gov/files/document/FFCRA-Part-43-FAQs.pdf Q5

LEGAL STANDARDS

Under Federal Rule of Civil Procedure 15(a)(2), a party may amend its pleading with the Court's consent, and the Court "should freely give leave when justice so requires," but "[t]here is no absolute right to amend." *Becker v. University of Nebraska at Omaha*, 191 F.3d 904, 907-08 (8th Cir. 1999). Denial of a motion to amend is within the sound discretion of the court. *Id.*

A court may properly deny a motion to amend a pleading if the amendment would be futile. *Popoalii v. Corr. Med. Servs.,* 512 F.3d 488, 497 (8th Cir.2008) (citations omitted). An amendment is futile if "the amended [pleading] could not withstand a motion to dismiss pursuant to Rule 12, Fed. R. Civ. P." *Lexington Ins. Co. v. S & N Display Fireworks, Inc.,* 2011 WL 5330744, at *2 (E.D. Mo. Nov. 7, 2011). Under Rule 12(b)(6), the Court must accept the facts alleged as true and grant all reasonable inferences in favor of the nonmoving party. *Neighborhood Enterprises, Inc. v. City of St. Louis,* 540 F.3d 882, 884–85 (8th Cir. 2008). However, the complaint must contain "enough facts to state a claim to relief that is plausible on its face." *Bell Atlantic Corp. v. Twombly*, 550 U.S. 544, 547 (2007). "A pleading that offers 'labels and conclusions' or 'a formulaic recitation of the elements of a cause of action will not do.'" *Ashcroft v. Iqbal*, 556 U.S. 662, 678 (2009) (citations omitted). "Plausibility" requires more than a "mere possibility of misconduct," and a complaint that alleges facts that are "merely consistent with" liability "stops short of the line between possibility and plausibility of 'entitlement to relief.'" *Id.* at 678-79 (quoting *Twombly*, 550 U.S. at 557).

A Court may also deny a motion to amend a pleading if it would cause undue delay and hardship on the non-moving party, or if it was filed in bad faith or with a dilatory motive. *Bell v. Allstate Life Ins. Co.*, 160 F.3d 452, 453 (8th Cir. 1998) (citing *Forman v. Davis*, 371 U.S. 178, 182 (1962)).

ARGUMENT

I. GRANTING GSL LEAVE TO PLEAD COUNTS I-VII WOULD BE FUTILE

Counts I-VII of the Proposed Amended Counterclaim ("PACC") are the same in substance as GSL's original counterclaims. Doc. No. 4. Those claims should be dismissed for the reasons stated in Doc. No. 23-24 & 45.

II. GSL SHOULD NOT BE GRANTED LEAVE TO ADD A FUTILE TORTIOUS INTERFERENCE CLAIM

A. THE TORTIOUS INTERFERENCE CLAIM FAILS BECAUSE GSL IS UNABLE TO IDENTIFY A VALID BUSINESS EXPECTANCY

The elements of a tortious interference with business expectancy are: "(1) A contract or a valid business relationship or expectancy (not necessarily a contract); (2) Defendant's knowledge of the contract or relationship; (3) Intentional interference by the defendant inducing or causing a breach of the contract or relationship; (4) The absence of justification; and (5) Damages resulting from defendant's conduct. *Conoco Inc. v. Inman Oil Co., Inc.,* 774 F.2d 895, 906 (8th Cir.1985) (citation omitted). A valid business expectancy is a "reasonable expectation of economic advantage or commercial relations." *Sloan v. Bankers Life & Cas. Co.*, 1 S.W.3d 555, 565 (Mo. App. 1999) (internal quotation marks omitted). "[M]ere hope" is not enough. *Stehno v. Sprint Spectrum, L.P.* 186 S.W.3d 247, 250 (Mo. banc. 2006) (citation omitted). The expectancy must be "reasonable and valid under the circumstances presented." *Western Blue Print Co., LLC v. Roberts*, 367 S.W.3d 7, 19 (Mo. banc 2012) (citation omitted). "One reason [an] expectancy must be properly pled with factual detail is to evaluate its objective reasonableness." *Blue Line Rental, LLC v. Rowland*, 2020 WL 1915252 at *3 (E.D. Mo. Apr. 20, 2020) ("if [plaintiff] had an objective expectation in *particular customers* or *particular employees*, it must give factual meaning and support to those expectations.") (emphasis in original). As such, failing to plead the identities of those who would have otherwise done business with a party necessarily fail. *Vilcek v. Uber USA, LLC,* 2016 WL 8674064 at *3 (E.D. Mo. Sept. 30, 2016) ("There are no allegations

of a regular course of similar prior dealings with specific customers with whom it could be said Defendants interfered . . . Plaintiffs' allegations are nothing more than speculation, conjecture and guesswork without a substantial evidentiary basis.") S*ee also Williams v. Finck & Assoc.*, 2010 WL 1992242 at *8 (E.D. Mo. May 18, 2010) ("To the extent Plaintiff alleges that Defendant interfered with his relationship with third parties, Plaintiff does not specify the names of employers who allegedly refused to hire him because of Defendant's conduct. . . As such, the court finds that Count IV should be dismissed for failure to state a cause of action.")

GSL fails to identify a valid business expectancy in two ways. ***First***, GSL identified "upon information and belief" a number of Administrative Service Only ("ASO") plans that Blue KC is believed to have administered and are somehow relevant to its claims. PACC, ¶¶ 107-109. Tellingly, despite having access to substantial discovery, GSL does not identify each ASO plan or contractual provision at issue. Its reliance on "information and belief" pleading at this phase is indicative of serious deficiencies underlying its claims. The failure to identify each ASO at issue is critical here because many of the claims (if not all) would be preempted by ERISA. Docs. 23, 24 p. 10-12, Doc. 45 p. 5-6; *Jones v. Kum & Go, LC*, 2010 WL 1371761; at *2-4 (E.D. Mo. Apr. 7, 2010) (a claim for tortious interference with contractual relations is essentially a claim for denial of benefits and preempted by ERISA). Further, with respect to many ASO's, the plan sponsor (rather than the administrative service provider, here Blue KC) retains the ultimate decision to pay or not pay a given claim. Without specific allegations identifying these ASO's Blue KC is prevented from filing a meaningful responsive pleading or a targeted motion to dismiss. ***Second***, GSL failed to identify a single patient who terminated his/her relationship with GSL or chose not to obtain services from GSL as a result of any act or omission of Blue KC. *See U.S. Bank National Association v. Parker,* 2010 WL 2735661 at *4 (E., D., Mo. July 9, 2010); *Schoedinger v. United Healthcare of Midwest, Inc.*, 2011 WL 97735, at *7 (E.D. Mo. Jan. 12, 2011) ("Failing to allege whether such actions caused any identified patient to terminate his/her business relationship

with the plaintiffs [healthcare provider] is fatal to the plaintiffs' cause of action."). Assuming GSL is now accepting cash paying patients, these patients would still be free to obtain services from GSL irrespective of any act or omission of Blue KC. [2]

B. THE TORTIOUS INTERFERENCE CLAIM FAILS BECAUSE BLUE KC IS PARTY TO THE PURPORTED EXPECTANCY

A party to an alleged business expectancy cannot be named as a defendant in the tortious interference claim involving that expectancy. *Community of Christ Copyright Corporation v. Devon Park Restoration Branch of Jesus Christ's Church,* 2009 WL 10672489 at *2 (W.D. Mo. Mar. 3, 2009) (citing *Franklin v. Harris*, 762 S.W.2d 847, 849 (Mo. App. 1989); *Jurisprudence Wireless Communications, Inc. v. Cybertel Corp.*, 26 S.W.3d 300, 302 (Mo. App. 2000) ("the tort interference with a business expectancy cannot lie against a party to a contract which creates the business expectancy") (citation omitted). Tortious interference will not lie against parties to the contract or expectancy. *Reed v. Curators of University of Missouri*, 509 SW 3d 816, 829 (Mo. App. W.D. 2016). Agents of a corporation are the corporation for purposes of evaluating a tortious interference claim. *Id.*

Particularly instructive on this issue is *Schoedinger*, 2011 WL 97735. In that case, the plaintiff, a healthcare provider, asserted a claim for tortious interference with a business expectancy and claimed that the defendant, a healthcare insurer, failed to reimburse the plaintiff for medical services rendered to insured patients based on the defendant's role as an "administrator of insured patient's health insurance." *Id.* at *6. In assessing this claim, the court determined that a claim for tortious interference could not exist because:

> ***As the health insurer . . . defendant is clearly a party to the business relationship*** which plaintiff contends defendant has interfered with by its actions regarding payment of benefit claims. This business relationship exists absent any direct contract between the parties . . .. The plaintiffs' tortious interference claim is premised upon the defendant's alleged failure to

[2] GSL's consent and release forms states, "**I understand that if my insurance company denies coverage or payment for the services provided to me or fails to remit timely payment on my claim (within thirty (30) days), I assume full financial responsibility and will pay all charges in full.**" Doc 14-6. (emphasis in original).

> perform as required by the parties' business relationship, i.e., pay for services due under the respective health plans of the plaintiffs' patients. A claim for tortious interference with a business expectancy cannot lie against a party to a contract which creates the business expectancy.

Id. (citations omitted) (emphasis added).

In similar circumstances, other courts have come to the same conclusion in holding that administrators of group health plans cannot be held liable for a tortious interference claim. *Hammond v. Lyndon Southern Insurance Co.*, 480 F.Supp.3d 1265, 1273-1274 (W.D. Ok. 2020) ("Plaintiff's claim against Jupiter [which administered the policy] for allegedly interfering with her insurance contract with Lyndon is based solely on Jupiter's acts on behalf of Lyndon with respect to the contract. Therefore, the Court finds that this claim fails as a matter of law."); *The William Powell Co. v. National Indemnity Co.*, 141 F.Supp.3d 773, 784-785 (S.D. Oh. 2015) ("As NICO and Resolute accurately argue, NICO's service agreement with OneBeacon provided the claims administrator with broad discretionary authority to administrate and settle claims on OneBeacon's behalf. Consequently, the acts forming the basis of [plaintiff's] tortious interference claim . . . are within the scope of the responsibilities OneBeacon assigned to NICO and Resolute. . .. Accordingly, NICO and Resolute are entitled to dismissal"); *Mintz v. Blue Cross of California*, 172 Cal.App.4th 1594, 1604 (Cal. App. 2009) ("In this case, Blue Cross is CalPERS's agent: for purposes of claims administration under the insurance contract between Mintz and CalPERS, Blue Cross was vested with the power to act for CalPERS, and therefore cannot be held liable for interference with the very contract it was charged with administering.")

GSL's proposed tortious interference claim is improper because Blue KC is an agent for its ASO plans insofar as it provided the administrative services described in paragraphs 262-264 of the PACC. Blue KC is party to the relationship at issue. GSL has alleged that Blue KC caused ASO plans to deny GSL's claims for services, and this was the result of Blue KC breaching its own contractual obligations to those same ASO plans. PACC, ¶¶ 111-114, 262, 264, & 267-268. Because a claim for

tortious interference cannot lie against a party to the business expectancy GSL's new proposed claim would be futile.

III. GSL SHOULD NOT BE GRANTED LEAVE TO ADD A FUTILE DEFAMATION CLAIM

A. GSL FAILS TO ADEQUATELY IDENTIFY PURPORTEDLY DEFAMATORY STATEMENTS

"[A] plaintiff must set forth specifically in his/her complaint the words and/or statements which are alleged to be defamatory. *King v. Union Station Holdings, LLC*, 2012 WL 5351598, at *4 (E.D. Mo. Oct. 30, 2012) (citations omitted); *Klein v. Victor,* 903 F. Supp. 1327, 1332 n. 1 (E.D. Mo. 1995) (holding that the court will not consider allegations that "other passages" of a book were also defamatory); *Freeman v. Bechtel Construction Company* 87 F.3d 1029, 1031 (8th Cir. 1996) (affirming dismissal of libel claim because, among other things, the complaint did not identify the specific defamatory statement).

The PACC only identifies one specific purportedly defamatory statement. PACC, ¶ 273. However, GSL also alleges "Blue KC has made a host of knowingly false statements about GSL," that the letter containing the specifically identified defamatory remark also "contains a host of outright falsehoods and misleading statements," and that "on information and belief, Blue KC has made substantially identical false representations on multiple other occasions to governmental actors." PACC, ¶ 270, 272, & 281. GSL has improperly insinuated that there are other defamatory remarks without identifying the same. Therefore, GSL's defamation count would fail, as to the other unidentified statements, because GSL has not identified specific statements at issue.

B. THE DEFAMATION CLAIM WOULD BE FUTILE AND WAS ASSERTED IN BAD FAITH BECAUSE BLUE KC'S STATEMENTS ARE TRUE

The only purportedly defamatory statement GSL identifies with any specificity is Blue KC's statement that GSL "posted an illusory 'cash price' that was never actually collected from individual cash-paying consumers." PACC ¶ 273. The statement at issue, however, is essentially true – ***GSL admitted that for the first many months of its operation it did not collect its full purported***

cash price from individuals.[3] These true statements are absolutely immune under both the common law of defamation and under Mo. Rev. Stat. § 375.993.2 (unless the statement is false, "no civil cause of action of any nature may arise against [insurer] for . . . any information relating to suspected or anticipated fraudulent insurance acts furnished to or received from law enforcement official (or federal or state governmental agency or office").

Blue KC's statement at issue here was included in a twelve-page letter sent on June 16, 2021, to eight government regulators and law enforcement entities. (**Exhibit I**). FACC, ¶¶ 271-272.[4] Blue KC identifies the evidence on which it is based and freely admits its investigation is, in part, dated. Blue KC stated:

> By posting an illusory "cash price" that was never actually collected from individual cash-paying consumers, GSL attempted to exploit the CARES Act by coercing insurers to pay for diagnostic testing at artificially inflated rates. . ..
>
> Evidence supporting the fact that GSL's posted cash pricing is a sham includes the following:
>
> > • Blue KC attempted to schedule diagnostic testing at GSL locations in both Missouri and Kansas and attempted to pay cash. At both locations, Blue KC's investigators were denied the opportunity to schedule testing and pay cash. They were also told that GSL only accepts insured customers. A manager at the Lenexa, Kansas GSL location indicated GSL would not allow consumers to pay out-of-pocket as their "systems" were not set up for cash payments;
> >
> > • A former employee of GSL informed us that GSL would only perform tests for insured patients. This employee worked at GSL's Beachwood, Ohio location;
> >
> > • Standard GSL consent forms include the following language: GSL "only accepts insurance patients who are seeking testing for diagnostic purposes" (emphasis added); and

[3] To defeat a defamation claim Blue KC need only prove the statement is "essentially" true. Under Missouri law, a statement is not considered "false" for purposes of defamation simply because it contains an erroneous fact. *Thurston v. Ballinger,* 884 S.W.2d 22, 26 (Mo.Ct.App.1994) ("A person is not bound to exact accuracy in his statements about another, if the statements are essentially true."). Rather, if a statement is essentially true, such that its divergence from the truth "would have no different effect on the reader's mind than that produced by the literal truth." *See id.* (quoting *Turnbull,* 459 S.W.2d at 519).

[4] *McLean*, 2021 WL 4783257 at *4 (noting that in considering a motion to dismiss a court may review "materials necessarily embraced by the Complaint.").

> • GSL may have recently changed its policy and may now accept cash patients under certain circumstances. GSL's website states it will accept cash patients, but GSL apparently does not collect the "cash price" from uninsured patients. Instead, GSL purports to use a "Community Financial Assistance" program. It appears that simply checking a radio button on GSL's website indicating that the prospective patient does not "currently have insurance" would entitle an uninsured patient to "up to a 70% discount." This "Community Financial Assistance" program seems designed to artificially maintain an excessive and illusory posted "cash price" . . .

Blue KC describes its investigation, the evidence on which its opinions rest, and couches its statement regarding what it has observed with the proviso, "***GSL may have recently changed its policy and may now accept cash patients under certain circumstances.***" Notably, GSL does not challenge the evidence on which Blue KC's conclusion is based (for instance, that a Blue KC investigator was refused the opportunity to pay cash at two separate GSL facilities).

Instead, Blue KC's reported observations are entirely consistent with GSL's own statements and discovery responses. GSL's spokesman reported, "***individual customers are not billed at their Lenexa lab***." (**Exhibit J**) GSL even admitted that it failed to collect the posted cash price from uninsured individuals for at least the first many months of its operation. GSL's interrogatory response notes, "At or around October 1, 2020, the cash price for rapid antibody testing was set at $199" but GSL's production shows that the first full cash payment collected was on December 22, 2020 – ***months after it began operating***. *See* (**Exhibit K**); s*ee also* GSL's Response to Blue KC's First Request for Production No. 8.[5] For the first many months of its existence, GSL admitted it did not collect the posted cash price from customers – just as Blue KC described.

Further, even outside of this litigation, GSL's attorneys have admitted that Blue KC's characterization was accurate. According to a letter from GSL's, attorney, dated January 25, 2021:

[5] Blue KC denies these documents constitute admissible evidence that the posted cash price was ever accepted – GSL has refused to produce unredacted documents and, as described below, these records are inconsistent with representations GSL made to state regulators. Nevertheless, these documents reflect GSL's position that no full cash price payments were accepted from individuals prior to December 22, 2020.

(Exhibit L) This position was clarified and affirmed by GSL, in a letter to the Washington State Attorney General's Office, dated February 17, 2021. (**Exhibit M**)

GSL admitted it "***never*** charged" an individual the posted cash price.[6] Then, on February 19, 2021, correspondence GSL sent to the Missouri Department of Commerce and Insurance, GSL represented that the cash price for tests is $380-$385, but ***any*** uninsured individual, could receive a 70% discount. The below screenshot is from that letter:

[6] Via letter dated December 17, 2021, GSL recently attempted to retract its admission.

l. Discuss the fee for self-pay testing for consumer.

Response: The fee for a self-pay consumer is the same as the amount charged the insurance carrier ($380) however, if the consumer needs financial assistance, it is available at up to 70% off the test price. For consumers who indicate they have no insurance or an economic hardship, at the time of signing up on the web-site there is an invitation to request financial assistance, by interacting with GS Labs online or by phone.

(**Exhibit N**) GSL has admitted time after time, that it offered one rate for uninsured patients and another for insured patients (who would not personally pay the full price).

Blue KC cannot be held to a higher standard than GSL's own lawyers. Public records, GSL's own comments, and GSL's own evidence show Blue KC's statements were essentially true and, therefore, not defamatory.

C. BLUE KC'S STATEMENT IS A PRIVILEGED STATEMENT OF OPINION

Expressions of opinion are absolutely privileged. *Nazeri v. Missouri Valley College,* 860 S.W.2d 303, 314 (Mo. Banc. 1993). In drawing the line between opinion and fact in a defamation case, Missouri Courts ask, "whether the ordinary reader would have treated the statement as opinion." *Bigfoot on Strip, LLC v. Winchester*, 2019 WL 4144320 at *6 (W.D. Mo. Aug. 30, 2019) (citations omitted). This determination is made by the Court and is based on the totality of the circumstances surrounding a given statement. *Clinch v. Heartland Health*, 187 S.W.3d 10, 17–18 (Mo. App. 2006) ("Whether a statement is fact or opinion is a question of law, and we make this determination based on the totality of the circumstances surrounding a given statement.").

Here, the alleged defamatory statement is clearly an opinion based on underlying facts (which remain uncontested). The opening paragraph of the June 16, 2021, letter states "**Based on our investigation, Blue KC is of the opinion** that these claims are the product of . . .." (**Exhibit I**, pg. 2) (emphasis added). Throughout the letter, Blue KC utilizes terms and phrases that necessarily reflect opinion, such as "these claims may constitute price gouging" (**Exhibit I**, pg. 5), "we do not believe" (**Exhibit I**, pg. 7), "these prices appear to be" (**Exhibit I**, pg. 7) "may indicate serious operational

concerns" (**Exhibit I**, pg. 9), "may implicate" (**Exhibit I**, pg. 9) "it appears specimens were collected," (**Exhibit I**, pg. 10), "we believe GSL submitted claims" (**Exhibit I**, pg. 10, n. 20) and "based on our review . . . it appears" (**Exhibit I**, pg. 11). "[t]hese reports raise serious concerns" (**Exhibit I**, pg. 4). This language demonstrates that the statements in question are opinions about the conclusions to be drawn from Blue KC's investigation. *Pape v. Reither*, 918 S.W.2d 376, 380 (Mo. Ct. App. 1996) (holding that a letter which stated, "[i]t is my position that you participated in fraudulent and or (sic) illegal acts . . . ." constituted a statement of opinion because "the phrase 'it is my position' clearly requires the conclusion that this statement is one of opinion . . . [and it] cannot be contorted to mean anything other than "it is my belief" or "I will attempt to prove . . . ."). *Ruziicka Elec. and Sons, Inc. v. International Broth. of Elec. Workers, Local 1, AFL-CIO*, 427 F.3d 511, 523 (8th Cir. 2005) (holding that words expressed to a city employee such as "thought" and "felt" in connection with work that was "dangerous," "improper," and "not up to code" was a privileged opinion).

Blue KC identified the "illusory 'cash price'" as one of many "concerns with respect to GSL's claims." (**Exhibit I**, pg. 5). Like its statements about its impressions and opinions, Blue KC reiterated throughout the correspondence that it was expressing "concerns" about GSL's practices. Here, it stated: "[t]hese reports raise serious concerns" (**Exhibit I**, pg. 4), "Blue KC also has a number of concerns" (**Exhibit I**, pg. 9), and "we have identified other issues of concern" (**Exhibit I**, pg. 11). Bringing concerns to relevant authorities in the form of an opinion statement is recognized as privileged. *Mandel v. O'Connor*, 99 S.W.3d 33, 38 (Mo. Ct. App. 2003) (holding that an alleged defamatory statement was privileged because "[w]hen read in their context, the words clearly indicate an opinion" as it included words such as "it would appear" in reference to "concerns" being brought by the defendant to a city council).

In identifying the particular concern at issue (GSL's failure to collect cash prices), Blue KC set forth evidence which informed its opinion. (**Exhibit I**, pg. 7-8). Blue KC also expressly stated that

"**GS Labs may have changed its policy and may now accept cash patients under certain circumstances**." (**Exhibit I**, pg. 8) (emphasis added). The fact that Blue KC freely identified the potential limits of its investigation demonstrates that the alleged defamatory statement was a statement of opinion, because Blue KC was only drawing its own conclusions from the evidence available to it. *Pape*, 918 S.W.2d at 381 ("allegations of fraudulent or illegal conduct are conclusions about the consequences that should attach to certain conduct, and as such they too are opinions.").

The context of the alleged defamatory statement demonstrates that it was a privileged statement of opinion. Blue KC also repeatedly used words and expressions in this letter indicating that it was offering an opinion about its concerns. This was specifically done in reference to the one alleged defamatory statement identified by GSL. As such, an ordinary reader would have treated the alleged defamatory statement as an opinion. Thus, this statement is privileged.

D. THE ALLEGED STATEMENT IS PROTECTED UNDER A QUALIFIED PRIVILEGE

Missouri law encourages members of the public to report their concerns to appropriate authorities, particularly when insurance fraud is suspected. Mo. Rev. Stat. § 375.993; *see also, Bugg v. Vanhooser Holsen & Eftink, P.C.,* 152 S.W.3d at 373, 378 (Mo. App. 2004). ("There are strong public policy reasons why we would not wish to discourage attorneys and members of the public from reporting their concerns. To be hypercritical in the evaluation of such letters would undermine the purpose of the privilege."). "[S]ocietal needs dictate that certain types of communications will enjoy a qualified privilege." *Wooten v. Pleasant Hope R-VI School Dist.*, 139 F.Supp.2d 835, 846 (W.D. Mo. 2000). "A qualified privilege arises from the necessity of full and unrestricted communication concerning a matter in which the parties have an interest or duty." *Bugg*, 152 S.W.3d at 377. (holding that defendant was entitled to judgment as a matter of law in connection with an alleged defamatory letter sent to the Chief Disciplinary Counsel of Missouri based on a qualified privilege). This qualified privilege is applicable when individuals have made alleged, defamatory statements concerning purported

wrongdoing to the government. *In re IBP Confidential Bus. Documents Litig.,* 755 F.2d 1300, 1309 (8th Cir. 1985).

As such, a communication is qualifiedly privileged when "it is made in good faith upon any subject-matter in which the person making the communication has an interest or in reference to which he has a duty, and to a person having a corresponding interest or duty." *Rice v. Hodapp,* 919 S.W.2d 240, 244 (Mo.1996); *see King, 2012* WL 5351598 at *6 (recognizing that "accusations" made by security personnel to law enforcement enjoyed qualified privileged); *Rucker v. KMart Corp.,* 734 S.W.2d 533, 535 (Mo. App. E.D. 1987) (holding that "[a] communication to law enforcement officers for the purpose of helping bring a criminal to justice is qualifiedly privileged"). "The determination of whether such a privilege applies is a question of law for the courts to decide." *Rice*, 919 S.W.2d at 244.

Here, the statement made by Blue KC – an entity who has an interest in GSL's wrongful conduct and who is interested in protecting its members, and the community, from insurance fraud was made to governmental authorities who protect the public from unscrupulous businesses. PACC, ¶ 271, (**Exhibit I**, pg. 1). Thus, the communication was made by a party who "has an interest or in reference to which he has a duty, and to a person having a corresponding interest or duty." *See Rice,* 919 S.W.2d at 244. Because the June 16, 2021, correspondence was sent to law enforcement and regulators from an interest in the matters described, a qualified privilege exists.

Once a court has determined that a statement enjoys qualified privilege is available, the party asserting the claim bears the burden of establishing malice. *Rucker,* 734 S.W.2d at 535. The Missouri Supreme Court has elaborated upon this burden as follows:

> To overcome the qualified privilege the plaintiff has to prove malice-in-fact that is, that the defendant was actuated by ill-will in what he did and said with a design to causelessly or wantonly injure the plaintiff. In *Minter v. Bradstreet Co.,* 174 Mo. 444, 73 S.W. 668 (1903), this Court stated that a plaintiff had to prove malice, which meant 'that the report in question was prepared and published, not in good faith, but with an intent to injure plaintiffs, or with a willful and wanton neglect of the rights and interests of the plaintiffs.' Merely proving negligence does not satisfy the malice requirement

> because negligence does not constitute willfulness, reckless disregard of others' rights or actual presence of an improper motive to injure.

McDowell v. Credit Bureaus of Southeast Mo., Inc., 747 S.W.2d 630, 632 (Mo. banc 1988) (internal citation omitted). Under federal law, malice "may be alleged generally," Fed. R. Civ. P. 9(b), but "to make out a plausible malice claim, a plaintiff must still lay out enough facts from which malice might reasonably be inferred." *Nelson Auto Center, Inc. v. Multimedia Holdings Corporation*, 951 F.3d 952, 958 (8th Cir. 2020) (citation omitted). *See also* RSMo § 375.993.2. (Such statements are absolutely privileged "except when a person ***knowingly and intentionally*** communicates false information") (emphasis added). "[E]very circuit that has considered the matter had applied the *Iqbal/Twombly* standard and held that a defamation suit may be dismissed for failure to state a claim where the plaintiff has not pled facts sufficient to give rise to a reasonable inference of actual malice." *Nelson*, 951 F.3d at 958 (quoting *Michel v. NYP Holdings, Inc.*, 816 F.3d 686, 702 (11th Cir. 2016) (collecting cases)). GSL has failed to plead a set of facts plausibly alleging actual malice.

GSL opines that Blue KC sent the June 16, 2021 correspondence "for the improper purpose of attempting to evade payment of its substantial financial obligations to GSL," and it had "the purpose of driving GSL . . . out of the Kansas City market . . ." (PACC, ¶¶ 284-285). These conclusory allegations are without support in the pleading. GSL does not demonstrate, allege, or explain how Blue KC could accomplish its supposed goals of "driving GSL . . . out of the Kansas City market" by sending the June 16, 2021, correspondence to state and federal regulators and law enforcement. Given that there are no factual allegations that move these claims from "possible" to "plausible," the Court is not required to accept the same as true. *See Iqbal*, 556 U.S. at 678. The correspondence does not reference or make any requests, express or implied, that seek to expel GSL from the Kansas City market. The correspondence only provides Blue KC's observations and opinions of GSL's activities. In short, there is no indication of malice in reference to the June 16, 2021.

The only fact GSL proposes to support its theory of knowing false statement or malice is a set of undated notes, which purports to show that Blue KC "knew" that the alleged statement was false. PACC, ¶¶ 275-278; (**Exhibit O)**. This item does not establish – or even suggest - Blue KC "knew" that the alleged statement was false. The June 3, 2021 notes only shows that another insurer had reviewed GSL's website, and that the other insurer related to Blue KC that GSL's website stated, "if a patient cannot afford the cash price, the patient can request financial assistance. However, if the patient does not request financial assistance, GSL will take the patient's credit card and charge the full amount of the test for the uninsured." This is the equivalent of double hearsay (another insurer interpreting GSL's website and then forwarding its observations to Blue KC). And, more importantly, it is perfectly consistent with Blue KC's own statements in the letter to regulators, which stated "GSL may have recently changed its policy and may now accepts cash patients under certain circumstances." (**Exhibit I**, pg. 8). The notes describe the ***possibility*** that a hypothetical uninsured customer could pay the full cash price (if the person did not request the lower available price.) However, this document does not identify any individual that ***actually*** paid the full price or even insinuate knowledge of such a hypothetical person.

GSL also states that "as further evidence that Blue KC knew that its attacks were false, Blue KC has proposed that GSL become an in-network provider – an offer that Blue KC presumably would not make to a firm that it believed to be engaged in widespread fraud and misconduct." PACC, ¶ 283. GSL's speculative presumption is mistaken. GSL does not even attempt to describe the terms of the in-network provider agreement at issue. And the absence of these terms is notable - there is nothing inconsistent with offering in-network status to a provider engaged in potential misconduct. In-network status provides tools to prevent balance billing, ensure providers are properly licensed, registered, and credentialed, and ADR provisions intended to limit litigation. GSL's speculative

presumption that an unidentified in-network agreement is inconsistent with its misconduct is not a well pled or pertinent fact which the court must accept as true.

Finally, when considering the qualified privilege, it is important not only to consider this litigation but others who would be deterred from reporting potential fraud, waste, and abuse if doing so subjected them to defamation litigation. As noted above, "[t]he people's right to petition the government for a redress of grievances is 'among the most precious of the liberties safe-guarded by the Bill of Rights.'" *In re IBP Confidential Bus. Documents Litig.*, 755 F.2d at 1309). Other courts who have reviewed like matters have created an absolute privilege for "unsolicited" and "nontestimonial communications directed to the government." *Id.* (citing *Webster v. Sun Co.,* 731 F.2d 1 (D.C.Cir.1984). "Requiring citizens to guarantee the accuracy of statements made in the course of petitioning the government, at the risk of multimillion dollar libel judgments, would lead to intolerable self-censorship, deterring not only falsity but truth as well." *Id.* (quoting, in part, *Gertz v. Robert Welch, Inc.* 418 U.S. 323, 341 (1974)). Accordingly, Blue KC's alleged defamatory statement should be considered with these important policy concerns in mind.

Given that a qualified privilege exists, and GSL's allegations do not properly plead malice, the defamation claim would not survive a motion to dismiss. Blue KC's statements are protected under both the common law qualified privilege and RSMo § 375.993 which protects all statements to law enforcement and state regulators regarding fraudulent insurance acts unless "knowingly and intentionally" false.

E. THE DEFAMATION COUNT FAILS BECAUSE GSL FAILS TO PLEAD DAMAGES

The proposed defamation claim also fails because GSL is unable to properly plead damages. Under Missouri law, "proof of actual reputational harm is an absolute prerequisite in a defamation action." *Kenney v. Wal-Mart Stores, Inc.,* 100 S.W.3d 809, 817 (Mo. banc 2003); *see also, Stockley v. Joyce*, 963 F.3d 809, 819 (8th Cir. 2020) (dismissing defamation claim based on similar vague allegations of

reputational damage); *Missouri Primate Found. v. People for Ethical Treatment of Animals, Inc.,* 2017 WL 4176431, at *5 (E.D. Mo. Sept. 21, 2017) (holding that allegations that the alleged defamatory statements "have damaged Plaintiffs' reputation" and "... Plaintiffs have been subject to ridicule, attorney's fees and costs, and other damages to be proven at trial" were conclusory and grounds to dismiss defamation claim)

Here, GSL has not adequately pleaded damages. ***First***, GSL's mere recitation of the boilerplate possibility of "reputational harm and loss of good will" is insufficient. PACC, ¶ 287. *See King* 2012 WL 5351598, at *4 (holding that allegations concerning damages "without any factual support, that her reputation and future pecuniary interests have been damaged by the defendant's "aforementioned allegations" were insufficiently pled"). And here, where the publication, was to regulators and law enforcement Blue KC did not publish in a manner where financial impact can be plausibly assumed. ***Second***, GSL pleaded "GSL has also been forced to incur very substantial amounts responding to inquiries from government agencies." PACC, ¶ 288. But slyly, it does not actually plead that these responses to inquiries were caused by Blue KC's statement. Afterall, GSL itself provided regulators the same statements as did Blue KC – that GSL "never" collected the full price from uninsured consumers. *See* Ex. G. Further, even had GSL pleaded that any act or omission of Blue KC actually caused it to "incur very substantial amounts responding to inquiries from government agencies" attorney's fees are generally not recoverable as damages as Missouri follows the "American Rule" in which each party pays their own attorney's fees. *Wilson v. Trusley*, 624 S.W.3d 385, 405 (Mo. App. W.D. 2021). *See also Williams v. Gulf Coast Collection Agency Co.*, 493 S.W.2d 367, 370 (Mo. App. 1973) (in defamation action "[t]he rule is that ordinarily attorney's fees cannot be recovered as damages") *c.f. Wandersee v. BP Prod. N. Am., Inc.*, 263 S.W.3d 623, 635 (Mo. banc. 2008) (attorney's fees awarded where statement resulted in collateral litigation); *see Wilson*, 624 SW 3d at 405 (discussing collateral

litigation exception and American Rule). In short, GSL has not adequately pleaded any recoverable damage.

IV. GSL SHOULD NOT BE GRANTED LEAVE TO ADD FUTILE ANTITRUST CLAIMS

GSL attempts to assert federal antitrust claims (Counts X – XIII) that seek would improperly transform a "relatively simple" rate reimbursement dispute into sprawling antitrust litigation.

A. EACH PROPOSED ANTITRUST CLAIM FAILS BECAUSE GSL LACKS ANTITRUST STANDING

GSL attempts to plead four federal antitrust claims (Counts X – XIII) that seek to transform a "relatively simple" rate reimbursement dispute between sophisticated commercial parties into purported antitrust violations. GSL lacks antitrust standing, which is an essential element of any private antitrust claim. *See Lovett v. Gen. Motors Corp.*, 975 F.2d 518, 520 (8th Cir. 1992). As the Eighth Circuit has long held, "[t]he question of standing to sue under the Clayton and Sherman Acts is one of law." *Midwest Commc'ns v. Minn. Twins, Inc.*, 779 F.2d 444, 449 (8th Cir. 1985). To establish antitrust standing, a plaintiff must plead sufficient facts to show it suffered an "antitrust injury," which is an "'injury of the type that the antitrust laws were intended to prevent and that flows from that which makes defendants' acts unlawful.'" *Fair Isaac Corp. v. Experian Info. Sols., Inc.*, 650 F.3d 1139, 1144-45 (8th Cir. 2011) (citation omitted). Importantly, "[a]s the Supreme Court has noted repeatedly, Congress enacted the antitrust laws to protect competition, not competitors." *Midwest Commc'ns*, 779 F.2d at 450. Thus, it is well-settled that a plaintiff may not convert an ordinary commercial dispute into an antitrust claim by simply alleging it was injured by another business. *Fair Isaac*, 650 F.3d at 1145 ("[A] plaintiff may be targeted and found to have not suffered an injury that is cognizable under the antitrust laws.").

In its proposed counterclaims, GSL has not alleged any harm to competition or the competitive process. Instead, GSL focuses almost exclusively on purported harm to ***itself*** as a result

of Blue KC's refusal to pay the inflated rates demanded ($380 for tests sold at wholesale for under $10). For example, under the heading "Anticompetitive Effects and Antitrust Injury," GSL alleges that, "[b]y steering patients away from ***GSL*** and refusing to reimburse for COVID-19 tests delivered to Blue KC subscribers, Blue KC has suffocated ***GSL's*** success, withholding a critical source of revenue that has prevented ***GSL*** from reaching or maintaining a minimum efficient scale." PACC ¶ 169 (emphasis added). Such allegations of supposed harm to a single firm (GSL), rather than to competition or the competitive process, are insufficient to establish antitrust standing. *See Bathke v. Casey's Gen. Stores, Inc.*, 64 F.3d 340, 344 (8th Cir. 1995) ("Inflicting painful losses on [another business] 'is of no moment to the antitrust laws if competition is not injured.'" (citation omitted)).

GSL's conclusory allegation that "by reducing GSL's footprint and hindering competition in the relevant markets, Blue KC has through its anticompetitive conduct prevented its subscribers and other patients in the relevant markets from having access to more, higher-quality, better-performing COVID-19 testing" (PACC ¶ 170) also misses the mark. It does not establish antitrust standing because it says nothing about how or why GSL cannot continue to compete in the market. To the contrary, GSL remains *perfectly free* to offer its COVID-19 testing, and there is no allegation that consumers cannot obtain COVID-19 testing from GSL if they so desire—GSL simply believes that is entitled to receive inflated reimbursement from Blue KC. In short, GSL is attempting to "substitute allegations of injury to [itself] for allegations of injury to competition," which it cannot do. *Brantley v. NBC Universal, Inc.*, 675 F.3d 1192, 1200 (9th Cir. 2012).

GSL also lacks antitrust standing because, as the Eighth Circuit has held repeatedly, "standing is generally limited to actual market participants, that is, *competitors or consumers*." *S.D. Collectibles, Inc. v. Plough, Inc.*, 952 F.2d 211, 213 (8th Cir. 1991) (emphasis added). Here, GSL alleges that the market being restrained or monopolized is the "Commercial Insurance Market for COVID-19 Testing." PACC, ¶¶ 291, 296, 302, 308. GSL is neither a consumer nor a competitor in this alleged market.

Instead, GSL may provide testing services to Blue KC's members, which Blue KC then (to the extent the claims are covered and otherwise payable) reimburses. PACC, ¶ 177. At best, GSL is one of many suppliers available to Blue KC members.

The Eighth Circuit has made clear that "[t]raditionally, suppliers of competitors in the relevant market have been denied standing because any alleged injury is considered derivative of the harm sustained by the competitor. . .. Suppliers are allowed standing only if they were directly involved in the market." *Kansas City Indus.*, 880 F.2d at 47. GSL is not directly involved in the alleged "Commercial Insurance Market for COVID-19 Testing." GSL only touches this alleged market to the extent insureds and plan enrollees seek its services. Thus, even if GSL had properly alleged that Blue KC had restrained or obtained a monopoly in the supposed "Commercial Insurance Market for COVID-19 Testing," the directly injured parties would be purchasers of insurance plans or excluded insurers. Any injury to GSL would be derivative of these direct injuries and therefore insufficient to establish antitrust standing. *See Norris v. Hearst Trust*, 500 F.3d 454, 466-68 (5th Cir. 2007).

B. EACH PROPOSED ANTITRUST CLAIM FAILS BECAUSE GSL DOES NOT PLEAD A PROPER RELEVANT MARKET OR THAT BLUE KC HAS MARKET POWER IN THAT MARKET

The proposed amended counterclaims should also be denied as futile because they would be subject to dismissal on the pleadings for lack of (1) a proper relevant market, or (2) that Blue KC has market power in that market. For each of the proposed antitrust claims, GSL "has the burden of alleging a relevant market" under the applicable analysis.[7] *Little Rock Cardiology Clinic PA v. Baptist*

[7] GSL's proposed Section 1 claim (Count X) is subject to rule of reason analysis, which requires GSL to allege and ultimately prove a substantial anticompetitive effect that harms consumers in the relevant market. *Ohio v. Am. Express Co.*, 138 S. Ct. 2274, 2284 (2018). GSL's proposed Section 2 claims (Counts XI-XIII) are subject to functionally the same analysis, which begins with the plaintiff alleging an anticompetitive effect harming consumers in the relevant market. *United States v. Microsoft*, 253 F.3d 34, 58-59 (D.C. Cir. 2001).

Health, 591 F.3d 591, 596 (8th Cir. 2009). "A relevant market consists of both a product market and a geographic market." *Id.* GSL does not adequately plead either of these markets.

A properly defined product market "should include products that have reasonable interchangeability for the purpose for which they are produced." *Id.* The relevant market allegedly being restrained and monopolized is the "Commercial Insurance Market for COVID-19 Testing." PACC ¶¶ 291, 296, 302. The fatal problem for GSL is that "Commercial Insurance for COVID-19 Testing" is not a product or service that anyone purchases or sells: individuals and firms purchase and sell commercial health insurance, not commercial health insurance specifically for COVID-19 testing. Several federal appellate courts, including the Eighth Circuit, have rejected similarly unsupportable product markets at the pleading stage. *Little Rock Cardiology*, 591 F.3d at 596-98 (affirming dismissal of antitrust claims while rejecting relevant product market of cardiology services paid for by commercial insurers).[8]

The alleged geographic market fares no better. "Properly defined, a geographic market is a geographic area 'in which the seller operates and to which . . . purchaser[s] can practicably turn for supplies.'" *Id.* at 598. GSL claims that the relevant geographic market is "the state of Missouri, the counties in which Blue KC has exclusive service area for its Blue mark, or localities within Missouri, or localities crossing into neighboring states." PACC ¶ 133. This geographic market, apart from being incoherent and hopelessly vague, is a transparent attempt to "gerrymander the relevant market," *Little Rock Cardiology*, 591 F.3d at 599, and therefore fails as a matter of law.

[8] *See also Tanaka v. Univ. of S. Cal.*, 252 F.3d 1059, 1063-64 (9th Cir. 2001) (affirming grant of motion to dismiss for alleged relevant product market of "UCLA women's soccer program"); *Queen City Pizza, Inc. v. Domino's Pizza, Inc.*, 124 F.3d 430, 436 (3d Cir. 1997) ("Where the plaintiff fails to define its proposed relevant market with reference to the rule of reasonable interchangeability and cross-elasticity of demand … the relevant market is legally insufficient and a motion to dismiss may be granted.").

Finally, GSL's Section 2 monopoly claims (Counts XI-XIII) fail for the additional reason that the proposed amended counterclaims do not allege that Blue KC has a "dominant share" of any relevant market. *Process Controls*, 753 F. Supp. 2d at 926. "[C]ourts generally require a market share of between 70% and 80%" for Section 2 monopoly claims. *Colorado Interstate Gas Co. v. Nat'l Gas Pipeline Co. of Am.*, 885 F.2d 694 n.18 (10th Cir. 1989).[9] While GSL's disjointed geographic market makes determining the relevant share difficult, it alleges that Blue KC's share of insured lives across PPO, HMO, Affordable Care Act exchange, and point-of-service products is 46% in the Kansas City area and 60% in the St. Joseph area.

As an initial matter, these alleged market shares are legally irrelevant because they do not purport to represent Blue KC's market share in the supposed "Commercial Insurance Market for COVID-19 Testing." In any event, these conclusory market share allegations cannot save GSL's Section 2 monopolization claims because they are well below the 70% market share required for such claims. *See, e.g.*, *Endsley v. City of Chicago*, 230 F.3d 276, 282 (7th Cir. 2000) (affirming grant of motion to dismiss and noting that "to survive a motion to dismiss, plaintiffs still must set forth facts sufficient to create an inference that defendant had enough market power to create a monopoly"); *FTC v. Facebook, Inc.*, 2021 WL 2643627, at *12 (D.D.C. June 28, 2021) (granting motion to dismiss because the allegation that Facebook had a market share "in excess of 60%" was too conclusory to allege market power).

CONCLUSION

GSL's motion for leave to file its First Amended Counterclaims should be denied.

[9] *See also Kolon Indus. Inc. v. E.I. DuPont de Nemours & Co.*, 748 F.3d 160, 174 (4th Cir. 2014) ("Although there is no fixed percentage market share that conclusively resolves whether monopoly power exists, the Supreme Court has never found a party with less than 75% market share to have monopoly power.").

Respectfully submitted,

CAPES, SOKOL, GOODMAN & SARACHAN, P.C.

By: */s/ Aaron E. Schwartz*
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David C. Hollander, #73250
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(314) 721-7701 (Telephone)
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schwartz@capessokol.com

Attorney for Blue Cross and Blue Shield of Kansas City

CERTIFICATE OF SERVICE

The undersigned hereby certifies that a true and accurate copy of the foregoing was served via on all parties of record by operation of the Court's electronic case filing and management system this 1st day of February 2022:

/s/ Aaron E. Schwartz

NEBRASKA

Good Life. Great Mission.

DEPT. OF HEALTH AND HUMAN SERVICES

Pete Ricketts, Governor

Sent via email to LNielsen@gslabsne.com & jjohnson@gslabsne.com
Confirmation of successful transmission constitutes proof of receipt

December 2, 2021

Lindsey E Nielsen, PhD
GS Labs LLC
17650 Wright Street Ste 5
Omaha, NE 68130

CLIA # 28D2183799

RE: ALLEGATION OF COMPLIANCE CREDIBLE AND EVIDENCE OF CORRECTION ACCEPTABLE

Dear Director/Owner(s):

In order for a laboratory to perform testing under the Clinical Laboratory Improvement Amendments of 1988 (CLIA), Public Law 100-578, it must comply with all CLIA requirements. These requirements are found in section 353 of the Public Health Service Act (42U.S.C. § 263a) and 42 Code of Federal Regulations, Part 493 (42 C.F.R. § 493). Laboratories are required to be in compliance with the applicable regulations. Compliance with these regulations is a condition of certification for the CLIA program.

By letter dated October 5, 2021, we notified you that based on the onsite compliant survey completed on October 1, 2021, your facility was not in compliance with Condition-level Clinical Laboratory Improvement Amendments of 1988 (CLIA) requirements. In our letter we requested that you submit a credible allegation of compliance and acceptance evidence of correction. We received your response on October 20, 2021, and have determined that your allegation of compliance is credible and evidence of correction is acceptable.

On November 19, 2021 we conducted an onsite revisit. **A review of submitted documentation and onsite revisit verified that your facility had achieved compliance with the deficiencies cited for the October 1, 2021 complaint survey. The attached CMS-2567 shows your facility to be in compliance at this time**.

We encourage your laboratory to maintain compliance with all CLIA requirements. It is the responsibility of the laboratory and its director to ensure that the laboratory is at all times following all CLIA requirements, to identify any problems in the laboratory and take corrective action specific to the problems, and to institute appropriate quality assessment measures to ensure that the deficient practices do not recur.

If it is discovered that the alleged corrective action was not implemented or that compliance was not maintained, the Nebraska Department of Health and Human Services, Division of Public Health,

Licensure Unit, will refer the case to the Branch Location Office of the Centers for Medicare & Medicaid Services (CMS) for appropriate action, and recommend that sanctions be taken against your laboratory's CLIA certificate.

If you have any questions regarding this survey, please contact this office by e-mail at DHHS.AcuteCareFacilities@nebraska.gov.

Sincerely,

Jean Ellis, RN BSN - Program Manager
DHHS Public Health - Licensure Unit - Office of Acute Care Facilities
PO Box 94986, Lincoln, NE 68509-4986
Email: jean.ellis@nebraska.gov

JE/le/smm

Enc: CMS-2567

From: Cohlmia, Charles L
Sent: Tuesday, December 29, 2020 1:22 PM
To: CLIA@health.mo.gov
Subject: Concerns - GS Labs

Good afternoon. This is Charles Cohlmia with the Jackson County Health Department.

Earlier this morning, I received a phone call from an individual who said she was a former employee of GS labs and had left due to serious concerns with the facility. I took notes while I was on the phone with her and, per instruction, I am forwarding the notes to this email address.

The woman on the phone (who permitted me to provide her name and phone number), mentioned numerous concerns regarding the operation of GS labs. She wanted to file a formal complaint.

The main sections of the complaint can be divided as below:

- Individuals given someone else's laboratory report
  - She reported that individuals would access the portal with their lab results only to have someone else's results entered into their record
- Individuals told the wrong laboratory result
  - Individuals being told they were negative when they were positive
- People not receiving any results due to failed reporting to the client
  - The laboratory would receive the results from the specimen, but would not tell the individuals that they had tested positive
- Problems with bio-waste management
  - Medical waste stacking up in bags in a room and not being dealt with properly
- Facilities under investigation (in KS) still doing testing
  - She had mentioned that a facility in KS was under investigation by the state and ordered to stop, but was still conducting testing. I'm not sure as to what the investigation means or if there is truth to it, but it was a concern of hers.
- Printing out false results for clients to get on airplanes
  - She had reported that individuals needed something to say they didn't have COVID-19 and the lab was printing out sheets that someone didn't have COVID-19 when their specimen had not returned.

mentioned that, should anyone need any additional information, she would be available to answer more questions.

Thank you.

Charles Cohlmia, MPH
Communicable Disease Prevention and Public Health Preparedness Division Manager
Jackson County Health Department
313 S. Liberty Street, Independence, Missouri 64050
Desk: (816) 404-9881 | Fax: (816) 404-9885 | Charles.Cohlmia@tmcmed.org
www.jacohd.org

From: Cohlmia, Charles L
Sent: Friday, January 29, 2021 1:08 PM
To: CLIA@health.mo.gov
Cc: Koob, Chase M; Treat, Taylor K; Kresl, Laura E; Peterson, Ashley N
Subject: RE: Concerns - GS Labs

Good afternoon.

I wanted to follow up on this. We have received additional reports of issues with this facility.

My epi staff member informed me that we had a record for a positive in our jurisdiction. The individual was called when he informed my staff that GS labs had told him he was negative and his wife (who was tested at the same time) was positive.

We called GS labs to confirm and they reported that BOTH were positive.

- What we had on record:
  - Husband: Positive
  - Wife: Not on Record
- What the husband thought:
  - Husband: Negative
  - Wife: Positive
- What GS labs reported when we called:
  - Husband: Positive
  - Wife: Positive

This raises additional concerns about this entity providing incorrect information to not only clients, but the state of Missouri as well. In the sense of surveillance and control of infectious disease, this situation makes it much more difficult to control the spread of COVID-19.

Please let me know any information regarding CLIA's efforts to correct these issues with GS labs and any additional information you need regarding this.

Charles Cohlmia, MPH
Communicable Disease Prevention and Public Health Preparedness Division Manager
Jackson County Health Department
313 S. Liberty Street, Independence, Missouri 64050
Desk: (816) 404-9881 | Fax: (816) 404-9885 | Charles.Cohlmia@tmcmed.org
www.jacohd.org

From: Cohlmia, Charles L
Sent: Tuesday, December 29, 2020 1:22 PM
To: 'CLIA@health.mo.gov' <CLIA@health.mo.gov>
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February 17, 2021

VIA E-MAIL (CRC@ATG.WA.GOV)

Anthony Ogle
Consumer Services Coordinator
Washington State Attorney General's Office
Consumer Protection Division
800 Fifth Avenue, Ste. 2000
Seattle, WA 98104

Re: Response to Complaint filed by Denise O'Brien–File No. 585880

Dear Mr. Ogle:

We write on behalf of GS Labs, LLC ("GS Labs") with respect to the complaint filed by Denise O'Brien ("Ms. O'Brien") on December 22, 2020. We received notice that your Office recently concluded its informal investigation and closed the file on Ms. O'Brien's complaint. Notwithstanding, considering the gravity of Ms. O'Brien's false allegations, we wish to provide your Office with a substantive response that sets the record straight regarding GS Labs' business practices.

I. Background

A. GS Labs formed as the COVID-19 pandemic began sweeping across the nation

GS Labs was formed in January 2020, with the aim of providing various clinical testing services from a moderate complexity lab, based in Omaha, Nebraska. Within days, the first confirmed case of COVID-19 in the United States was confirmed, and before long the pandemic had swept across the nation. By March, most of the country was locked down, and millions of Americans were out of work.

B. GS Labs shifted its business model in response to the public health emergency

In the months that followed, as businesses closed and scientists around the world scrambled to understand COVID-19, GS Labs responded to the public health emergency by investing in groundbreaking COVID-19 testing technology, and shifted its entire business model by launching nineteen COVID-19 testing sites across the nation. Unlike most facilities that offer COVID-19 testing (e.g., hospitals, clinics), GS Labs had to develop the infrastructure for delivering its testing services from the ground up, which required an enormous investment.

GS Labs provides consumers with three COVID-19[1] testing sites in Washington, which are located in Lynnwood, Bellevue, and Federal Way. Although there are many COVID-19 testing facilities throughout Washington, none can match the unparalleled level of service that GS Labs provides:

- State-of-the-art COVID-19 testing technology.
- Testing services administered by Registered Nurses.
- Testing services available day and night, seven days a week.
- Consumers receive COVID-19 tests from the safety of their vehicles.
- Consumers can receive COVID-19 tests within an hour of scheduling their appointment.

C. GS Labs provides three types of COVID-19 tests that complement one another

GS Labs provides three different types of COVID-19 tests: (1) a "Rapid Antigen" ("Antigen") test; (2) a "Polymerase Chain Reaction" ("PCR") test; and (3) a "Rapid Antibody" ("Antibody") test. Each test has a unique set of inherent tradeoffs, so the three tests are complimentary and often performed in conjunction with one another.

The Antigen test requires a nasal swab, and detects protein fragments that are specific to COVID-19—if found, these protein fragments indicate that the patient is currently infected with COVID-19. Results can take as little as 20 minutes, depending on the volume of tests being processed. These results are relatively quick, but the tradeoff is that the protein fragments can take many days to develop, so a patient infected with COVID-19 may nevertheless test negative if the Antigen test is performed within a week (or more) after exposure.

The PCR test requires a nasal or oral swab, and detects genetic material that is specific to COVID-19—if found, this genetic material indicates that the patient is currently infected with COVID-19. Results can take between 2 and 5 days, or longer depending on the volume of tests being processed. These results are relatively slow, but the tradeoff is that the genetic material is produced relatively quickly, so the PCR test is less prone to "false negatives" than the Antigen test and can more reliably indicate whether a patient is currently infected with COVID-19.

The Antibody test requires a blood sample (via finger prick), and detects antibodies that often develop in someone after they have been infected with COVID-19. Results can take as little as 20

[1] Technically, the tests are able to detect SARS-CoV-2, which is the virus that causes COVID-19. For the sake of simplicity, this technical distinction is disregarded.

minutes, depending on the volume of tests being processed. Unlike the Antigen test and PCR test, the Antibody test does not indicate that the patient is currently infected with COVID-19. Indeed, the extent to which antibodies can protect a person from becoming re-infected with COVID-19 remains unclear, but the Antibody test *can* confirm that the patient has been infected with COVID-19 at some point in the past.

II. Ms. O'Brien's Complaint

On December 20, 2020, Ms. O'Brien received all three COVID-19 tests at GS Labs' testing site located in Federal Way, Washington. Two days later, Ms. O'Brien filed a complaint with your Office. At bottom, Ms. O'Brien's complaint alleges that: (1) GS Labs performed certain COVID-19 tests without her consent; (2) GS Labs is "price gouging" consumers with its COVID-19 tests; and (3) GS Labs' website is misleading and deceptive. Each allegation is false and will be addressed in turn.

A. Ms. O'Brien expressly authorized and consented to all three COVID-19 tests

Ms. O'Brien alleges that she was "deceptively given" the PCR test and Antibody test because she "was never asked if [she] wanted" those tests and it "was not made clear" that she "would get those." However, Ms. O'Brien's allegation belies the fact that she expressly authorized GS Labs to perform all three COVID-19 tests when she scheduled her appointment, and then reaffirmed her express consent to have all three tests performed once she arrived at GS Labs' testing site.

Ms. O'Brien scheduled her COVID-19 testing appointment through GS Labs' website, which required her to acknowledge and sign a "GS Labs COVID-19 Rapid *Antigen*, Rapid IgM/IgG *Antibody* and *PCR* Test Consent & Release Form" (the "Consent Form"). *See* Ex. A (Ms. O'Brien's signed Consent Form) (emphasis added). Ms. O'Brien's Consent Form expressly authorized GS Labs to perform all three COVID-19 tests on behalf of Ms. O'Brien, as evinced by the following language:

- "I voluntary consent and authorize GS Labs to conduct collection, testing, and analysis for the purposes of the CareStart COVID-19 *Antigen* test."
- "I voluntarily consent and authorize GS Labs to conduct collection, testing, and analysis for the purposes of performing a COVID-19 *PCR* test … In the event of a negative rapid antigen test result, I authorize GS Labs to conduct a confirmatory *PCR* test if I choose to provide a *PCR* specimen at the point of care."
- "I have reviewed the Frequently Asked Questions sheet regarding the Assure COVID-19 IgG/IgM Rapid Test Device/SARS-CoV-2 *antibody* test. I authorize GS Labs to draw my blood to complete this test."

Ex. A, p. 1 (emphasis added). Therefore, by acknowledging and signing the Consent Form, Ms. O'Brien expressly authorized GS Labs to perform the Antigen test, PCR test, and Antibody test.

Moreover, by acknowledging and signing the Consent Form, Ms. O'Brien affirmed that she "read the test descriptions, risks, and associated Frequently Asked Questions for the Rapid Antibody Test, Rapid Antigen Test and the PCR Test" (the FAQ's Page). *See* Ex. A, p. 3. The FAQ's Page explains all three COVID-19 tests, the differences between them, and how each test is administered, among other things. *See* Ex. D.

Additionally, once Ms. O'Brien arrived at the GS Labs testing site, a Registered Nurse reiterated verbatim—from a script—the privacy and consent disclosures, and explained all three COVID-19 tests and how each test is administered, to ensure that Ms. O'Brien was able to make an informed decision regarding which test(s) she wished to have performed. Indeed, GS Labs maintains very strict policies regarding informed consent, so all patients are provided with ample and redundant disclosures.

By this time, Ms. O'Brien had expressly authorized GS Labs to perform all three COVID-19 tests, was well-informed regarding the tests and how each test is administered, and was well-aware that each test required its own sample, and that only the Antibody test required a blood sample. After acknowledging this information in written form, and having it reiterated in person just a moment prior, Ms. O'Brien provided the Registered Nurse with three samples: two swabs and one blood sample. In sum, there is simply no reasonable basis for Ms. O'Brien to allege that she was "deceptively given" COVID-19 tests.

B. GS Labs is not "price gouging" consumers with its COVID-19 testing services

Ms. O'Brien claims that GS Labs is "price gouging" consumers by "charging absolutely exorbitant prices" for its COVID-19 testing services, and then quotes the "cash prices" that are listed on GS Labs' website. Ms. O'Brien is mistaken, because GS Labs has *never* charged a consumer for the "cash price" of a COVID-19 test, even if they have no health insurance. Moreover, consumers with health insurance, like Ms. O'Brien, pay *nothing* for their COVID-19 tests, even where insurance ultimately covers none of the costs. Ms. O'Brien submitted her health insurance information when she scheduled her testing appointment, so she was charged *nothing* for the COVID-19 tests that she received.

1. No "price gouging"; consumers are not charged the "cash price"

First, it is important to note that the "cash prices" listed on GS Labs' website generally are charged only to insurance companies, and not consumers. And while Ms. O'Brien may have been confused by these "cash prices," GS Labs is statutorily required to post that information on its website. Indeed, the CARES Act § 3202(b)(1) requires that "each provider of a diagnostic test for COVID 19 shall make public the *cash price* for such test on a public internet website of such provider." (emphasis added). Again, these "cash prices" apply to insurance companies only, though they do reflect GS Labs' actual costs to develop and deliver its COVID-19 testing services, as explained *infra* § II.B.2.

GS Labs is an out-of-network provider, so the CARES Act § 3202(a)(2) further requires that insurance companies "reimburse [GS Labs] in an amount that equals the cash price for such service as listed by [GS Labs] on a public internet website, or such plan or issuer may negotiate a rate with [GS Labs] for less than such cash price." To date, no insurance company has contacted GS Labs to negotiate a lesser rate than the "cash price."

2. No "price gouging" because "cash prices" reflect GS Labs' actual costs

Second, the "cash prices" that are charged insurance companies reflect GS Labs' costs for the business to develop and deliver its COVID-19 testing services. As explained *supra* § I.B., unlike most facilities that offer COVID-19 tests (e.g., hospitals, clinics), GS Labs was built from the ground up *during* the pandemic, and without the luxury of relying on an already-established infrastructure. GS Labs had to invest an enormous amount of capital to develop quickly its capacity to deliver COVID-19 testing services. Likewise, GS Labs is unable to displace developmental costs across different industries or services because GS Labs *only* provides COVID-19 testing services.

In addition to the enormous amount of capital that GS Labs invested in infrastructure this past year, which necessarily increases GS Labs' costs and consequently its prices, GS Labs provides testing services that are unmatched by any other testing facility in Washington. As noted *supra* § I.B., GS Labs employs Registered Nurses to administer COVID-19 tests, and GS Labs' testing services are available day and night, seven days a week. GS Labs provides consumers with unparalleled access to exceptional COVID-19 testing services, and making those services available increases GS Labs' costs, which in turn lead to increased prices.

3. No colorable "price gouging" claim can be brought

Washington has no "price gouging" statute, but many states do, and such statutes identify "price gouging" as a "gross disparity" between the price that a business charges for a product pre-emergency compared to during the emergency, so long as "the disparity is not substantially attributable to increased prices charged by the [product] suppliers or increased costs due to [the] emergency." *See, e.g.*, 9 Vt. Stat. Ann. § 2461d(c) (2005). There is no reasonable basis to suggest that GS Labs has been "price gouging." GS Labs was formed *during* the COVID-19 pandemic, so it never had any "pre-emergency" prices that can be compared. Moreover, the "cash prices" reflect the actual pro rata costs of GS Labs' testing services, and GS Labs has *never* charged a consumer for the "cash price" of a COVID-19 test.

Although "Washington does not have a specific statute addressing price gouging," "[p]rice gouging during an emergency violates the Consumer Protection Act's prohibition on unfair business practices." *AG Ferguson Launches "See It, Snap It, Send It" Campaign Encouraging Washingtonians to Report Price Gouging*, News, Washington State Office of the Attorney General, https://www.atg.wa.gov/news/news-releases/ag-ferguson-launches-see-it-snap-it-send-it-campaign-encouraging-washingtonians (last visited Feb. 13, 2021). But, here, there is no reasonable basis to suggest that GS Labs has violated the CPA, either.

To establish a prima facie claim of "unfair business practices" under the CPA, a plaintiff must establish, among other things, that she was "injured" by the defendant's unfair or deceptive act or practice. *Hangman Ridge Training Stables v. Safeco Title Ins. Co.*, 105 Wn.2d 778, 784–85, 719 P.2d 531 (1986). Personal "injuries" (e.g., mental distress, inconvenience) are not actionable under the CPA, so the plaintiff must establish that she suffered an economic "injury" to her business or property. *Panag v. Farmers Ins. Co. of Wash.*, 166 Wn.2d 27, 57, 204 P.3d 885 (2009) (citation omitted). Ms. O'Brien suffered no "injury" under the CPA because she paid *nothing* for the COVID-19 tests that GS Labs performed for her and no one is seeking that she pay anything.

C. GS Labs' website is neither misleading nor deceptive

As explained *supra* § II.B.1, the CARES Act requires GS Labs to "make public the cash price for [its COVID-19 tests] on a public internet website," § 3202(b)(1), and such "cash prices" are charged to insurance companies that must either "reimburse [GS Labs] in an amount that equals the cash price" or "negotiate a rate with [GS Labs] for less than such cash price." § 3202(a)(2). In full compliance with the CARES Act, GS Labs has published on its website—just one click from the homepage—the "cash prices" for COVID-19 tests that are charged to insurance companies.

Ms. O'Brien alleges that GS Labs' "website is very misleading, stating testing will be billed thru [sic] insurance," and further alleges that consumers "must go very deep into their website to find hidden that they are charging absolutely exorbitant prices." Setting aside the fact that the "cash prices" are neither "exorbitant" nor charged to consumers, there is nothing "misleading" about GS Labs' website. On the contrary, GS Labs' website is simple, informative, and very transparent.

GS Labs' website provides consumers with a user-friendly process for learning about, scheduling, and ultimately receiving COVID-19 tests. Attached hereto as Exhibits B–D are screenshots of GS Labs' website as it appeared when Ms. O'Brien used it to schedule her testing appointment in late December 2020.

On the homepage of GS Labs' website, there is a tab near the top labelled "Test Information." *See* Ex. B. Clicking on this "Test Information" tab reveals the "COVID-19 Pricing Transparency" page (the "Pricing Transparency Page"), and the FAQs Page—this is the same FAQs Page that consumers *must read* before acknowledging and signing the Consent Form. *See* Ex. A, p. 3. The Pricing Transparency Page lists the "cash price" for GS Labs' COVID-19 tests, as required by the CARES Act § 3202(b)(1). *See* Ex. C. The FAQs Page provides, among other things, the following disclosures under the heading "COVID-19 Rapid Test Cost":

> Submit your insurance info online before your appointment **and pay $0**. After your COVID-19 test(s), you may receive an Explanation of Benefits letter (EOB) from your insurance company—this does NOT mean you owe a balance to GS Labs for your COVID-19 test(s). **Your insurance company's payment will be treated as payment in full by GS Labs**, based on current regulations under the CARES Act and FFCRA. **You are not responsible for paying any outstanding balance**. If you provided us with insurance

> information when you registered for your appointment, **you won't pay anything** out-of-pocket.

Ex. D (underlining and Caps emphasis in original; bold added). Unquestionably, there is nothing "misleading" about this: the FAQs Page clearly explains that consumers with health insurance will owe *nothing* for GS Labs' COVID-19 testing services, regardless of whether insurance covers all or only some of the costs. Moreover, consumers do not have to "go very deep" into GS Labs' website to find this information, nor is this information "hidden" by any stretch of the imagination—the Pricing Transparency Page and the FAQs Page are one click away from the homepage.

D. Final thoughts

Ultimately, Ms. O'Brien concludes her complaint by proposing that she pay for the Antigen test at a "discount" price of "$114.00." This statement further suggests that Ms. O'Brien did not read the Consent Form before signing it, did not read the FAQs Page as required by the Consent Form, did not read any of the numerous disclosures on GS Labs' website, and did not listen to the Registered Nurse who explained everything to her when she arrived at the testing site. *See generally Del Rosario v. Del Rosario*, 152 Wn.2d 375, 385, 97 P.3d 11 (2004) ("Washington adheres to the general contract principle that parties have a duty to read the contracts they sign.") (citing *Nat'l Bank of Wash. v. Equity Investors*, 81 Wn.2d 886, 912, 506 P.2d 20 (1973)); *cf. Beard v. PayPal, Inc.*, No. CIV.A. 09-1339-JO, 2010 WL 654390, at *2 (D. Or. Feb. 19, 2010) (enforcing online "clickwrap agreement" where plaintiffs had access to the entire User Agreement on defendant's website and checked box indicating they had read and agreed to it.) (citation omitted). To the extent there was any misunderstanding, it obviously resulted in a windfall to Ms. O'Brien.

These unprecedented times have been challenging and stressful for everyone—to date, COVID-19 has taken the lives of over 500,000 Americans, and millions of Americans remain out of work. Indeed, these unprecedent times have called for unprecedented measures, and GS Labs answered that call by taking on the "Herculean task" of developing and delivering widespread COVID-19 testing services, which is necessary to prevent even more lives from being lost during the second and third waves of the COVID-19 infections.[2] Recognizing that the costs of developing and delivering COVID-19 testing services would be enormous—nation-wide testing would cost "at least $100 billion and upward of $500 billion over the long haul"[3]—GS Labs responded to the public health emergency by launching nineteen COVID-19 testing locations across twelve states. Notwithstanding these enormous costs, GS Labs has made every effort to ensure that its COVID-19 testing services are affordable. Indeed, consumers without insurance do not pay the "cash price" for COVID-19 tests, and consumers with insurance pay *nothing*, even if insurance companies refuse to cover the costs—which they often do.

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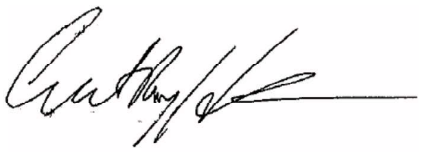
[2] *The US Economy Can't Reopen Without Widespread Coronavirus Testing. Getting There Will Take a Lot of Work and Money*, CNBC, https://www.cnbc.com/2020/04/16/coronavirus-testing-needs-to-be-widely-done-before-economy-reopens.html (last visited Feb. 17, 2021).
[3] *Id.*

Now more than ever, widespread access to COVID-19 testing is necessary and must be encouraged, especially considering the fact that "[c]ommunities of color are disproportionately burdened by the COVID-19 pandemic."[4] It is critical that GS Labs' finite resources remain focused on providing COVID-19 testing services for communities in need, so we greatly appreciate this opportunity to set the record straight regarding GS Labs' business practices.

If your Office has any remaining questions or concerns, please feel free to contact the undersigned counsel at the address noted above.

Sincerely,



Curt Roy Hineline

Attachments
cc: Client
Denise O'Brien

[4] *Why COVID-19 Testing is the Key to Getting Back to Normal*, National Institutes of Health, U.S. Department of Health & Human Services, https://www nia.nih.gov/news/why-covid-19-testing-key-getting-back-normal (last visited Feb. 17, 2021).

STATE OF KANSAS
OFFICE OF THE ATTORNEY GENERAL
ROOFING REGISTRATION UNIT

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December 22, 2020

GS Labs LLC - Lenexa
15729 College Blvd.,
Lenexa, KS 66219

Attn: Heather Allred
Brouse McDowell
300 Madison Avenue, Ste. 100
Toledo, OH 42604

Via email to: hallred@brouse.com

RE: Cease and Desist Notice

Dear Ms. Allred,

The Consumer Protection Division of Attorney General Derek Schmidt's office is charged with enforcing the Kansas Consumer Protection Act, K.S.A. 50-623 *et seq.* ("KCPA"). In order to provide consumer protection against fraudulent, deceptive, or unconscionable business practices, the KCPA empowers this Office to initiate formal proceedings to obtain necessary information regarding suspected violations. Those who violate the KCPA may be subject to civil penalties of up to $10,000 per violation.

We have learned that GS Labs LLC (hereinafter "you" or "your") is marketing or promoting COVID-19 tests at prices that grossly exceed the price at which similar tests or services are readily obtainable in the State and region around GS Labs testing facility. Specifically, on December 15, 2020, this office became aware that GS Labs LLC was advertising COVID-19 testing at cash prices as high as $999 for PCR testing, as high as $699 for rapid antigen testing, and $599 for rapid antibody testing. According to an August evaluation of hospital cash prices for COVID-19 testing in the Journal for General Internal Medicine,[1] the median cash price ranged from $57 to $124, with the highest cash price at $525 for a PCR test. Setting the price in a consumer transaction to grossly

[1] Roy Xiao and Vinay K. Rathi, *Price Transparency for COVID-19 Testing Among Top US Hosptials*, 2020 J. GEN. INTERN MED. 1, Https://www.ncbi.nlm.nih.gov/pmc/articles/PMC7500717/.

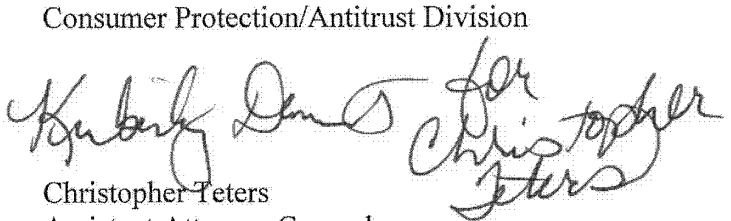
exceed the price at which similar property or services are or were readily obtainable in similar transactions, pursuant to and profiteering from a disaster are unconscionable acts and practices, pursuant to K.S.A. 50-627(b)(2) and K.S.A 50-6,106(b)(1)(B) respectively, and violations of the KCPA.

Additionally, this office believes that GS Labs is misleading consumers about the out-of-pocket expenses for testing in your Kansas facility. According to the GS Labs website, consumers will pay "$0 out-of-pocket." However, our office has learned that GS Labs may be charging some consumers $49 as an administrative fee. Charging this fee despite your advertising would be a deceptive act or practice in violation of K.S.A. 50-626(b)(2) and (3), also violations of the KCPA.

The Kansas Attorney General's Office demands that you immediately and permanently cease and desist from advertising, marketing or selling products and services in Kansas in any manner that charges unconscionable prices in relation to prices of testing readily available in the area and by failing to disclose all fees for associated products and services. Additionally, by no later than January 15, 2020, please provide a response to this notice describing the specific steps you have taken to address the concerns identified in this notice. Include copies of any related documentation with your response. Finally, you are hereby directed to preserve all written and electronic materials related to your purchase, sale or advertisement of any products or services related to COVID-19 until further notice from this Office. This notice does not preclude legal action by this Office and failure to respond to this notice may result in legal action by this Office.

Feel free to contact Assistant Attorney General Christopher Teters if you have questions or wish to discuss the matter.

Sincerely,
OFFICE OF ATTORNEY GENERAL
DEREK SCHMIDT
Consumer Protection/Antitrust Division



Christopher Teters
Assistant Attorney General

CC:

GS Labs LLC - Headquarters
Attn: Aaron B. Johnson
1700 Farnam Street
Omaha, Nebraska 68102

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June 16, 2021

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COVID19CashPrice@cms.hhs.gov

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RE: GS Labs, LLC, COVID-19 Diagnostic Claims

Dear Ladies and Gentlemen,

I represent Blue Cross and Blue Shield of Kansas City ("***Blue KC***") with respect to the matters identified in this letter. I write to notify you of several provider misrepresentations, billing and record anomalies, and potentially fraudulent or abusive activities with respect to over $5 million in claims GS Labs, LLC ("***GSL***") submitted to Blue KC regarding COVID-19 diagnostic testing. Based on our investigation, Blue KC is of the opinion that these claims are the product of:

- Price gouging;
- Violations of the CARES Act's obligation to post an accurate "cash price" for COVID-19 diagnostic testing; and/or
- Other circumstances which make the testing in question medically unnecessary or otherwise suspicious.

We would welcome the opportunity to discuss this matter with you once you have had time to consider the facts in this correspondence. In the interim, if we can provide other information or data, please do not hesitate to contact me.

BLUE KC BACKGROUND

Blue KC is a Missouri not-for-profit corporation with its principal place of business in Kansas City, Missouri. It is an independent licensee of the Blue Cross Blue Shield Association. The Blue Cross Blue Shield Association is a national association of 35 independent, community-based and locally operated Blue Cross Blue Shield companies. Blue Cross Blue Shield companies provide health insurance to more than 110 million people in all 50 states, Washington, D.C., and Puerto Rico. Blue KC provides a full spectrum of health care plans and services to approximately one million members in the Greater Kansas City region and Northwest Missouri. It offers hospital service plans and medical service plans, on a prepaid basis, to individual subscribers, to subscriber groups, and to employers. Blue KC also administers the Federal Employee Program (FEP) for the Kansas City, Missouri area.

THE GSL CLAIMS

On or about March 2, 2021, Blue KC received correspondence from counsel for GSL notifying Blue KC that GSL would soon submit claims for certain COVID-19 diagnostic testing and describing GSL's position with respect to Section 3202 of the CARES Act. **Exhibit A, March 2, 2021 Correspondence**. In that correspondence GSL claimed that it had posted the following "cash prices" for certain COVID-19 diagnostic testing and, as a result, Blue KC was required to pay the posted price:

Test Type	Short Description	Billing Code (CPT)	GSL's Purported "Cash Price"	MAC Allowable Rates[1]
COVID-19 Rapid Antigen Test	Rapid Antigen test detects protein fragments specific to the Coronavirus.	87811	$380.00	$41.38
COVID-19 Rapid Antibody Test	Rapid Antibody test detects two different types of antibodies (IGM and IgG) that may develop in patients after exposure to COVID-19. This test requires a blood sample.	86328	$380.00	$45.23
COVID-19 PCR Test[2]	Also called a molecular test, this test detects genetic material of the virus using a lab technique called polymerase chain reaction. Many consider this test to be the most accurate diagnosing COVID-19.	87635	$385.00	$51.33
BIO-Fire PCR Test 2.1	Like the PCR Test, but it detects 22 target respiratory pathogens including COVID-19	0202U	$979.00	$416.78[3]
GenMark ePlex Respiratory Pathogen 2 Panel	Like the PCR Test, but it detects 21 target respiratory pathogens including COVID-19	0225U	$979.00	$416.78

Several weeks after Blue KC received the correspondence from GSL's counsel, Blue KC began to receive electronic claim submissions from GSL. The majority of those claims (over 95%) involve testing purportedly provided by GSL in Lenexa, Kansas and Lee's Summit, Missouri. As of today, Blue KC has received over $5 million in claims from GSL relating to over 7,500 unique members.

[1] Medicare Administrative Contractors (MACs) are responsible for developing allowable rates for the Medicare program for newly created procedure codes. GS labs did not include MAC allowable rates in its correspondence. We provide these established rates now for context.

[2] PCR testing is appropriately billed using code 87637 where the test attempts to detect several pathogens including COVID-19, influenza, and respiratory syncytial virus. This expanded testing is sometimes referred to as a "small panel test." The 21 and 22 target panels claimed by GSL are sometimes referred to as a "large panel test." The large panel testing attempts to detect up to 22 pathogens.

[3] The local MAC does not reimburse for the 0202U and 0225U codes. Other MACs set allowable reimbursement rates at $416.78.

Approximately $300,000 in claims relate to the Federal Employee Program or Medicare Advantage policies.

Broken down by type of diagnostic test, a large majority of the claims (over 90%) seek reimbursement for COVID-19 rapid antibody and COVID-19 rapid antigen tests. As is discussed in greater detail below, these two tests were nearly always billed together – that is to say, where one is claimed, the other is almost always claimed along with it. GSL has also submitted claims for a small number of single target Covid-19 PCR tests, large panel Bio-Fire tests, and large panel ePlex test.

MEDIA REPORTS AND CIVIL LITIGATION

Through our investigation, we identified a number of media reports involving GSL. These reports raise serious concern regarding GSL's practices. Select media reports regarding GSL and 88Med, a related entity, include the following:

- "I walked around with COVID for a week, because of late results" December 19, 2020;[4]
- "Kansas looks at whether Lenexa lab price gouged on Covid-19 tests" December 22, 2020;[5]
- "Lab's 3-month data delay leads to abnormally high daily Covid total in Allegheny County" April 14, 2021;[6]
- "Slow reporting from labs can hinder coronavirus response, create doubt" May 7, 2021 (stating, "The late reports potentially sow doubt in data used to gauge the severity of virus spread"); and,[7]
- "Citing confusing reports, 88Med not recommended by Douglas County Health Department for COVID testing" December 7, 2020[8]

We also identified civil litigation involving two individuals associated with GSL (Gabe Sullivan and Dr. Darin Jackson) pending in the United States District Court for the District of Nebraska. According to the Complaint, Sullivan was terminated from employment with LMMC, LLC in 2018 for "misconduct" that "exposed [the company] to potential liability." *See* 8:19-cv-00560-JFB-SMB. The

[4] https://www.kctv5.com/i-walked-around-with-covid-for-a-week-because-of-late-results-gs-labs-subcontractor/article_be3f0647-7948-5cd1-ba8e-fb5f75c432cd.html
[5] https://www.bizjournals.com/kansascity/news/2020/12/22/covid-19-test-price-gouging-inquiry-gs-labs.html
[6] https://triblive.com/local/westmoreland/labs-3-month-data-delay-leads-to-abnormally-high-daily-covid-total-in-allegheny-county
[7] https://triblive.com/local/westmoreland/slow-reporting-from-labs-can-hinder-response-to-coronavirus-outbreaks
[8] https://www.3newsnow.com/news/investigations/citing-confusing-reports-88med-not-recommended-by-douglas-county-health-department-for-covid-testing

complaint pleads Sullivan's misconduct resulted in an insurance overpayment of $1.9 million. Sullivan was alleged to have:

> [F]ailed to implement policies and procedures that ensured that [Sullivan's former employer] was in compliance with the contractual requirements and billing policies of insurance companies. In fact, Sullivan intentionally implemented procedures that he knew were not compliant with insurance company requirements. In an email shortly before his termination from [Sullivan's former employer], and as a contributing factor to his termination . . . . Sullivan wrote: "What we were doing wasn't wrong it just doesn't follow their personal guidelines. . . . We need to beat them at their own game and out smart them until they change the rules again."

Exhibit B, LMMC, LLC Complaint.

GSL CLAIM IRREGULARITIES

Blue KC has identified a number of concerns with respect to GSL's claims. These are outlined in summary fashion below:

1.) GSL's posted "cash prices" are grossly excessive and amount to price gouging.

GSL's claims for certain diagnostic tests are ***up to ten times higher than MAC allowable rates and other local clinics***. These claims may constitute price gouging or disaster profiteering under 15 CSR 60-8.030 and K.S.A. 50-6,106. The two tests types most frequently used by GSL, and for which GSL demands a $380 reimbursement, are available to labs for between $10 and $20 per test. *See e.g.* https://www.covidtests.shop/product/healgen-antibody-rapid-test/ ($9.00 per rapid antibody test); https://www.covidtests.shop/product/covid-19-antigen-rapid-test-kit/ ($11.80 per rapid antigen test).

Although other providers of COVID-19 diagnostic testing services may post a cash price above the prices allowed by local MACs, the prices that GSL claims to have posted far exceed reasonable rates. In fact, the Kansas City metropolitan area is well-served by many other providers offering the same or similar tests at substantially lower cash prices:

Test Type	GSL's "Cash Price"	MAC Allowable Rates	Walgreens [9]	CVS[10]	Performance Health KC[11]	Truman Med. Ctr.[12]	St. Luke's Convenient Care[13]
Rapid Antigen Test (87811)	$380.00	$41.38	No out of pocket cost	No out of pocket cost	$150	N.A.	N.A.
Rapid Antibody Test (86328)	$380.00	$45.23	N.A.	$38[14]	$45	N.A.	N.A.
PCR Test (87635)	$385.00	$51.33	$129 ($100 for laboratory services, $29 for clinic visit)	$139 ($100 for the laboratory services, $39 for clinic visit)	$170 ($85 for visit and sample collection, $85 for lab fee)	$35	$51.31
BIO-Fire PCR Test (0202U)	$979.00	$416.78	Not listed	Not listed	Not listed	Not listed	Not listed
ePlex PCR Test (0225U)	$979.00	$416.78	Not listed	Not listed	Not listed	Not listed	Not listed

Further, GSL charged members an "administrative fee" in addition to any amounts collected from insurers. As of December 12, 2020, GSL website showed, in addition to the cash price it collects, a $49.00 "Admin Fee" in addition to the fees identified above. We do not have clear evidence if this practice extended to the claims submitted to Blue KC or if, and when, this practice ended.

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[9] https://www.walgreens.com/findcare/covid19/testing#!
[10] https://www.cvs.com/minuteclinic/covid-19-testing/?cid=ps_questtest&gclid=Cj0KCQjw5PGFBhC2ARIsAIFIMNdOO4zobpmC5BFAGy0574lHFK66-6uJxuKIMuerK80Icxbb-dhGPeEaAtZKEALw_wcB&gclsrc=aw.ds
[11] https://performancehealthkc.com/covid19-testing
[12] https://www.mdsave.com/p/truman-medical-center-lakewood-lab-work-and-drug-testing/covid-19-test/d78bfac867de
[13] https://www.saintlukeskc.org/covid-19/testing
[14] https://www.cvs.com/content/antibody-testing?icid=coronavirus-lp-nav-antibody-testing

However, medical records reviewed by Blue KC state the following: "In order to set you up as a user in our system and give you access to same-day scheduling and same-day results, GS Labs is charging a $49 set up fee at participating locations. It is not a co-pay or coinsurance or a deductible."

In addition to the claims noted above, GSL also typically submits a $50 specimen collection claim using the "G2023" procedure code. The G2023 code is used for "specimen collection for severe acute respiratory syndrome coronavirus 2 (SARS-CoV-2) (Coronavirus disease [COVID-19]), any specimen source."

We do not believe GS Labs set these prices in good faith. Instead, these prices appear to be clear instances of price gouging and/or disaster profiteering.

2.) GSL's posted "cash price" is a sham.

GSL's scheme is, at its core, quite simple. By posting an illusory "cash price" that was never actually collected from individual cash-paying consumers, GSL attempted to exploit the CARES Act by coercing insurers to pay for diagnostic testing at artificially inflated rates.

The Families First Coronavirus Response Act Section 6001 requires insurers to provide coverage for certain COVID-19 diagnostic testing. The CARES Act Section 3202 discusses how the pricing for the mandatory coverage is to be set. Assuming there is no pre-existing established pricing agreement, the rate for diagnostic testing under the CARES Act is "an amount that equals the cash price for such service as listed by the provider on a public internet website" or a negotiated rate less than the cash price. *See* CARES Act § 3202(a). The CARES Act does not permit providers to post an arbitrarily inflated price as a "cash price" – instead, it requires providers to post an accurate "cash price." *See* CARES Act § 3202(b)(1)("each provider … shall make public the cash price for such test on a public internet website of such provider."). "Cash price means the charge that applies to an individual who pays cash (or cash equivalent) for a COVID–19 diagnostic test." 45 C.F.R. § 182.20 (effective January 1, 2021).

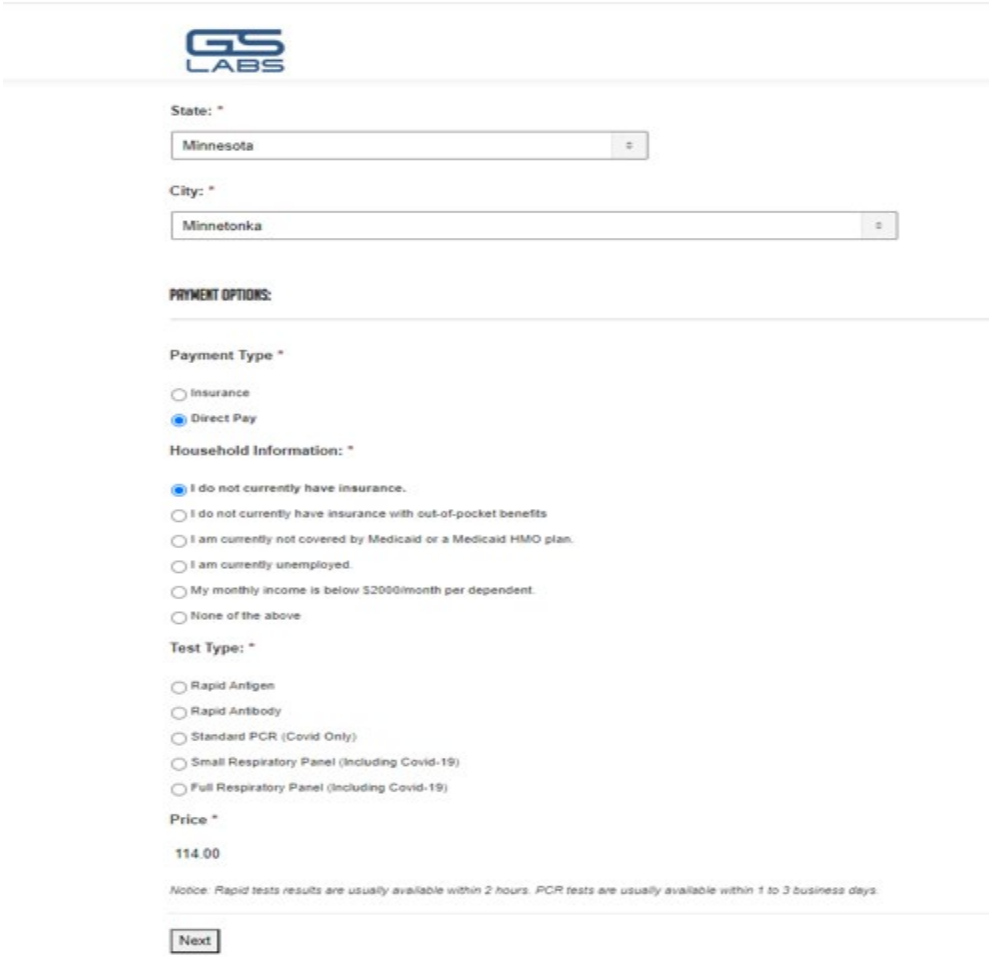
Despite clear language in the CARES Act requiring GSL to post an accurate "cash price," GSL did not post a "cash price" GSL instead posted an inflated and illusory price for COVID diagnostic testing set soley to gouge insurers and the insureds who ultimately bear the costs. Evidence supporting the fact that GSL's posted cash pricing is a sham includes the following:

- Blue KC attempted to schedule diagnostic testing at GSL locations in both Missouri and Kansas and attempted to pay cash. At both locations, Blue KC's investigators were denied the opportunity to schedule testing and pay cash. They were also told that GSL only accepts insured customers. A manager at the Lenexa, Kansas GSL location indicated GSL would not allow consumers to pay out-of-pocket as their "systems" were not set up for cash payments;

- A former employee of GSL informed us that GSL would only perform tests for insured patients. This employee worked at GSL's Beachwood, Ohio location;

- Standard GSL consent forms include the following language: GSL "***only accepts insurance patients*** who are seeking testing for diagnostic purposes" (emphasis added); and

- GSL may have recently changed its policy and may now accept cash patients under certain circumstances. GSL's website states it will accept cash patients but GSL apparently does not collect the "cash price" from uninsured patients. Instead, GSL purports to use a "Community Financial Assistance" program.[15] It appears that simply checking a radio button on GSL's website indicating that the prospective patient does not "currently have insurance" would entitle an uninsured patient to "up to a 70% discount." This "Community Financial Assistance" program seems designed to artificially maintain an excessive and illusory posted "cash price." A screen shot of GSL's website is included below demonstrating that the "cash price" it posted is not accurate:



The "cash prices" posted by GSL on its website does not reflect an accurate cash price. Instead, these prices simply reflect an attempt to exploit the public during the midst of a pandemic.

[15] https://gslabstesting.com/covid-rapid-testing-lees-summit/

3.) GSL medical records are insufficient and may indicate serious operational concerns.

Not only is the pricing of GSL's diagnostic testing suspicious, but Blue KC also has a number of concerns with respect to how GSL conducts its testing operations as a result of its failure to keep adequate records. The failure to keep adequate medical records may implicate KSA 65-2837 and other related statues and regulations.

For instance, Blue KC has been unable to verify whether antibody testing performed by GSL is conducted in a manner consistent with the test manufacturer's express instructions. A member interview confirmed that GSL is using the "fingerstick" method to obtain blood samples for antibody testing. This method of sample collection would be inappropriate for certain antibody tests like the Healgen rapid antibody test. According to Healgen's "Instructions for Use", its rapid antibody test "can be performed using either venous whole blood, serum or plasma" but not with a fingerstick sample. The manufacturer's instructions take the recommendation not to use fingerstick even further stating, "[t]his product is *only* used for testing of individual serum, plasma (Li+ heparin, K2EDTA and sodium citrate), and venous whole blood. Other specimen types have not been evaluated and *should not be used* with this assay."[16] Although Blue KC does not have dispositive evidence establishing which antibody test GSL administered, the language used in medical records provided is consistent with the Healgen test.

Similarly, GSL has submitted no medical records substantiating that test readings were performed accurately. For instance, the Assure Rapid Antibody test notes that the results should not be read "earlier than 15 minutes or after 30 minutes"[17] after the sample is added to the test device. However, the records GSL provided do not state when the testing was read. In short, the records provided to date are so deficient Blue KC cannot assess the validity of results.

As a result of GSL's inability to provide complete and comprehensive medical records for the claims it has made Blue KC has been unable to verify that GSL is complying with the Clinical Laboratory Improvement Amendments (CLIA). According to the CLIA, every entity is prohibited from requesting or "accept[ing] materials derived from the human body for laboratory examination or other procedure" unless there is an effective certificate issued to the laboratory. *See* 42 U.S.C.A. § 263a. While GSL has various CLIA waivers, the facilities in Missouri and Kansas have no CLIA certifications and are instead operating under CLIA Waivers. *See* https://www.cdc.gov/clia/LabSearch.html.

[16] https://www.fda.gov/media/138438/download
[17] https://www.fda.gov/media/139792/download

State	CLIA Number	Laboratory Type	Certificate Type	Laboratory Name & Address
Kansas	17D2203899	Independent	Waiver	GSL 15729 College Blvd, Lenexa, KS 66219 Tel: (855) 569-8872
Missouri	26D2205929	Independent	Waiver	GSL 1103 SW Oldham Pkwy, Lee's Summit, MO 64081 Tel: (402) 681-4030
Nebraska	28D2183799	Independent	Registration	GSL LLC 17650 Wright Street Ste 5, Omaha, NE 68130 Tel: (402) 650-7333
	28D2205089	Independent	Waiver	GSL 1804 N 168th, Omaha, NE 68118 Tel: (855) 569-8872

At least two (and potentially three) tests offered by GSL require a "moderate" CLIA laboratory certification. Nevertheless, GSL billed Blue KC for the following tests that it indicated were performed at its labs in Lenexa and Lee's Summit:[18]

- Healgen Rapid Antibody Test (EUA limits its use to laboratories certified under the CLIA to perform moderate or high complexity tests);[19]
- The BioFire Respiratory Panel 2.1 (EUA limits its use to laboratories certified under the CLIA to perform moderate or high complexity tests);[20]and
- The ePlex Respiratory Pathogen Panel 2 (EUA limits its use to laboratories certified under the CLIA to perform moderate or high complexity tests).[21]

[18] With respect to the two types of large panel tests it appears specimens were collected at the Missouri and Kansas locations, and then shipped to the Nebraska location for processing.
[19] As noted above, Blue KC is unable to conclusively determine which antibody test or tests were used.
[20] https://www.fda.gov/media/137583/download. We believe GSL submitted claims for the BioFire Respiratory Panel 2.1 under both 0202U and 87635.
[21] https://www.fda.gov/media/142905/download

4.) GSL provided medically unnecessary testing.

Based on our review of the medical records produced to date, it appears GSL administered unnecessary and inappropriate testing.

- GSL does not exercise patient-specific independent clinician judgment in ordering any of the diagnostic testing at issue. Instead, GSL apparently relies on standing, blanket orders. **Exhibits C and D;**

- GSL violated the terms of its own standing orders and provided testing even when not called for by its own orders. The standing orders state that the patient must be "concerned that he or she has been exposed to and/or infected with COVID-19" or present with symptoms consistent with COVID-19 disease. There were, however, instances where individuals denied both but were still tested;

- GSL's own standing orders do not authorize antibody testing. Based on the documents we have reviewed, it appears that no clinician affiliated with GSL ordered antibody testing despite the fact that the large majority of GSL patients received antibody testing. Based on the records reviewed to date, it appears GSL never determined antibody testing was appropriate for any Blue KC member;

- GSL routinely performs antigen and antibody tests together as a matter of course. GSL submitted thousands of claims including both antibody and antigen testing. We are aware of no legitimate medical reason to perform both rapid antigen and rapid antibody tests as a matter of course on each patient receiving either test;

- In some instances, PCR, antigen, and antibody testing were performed at the same time, on the same member, without an apparent medical basis to do so; and

- GSL submitted claims for large panel PCR testing using various procedure codes. Associated medical records identify no symptoms, suspected exposures, other test results, or justifications which would warrant using these expensive and extensive tests rather than simple antigen or targeted PCR tests. Records provided do not indicate whether the results of the test for infections other than COVID-19 were recorded or transmitted to the members.

5.) In some instances the medical coding does not match the tests performed.

- In some instances, medical records show a simple antigen or antibody test was performed but was billed as a large panel ePlex or Biofire test;

- In other instances, the records appear to show submissions that GSL performed a large panel PCR test but submitted a claim for single target PCR test (87635);

- GSL submitted duplicative amended claims which, ultimately added additional services to the same date of service. In the example described below involving a single member and a single claimed date of service, GSL first submitted a claim for rapid antibody and antigen tests, then

submitted a claim for a large panel PCR test, and finally submitted a claim for the rapid antigen and antibody tests, and the single target PCR test.

Claim ID	Procedure Code(s)	Billed Amount	Date Claim Received
21099F274000	87811, G2023, 86328	$810.00	4/8/2021
21102F5A6E00	87811, G2023, 86328	$810.00	4/12/2021
21104F0FFB00	87811, G2023, 86328	$810.00	4/13/2021
21112F73EC00	0202U	$979.00	4/22/2021
21133F30B400	87811, G2023, 86328, 87635	$1,195.00	5/12/2021

6.) One witness, a former employee, reported that GSL forges consent forms.

We were able to speak with a former employee of GSL who claimed signatures on patient intake forms were forged by managers or other lab personnel at the direction of a supervisor. For example, the former employee stated that if a family of four came in to be tested, a manager would sign the HIPAA release form for three children instead of the parent. This employee worked at a GSL Ohio facility between December 2020 and January 2021.

Please note that we have identified other issues of concern with respect to the claims submitted by GS Labs and this correspondence provides only a high level overview. We look forward to discussing these matters with you. In the interim, please advise if we can provide additional documents or data.

Sincerely,

Aaron E. Schwartz

AES/led
Enclosures
cc: Nicholas M. Koechig
Cody J. Raysinger
Sara B. Albert
David Stevens
Morgan Dodson
Ashlee Heath
Coni Fries
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March 2, 2021

VIA U.S. MAIL-AND EMAIL (MARK.NEWCOMER@BLUEKC.COM)

Mark Newcomer
Vice President & General Counsel
Blue Cross Blue Shield of Kansas City
2301 Main Street
8th Floor, NW
Kansas City, MO 64108

******NOTICE OF CARES ACT REQUIREMENTS******
PLEASE ENSURE REVIEW BY LEGAL COUNSEL
AS SOON AS POSSIBLE

Payment of Claims for COVID-19 Testing as an Out-of-Network Provider

Dear Mr. Newcomer:

We are writing on behalf of our client, GS Labs, LLC, which is an out-of-network provider that performs rapid antigen, rapid antibody and PCR COVID-19 testing.

GS Labs will soon be submitting $4,527,380.00 in claims for COVID-19 testing of your insurance company's enrollees. The dual purposes of this letter are:

1. To advise that GS Labs has been registered with your company as an out-of-network ("OON") provider through a medical claims clearinghouse, and will soon be submitting claims for COVID-19 test provided to your enrollees; and

2. To ensure that your company is fully aware of the requirements of section 3202 of the Cares Act, and electronically prepared to process and reimburse claims from GS Labs as an OON provider of COVID-19 tests, consistent with the requirements of the CARES Act.

Under Section 3202 of the CARES Act, if a payer does not have a negotiated rate with a provider furnishing COVID-19 testing (i.e., if the provider is out-of-network ("OON")), the payer "**shall reimburse the provider in an amount that equals the cash price for such service as listed by the provider on a public internet website**" or the payer may enter into negotiations with the provider for a contracted rate. For COVID-19 testing conducted by an

out-of-network provider, payment for testing **must be paid directly to the provider**, even if your normal process for out-of-network claims would be to reimburse plan members directly for such services. The plan members are to be charged no co-payment, and balance billing is prohibited.

Since GS Labs began performing COVID-19 tests, it has seen a broad spectrum of health insurer responses to its OON claims for these tests. At least initially, very few health insurers were in compliance with the CARES Act. Some insurers boldly posted notices on their websites advising of policies on payment for COVID-19 testing, which were clearly in violation of the CARES Act. Other health insurers paid identical claims for COVID-19 tests inconsistently, with random explanations provided on EOBs: some with unilateral discounts, others discounted for enrollee co-pays or calculated in relation to the Medicare fee schedule. We have interpreted these types of responses as arising from the health insurer's lack of familiarity with the CARES Act.

That brings us back to the second reason for this letter: Since GS Labs will shortly be submitting its claims for COVID-19 tests provided to your company's enrollees, we want to give you an opportunity to ensure that your claims system is ready to handle these claims properly and compliantly.

In their Frequently Asked Questions guidance, the Departments of Labor, Health and Human Services, and Treasury (the "Departments") issued a response on April 11, 2020, to a question directly on point to this scenario:

> **Q7. Are plans and issuers required to provide coverage for items and services that are furnished by providers that have not agreed to accept a negotiated rate as payment in full (i.e., out-of-network providers)?**
>
> **Yes.** Section 3202(a) of the CARES Act provides that a plan or issuer providing coverage of items and services described in section 6001(a) of the FFCRA shall reimburse the provider of the diagnostic testing as follows:
>
> 1. If the plan or issuer has a negotiated rate with such provider in effect before the public health emergency declared under section 319 of the PHS Act, such negotiated rate shall apply throughout the period of such declaration.
>
> 2. **If the plan or issuer does not have a negotiated rate** with such provider, the plan or issuer **shall reimburse the provider** in an amount that equals the **cash price** for such service as listed by the provider on a public internet website, or the plan or issuer **may negotiate a rate** with the provider for less than such cash price.

(Emphasis added). You should anticipate that the claims submitted to your company by GS Labs will set out the GS Labs Cash Price on the date of service identified in the claim. GS labs expects to be reimbursed in the full amount of the Cash Price, and to receive payment directly.

Please note that Blue Cross Blue Shield of Nebraska has confirmed its agreement to pay $385 per test for both antigen and antibody tests for COVID-19, and to pay GS Labs directly as an OON provider.

GS Labs also expects that your company will **not** show a balance owing by the enrollee in responsive EOBs. This was confirmed by a subsequent FAQ issued by the Departments on June 23, 2020. The Departments clarified that balance billing of plan members was prohibited. The FAQ regarding balance billing prohibitions provides:

> **Q9. Does section 3202 of the CARES Act protect participants, beneficiaries, and enrollees from balance billing for a COVID-19 diagnostic test?**
>
> The Departments read the requirement to provide coverage without cost sharing in section 6001 of the FFCRA, together with section 3202(a) of the CARES Act establishing a process for setting reimbursement rates, as **intended to protect participants, beneficiaries, and enrollees from being balance billed for an applicable COVID-19 test**. Section 3202(a) contemplates that a provider of COVID-19 testing will be reimbursed either a negotiated rate or an amount that equals the cash price for such service that is listed by the provider on a public website. In either case, the amount the plan or issuer reimburses the provider constitutes payment in full for the test, **with no cost sharing to the individual or other balance due** . . .

(Emphasis added).

As indicated in the FAQ guidance quoted above, your company must pay GS Labs at its publicly posted cash price rates, which are currently:

Test Name	Description	Billing Code (CPT)	Cash Price
COVID-19 RAPID ANTIGEN TEST	The COVID-19 rapid antigen test detects protein fragments specific to the Coronavirus.	87811	$380.00
COVID-19 RAPID ANTIBODY TEST	This test detects two different types of antibodies (IgM and IgG) that may develop in most patients after exposure to SARS-CoV-2.	86328	$380.00

COVID-19 PCR TEST	When supplies are available, we offer COVID-19 Polymerase Chain Reaction (PCR) test	87635	$385
COVID-19 BIO-FIRE PCR TEST	Test detects 22 target organisms including respiratory syndrome coronavirus 2 (COVID-19).	0202U	$979
COVID-19 EPLEX PCR Test	Test similar to Bio-Fire	0225U	$979

See www.gslabstesting.com/covid-19-pricing-transparency/. If you wish to negotiate a lower rate with GS Labs on future COVID-19 tests, you may contact me to open discussions regarding pricing and payment terms. The preceding is, however, without prejudice to GS Labs' right to obtain payment at its publicly posted rates if negotiations are unproductive.

We would appreciate your confirmation that your insurance company is prepared to meet the requirements for compliance with the CARES Act. If you determine that it will take a few days to make the necessary programming changes, we would be willing to hold the claims for a couple of days to ensure that they are processed properly the first time. For confirmation or negotiations, my contact information is above.

Sincerely,

Barbara E. Person
FOR THE FIRM

Cc: Evan White

IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF NEBRASKA

LMMC, LLC and LMMC HOLDINGS, LLC Plaintiffs, v. GABRIEL M. SULLIVAN, MONI SULLIVAN, DR. DARIN JACKSON, LIMITLESS OPTIONS, LLC, and INFINITE OPTIONS, LLC, Defendants.	Case No. 8:19-cv-560 **COMPLAINT** **JURY TRIAL DEMANDED**

Plaintiffs LMMC, LLC ("LMMC") and its related company LMMC Holdings, LLC ("LMMC Holdings") for their Complaint against Defendants Gabriel M. Sullivan ("Sullivan"), Moni Sullivan ("Ms. Sullivan"), Dr. Darin Jackson ("Dr. Jackson"), Limitless Options, LLC ("Limitless Options"), and Infinite Options, LLC ("Infinite") (collectively referred to herein as "Defendants"), state and allege as follows:

NATURE OF THE ACTION

1. This is an action for, among other things, Lanham, Act violations and breach of contract, resulting from Defendant Sullivan's breaches of his fiduciary and other duties to LMMC, Sullivan's violation of a Repurchase Agreement and Consulting Agreement, between LMMC and Sullivan, and several other tortious and improper acts committed by Defendants.

2. LMMC, LLC is an innovative health clinic specializing in male health. LMMC helps men of address medical conditions such as low testosterone, hormone deficiencies decreased libido, sleep issues, weight gain, lack of energy and focus, loss of muscle mass, joint

pain, erectile dysfunction, and more. LMMC Holdings, LLC is an affiliated company of LMMC, LLC.

3. LMMC's expertise in men's health is unparalleled. As part of its superior patient treatment and service, LMMC employs only medical providers who are dedicated to treating its patients' symptoms and hormone deficiencies with proven therapies.

4. LMMC prides itself of the quality of the medical care provided to its patients, and stands above its competitors as a result of its ethical and honorable standards of business practice.

5. In late 2015 and early 2016, Sullivan and Daniel P. Molloy ("Molloy") entered into discussions regarding owning and operating a men's health clinic. Sullivan had prior experience in men's health care and held himself out as an expert in the operations of a men's health clinic. Molloy was an entrepreneur and investor and had expertise in advertising and marketing.

6. In May 2016, Sullivan and Molloy formed LMMC, LLC, with Molloy owning 75% of the membership interests of the organization and Sullivan owning 25% of the membership interests.

7. Sullivan was also employed by LMMC from May 2016 until May 2018 as the its Director of Operations and was paid an annual salary and received benefits. As Director of Operations of LMMC, Sullivan managed the day to day operations of the medical clinic and directed and implemented the policies and procedures of LMMC.

8. From late 2017 and through 2018, LMMC discovered that Sullivan implemented policies and procedures that were harmful to LMMC and not in the best interests of the organization and, as a result, exposed LMMC to potential liability.

9. In May 2018, based on this misconduct, and dissatisfaction with Sullivan's performance, LMMC terminated Sullivan's employment. In addition, the parties entered into a Repurchase Agreement and Consulting Services Agreement ("Consulting Agreement") pursuant to which LMMC re-purchased Sullivan's interest in LMMC and Sullivan agreed, among other things, not to solicit LMMC's patients or employees as more specifically set forth in the Consulting Agreement, not to compete with LMMC, and not to disparage LMMC.

10. In August 2018, it became apparent to LMMC that among other things, Sullivan was not able to fulfill his role as consultant to LMMC in a "professional and competent manner" and LMMC terminated Sullivan's consulting relationship in accordance with the terms of the Consulting Agreement.

11. Rather than fulfill his obligations to LMMC, Defendant has now violated his Repurchase Agreement and Consulting Agreement by forming and working with Defendant Infinite Options Men's Clinic, soliciting LMMC's patients, and by disparaging LMMC in the marketplace.

12. Infinite, Limitless Options, Dr. Jackson, and Ms. Sullivan have further tortiously interfered with LMMC's contractual relationship with Sullivan by, among other things, working with Sullivan to set up a competing business with LMMC and soliciting LMMC's patients, contrary to the terms and obligations of the Repurchase Agreement and Consulting Agreement.

PARTIES

13. LMMC owns and operates a medical clinic specializing in men's health located in the Omaha, Nebraska metro area. LMMC Holdings is an affiliated company of LMMC.

14. Mr. Sullivan is an individual citizen currently working in Douglas County at 17650 Wright Street, Omaha, Nebraska 68130. He is an owner of Infinite, a company that competes with LMMC.

15. Ms. Sullivan is Mr. Sullivan's wife, an individual citizen who, upon information and belief, resides in Douglas County, Nebraska.

16. Dr. Darin Jackson, an individual, is an owner of Infinite, a company that competes with LMMC, and currently works at 17650 Wright Street, Omaha, Nebraska 68130.

17. Infinite is a men's health clinic currently operating at 17650 Wright Street, Omaha, Nebraska 68130.

18. Limitless Options, LLC is a Nebraska entity that competes with LMMC.

JURISDICTION AND VENUE

19. This Court has jurisdiction over Defendants in that this is a civil action arising under the Lanham Act, 15 U.S.C. § 1125. This Court has supplemental jurisdiction over the other claims in this complaint under 28 U.S.C. § 1367 because the claims form part of the same case or controversy.

20. Venue is proper in this Court under 28 U.S.C. § 1391(b)(2) because a substantial part of the events giving rise to the claims occurred in this judicial district and under 28 U.S.C. § 2201 and 28 U.S.C. §1400(a) because Defendants can be found in this judicial district.

STATEMENT OF FACTS

Business of LMMC and Sullivan's role at LMMC Prior to May 2018

21. As set forth above, LMMC provides specialized health care services focusing on men's health.

22. Through its physicians and other team members, LMMC offers unparalleled expertise in treating unique men's health issues.

23. From LMMC's inception until the end of 2017, Sullivan was responsible for the day to day operations of the clinic and directing and implementing the policies and procedures of

LMMC. This included responsibility for all aspects of the clinic, from human resources and hiring, through patient relations, fiscal management and billing practices.

24. As part of this leadership role, Sullivan developed and coordinated the guidelines and procedures that governed the medical billing and coding practices for LMMC. Specifically, and among other things, Sullivan was responsible for (i) setting rates and charges for services provided at the clinic; (ii) contracting LMMC as a participating provider with insurance companies; (iii) directing what claims for clinical services were submitted for payment to insurance companies and/or patients; (iv) ensuring that appropriate documentation was maintained in the patient's medical records for all billed services in accordance with insurance company contractual requirements; (v) hiring and managing the relationship with the outsourced medical billing company; and (iv) ensuring compliance with laws and regulations and insurance company requires regarding coding of services and submission of claims.

25. Sullivan further had substantial contact with LMMC's patients on a regular basis. He had access to their entire files, including their contact information and specific healthcare needs, as well as LMMC's proprietary and confidential policies and procedures.

26. Sullivan ceased to be an employee of LMMC as of May 2018, and his ownership interest in LMMC was repurchased by LMMC in May 2018 pursuant to the Repurchase Agreement.

Terms of the Repurchase Agreement and Consulting Services Agreement

27. Pursuant to the Repurchase Agreement, LMMC purchased Sullivan's interest in LMMC for $750,000 in or around May 2018.

28. As part of the repurchase of Sullivan's interest in LMMC, Sullivan and LMMC entered into a Consulting Agreement to effectuate the orderly transition of the operations of the clinic. Pursuant to the Consulting Agreement, Sullivan agreed to provide certain consulting

services to LMMC for a two year period of time. The Consulting Agreement was terminated by LMMC due to Sullivan's breaches in August 2018.

29. By signing the Consulting Agreement, Sullivan agreed that the "methodologies, processes, strategies, reports and documents of LMMC" were confidential and constitute valid trade secrets of LMMC. [Consulting Agreement at ¶ 6.1]. Sullivan agreed not to "disclose or divulge any of such Confidential Information he has acquired or may in the future acquire as a result of his prior affiliation, employment, and/or ownership interests in LMMC . . . ." [*Id.*]. Sullivan further agreed that he would not "utilize said Confidential Information in any respect, except as set forth in this Agreement or as required by applicable law, without the express written consent of LMMC." [*Id*].

30. Sullivan further agreed that he would not solicit any employees or LMMC or any client of LMMC during his engagement with LMMC and for a two-year period following the termination of the Consulting Agreement. [Consulting Agreement at ¶ 6.2]. The Consulting Agreement defines "Client of LMMC" to include clients or customers (i) for whom Sullivan may have been responsible for the relationship at the termination of Sullivan's Consulting Agreement with LMMC; (ii) with whom Sullivan had direct contact in the performance of his duties for LMMC within the twelve month period preceding the termination of the Agreement; and (iii) for whom Sullivan, directly or indirectly, performed services on behalf of LMMC within the twelve month period preceding termination of the Agreement. [*Id.*].

31. By signing the Consulting Agreement and selling his interest in LMMC, Sullivan also agreed to a Non-Competition clause in which he agreed as follows: "[d]uring Mr. Sullivan's engagement with LMMC and during the Restriction Period, Mr. Sullivan shall not, without the express written approval of LMMC, directly or indirectly, either for or on behalf of himself or

any third party, within the Omaha, Nebraska Metro area, the state of Nebraska, Iowa, Missouri, Kansas, Illinois and Minnesota either (i) compete with the business of LMMC, whether as an employee, employer, consultant, agent, principal, partner, shareholder, corporate officer, director, or through any other kind of ownership; or (ii) engage in or render any services to any business engaged in the business in which LMMC is involved, becomes involved or is reasonably considering becoming involved from the date of this [Consulting] Agreement until its termination. The Parties agree that Mr. Sullivan is under no such restrictions in Florida." [Consulting Agreement at ¶ 6.3].

32. Sullivan further agreed not to make any "disparaging, malicious, critical, false or otherwise detrimental comments to any person or entity concerning LMMC or any of its employees, contractors, members, managers, officers, shareholders, or affiliates; the products, services or programs provided or to be provided by LMMC; or the business affairs or the financial condition of LMMC." [Consulting Agreement at ¶ 6.4].

33. Moreover, in the Consulting Agreement, Sullivan agreed and represented that he would "have no right to sublicense, reproduce, grant access to, sell or otherwise use any LMMC Intellectual Property other than in connection with the operation of LMMC and the Clinic within the scope of this Agreement without the prior consent of LMMC. Mr. Sullivan shall have no ownership interest and no rights or interest in (other than a license to use the Intellectual Property in connection with this Agreement) the Intellectual Property." [Consulting Agreement at ¶ 3.2]

34. "Intellectual Property" is defined to include "procedures, manuals, methodologies, pricing formulae, negotiating strategies, and other similar items conceived, designed, developed, perfected, made, implemented, or used by LMMC in connection with Products and Services provided hereunder or in connection with pricing of Products and

Services, whether acquired prior to, on, or after the Commencement Date" [Consulting Agreement at ¶ 3.2].

Sullivan's Breaches of his Duties of LMMC

35. As an employee of LMMC, Sullivan owed a duty of loyalty to LMMC under Nebraska law.

36. As a member of LMMC, Sullivan owed fiduciary duties to LMMC to act at all times in the best interests of LMMC.

37. Following Sullivan's departure from LMMC, LMMC discovered that Sullivan breached his duties to LMMC as both an employee and a member of the company.

38. For example, Sullivan, who was responsible for patient services and billing as described more particularly above, failed to implement policies and procedures that ensured that LMMC was in compliance with the contractual requirements and billing policies of insurance companies. In fact, Sullivan intentionally implemented procedures that he knew were not compliant with insurance company requirements. In an email shortly before his termination from LMMC, and as a contributing factor to his termination from LMMC, Sullivan wrote: "What we were doing wasn't wrong it just doesn't follow their personal guidelines. . . . We need to beat them at their own game and out smart them until they change the rules again."

39. Sullivan further created hostile relationships with pharmaceutical drug representatives and other third party professionals on whom LMMC relies, resulting in certain vendors and companies refusing to do business with LMMC, causing harm to LMMC.

40. As a result of Sullivan's actions at LMMC relating to billing and other matters, for which Sullivan was solely responsible, in August 2018 an insurance company alleged that from January 1, 2016 to January 1, 2018, LMMC was in direct violation of its provider

participation agreement and its billing policies and procedures and, at as a result, LMMC was assessed a significant overpayment in excess of $1.9 million.

Sullivan's Breaches of the Repurchase Agreement and Consulting Agreement

41. In violation of the Repurchase Agreement and Consulting Agreement, Sullivan is now an owner of and working with Infinite, a direct competitor of LMMC's, performing similar services as he did for LMMC in direct competition with the business of LMMC and/or engaging in or rendering series to a business engaged in the business in which LMMC is involved. Dr. Jackson is a co-owner of Infinite.

42. Upon information and belief, Infinite opened in August 2018 to compete directly with LMMC.

43. Infinite defines its mission as virtually identical to LMMC's business: "Whether it's high blood pressure, low energy, erectile dysfunction, lack of focus, depression, weight gain, low libido or you are just looking for an annual check-up, Infinite Options Men's Clinic's board-certified physicians who are dedicated to treating your symptoms using proven methods that achieve unmistakable results! From Primary Care to Erectile Dysfunction and Testosterone replacement Therapy, Infinite Options Men's Clinic provides ALL of the health and wellness options you will ever need." https://lowtomaha.com/

44. As such, Infinite is engaged in business and renders services in the business in which LMMC is involved and competes with the business of LMMC.

45. Plaintiffs are now aware that Sullivan has been working, directly or indirectly, with Infinite since at least August 2018 and continues to work with Infinite in direct competition with the business or LMMC or otherwise engage in or render services to Infinite, in violation of the Consulting Agreement. Specifically, Sullivan sees patients at Infinite and provides assistance

to Infinite in connection with Infinite's business of providing specialized men's health services, explicitly relating to low testosterone.

46. Moreover, Sullivan, directly and indirectly, has been soliciting patients of LMMC with whom he had contact or was responsible while at LMMC to move their treatment away from LMMC and to Infinite. Upon information and belief, patients of LMMC have, in fact, sought treatment at Infinite as a result of Sullivan's efforts.

47. When talking with LMMC patients, Sullivan lures patients to Infinite by wrongfully using LMMC Confidential Information in violation of the terms of the Consulting Agreement. For example, Sullivan has utilized his knowledge of LMMC's pricing to solicit patients by telling them they will pay less for services at Infinite.

48. Sullivan, while the owner of and working for Infinite, has further been offering to fabricate medical records to ensure that the treatment qualifies for the medical policies of a certain insurance company in an attempt to attract clients of LMMC to transfer their business to Infinite.

49. Infinite, by accepting the services of Sullivan and by otherwise participating in Sullivan's breaches of the Consulting Agreement, has interfered with LMMC's contractual rights with Sullivan, as well as with LMMC's business relationships with its patients.

50. Ms. Sullivan has interfered with LMMC's rights and obligations under the Repurchase and Consulting Agreement by actively competing with LMMC and soliciting clients for the benefit of Infinite and Sullivan. For example, on September 19, 2019, Ms. Sullivan added a public Facebook post in which she advertised Infinite's services which directly compete with LMMC's services.

51. As a result of Defendants' actions, LMMC has lost clients and business, as well as new business prospects, in Nebraska and elsewhere to Defendants.

52. Defendants' competition with LMMC and siphoning of LMMC's clients in breach of the Consulting Agreement has continued up to the filing of this Complaint and shows no signs of abating.

Infinite's Improper Appropriation and Use of Trademarks, Service Marks and Trade Names

53. LMMC Holdings, LLC has used several trademarks comprising LIMITLESS in interstate commerce, including in connection with medical services, since at least as early as July 19, 2018.

54. In particular, LMMC Holdings, LLC has used the trademarks LIMITLESS, LIMITLESS MALE, LIMITLESS MALE MEDICAL, LIMITLESS MALE MEDICAL CLINIC, and corresponding logo design marks including the design marks pictured below (the "Limitless Marks"), and has garnered significant brand recognition and goodwill in the Limitless Marks in connection with various medical services and products.

55. LMMC Holdings, LLC owns Nebraska registered Trade Names "Limitless Male" and "Limitless Male Medical Clinic." The Trade Name Applications were filed August 22, 2018 and August 23, 2018, respectively. LMMC Holdings, LLC authorizes LMMC to use its Trademarks, Service Marks, and Trade Names in connection with its business.

56. On September 4, 2018, Sullivan filed a trademark application (U.S. Application Serial No. 88103872) with the United States Patent and Trademark Office ("USPTO") for the mark LIMITLESS OPTIONS MEN'S CLINIC on behalf of "Limitless options", the purported owner of the mark, in connection with "Medical treatment and supplies and drugs as well as some supplemental goods."

57. In the federal trademark application, Sullivan declared that no others have the right to use a mark resembling LIMITLESS OPTIONS MEN'S CLINIC so as to be likely to cause confusion or mistake, or to deceive. Sullivan also asserted use of LIMITLESS OPTIONS MEN'S CLINIC in U.S. commerce by Limitless options since at least as early as August 15, 2017 in connection with "Medical treatment and supplies and drugs as well as some supplemental goods."

58. An official USPTO Notice of Abandonment issued on July 23, 2019 with respect to the LIMITLESS OPTIONS MEN'S CLINIC application. The application was refused, dismissed, or invalidated by the USPTO and the application is no longer active.

59. On February 19, 2019, LMMC Holdings, LLC filed federal trademark applications to register LIMITLESS MALE, LIMITLESS MALE MEDICAL and LIMITLESS MALE MEDICAL CLINIC, each in connection with "Health assessment services; Health care services for treating common symptoms of low testosterone, including low libido, weight gain, lack of concentration, decreased muscle and strength, low energy and diminished sexual performance; Health care services, namely, diagnosis and treatment of symptoms of low testosterone; Health care services, namely, testosterone testing, testosterone replacement therapy, platelet-rich plasma therapy, erectile dysfunction treatments, and human growth hormone

replacement therapy; Medical services." Such trademark applications are pending at the USPTO.

60. The USPTO issued Office actions on May 1, 2019 indicating the applied-for LIMITLESS OPTIONS MEN'S CLINIC mark may create a likelihood of confusion with the LIMITLESS MALE MEDICAL CLINIC mark, the LIMITLESS MALE MEDICAL mark, and the LIMITLESS MALE mark.

61. LMMC has used, prominently displayed and significantly invested in advertising the Limitless Marks in connection with LMMC's medical services and products such that customers strongly associate LMMC products and services with the Limitless Marks. The Limitless Marks are distinctive in connection with LMMC's medical services and products and symbolize and represent considerable goodwill in the marketplace.

62. After LMMC's adoption and use of the Limitless Marks, and after the Limitless Marks had garnered considerable strength in the marketplace and had come to symbolize considerable goodwill, Sullivan, Infinite and Limitless Options appropriated some of the most significant and recognizable aspects of the Limitless Marks and adopted and attempted to register LIMITLESS OPTIONS MEN'S CLINIC and adopted and used LIMITLESS OPTIONS and derivatives of that mark including the logo design mark pictured below (the "Limitless Options Marks"), in bad faith, in connection with a variety of medical services and products including those that are identical to and directly overlap with the products and services provided by LMMC in connection with the Limitless Marks, to an identical demographic of customers.

63. Infinite and Limitless Options continue to advertise and offer services that compete with those of LMMC under the Limitless Options Marks, including on social media and elsewhere including https://menslimitlessoptions.com/.

64. Infinite and Limitless Options have infringed the Limitless Marks in interstate commerce by operating a men's health clinic in connection with the Limitless Options Marks and selling, advertising and rendering competitive medical services and products to an identical demographic of customers.

65. Infinite and Limitless Options adopted and have used the Limitless Options Marks in bad faith and with an intent to cause confusion, mistake and to deceive.

COUNT I
VIOLATION OF SECTION 43(a) OF THE LANHAM ACT, 15 U.S.C. § 1125(a)(1)(A)
(Infinite and Limitless Options)

66. LMMC hereby restates and realleges paragraphs 1-65 above as if set forth fully herein.

67. LMMC Holdings, LLC is the owner of the Limitless Marks, which have been prominently used and advertised in U.S. commerce in connection with LMMC's medical services, and is also the owner of trade name registrations for Limitless Male and Limitless Male Medical Center.

68. LMMC owns considerable common law rights in the Limitless Marks in connection with medical services by virtue of extensive use and advertising of the Limitless Marks to identify LMMC's medical services in interstate commerce and distinguish them from goods and services of others.

69. One of Infinite's owners is a former owner and employee of LMMC.

70. Infinite and Limitless Options are attempting to operate in the same industry as LMMC and LMMC Holdings, LLC and provide substantially similar services in the same

customer/patient market as LMMC, using similar manners of marketing as LMMC (e.g., website, social media).

71. Infinite and Limitless Options derived the Limitless Options Marks from the Limitless Marks and adopted and have used the Limitless Options Marks in bad faith in connection with services that are identical to those of LMMC, with an intent to deceive and cause customer mistake or confusion as to source, affiliation, origin, sponsorship or approval of the products and services of Infinite and Limitless Options, and those of Plaintiffs.

72. Infinite and Limitless Options prominently use the word "Limitless" in connection with marketing and promoting their businesses, including within the Limitless Options Marks, in a manner that is likely to cause confusion, mistake and deception as to affiliation, connection or association of Infinite or Limitless Options with LMMC and as to the origin, sponsorship or approval of Infinite's or Limitless Options' goods and services by LMMC.

73. Infinite's or Limitless Options' prominent use of "Limitless" and other elements in the Limitless Marks, including use of those elements in the Limitless Options Marks, in connection with Infinite's or Limitless Options' business is intended to, and likely to, cause consumer confusion as to LMMC's affiliation with Infinite or Limitless Options and sponsorship, endorsement or approval of Infinite-related or Limitless-Options-related services. Infinite's and Limitless Options' attempts to imply an affiliation between LMMC and Infinite and Limitless Options (which does not exist) for the purpose of marketing the services of Infinite and Limitless Options deceives customers by trading on LMMC's established name, trademarks, and goodwill in the men's health industry.

74. Such ongoing use of the Limitless Options Marks has been without permission of LMMC. Such ongoing use is not a descriptive use and is not necessary to describe the services of

Infinite or Limitless Options. The use of the Limitless Options Marks by Infinite or Limitless Options does not reflect a true and accurate relationship between Infinite or Limitless Options and LMMC (and its products and/or services).

75. Upon information and belief, such ongoing use of "Limitless" and other elements that overlap with those comprising the Limitless Marks by Infinite or Limitless Options, including in the Limitless Options Marks, has been with intention to deceive and confuse the relevant public, and has resulted in actual confusion, evidencing a likelihood of confusion.

76. As a result of the prominent use of "Limitless", and other elements of the Limitless Marks, in the Limitless Options Marks in connection with the services offered by Infinite and Limitless Options, Infinite and Limitless Options are in violation of Section 43(a) of the Lanham Act, 15 U.S.C. § 1125(a)(1)(A).

77. The actions of Infinite and Limitless Options are likely to damage LMMC.

78. The actions of Infinite and Limitless Options have caused and will continue to cause LMMC commercial and competitive injury and damage (including monetary damages) if they are not enjoined.

COUNT II
BREACH OF CONTRACT
(Against Sullivan)

79. LMMC realleges and incorporates herein by this reference Paragraphs 1 through 78 of this Complaint.

80. Sullivan signed a valid and binding Repurchase Agreement and Consulting Agreement that contained reasonable restrictions necessary to protect LMMC's legitimate interests of client relationships, goodwill, and loyalty.

81. These restrictions were not unduly harsh or oppressive Sullivan, and Sullivan acknowledged and agreed as such.

82. Sullivan has breached the Repurchase Agreement and Consulting Agreement by, among other things, directly and/or indirectly, for himself or a third party, competing with business of LMMC and engaging in and rendering services to a business engaged in the business in which LMMC is involved. Sullivan has also directly and/or indirectly solicited LMMC clients, diverted clients away from LMMC, and induced LMMC clients to cease doing business with LMMC and to engaged Sullivan and/or a third party for products and services offered by LMMC.

83. Sullivan has further improperly maintained and used LMMC's Confidential Information and Intellectual Property as described herein.

84. As a result of the foregoing, LMMC has suffered harm, and continues to suffer harm, in an amount to be determined at trial, through Sullivan's efforts to harm LMMC by working for and/or rendering services to a competing business through use of LMMC Confidential Information, Intellectual Property, and otherwise, and Sullivan's efforts to steal LMMC's clients and destroy its client goodwill, in violation of the agreements signed by Sullivan.

COUNT III
UNFAIR COMPETITION
(Against All Defendants)

85. LMMC realleges and incorporates herein by this reference Paragraphs 1 through 84 of this Complaint.

86. Sullivan provided services for LMMC for approximately 2.5 years, including most recently pursuant to the Consulting Agreement.

87. Sullivan worked directly with LMMC's clients including patient relations and accounts receivable to facilitate the health-related services to those clients.

88. Sullivan worked for several years as the "face" of LMMC promoting LMMC's business and developing its client goodwill.

89. Upon information and belief, Defendants are now unfairly competing with LMMC and exploiting LMMC's goodwill by contacting, soliciting, and accepting LMMC's clients in an effort to obtain business for themselves.

90. As a result of the foregoing, LMMC has suffered harm, and continues to suffer harm, in an amount to be determined at trial, through Defendants' efforts to steal LMMC's clients and to destroy its client loyalty and goodwill.

COUNT IV
TORTIOUS INTERFERENCE WITH LMMC'S RELATIONSHIPS OR EXPECTATIONS
(Against All Defendants)

91. LMMC realleges and incorporates herein by this reference Paragraphs 1 through 90 of this Complaint.

92. LMMC has valuable business relationships and expectancies with its clients in Nebraska, Iowa and throughout the United States, and it has a valid expectation that the client relationships will continue.

93. The Defendants had knowledge of the valid client relationships and expectancies among LMMC and its clients.

94. Defendants have made multiple direct and/or indirect contacts with LMMC's clients, and have accepted business from LMMC's clients, in an effort to interfere with LMMC's business relationships and/or expectancies with its customers in Nebraska and throughout the Midwest.

95. Defendants unjustifiably and intentionally interfered with LMMC's valuable business and client relationships and expectancies when they induced LMMC's clients to

terminate their client relationship with LMMC and accepted LMMC clients in breach of the Repurchase Agreement and Consulting Agreement, and otherwise engaged in the improper activities described above.

96. Defendants also unjustifiably and intentionally interfered with LMMC's business relationships and expectancies when Defendants induced LMMC clients, to leave their physician relationship with LMMC in order to improperly exploit LMMC's client goodwill.

97. As a result of the foregoing, LMMC has suffered harm, and continues to suffer harm, in an amount to be determined at trial, through Defendants' efforts to steal LMMC's valuable business and client relationships and expectancies.

COUNT V
TORTIOUS INTERFERENCE WITH LMMC'S CONTRACTUAL RELATIONSHIP
(Against All Defendants)

98. LMMC realleges and incorporates herein by this reference Paragraphs 1 through 97 of this Complaint.

99. LMMC has a valuable contractual relationship with Sullivan and it has a valid expectation that the contractual relationship will continue and that Sullivan would abide by his agreement to protect the Confidential Information of LMMC, as well as his non-competition and non-solicitation obligations.

100. Defendants had knowledge of the valid contractual relationship between LMMC and Sullivan.

101. Defendants induced or otherwise caused Sullivan not to perform his obligations under the Repurchase Agreement and Consulting Agreement by, among other things, encouraging Sullivan to compete with the business of LMMC and provide services to Infinite that are within the business of LMMC, as well as accepting LMMC clients solicited, directly and/or indirectly, by Sullivan. Infinite further has accepted confidential and proprietary

information of LMMC's provided by Sullivan, in violation of Sullivan's contractual obligations to LMMC.

102. As a result of the foregoing, LMMC has suffered harm, and continues to suffer harm, in an amount to be determined at trial, through Defendants' efforts to steal LMMC's valuable business and client relationships and expectancies.

COUNT VI
UNJUST ENRICHMENT
(Against All Defendants)
(In the Alternative)

103. LMMC realleges and incorporates herein by this reference Paragraphs 1 through 102 of this Complaint.

104. As an owner, employee, and consultant for LMMC, Sullivan was provided access to, among other things, LMMC's proprietary policies and procedures and LMMC's client and patient lists and information.

105. Defendants have solicited and accepted LMMC clients for the purpose of providing these clients with products and/or services of the type or character previously provided by LMMC, and have improperly used LMMC Confidential Information in Infinite competing business.

106. Defendants are receiving the benefits of the clients which transferred Infinite without paying compensation to LMMC and, as such, Defendants are being unjustly enriched.

107. Sullivan has further been unjustly enriched by his receipt of $750,000 for his interest in LMMC pursuant to the Repurchase Agreement. Sullivan has received the benefit of the $750,000 despite that fact that, subsequent to the repurchase, LMMC discovered that Sullivan had engaged in policies that caused harm to LMMC.

108. Justice and fairness dictate that Defendants should compensate LMMC for the clients that transferred and for clients that have been obtained by the improper use of LMMC's Confidential Information and should be required to reimburse LMMC for the portion of the $750,000 that was paid to him pursuant to the Repurchase Agreement that represents the inflated value of LMMC prior to LMMC discovered the improper actions of Sullivan.

109. As a result of Defendants' actions, LMMC has suffered and continues to suffer damages and harm in an amount to be determined at trial.

COUNT VII
BREACH OF DUTY OF LOYALTY AND FIDUCIARY DUTY
(Against Sullivan)

110. LMMC realleges and incorporates herein by this reference Paragraphs 1 through 109 of this Complaint.

111. Sullivan was an owner of LMMC, an employee of LMMC and a consultant to LMMC.

112. As a member of a closely-held LLC, Sullivan owed fiduciary duties to LMMC and its other members.

113. As an employee and consultant to LMMC, Sullivan owed a duty of loyalty to LMMC

114. Sullivan has breached his fiduciary duties and duty of loyalty by, among other things,

a. Failing to implement appropriate billing and other policies and procedures, resulting in a substantial pecuniary loss to LMMC and damaging its reputation and relations with insurance companies;

b. Competing with and providing services to Infinite who competes with the business of LMMC;

c. Soliciting LMMC clients with whom Sullivan had direct contact during the twelve (12) months prior to his departure and/or for whom Sullivan was responsible for the purpose of providing these clients with products and/or services of the type or character previously provided by LMMC;

d. Accepting LMMC clients with whom Defendants had personal contact during the twelve (12) months prior to his departure and/or for whom Sullivan was responsible for the purpose of providing these clients with products and/or services of the type or character previously provided by LMMC; and

e. Improperly maintaining and using LMMC's Confidential Information and Intellectual Property.

115. As a direct and proximate result of LMMC's breach of his duty of loyalty to LMMC, LMMC has suffered, and continues to suffer, damages in an amount to be determined at trial and Sullivan has to forfeit and repay all compensation he received while breaching his fiduciary duties.

COUNT VIII
VIOLATION OF THE NEBRASKA DECEPTIVE TRADE PRACTICES ACT, NEB. REV. STAT §§ 87-301 ET SEQ.

116. LMMC hereby restates and realleges paragraphs 1-115 above as if set forth fully herein.

117. LMMC Holdings, LLC is the owner of the Limitless Marks and trade name registrations Limitless Male and Limitless Male Medical, and has considerable valuable trademark rights in common law in the Limitless Marks.

118. Use of the Limitless Options Marks by Infinite or Limitless Options in connection with their services rendered is likely to cause, and has caused, confusion or misunderstanding of an affiliation with, and sponsorship by, LMMC.

119. The conduct of Infinite and Limitless Options is a deceptive trade practice as defined by, and in violation of, the Nebraska Deceptive Trade Practices Act, Neb. Rev. Stat. § 87-302.

120. Upon information and belief, there have been actual incidents of confusion as to the affiliation between Infinite or Limitless Options and LMMC.

121. The actions of Infinite and Limitless Options have caused and will continue to cause LMMC commercial and competitive injury and monetary damages if they are not enjoined.

COUNT IX
MISUSE OF TRAD NAME UNDER NEB. REV. STAT §§ 87-208 ET SEQ.
(Against Infinite and Limitless Options)

122. LMMC hereby restates and realleges paragraphs 1-121 above as if set forth fully herein.

123. Infinite and Limitless Options have, without LMMC's consent, used colorable imitations of LMMC's registered trade names in connection with the business of Infinite and Limitless Options in a manner likely to cause confusion, mistake or deception of purchasers.

124. Infinite and Limitless Options have applied colorable imitations of LMMC's registered trade names to their business through advertisements, signage and other media in a manner intended to cause confusion, mistake or deception of purchasers.

125. The conduct of Infinite and Limitless Options is misuse of a trade name as defined by, and in violation of, Neb. Rev. Stat. § 87-216.

126. The wrongful use and display of, and promotion and sale of goods and services in connection with, colorable imitations of LMMC's registered trade names by Infinite and Limitless Options have caused and will continue to cause LMMC injury and damage.

RELIEF REQUESTED

WHEREFORE, Plaintiffs pray for judgment against Defendants, as well as for the following relief:

(i) General damages in an amount to be proven at trial including, without limitation, the purchase price paid to Sullivan in connection with the purchase of his LMMC shares and the damages to LMMC arising from Sullivan's improper implementation of certain policies and procedures at LMMC;

(ii) Lost profits in an amount to be proven at trial;

(iii) Lost revenue and/or costs associated with the rebuilding of LMMC's client base;

(iv) Injunctive relief enjoining the Defendants from certain improper activities, including, without limitation, competing with LMMC, solicitations and/or acceptance of LMMC's clients, use of LMMC's Confidential Information and Intellectual Property, and/or the solicitation of LMMC's employees;

(v) Injunctive relief enjoining Defendants from improper use of Plaintiffs' trade names and other Intellectual Property;

(vi) An accounting of Defendants' ill-gotten gains;

(vii) Prejudgment and postjudgment interest;

(viii) Costs and attorneys' fees as permitted by law; and

(ix) Such other relief the Court deems just, equitable, or allowed by the pleadings.

Dated this 23rd day of December, 2019

LMMC, LLC and LMMC HOLDINGS, LLC,

Plaintiffs

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Standing Order for Performing COVID-19 PCR Testing on Adults and Children

Purpose: To prevent the spread of infectious diseases through identification of specific organisms leading to appropriate treatment and public health disease control actions and recommendations.

Policy: Under this standing order, nurses working for GS Labs and other healthcare professionals working for GS Labs as allowed by state law, may perform a Nasopharyngeal swab (NP), Oropharyngeal swab, Nasal swab or saliva collection on adults or children over the age of 12 months, who have been identified by GS Labs as in need of testing, for COVID-19 via the patient eligibility criteria listed below.

All staff performing this test will be trained in specimen collection and proper personal protective equipment specific to this test and be prepared to perform this procedure.

Patient Eligibility:
For the Provider to collect a specimen and for the patient to be eligible and have the testing considered medically necessary, the patient must meet the criteria listed below:

1. Individual who is concerned that he or she has been exposed to and/or infected with COVID-19.

2. And/or an individual with any of the following symptoms consistent with COVID-19:
   - Fever (100.4° Fahrenheit or higher), chills, or shaking chills
   - Cough (not due to other known cause, such as chronic cough)
   - Difficulty breathing, shortness of breath or wheezing
   - Sore throat
   - Headache
   - Muscle aches or body aches
   - Nausea, vomiting, or diarrhea
   - Fatigue
   - Nasal congestion or runny nose (not due to other known causes, such as allergies)
   - New loss of taste or smell

Procedure:

1. Verify that the individual has been identified as needing testing for COVID-19 based off the patient eligibility criteria listed above.

2. Review and be familiar with personal protective equipment (PPE) required for doing the specimen collection.

3. Review and be familiar with the procedure for performing a nasopharyngeal swab, oropharyngeal swab, anterior nasal swab or saliva collection.

4. Ensure proper handling, storage, and shipment of specimens.

5. Ensure all supplies including specimen test kits, PPE, storage, and shipment of specimens, and required forms for testing and documentation are available.

6. Although prior written consent from the individual will be obtained, inform everyone to be tested of the procedure and receive verbal agreement for testing. If individual to be tested is a minor, obtain verbal or written agreement from a parent or legal guardian.

7. GS Labs will use an algorithm and consider the patient's exposure history, symptoms and risk factors in categorizing the patients into Low-Risk, Intermediate-Risk and High-Risk groups. The risk groups listed below

will determine which PCR test is performed. The Low-Risk Group will receive the single pathogen COVID-19 test. The Intermediate-Risk Group will receive the small respiratory panel test including COVID-19, influenza and RSV. The High-Risk Group will receive the full respiratory panel that tests for multiple viral and bacterial respiratory pathogens including COVID-19.

High Risk Group Criteria: (full respiratory panel PCR test ordered)

- Patients over 65 years of age
- Patients 10 years of age and younger
- History of Chronic pulmonary disease (COPD, Emphysema, Asthma, Interstitial lung disease, etc)
- History of Chronic cardiovascular disease (Angina, Heart attack, Stroke, Arrythmia etc)
- History of diabetes
- BMI 30 or higher
- Patients that are immunocompromised
- History of autoimmune disease
- Patients that smoke
- Patients that are currently pregnant
- Difficulty breathing, shortness of breath, or wheezing
- Cough (not due to other known cause such as chronic cough)
- Nasal congestion or runny nose (not due to other known causes, such as allergies)
- Sore throat

Intermediate Risk Group Criteria: (small respiratory panel PCR test ordered)

- Fever (100.4 Fahrenheit or higher), chills, or shaking chills
- Muscle aches or body aches
- Headache
- Fatigue

Low Risk Group Criteria: (single pathogen COVID-19 PCR test)

- Exposure history and no symptoms
- Nausea, vomiting, diarrhea
- New loss of taste or smell
- Cash pay patient getting test for non-medical reasons (Travel purposes)

8. After the specimen is obtained and the COVID PCR test has been performed, GS Labs personnel will inform the individual of their results. In addition, GS Labs personnel will report the results to the health departments at both the county and state level.

This order is amended on an as needed basis as new medical information relating to the COVID-19 Pandemic and the United States, HHS Public Health Emergency becomes available to the medical community.

This order shall remain in effect until rescinded or until 12/31/2021.

Steven W. Powell, MD

12/20/2020
Date

Standing Order for Performing COVID-19 PCR Testing on Adults and Children

Purpose: To prevent the spread of infectious diseases through identification of specific organisms leading to appropriate treatment and public health disease control actions and recommendations.

Policy: Under this standing order, nurses working for GS Labs and other healthcare professionals working for GS Labs as allowed by state law, may perform a Nasopharyngeal swab (NP), Oropharyngeal swab, Nasal swab or saliva collection on adults or children over the age of 12 months, who have been identified by GS Labs as in need of testing, for COVID-19 via the patient eligibility criteria listed below.

All staff performing this test will be trained in specimen collection and proper personal protective equipment specific to this test and be prepared to perform this procedure.

Patient Eligibility:
For the Provider to collect a specimen and for the patient to be eligible and have the testing considered medically necessary, the patient must meet the criteria listed below:

1. Individual who is concerned that he or she has been exposed to and/or infected with COVID-19.

2. And/or an individual with any of the following symptoms consistent with COVID-19:
   - Fever (100.4° Fahrenheit or higher), chills, or shaking chills
   - Cough (not due to other known cause, such as chronic cough)
   - Difficulty breathing, shortness of breath or wheezing
   - Sore throat
   - Headache
   - Muscle aches or body aches
   - Nausea, vomiting, or diarrhea
   - Fatigue
   - Nasal congestion or runny nose (not due to other known causes, such as allergies)
   - New loss of taste or smell

Procedure:
1. Verify that the individual has been identified as needing testing for COVID-19 based off the patient eligibility criteria listed above.

2. Review and be familiar with personal protective equipment (PPE) required for doing the specimen collection.

3. Review and be familiar with the procedure for performing a nasopharyngeal swab, oropharyngeal swab, anterior nasal swab or saliva collection.

4. Ensure proper handling, storage, and shipment of specimens.

5. Ensure all supplies including specimen test kits, PPE, storage, and shipment of specimens, and required forms for testing and documentation are available.

6. Although prior written consent from the individual will be obtained, inform everyone to be tested of the procedure and receive verbal agreement for testing. If individual to be tested is a minor, obtain verbal or written agreement from a parent or legal guardian.

7. After the specimen is obtained and the COVID PCR test has been performed, GS Labs personnel will inform the individual of their results. In addition, GS Labs personnel will report the results to the health departments at both the county and state level.

This order is amended on an as needed basis as new medical information relating to the COVID-19 Pandemic and the United States, HHS Public Health Emergency becomes available to the medical community.

This order shall remain in effect until rescinded or until 12/31/2021.

Darin Jackson, MD

11/15/20
Date

Kyle Palmer
Dec 21, 2020 - Coronavirus

Lenexa lab flagged for potential price gouging of COVID-19 tests — what consumers need to know

The Shawnee Mission Post is making much of its local coverage of the coronavirus pandemic accessible to non-subscribers. (If you value having a news source covering the situation in our community, we hope you'll consider subscribing here).

A company that runs a testing lab in Lenexa says it "will fully cooperate" with the state of Kansas after being flagged by regulators for potential price gouging.

In a letter issued last week, the Kansas Insurance Department said it had been made aware of GS Labs, 15720 College Blvd., pricing a single diagnostic COVID-19 PCR test at $1,000.

The price listed on GS Labs' website has since dropped to $699 per test, which state regulators say is still well above the national average of roughly $185.

These are prices that providers seek to get reimbursed by health insurers and are not typically charged to patients directly. Still, regulators say consumers could ultimately bear the burden if such exorbitant charges are allowed to go unchecked.

"If these astronomical costs charged by unscrupulous providers are borne by the health plans and insurers without recompense, consumers will ultimately pay more for their health care as health insurance costs will rise," Justin McFarland, general counsel for the Kansas Insurance Department, wrote in last week's letter.

Lenexa lab 'new to this'

GS Labs is a health care testing startup based in Omaha that began operations in January and now has 15 locations in 10 different states, including the Lenexa lab, which opened Nov. 28, according to company spokesman Kirk Thompson.

Johnson Countians may see billboards advertising GS Labs' services, including one on southbound Interstate 35 near the Rainbow Blvd. exit.

Thompson said GS Labs offers daily testing from 8 a.m. to 8 p.m., with patients able to book same-day appointments and get results within 30 minutes.

"We are here to help the community," he said. "There is overwhelming demand for COVID-19 testing right now, and we take great pride in our services."

But he also said GS Labs is "new to this and feeling this out as we go."

He said they discovered there were issues with their listed prices at the Lenexa lab when the Kansas Insurance Department sent its letter last week. Thompson said now GS Labs "will fully cooperate" with the state to work out its pricing.

"Our ears are open," he said. "The last thing we want is to be perceived as price gougers."

Thompson said individual customers are not billed at their Lenexa lab. He also said they have held back submitting any reimbursement claims to insurers while they work out their pricing with state regulators.

What consumers need to know

Like many health care costs, disputes over COVID-19 testing prices play out beyond the view of most patients. For Johnson Countians wanting to get tested, here are a few important things to note:

- **There are plenty of free options:** Community-based testing sites operated by the state of Kansas, Johnson County and some private pharmacies, including Walgreens, CVS and Walmart, do not charge for COVID-19 tests. If you get tested at another provider, you may get billed depending on your insurance plan. There have been reports in other states of consumers who got tested at emergency rooms or out-of-network providers getting eye-popping bills later.
- **Most insurance plans should cover testing:** Congress passed a law in March that appears to clear most people from facing co-pays or deductible costs related to COVID-19 testing. But there is a lot of confusion about the federal rules, and there have been reports of individuals getting billed later by insurers or providers. The Kansas Insurance Department is taking complaints from customers who think they have been unfairly charged for a COVID-19 test.
- **Check to see if you need to make an appointment:** To get a drive-thru test at the Johnson County Department of Health and Environment's offices in Olathe, an appointment is required. The state of Kansas also urges people to book an

appointment at its community testing sites at GoGetTested.com but also accepts drive- or walk-ups. Other sites, like a new daily one at the Roeland Park Community Center, do not require appointments, but patients are still encouraged to make one here.

- **You do not need a doctor's order:** Diagnostic testing done at community-based sites, as well as at many private health care providers, like AdventHealth Shawnee Mission, is typically open to anyone, regardless of whether they're showing symptoms or not.

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February 17, 2021

VIA E-MAIL (CRC@ATG.WA.GOV)

Anthony Ogle
Consumer Services Coordinator
Washington State Attorney General's Office
Consumer Protection Division
800 Fifth Avenue, Ste. 2000
Seattle, WA 98104

Re: Response to Complaint filed by Denise O'Brien–File No. 585880

Dear Mr. Ogle:

We write on behalf of GS Labs, LLC ("GS Labs") with respect to the complaint filed by Denise O'Brien ("Ms. O'Brien") on December 22, 2020. We received notice that your Office recently concluded its informal investigation and closed the file on Ms. O'Brien's complaint. Notwithstanding, considering the gravity of Ms. O'Brien's false allegations, we wish to provide your Office with a substantive response that sets the record straight regarding GS Labs' business practices.

I. Background

A. GS Labs formed as the COVID-19 pandemic began sweeping across the nation

GS Labs was formed in January 2020, with the aim of providing various clinical testing services from a moderate complexity lab, based in Omaha, Nebraska. Within days, the first confirmed case of COVID-19 in the United States was confirmed, and before long the pandemic had swept across the nation. By March, most of the country was locked down, and millions of Americans were out of work.

B. GS Labs shifted its business model in response to the public health emergency

In the months that followed, as businesses closed and scientists around the world scrambled to understand COVID-19, GS Labs responded to the public health emergency by investing in groundbreaking COVID-19 testing technology, and shifted its entire business model by launching nineteen COVID-19 testing sites across the nation. Unlike most facilities that offer COVID-19 testing (e.g., hospitals, clinics), GS Labs had to develop the infrastructure for delivering its testing services from the ground up, which required an enormous investment.

GS Labs provides consumers with three COVID-19[1] testing sites in Washington, which are located in Lynnwood, Bellevue, and Federal Way. Although there are many COVID-19 testing facilities throughout Washington, none can match the unparalleled level of service that GS Labs provides:

- State-of-the-art COVID-19 testing technology.
- Testing services administered by Registered Nurses.
- Testing services available day and night, seven days a week.
- Consumers receive COVID-19 tests from the safety of their vehicles.
- Consumers can receive COVID-19 tests within an hour of scheduling their appointment.

C. GS Labs provides three types of COVID-19 tests that complement one another

GS Labs provides three different types of COVID-19 tests: (1) a "Rapid Antigen" ("Antigen") test; (2) a "Polymerase Chain Reaction" ("PCR") test; and (3) a "Rapid Antibody" ("Antibody") test. Each test has a unique set of inherent tradeoffs, so the three tests are complimentary and often performed in conjunction with one another.

The Antigen test requires a nasal swab, and detects protein fragments that are specific to COVID-19—if found, these protein fragments indicate that the patient is currently infected with COVID-19. Results can take as little as 20 minutes, depending on the volume of tests being processed. These results are relatively quick, but the tradeoff is that the protein fragments can take many days to develop, so a patient infected with COVID-19 may nevertheless test negative if the Antigen test is performed within a week (or more) after exposure.

The PCR test requires a nasal or oral swab, and detects genetic material that is specific to COVID-19—if found, this genetic material indicates that the patient is currently infected with COVID-19. Results can take between 2 and 5 days, or longer depending on the volume of tests being processed. These results are relatively slow, but the tradeoff is that the genetic material is produced relatively quickly, so the PCR test is less prone to "false negatives" than the Antigen test and can more reliably indicate whether a patient is currently infected with COVID-19.

The Antibody test requires a blood sample (via finger prick), and detects antibodies that often develop in someone after they have been infected with COVID-19. Results can take as little as 20

[1] Technically, the tests are able to detect SARS-CoV-2, which is the virus that causes COVID-19. For the sake of simplicity, this technical distinction is disregarded.

minutes, depending on the volume of tests being processed. Unlike the Antigen test and PCR test, the Antibody test does not indicate that the patient is currently infected with COVID-19. Indeed, the extent to which antibodies can protect a person from becoming re-infected with COVID-19 remains unclear, but the Antibody test *can* confirm that the patient has been infected with COVID-19 at some point in the past.

II. Ms. O'Brien's Complaint

On December 20, 2020, Ms. O'Brien received all three COVID-19 tests at GS Labs' testing site located in Federal Way, Washington. Two days later, Ms. O'Brien filed a complaint with your Office. At bottom, Ms. O'Brien's complaint alleges that: (1) GS Labs performed certain COVID-19 tests without her consent; (2) GS Labs is "price gouging" consumers with its COVID-19 tests; and (3) GS Labs' website is misleading and deceptive. Each allegation is false and will be addressed in turn.

A. Ms. O'Brien expressly authorized and consented to all three COVID-19 tests

Ms. O'Brien alleges that she was "deceptively given" the PCR test and Antibody test because she "was never asked if [she] wanted" those tests and it "was not made clear" that she "would get those." However, Ms. O'Brien's allegation belies the fact that she expressly authorized GS Labs to perform all three COVID-19 tests when she scheduled her appointment, and then reaffirmed her express consent to have all three tests performed once she arrived at GS Labs' testing site.

Ms. O'Brien scheduled her COVID-19 testing appointment through GS Labs' website, which required her to acknowledge and sign a "GS Labs COVID-19 Rapid *Antigen*, Rapid IgM/IgG *Antibody* and *PCR* Test Consent & Release Form" (the "Consent Form"). *See* Ex. A (Ms. O'Brien's signed Consent Form) (emphasis added). Ms. O'Brien's Consent Form expressly authorized GS Labs to perform all three COVID-19 tests on behalf of Ms. O'Brien, as evinced by the following language:

- "I voluntary consent and authorize GS Labs to conduct collection, testing, and analysis for the purposes of the CareStart COVID-19 *Antigen* test."
- "I voluntarily consent and authorize GS Labs to conduct collection, testing, and analysis for the purposes of performing a COVID-19 *PCR* test … In the event of a negative rapid antigen test result, I authorize GS Labs to conduct a confirmatory *PCR* test if I choose to provide a *PCR* specimen at the point of care."
- "I have reviewed the Frequently Asked Questions sheet regarding the Assure COVID-19 IgG/IgM Rapid Test Device/SARS-CoV-2 *antibody* test. I authorize GS Labs to draw my blood to complete this test."

Ex. A, p. 1 (emphasis added). Therefore, by acknowledging and signing the Consent Form, Ms. O'Brien expressly authorized GS Labs to perform the Antigen test, PCR test, and Antibody test.

Moreover, by acknowledging and signing the Consent Form, Ms. O'Brien affirmed that she "read the test descriptions, risks, and associated Frequently Asked Questions for the Rapid Antibody Test, Rapid Antigen Test and the PCR Test" (the FAQ's Page). *See* Ex. A, p. 3. The FAQ's Page explains all three COVID-19 tests, the differences between them, and how each test is administered, among other things. *See* Ex. D.

Additionally, once Ms. O'Brien arrived at the GS Labs testing site, a Registered Nurse reiterated verbatim—from a script—the privacy and consent disclosures, and explained all three COVID-19 tests and how each test is administered, to ensure that Ms. O'Brien was able to make an informed decision regarding which test(s) she wished to have performed. Indeed, GS Labs maintains very strict policies regarding informed consent, so all patients are provided with ample and redundant disclosures.

By this time, Ms. O'Brien had expressly authorized GS Labs to perform all three COVID-19 tests, was well-informed regarding the tests and how each test is administered, and was well-aware that each test required its own sample, and that only the Antibody test required a blood sample. After acknowledging this information in written form, and having it reiterated in person just a moment prior, Ms. O'Brien provided the Registered Nurse with three samples: two swabs and one blood sample. In sum, there is simply no reasonable basis for Ms. O'Brien to allege that she was "deceptively given" COVID-19 tests.

B. GS Labs is not "price gouging" consumers with its COVID-19 testing services

Ms. O'Brien claims that GS Labs is "price gouging" consumers by "charging absolutely exorbitant prices" for its COVID-19 testing services, and then quotes the "cash prices" that are listed on GS Labs' website. Ms. O'Brien is mistaken, because GS Labs has *never* charged a consumer for the "cash price" of a COVID-19 test, even if they have no health insurance. Moreover, consumers with health insurance, like Ms. O'Brien, pay *nothing* for their COVID-19 tests, even where insurance ultimately covers none of the costs. Ms. O'Brien submitted her health insurance information when she scheduled her testing appointment, so she was charged *nothing* for the COVID-19 tests that she received.

1. No "price gouging"; consumers are not charged the "cash price"

First, it is important to note that the "cash prices" listed on GS Labs' website generally are charged only to insurance companies, and not consumers. And while Ms. O'Brien may have been confused by these "cash prices," GS Labs is statutorily required to post that information on its website. Indeed, the CARES Act § 3202(b)(1) requires that "each provider of a diagnostic test for COVID 19 shall make public the *cash price* for such test on a public internet website of such provider." (emphasis added). Again, these "cash prices" apply to insurance companies only, though they do reflect GS Labs' actual costs to develop and deliver its COVID-19 testing services, as explained *infra* § II.B.2.

GS Labs is an out-of-network provider, so the CARES Act § 3202(a)(2) further requires that insurance companies "reimburse [GS Labs] in an amount that equals the cash price for such service as listed by [GS Labs] on a public internet website, or such plan or issuer may negotiate a rate with [GS Labs] for less than such cash price." To date, no insurance company has contacted GS Labs to negotiate a lesser rate than the "cash price."

2. No "price gouging" because "cash prices" reflect GS Labs' actual costs

Second, the "cash prices" that are charged insurance companies reflect GS Labs' costs for the business to develop and deliver its COVID-19 testing services. As explained *supra* § I.B., unlike most facilities that offer COVID-19 tests (e.g., hospitals, clinics), GS Labs was built from the ground up *during* the pandemic, and without the luxury of relying on an already-established infrastructure. GS Labs had to invest an enormous amount of capital to develop quickly its capacity to deliver COVID-19 testing services. Likewise, GS Labs is unable to displace developmental costs across different industries or services because GS Labs *only* provides COVID-19 testing services.

In addition to the enormous amount of capital that GS Labs invested in infrastructure this past year, which necessarily increases GS Labs' costs and consequently its prices, GS Labs provides testing services that are unmatched by any other testing facility in Washington. As noted *supra* § I.B., GS Labs employs Registered Nurses to administer COVID-19 tests, and GS Labs' testing services are available day and night, seven days a week. GS Labs provides consumers with unparalleled access to exceptional COVID-19 testing services, and making those services available increases GS Labs' costs, which in turn lead to increased prices.

3. No colorable "price gouging" claim can be brought

Washington has no "price gouging" statute, but many states do, and such statutes identify "price gouging" as a "gross disparity" between the price that a business charges for a product pre-emergency compared to during the emergency, so long as "the disparity is not substantially attributable to increased prices charged by the [product] suppliers or increased costs due to [the] emergency." *See, e.g.*, 9 Vt. Stat. Ann. § 2461d(c) (2005). There is no reasonable basis to suggest that GS Labs has been "price gouging." GS Labs was formed *during* the COVID-19 pandemic, so it never had any "pre-emergency" prices that can be compared. Moreover, the "cash prices" reflect the actual pro rata costs of GS Labs' testing services, and GS Labs has *never* charged a consumer for the "cash price" of a COVID-19 test.

Although "Washington does not have a specific statute addressing price gouging," "[p]rice gouging during an emergency violates the Consumer Protection Act's prohibition on unfair business practices." *AG Ferguson Launches "See It, Snap It, Send It" Campaign Encouraging Washingtonians to Report Price Gouging*, News, Washington State Office of the Attorney General, https://www.atg.wa.gov/news/news-releases/ag-ferguson-launches-see-it-snap-it-send-it-campaign-encouraging-washingtonians (last visited Feb. 13, 2021). But, here, there is no reasonable basis to suggest that GS Labs has violated the CPA, either.

To establish a prima facie claim of "unfair business practices" under the CPA, a plaintiff must establish, among other things, that she was "injured" by the defendant's unfair or deceptive act or practice. *Hangman Ridge Training Stables v. Safeco Title Ins. Co.*, 105 Wn.2d 778, 784–85, 719 P.2d 531 (1986). Personal "injuries" (e.g., mental distress, inconvenience) are not actionable under the CPA, so the plaintiff must establish that she suffered an economic "injury" to her business or property. *Panag v. Farmers Ins. Co. of Wash.*, 166 Wn.2d 27, 57, 204 P.3d 885 (2009) (citation omitted). Ms. O'Brien suffered no "injury" under the CPA because she paid *nothing* for the COVID-19 tests that GS Labs performed for her and no one is seeking that she pay anything.

C. GS Labs' website is neither misleading nor deceptive

As explained *supra* § II.B.1, the CARES Act requires GS Labs to "make public the cash price for [its COVID-19 tests] on a public internet website," § 3202(b)(1), and such "cash prices" are charged to insurance companies that must either "reimburse [GS Labs] in an amount that equals the cash price" or "negotiate a rate with [GS Labs] for less than such cash price." § 3202(a)(2). In full compliance with the CARES Act, GS Labs has published on its website—just one click from the homepage—the "cash prices" for COVID-19 tests that are charged to insurance companies.

Ms. O'Brien alleges that GS Labs' "website is very misleading, stating testing will be billed thru [sic] insurance," and further alleges that consumers "must go very deep into their website to find hidden that they are charging absolutely exorbitant prices." Setting aside the fact that the "cash prices" are neither "exorbitant" nor charged to consumers, there is nothing "misleading" about GS Labs' website. On the contrary, GS Labs' website is simple, informative, and very transparent.

GS Labs' website provides consumers with a user-friendly process for learning about, scheduling, and ultimately receiving COVID-19 tests. Attached hereto as Exhibits B–D are screenshots of GS Labs' website as it appeared when Ms. O'Brien used it to schedule her testing appointment in late December 2020.

On the homepage of GS Labs' website, there is a tab near the top labelled "Test Information." *See* Ex. B. Clicking on this "Test Information" tab reveals the "COVID-19 Pricing Transparency" page (the "Pricing Transparency Page"), and the FAQs Page—this is the same FAQs Page that consumers *must read* before acknowledging and signing the Consent Form. *See* Ex. A, p. 3. The Pricing Transparency Page lists the "cash price" for GS Labs' COVID-19 tests, as required by the CARES Act § 3202(b)(1). *See* Ex. C. The FAQs Page provides, among other things, the following disclosures under the heading "COVID-19 Rapid Test Cost":

> Submit your insurance info online before your appointment **and pay $0**. After your COVID-19 test(s), you may receive an Explanation of Benefits letter (EOB) from your insurance company—this does NOT mean you owe a balance to GS Labs for your COVID-19 test(s). **Your insurance company's payment will be treated as payment in full by GS Labs**, based on current regulations under the CARES Act and FFCRA. **You are not responsible for paying any outstanding balance**. If you provided us with insurance

> information when you registered for your appointment, **you won't pay anything** out-of-pocket.

Ex. D (underlining and Caps emphasis in original; bold added). Unquestionably, there is nothing "misleading" about this: the FAQs Page clearly explains that consumers with health insurance will owe *nothing* for GS Labs' COVID-19 testing services, regardless of whether insurance covers all or only some of the costs. Moreover, consumers do not have to "go very deep" into GS Labs' website to find this information, nor is this information "hidden" by any stretch of the imagination—the Pricing Transparency Page and the FAQs Page are one click away from the homepage.

D. Final thoughts

Ultimately, Ms. O'Brien concludes her complaint by proposing that she pay for the Antigen test at a "discount" price of "$114.00." This statement further suggests that Ms. O'Brien did not read the Consent Form before signing it, did not read the FAQs Page as required by the Consent Form, did not read any of the numerous disclosures on GS Labs' website, and did not listen to the Registered Nurse who explained everything to her when she arrived at the testing site. *See generally Del Rosario v. Del Rosario*, 152 Wn.2d 375, 385, 97 P.3d 11 (2004) ("Washington adheres to the general contract principle that parties have a duty to read the contracts they sign.") (citing *Nat'l Bank of Wash. v. Equity Investors*, 81 Wn.2d 886, 912, 506 P.2d 20 (1973)); *cf. Beard v. PayPal, Inc.*, No. CIV.A. 09-1339-JO, 2010 WL 654390, at *2 (D. Or. Feb. 19, 2010) (enforcing online "clickwrap agreement" where plaintiffs had access to the entire User Agreement on defendant's website and checked box indicating they had read and agreed to it.) (citation omitted). To the extent there was any misunderstanding, it obviously resulted in a windfall to Ms. O'Brien.

These unprecedented times have been challenging and stressful for everyone—to date, COVID-19 has taken the lives of over 500,000 Americans, and millions of Americans remain out of work. Indeed, these unprecedent times have called for unprecedented measures, and GS Labs answered that call by taking on the "Herculean task" of developing and delivering widespread COVID-19 testing services, which is necessary to prevent even more lives from being lost during the second and third waves of the COVID-19 infections.[2] Recognizing that the costs of developing and delivering COVID-19 testing services would be enormous—nation-wide testing would cost "at least $100 billion and upward of $500 billion over the long haul"[3]—GS Labs responded to the public health emergency by launching nineteen COVID-19 testing locations across twelve states. Notwithstanding these enormous costs, GS Labs has made every effort to ensure that its COVID-19 testing services are affordable. Indeed, consumers without insurance do not pay the "cash price" for COVID-19 tests, and consumers with insurance pay *nothing*, even if insurance companies refuse to cover the costs—which they often do.

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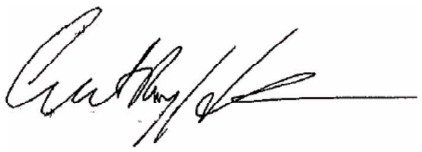
[2] *The US Economy Can't Reopen Without Widespread Coronavirus Testing. Getting There Will Take a Lot of Work and Money*, CNBC, https://www.cnbc.com/2020/04/16/coronavirus-testing-needs-to-be-widely-done-before-economy-reopens.html (last visited Feb. 17, 2021).
[3] *Id.*

Now more than ever, widespread access to COVID-19 testing is necessary and must be encouraged, especially considering the fact that "[c]ommunities of color are disproportionately burdened by the COVID-19 pandemic."[4] It is critical that GS Labs' finite resources remain focused on providing COVID-19 testing services for communities in need, so we greatly appreciate this opportunity to set the record straight regarding GS Labs' business practices.

If your Office has any remaining questions or concerns, please feel free to contact the undersigned counsel at the address noted above.

Sincerely,



Curt Roy Hineline

Attachments
cc: Client
Denise O'Brien

[4] *Why COVID-19 Testing is the Key to Getting Back to Normal*, National Institutes of Health, U.S. Department of Health & Human Services, https://www nia.nih.gov/news/why-covid-19-testing-key-getting-back-normal (last visited Feb. 17, 2021).