

## INTERNAL MEMORANDUM

**TO:** Nikolai Chamberlain, Executive Vice President, General Counsel, and Corporate Security  
**FROM:** Chief Compliance Officer  
**DATE:** May 15, 2020  
**SUBJECT:** Compliance Issues to Address at CPS Board of Director's Meeting

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### PURPOSE

This memo will outline the potential legal, regulatory, and compliance issues that may be facing Cervical Pain & Spine, Inc. (CPS), as a result of the information described in the March 29, 2019 Whitelaw Compliance Group (WCG) Report File. This memo will outline (1) board liability concerns (2) fraud and abuse concerns, (3) compliance concerns, and (4) recommended actions.

### CONFIDENTIALITY

The contents of this document are confidential and protected by the attorney-client privilege. Information in this memo should not be discussed outside of the CPS Board of Directors without clear direction from General Counsel.

### BOARD LIABILITY CONCERNS

*Responsible Corporate Officer Doctrine*<sup>1</sup>: Aside from the liability outlined below, it is imperative to alert all members of the Executive Board that they may be liable for these violations as well. The Board of Directors, including officers, have fiduciary duties of care and oversight over this organization. They may be liable for both financial penalties and imprisonment as a result of the violations outlined in this memo.

### BACKGROUND

This memo will discuss several issues from the WCG Report that may implicate company liability. These scenarios will be discussed in more detail under the fraud and abuse law concerns heading but are referenced here to provide background and the naming convention used within that section.

- (1) ***Alavera Consulting Contract (Alavera)***: Dr. Alavera is a CPSS customer and also signed a contract with CPSS in 2016 to provide consulting services. Payment for his services were sent to the "Alavera Children's International Surgical Foundation."
- (2) ***Silberstein Memorial Cadaver Labs (Silberstein)***: CPSS hosted annual training labs in Miami, FL, at Hannum Hospital from 2016–2018 for its top twenty surgical targets.
- (3) ***Julius Sergott Development Contract (Sergott)***: Dr. Sergott is CPSS' largest customer in the Northeast Region. He has a joint development agreement with CPSS to provide consulting services and with CPSR for product development work.

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<sup>1</sup> *United States v. Park*, 421 U.S. 658 (1975).

- (4) **The ROI Dashboard (ROI):** Storch requested ROIs be presented to the Executive Management Team on a quarterly basis. These ROIs have been presented at meetings where Chamberlain was not present. The WCG report also indicated Sistrone's sudden departure is connected to Storch's request for ROIs.
- (5) **Mini-Space Promotional Activities (Mini-Space):** The Mini-Space product line advertisements claim that its spacers "have the flexibility of aluminum, combined with the carbon fiber strength of a fighter jet," and have "unsurpassed safety, efficacy and flexibility." Additionally, CPSS started a customer loyalty program with the mini-space product line, providing a 15% discount to physicians who use CPSS products in a certain percentage of their cases.

## FRAUD AND ABUSE LAW CONCERNS

**False Claims Act** (31 U.S.C. §§ 3729-3733): The False Claims Act (FCA) prohibits the submission of false claims to the Centers for Medicare and Medicaid Services. An FCA violation occurs when one entity knowingly causes a false or fraudulent claim for payment or approval to be presented to the U.S. Government. The penalties for an FCA violation may include civil monetary penalties in the amount of up to \$11,000 per claim plus treble damages (three times the amount of the false claim).

The WCG Report suggests at least one FCA violation: Alavera is a client of CPSS and he bills both federal and private payors for the products he purchases. The WCG's Report demonstrates that CPS had *actual knowledge* of this violation and continued to sell him products. Additionally, CPSS records indicate that it paid Alavera for his work by paying a charitable organization run by Alavera and his wife, but there are no IRS records establishing this organization's charitable status. This does not necessarily mean CPSS is involved in a scheme to defraud the government, but it is something that should be investigated further.

To be liable for an FCA violation, there is no need to prove that CPS *intended* to defraud the government. Involvement with knowledge is enough, and that is likely sufficient to find CPS violated the FCA.

**Anti-Kickback Laws** (42 U.S.C. § 1320a-7(b)(b)): The Anti-Kickback law (AKB) states that it is illegal to knowingly and willfully solicit or offer to pay any remuneration in return for referring an individual to a person for the furnishing of any business for which payment may be made in whole or in part by Medicaid or Medicare. The penalties for an AKB violation are a felony conviction, a maximum fine of \$25,000, imprisonment of up to 5 years, civil monetary penalties of up to \$50,000 plus treble damages *per violation*, and additional exposure to FCA claims.

The WCG Report suggests at least five different AKB violations: First, Alavera signed a contract to provide consulting services to CPSS for the rate of \$500/hour or \$4,000/day. CPSS did not sign the contract, and there is no record of Alavera doing any work for CPSS. Additionally, CPSS records indicate that Alavera was paid \$24,000 (only \$14,000 of which was reported). This scenario gives the appearance that Alavera (who is a client of CPSS) is being paid by means of a questionable charity, and yet the only thing he is doing is making purchases from CPSS.

This may lead to an investigation of CPSS offering remuneration (in the form of supporting Alavera's charity) in return for increased sales.

Second, regarding Silberstein, for each of the three years of the training labs, CPSS invited only its top twenty surgical sales targets to attend. Furthermore, it paid each attendee an honorarium of \$500 and each speaker an honorarium of \$1,000. Both received free meals and hotel rooms for three days, and the spouses and children of each attendee and instructor received free meals. Although this behavior is not a per se violation of AKB, it is certainly suspect, especially considering only the top sales targets are invited, and that all attendees received meals and hotels for three days even though the training lasted 1.5 days. Additionally, CPSS paid the location of the event, Hannum Hospital, \$20,000, despite the fact the Hannum Hospital requested \$10,000. It is not clear whether or not Hannum Hospital purchases products from CPSS, but if they do, this may present another AKB violation.

Third, Sergott, CPSS' largest customer in the Northeast Region, has a joint development agreement with CPSS to receive \$500/hour or \$4,000/day for consulting work, and with CPSR for 6% royalties for any development work that leads to a new product. According to the WCG Report, Sergott did no work for CPSS or CPSR aside from attending two initial product development meetings, but there are no records that he contributed at these meetings. Sergott was paid \$8,000 for attending the meetings. This payment, despite no record of work, also requires additional investigation as it is suspect for AKB violation. In addition to this suspect interaction, the WCG Report indicates that Sergott was paid \$50,000 by CPSR in May 2018 despite no additional work. This could indicate remuneration for being CPSS' client.

Fourth, although not a direct AKB violation, the WCG Report indicates that ROI reports have been presented at several executive management meetings. These ROI reports not only contain information that could be incriminating regarding AKB violations, they were also presented and discussed *only* at meetings in which the general counsel was not present. This means that the information discussed is not protected by the attorney-client privilege, and also has the appearance that the other executive members wanted to hide the information within the ROI reports.

Fifth, in 2018 CPSS launched a customer loyalty program, offering surgeons a 15% discount if they used CPSS products in at least 45% of their back-surgery cases, and committed to increasing to using CPSS devices in at least 75% of cases in three years. Although incentive programs are not a per se violation of AKB, they are certainly suspect behavior as they induce purchase of certain products. There is no record of this loyalty program being written down, which could allow for inconsistent application. Additionally, AKB exists, partially, to protect patients and prioritize their safety. This program prioritizes profits over patient safety, requiring participants to use CPSS products even if it is not the best choice for the patient. This program should be further explored.

**Stark Law** (42 U.S.C. § 1395nn): Stark Law (Stark), prohibits physicians, who have a financial relationship with a provider of designated health services (including durable medical equipment), from making referrals of Medicare or Medicaid patients to such providers for purposes of receiving any of the designated health services. There is no intent requirement under Stark, so

even accidental violation is a violation. Penalties for violating Stark include repayment of all amounts billed to Medicare or Medicaid from violations, and civil monetary penalties of up to \$100,000.

The WCG Report suggests several relationships that are suspect to include Stark violations. Alavera and Sergott are both clients of CPSS but also consultants, suggesting they may represent CPSS *and* make referrals of CPSS products while also having a financial incentive. Additionally, the instructors at the Silberstein training labs may be involved with CPSS in the same way, requiring more investigation to determine if these relationships could be Stark violations.

***Sunshine Act*** (42 U.S. Code § 1320a–7h): The Sunshine Act (Sunshine) was enacted to increase financial transparency and disclosure of conflicts of interest. It requires that all payments and transfers of value to physicians and teaching hospitals be reported to CMS’ Open Reporting System. Violations of Sunshine may result in civil monetary penalties of \$1,000–\$10,000 for each payment or item of value not reported. The limit on penalties for inadvertent violations is \$150,000, but for knowing violations is \$1,000,000.

The CWG Report indicates at least three knowing violations of Sunshine: First, Alavera received an unreported payment for \$10,000. Before CPST made this payment, there is an email from a sales representative asking Sistrone if they can bypass the typical protocol required to approve payments.

Second, Hannum Hospital received payment of \$20,000 from CPSS, despite only asking for \$10,000, and there is no clear record of who exactly received that additional money or why it was paid. It was not clearly reported.

Third, attendees, instructors, spouses, and children at the training labs received hotel and meal costs paid for them. Sunshine requires reporting of all of these items too, and there is no budget or payment documentation of these amounts. The honorariums paid to the attendees and instructors are the only items of value reported from the trainings.

Fourth, Sergott received a payment for \$50,000 that was not reported, for work he did not do.

Lastly, as mentioned above, the ROI documents presented at certain executive meetings likely contain incriminating information about these payments.

***FDA and FTC Promotional Restrictions:*** The U.S. Food & Drug Administration (FDA) and Federal Trade Commission (FTC) regulate all false and misleading advertising of drugs and devices and can bring causes of action against CPS if it or one of its agents violates the approved marketing of the device.

The WCG Report Indicates that CPSS is making unsubstantiated claims regarding its Mini-Space product line. CPSS made claims that the spacers “have the flexibility of aluminum, combined with the carbon fiber strength of a fighter jet,” and have “unsurpassed safety, efficacy and flexibility.” Not only is CPSS not entitled to make unsubstantiated claims, but its agents (consultants or instructors) are also not entitled to make false marketing claims about its

products. Furthermore, there are video recordings of these marketing claims. If this video was leaked to social media, there are strict marketing guidelines that should be used on that platform as well.

***Qui Tam Claims*** (31 U.S.C. §§ 3730(b)– 3730(c)(2)(D)): Under the False Claims Act, a person can bring a claim against a company on behalf of the government as a whistleblower. This is known as a Qui Tam claim. The person bringing this claim will receive a financial incentive for bringing this claim. The WCG Report uncovers the reason that Sistrone suddenly resigned from CPS (as a result of a threat from Murphy and Brand). Sistrone would be free to raise a Qui Tam claim against CPS. Considering that Qui Tam lawsuits have been an *incredibly* successful way to bring FCA claims, and Sistrone’s intimate knowledge of the organization, it is a very real possibility that he could expose CPS to liability to the claims mentioned above.

Additionally, currently employed persons can bring Qui Tam claims. In March 2018, a Senior Account Representative, Constance Stefani, was assaulted by Sergott, and instead of handling this employee complaint in accordance with OSHA policies to prevent violence in the workplace, this complaint was brushed aside. Stefani also has inside information into the way that Sergott has been paid despite his lack of done work for the company, and could expose CPS to a Qui Tam claim.

#### **COMPLIANCE CONCERNS:**

***Lack of compliance program:*** Although CPS is not required to have a compliance program, having a program in place indicates to government regulators that care is being taken to ensure compliance with fraud and abuse laws. The fact that CPS does not currently have a program in place can be used by government regulators to show a lack of compliance with the fiduciary duties of care and oversight. Having hired a Chief Compliance Officer will indicate to government regulators a commitment to bettering CPS’s compliance in the future, so CPS is making progress in this area.

***Reporting concerns:*** In addition to compliance concerns, the WCG Report indicates additional concerns regarding reporting.

*Reporting of compliance concerns:* Currently the Chief Compliance Officer (CCO) does not report directly to the CEO. Indirect reporting to the CEO may give the appearance to government regulators that compliance concerns are being altered, missed, or not prioritized.

*Reporting of employee concerns:* The WCG Report recognizes several instances where employees had compliance related concerns but either could not report their issues or did report their issues and they were not handled appropriately. Government regulators may view this as not having an open line of communication for employees to address compliance concerns. Additionally, it may lead to Qui Tam claims.

*Reporting of financial concerns:* The WCG Report outlines several instances of payments being made without record or without an explanation, or payments being made to parties without proof of their charitable status. These instances indicate that there is a problem with

CPS's financial reporting. This issue can be used by government regulators to demonstrate a lack of officer's duty of care and oversight of this organization. It can also lead to further compliance violations.

#### **ACTION ITEMS:**

**Stop:** It is imperative to stop engaging in the items listed above that indicate possible violations. Government regulators will need to see that this behavior has stopped.

**Keep all conversations with General Counsel and/or hire outside counsel:** In order to use the attorney-client privilege to keep conversations and work confidential, and attorney must be involved and present.

**Implement Compliance Program:** The Chief Compliance Officer was hired to implement this program and must be supported in this endeavor by the other executives.

**Self-disclosure:** CPS should consider self-disclosure of some or all of these violations. Self-disclosure *can* limit liability for certain penalties but does not guarantee that CPS will avoid liability.

**Institute and Anonymous Compliance Hotline:** Given the various compliance concerns raised in WCG Report, it is imperative to offer employees a safe place to report compliance concerns.

**Reconsider Board Members:** The WCG reports several compliance concerns with behaviors of Murphy and Brand. CPS should consider if it is causing more harm than good to have these two employees retain positions within the company and even more importantly, whether they should retain positions of authority.

**Reconsider Reporting Structure:** At the very least, the CCO should report directly to the CEO to ensure that the CEO is aware of any and all compliance concerns. Other reporting structures should be evaluated.

**Freeze all Purging of Emails or Documents company-wide:** The WCG Report indicates that when Sistrone left CPS his emails were purged. Considering the likelihood that CPS could be investigate by federal regulators, it is imperative to freeze any destruction of company files, including emails.

## INTERNAL COMMUNICATION

**TO:** Head of CPSS Field Force (to be shared with Sales Force)

**FROM:** Chief Compliance Officer

**DATE:** May 15, 2020

**SUBJECT:** Sales Force Reminders

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**PURPOSE:** The purpose of this communication is to address several company-wide compliance concerns that have been raised and to provide specific direction regarding what to do or not do to avoid these concerns in the future.

**CONFIDENTIALTY:** Anything written in this memorandum is considered confidential and may not be discussed with those outside of the organization. If you have any questions for concerns, please contact your Chief Compliance Officer at CCO@CPS.com.

### GO AHEAD: DO

- **DO respect clients:** Thank you for respecting your clients and working hard to represent our company!
- **DO report suspicious behavior to the CCO:** If you see something, say something. Anything that seems like it might be problematic should be reported directly to the Chief Compliance Officer via email (CCO@CPS.com) or phone (676) 888-1234. This includes reporting behavior from your superiors that seems like it could be problematic. You will *not* be punished for reporting these concerns.
- **DO be watchful:** Be watchful for concerns with communications and behaviors of your fellow sales representatives, yourself, your supervisors and managers, and your clients.
- **DO ask first before acting:** If you are unsure about a certain behavior in which you are wanting to engage in, or unsure about a behavior that your superior has ordered, ask *before* you act on it!





### **STOP: DO NOT**

- DO NOT make statements about CPS products that are not approved by FDA. If you are unsure whether certain statements are approved, contact the CCO.
- DO NOT state that products can be used for purposes not approved by the FDA.
- DO NOT offer physicians things of value (such as meals, gifts, tickets for events) in exchange for a sale. Do not offer gifts unless you have been approved *before you give them this gift*.
- DO NOT make a sale to a physician if you know he/she plans to engage in fraudulent behavior. Instead, report this physician's behavior to the CCO.
- DO NOT tolerate threats from anyone. If you are threatened in any way by a client or another member of this organization, contact the CCO immediately.

### **BUT WHY?**

**Your compliance team is NOT here to prevent sales or ruin your ability to do your job. Your compliance team is here to protect YOU and CPS from:**

- Dismissal from company
- Criminal investigation
- Criminal liability (being imprisoned or fined)
- Personal reputational harm
- Company reputational harm

