

# ROY SNELL HEALTH CARE REGULATORY & COMPLIANCE WRITING COMPETITION

## 2020 PROBLEM

*The Competition Problem (the “Problem”) is purely fictional and prepared solely for this educational purpose.*

### BEFORE THE OPENING BELL



We have noted for some time now that the uncertain health of the U.S. economy and fears that another recession lurks just over the horizon has negatively impacted some sectors of the stock market more than others. Perhaps no industry has been harder hit by all this uncertainty than healthcare.

Now heading into a Presidential election year, Congress and the Democratic candidates, with their neverending debates on how to repeal or fix Obamacare and containing skyrocketing healthcare costs via Medicare For All have deflated this traditional recession-proof sector, and spooked investors are moving their money out of the healthcare sector as recommended by Goldman Sachs and other analysts.

However, a few bright spots still remain in the healthcare sector. On Friday, Cervical Pain & Spine (NASDAQ: CPS) announced its fourth-quarter earnings significantly beat analysts' expectations when the company posted a 40% increase in revenues over the same quarter last year. Overall, CPS stock is up by 27.5% for the year despite the ongoing market volatility.

According to CEO Justin Storch, CPS's success is due to it being a "one-stop-shop" for orthopedic and neurosurgeons treating chronic back pain, and the success of its "Mini-Space" line of minimally invasive orthopedic spacers that have dramatically cut surgery and patient rehabilitation times.

Before the opening bell, CPS stock is up \$2.25 per share on the NASDAQ in aftermarket trading. Meanwhile, the Dow Futures this morning are down two-tenths of one percent overall.

*I'm David Brancaccio, and this is the Marketplace Morning Report for Monday, January 13, 2020.*

## OVERVIEW OF THE CERVICAL PAIN & SPINE EMPIRE

Cervical Pain & Spine, Inc. (“CPS”) was founded in 2002 by billionaire, and former pro-golfer, Justin Storch, who is well known in both the medical device and pharmaceutical worlds for his disruptive business models and unconventional sales techniques. Headquartered in Greenville, South Carolina, the company proclaims “we bring mobility back to life” for patients suffering from all types of spinal abnormalities and injuries. As Storch likes to tell anyone who will listen, “If CPS had been around when I was on the PGA Circuit, I still would be chasing Green Jackets rather than sitting behind a desk!”

### CPS Management Team

Storch has assembled a management team with widely divergent backgrounds and talents and he touts this to investors as a CPS differentiator. Figure 1, which is drawn in part from various CPS 10-K filings with the Securities and Exchange Commission (“SEC”), highlights some of the company’s key executives and their backgrounds.

Figure 1: Cervical Pain & Spine, Inc. Key Executives (not a complete list)

Name	Position	Operating Unit	Background
<b>Justin Storch</b>	CPS Founder and Chief Executive Officer	CPS Corporate	A billionaire and former pro-golfer, Storch also is a former Fortune 500 pharmaceutical CEO.
<b>Nikolai (“Niki”) Chamberlain</b>	Executive Vice President, General Counsel & Corporate Secretary	CPS Corporate	Chamberlain joined CPS in 2016 after Storch hired her away from her plaintiff’s practice at Motley Rice LLC where she successfully sued numerous pharmaceutical and medical device companies.  Prior to joining Motley Rice, Chamberlain led the healthcare legal support team for Lehman Brothers for 20 years until the firm’s collapse in 2008. She also is a member of the CPS Corporate Executive Management Team (“CEMT”).
<b>You</b>	Chief Compliance Officer	CPS Corporate	Hired in August 2019 as CPS’s first CCO, you report directly to Chamberlain with a dotted-line into Storch and another dotted-line into the Audit Committee of the CPS Board of Directors.
<b>Mitchell (“Mitch”) Murphy</b>	President	CPS Surgical (“CPSS”)	Mitch Murphy joined CPS from Zimmer Biomet in late 2002 as Storch’s first hire. Prior to leaving Zimmer, Murphy led their implantables division which doubled revenues during his seven-year tenure.  Murphy started his career as a sales representative with C.R. Bard, Inc. in 1990 and quickly was promoted to increasing

Name	Position	Operating Unit	Background
			positions of responsibility. When he left Bard in 1995 for Zimmer, he was President of Bard's Urology Division ("BUD"). In addition to being President of CPSS, he is a member of the CEMT.
<b>Douglas Brand</b>	Senior Vice President, Sales & Marketing	CPS Surgical ("CPSS")	Douglas Brand joined CPSS in 2003 from Ethicon where he was VP of Marketing. Prior to joining Ethicon, Brand worked at C.R. Bard, Inc. from 1981 to 1997 in a variety of Bard divisions including BUD.
<b>Mark Sistrone</b>	Vice President, Sales	CPS Surgical ("CPSS")	Douglas Brand hired Sistrone away from C.R. Bard, Inc. to head up sales for CPSS in 2015. In July 2018, Sistrone abruptly left CPSS "to pursue other activities and spend more time with his wife and baby daughter."
<b>Janice Sturgeon</b>	President	CPS Therapeutics ("CPST")	Janice Sturgeon joined the CPS Team in 2014 after having served as Senior Vice President, Global Marketing for Sanofi S.A. in Paris, France. She also serves as a member of the CEMT.
<b>James ("Ludy") Ludecker</b>	Senior Vice President, Sales, Marketing & Medical Affairs	CPS Therapeutics ("CPST")	James Ludecker joined CPS Therapeutics in 2015 from Sandoz Pharmaceuticals, the generic and biosimilars division of Novartis. While at Sandoz, he led the company's portfolio transition from just generic pharmaceuticals to a mix of generics and biosimilar products.
<b>Eileen Monahan, M.D., Ph.D.</b>	Chief Medical Officer and President	CPS Research ("CPSR")	<p>Eileen Monahan joined CPS in 2003 as CPS's Chief Medical Officer and President of CPS Research. A Harvard-educated, board-certified, ophthalmologist, she also holds a Ph.D. in biomedical engineering from the Massachusetts Institute of Technology.</p> <p>Prior to joining the CPS Family, Dr. Monahan was Chief of Staff at Brigham and Woman's Hospital in Brookline, MA. and was a member of the National Eye Institute's science advisory board. In her role as President of CPSR, Dr. Monahan is a member of the CEMT.</p>

## Company Products & Overall Corporate Structure

The company product offerings include both traditional medical devices (e.g., screws and plates), surgical instruments (e.g., hammers, chisels, and ultrasonic cutting tools), and pharmaceutical products (e.g., nerve blocks, generic analgesics, and other topical pain management products).

## “The CPS Family”

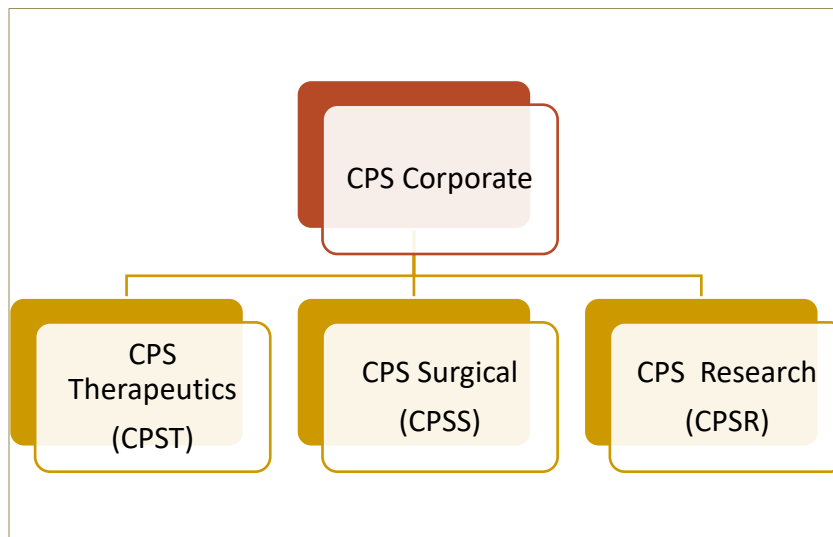
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Based on Nikolai Chamberlain’s advice, CPS in 2017 split its operations and product lines into three separate independent operating companies for liability purposes. The three companies known collectively within the company as the “CPS Family” are:

- CPS Therapeutics, LLC. (“CPST”), the pharmaceutical division,
- CPS Surgical, LLC. (“CPSS”), the medical device division, and
- CPS Research, LLC. (“CPSR”), the research division.

Figure 2 shows the current corporate structure. While CPST, CPSS, CPSR operate as independent companies, they have interlocking Boards of Directors as Chamberlain and Storch serve on all three operating company boards. The three operating companies also share financial accounting, IT, Legal, Compliance, inventory management, and Human Resources services provided by CPS Corporate. In addition, each operates under the CPS Corporate umbrella of policies and procedures.

Figure 2: The CPS Family of Companies



CPS Therapeutics (“CPST”) has grown to 150 employees made up of marketing, medical science liaisons (“MSLs”), and support staff to manage the CPST contract sales force provided by two third-party vendors, as well as providing healthcare professional (“HCP”) speaker and grant support. CPST also employs a network of independent consultant nurse educators that support “key” CPST and CPSS customers.

CPS Surgical (“CPSS”) currently has 45 employees who handle the marketing and sales of all CPS devices through an independent network of distributors in the U.S., each having local independent territories.

CPS Research (“CPSR”) employs 20 staff members dedicated to providing regulatory affairs support, as well as clinical and non-clinical research support to both CPST and CPSS under the direction of CPS’s Chief Medical Officer. To date, that support primarily has been dedicated to CPST.

Since the company’s inception, Storch and his Corporate Executive Management Team (“CEMT”) have struggled to integrate cross-operating company support between CPST and CPSS.

Getting sufficient time and attention from CPST's MSLs, nurse educators, and other support staff for CPSS activities is something the company has struggled to address, but is complicated by differing reporting and compensation structures.

This somewhat complex support model was the brainchild of Storch, who has an almost pathological loathing of bloated corporate bureaucracies and a singular focus on containing costs. As a result, the cross-company support structure is not set out in writing (i.e., through Service Level Agreements) or any of the company's official corporate organizational charts.

## LOOKING BEHIND THE CURTAIN

Now that you have joined CPS as its first Chief Compliance Officer, your first order of business has been focused on developing and establishing a general enterprise-wide corporate compliance program. However, in your last one-on-one with Chamberlain, she asked you to undertake a detailed compliance review of CPSS's marketing and sales programs because she has been concerned for some time now that both Murphy and Brand have been "pushing the envelope." She also told you that lately she has become even more concerned because, at the last CEMT meeting, Murphy outlined how CPSS had leveraged CPST's MSL's and nurse educators to help sell the Mini-Space and achieve double-digit product sales. At the end of the meeting, she handed you a file more than four-inches thick that she was saving until you came on board, and she suggested that you start there. Her last message to you was not to share the contents of the file with anyone because "this one is a hot potato."

### The WCG Report

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Upon returning to your office, you begin looking through Chamberlain's so-called "hot potato" file. The first thing you see is a report dated March 29, 2019, from the Whitelaw Compliance Group ("WCG") to Chamberlain labeled "Privileged & Confidential – Prepared At the Request of Counsel" and titled "Compliance Assessment of CPS Surgical Marketing and Sales Practices." It is a lengthy report with numerous supporting documents, including numerous emails.

After reading through the Executive Summary, two points immediately jump out at you. First, WCG concluded that there were a number of sales and marketing activities that raised compliance concerns, and second that "it appears that these problematic activities were sanctioned, endorsed, and even driven with the full knowledge and support of CPSS President Mitch Murphy and SVP Douglas Brand with the help of CPSS's former VP of Sales, Mark Sistrone. The WCG report went on to describe several representative and problematic activities in excruciating detail.

### Alavera Consulting Contract

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The WCG report detailed a two-year contract with the neurosurgeon, Dr. Jose Alavera, for consulting services at the rate of \$500.00 per hour or a per diem of \$4,000.00. Although Alavera signed the contract in 2016, the CPSS signature line was blank. WCG noted that Dr. Alavera also is a key customer for CPSS and he buys company products which are then billed to both federal and private payors.

The contract also directs that any payments for Dr. Alavera's services should be made payable to the "Alavera Children's International Surgical Fund," which the contract lists as a 501(c)(3) charitable organization run by Dr. Alavera and his wife, Minny. However, WCG noted that no official IRS communication establishing the Fund's charitable status was found in the contract file.

While CPSS apparently made no payments to Dr. Alavera or the Fund in 2016, a spreadsheet in the contract file showed CPSS made 15 payments to the Fund on behalf of Dr. Alavera in 2017. 14 out of 15 payments were in the amount of \$1,000 totaling \$14,000, while the last payment on December 20, 2017, was for \$10,000.

In the case of the \$10,000 payment, the file contained a December 15<sup>th</sup> email from Tony Brooks, CPSS's top-selling National Account Representative ("NAR") to Sistrone stating,

"Dr. A. told me that he is leaving in January for the Philippines to perform charity cases underwritten by his Fund and wondered if we could support him with a \$10,000 grant. I told him that the grant has to go through CPST, and their approval is notoriously difficult to obtain. Can't we just pay him under his existing consulting contract (maybe consider it as an advance payment that is on account) so we can bypass CPST?"

According to WCG, Brooks apparently received no response from Sistrone, but that could not be confirmed because Sistrone's email account was purged when he left the company in 2018. However, CPSS cut a check to Dr. Alavera's Fund for \$10,000 on December 20, 2017.

WCG also could not locate invoices or details of the actual work Dr. Alavera undertook for CPSS in the files, and WCG noted that CPSS's 2017 Open Payments Disclosure attested to by Murphy showed Dr. Alavera as having received only \$14,000 in total for the full year.

### **Silberstein Memorial Cadaver Labs**

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In 2016, 2017 and 2018, CPSS together with Hannum Hospital in Miami, Florida hosted annual cadaver lab training programs to showcase CPS Surgical's product line and to train potential high-volume orthopedic and neurosurgeons on the latest techniques involving CPSS products. Named for Hannum Hospital's late head of neurosurgery, Dr. William Silberstein, who died in 2015 from a stroke brought on by his life-long migraine affliction, the Labs were held on the first Friday in February for CPSS's top 20 surgical sales targets. Each program was a day and a half.

Although no budgets or other documentation about the Labs were located, WCG, using accounts payable records, found that each attendee was paid a \$500 honorarium to attend (instructors received \$1,000). CPSS used master billing accounts to avoid the need for individual expense accounts, and paid for three days of meals and hotel rooms for both attendees and instructors. Additionally, WCG noted that CPSS covered the meals for the spouses and children of the instructors. Tracing the payments to CPSS's Open Payments Disclosures, WCG found that only the honoraria were listed, but the meals and room charges were not.

In addition, Hannum requested \$10,000 for the use of its facilities and to provide the practice cadavers, which CPSS normally paid to Hannum in January right before the events were held. In reviewing the checks to Hannum, WCG noted that the January 2018 check was for \$20,000, although it is unclear what the extra \$10,000 was for.

## Julius Sergott Development Contract

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Dr. Julius Sergott is one of New York City's most prominent orthopedic and plastic surgeons and CPSS's largest customer in the Northeast Region. In 2015, CPSS converted his consulting contract for \$900.00 per hour or \$7,200 per day with CPSS into a joint development agreement and set his compensation at \$500.00 per hour or \$4,000.00 per day for consulting work with CPSS and 6% royalties for any development work with CPSS leading to a new product.

From 2016 to 2018, Dr. Sergott apparently did no consulting work for CPSS, but he attended two initial CCSR product development meetings on proposed line extensions (Projects 16MS002 and 17MS005) for the Mini-Space for which he was paid \$8,000.00. He, however, did not attend any other project meetings or provide any additional input. In fact, the two development files contained no record of Sergott ever providing product input to CCSR or CPSS.

Project 16MS002 was canceled after the initial development meeting Sergott attended, but Project 17MS005 ultimately was launched in late 2017 as the Pediatric Micro Mini-Space. Since the launch of Project 17MS005, Sergott has demanded payment of his 6% royalty every time a CPST sales representative calls on his hospital to discuss pharmaceutical products. In fact in March 2018, Constance Stefani, a CPST Senior Account Representative, emailed Sistrone complaining:

"Sergott accosted me in the hallway again this month even though I told him CPST has nothing to do with his development contract. This time he pushed me and snarled that the company owed him his royalty and he would make it pay if he did not get it soon. The man's an ass, and you need to do something about him."

Sistrone replied to her:

"He may be an ass, but he is our largest customer in the Northeast so go easy on him. We will take care of it."

When Sistrone brought the issue to the attention of Murphy and Brand, Brand emailed Sistrone that:

"He contributed nothing to the project, and so is owed nothing. Besides we paid him for the two meetings, he did attend."

Murphy was blunter in his email noting, "Sergott can rot in hell before I pay him for doing nothing."

Despite the positions expressed by Brand and Murphy, WCG uncovered a \$50,000 payment to Sergott made by CCSR, and approved by Eileen Monahan in May 2018. The Accounts Payable file lists the check as royalties for Sergott's contributions on Project 17MS005. This payment, however, was not disclosed on any CPS Open Payments Disclosures.

## The ROI Dashboard

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The WCG report also detailed an effort by both CPSS and CPS Corporate to determine the value the company was receiving from its various interactions with healthcare professionals. As the WCG report outlined, it appears to have started in January 2016 when Storch emailed Murphy telling him:

"We have got to get this expense thing under control before it kills us. CPS is not a charity, but a business charged with making money and we don't make money by giving it away. Our shareholders are trusting us to safeguard and grow their investment. If we don't do it, they will take their money elsewhere. Therefore, I want



you to prepare an ROI dashboard to share with the CEMT on a quarterly basis. I know you'll object to the extra work, but if you don't do it, I will find someone who will."

Murphy, in turn, told Brand and Sistrone to "make it happen." Sistrone, however, objected emailing Brand and Murphy, "I think we should speak with Niki [Chamberlain] as this approach seems very dangerous to me." Both Brand and Murphy told Sistrone not to speak with Chamberlain because

"Comrade Niki forgets that sales runs this company. She worries about everything and is always throwing a wet blanket over everything we need to do. Besides Storch wants this and that is all that matters." [Murphy]

"I agree. The last thing we need is the "sales prevention" department telling us how to do our jobs!" [Brand]

At the beginning of March 2018, Sistrone, despite the responses by Brand and Murphy, requested a meeting with Chamberlain that apparently never happened because of a sudden family crisis. Murphy and Brand later found out about Sistrone's attempt to go directly to Chamberlain through their shared administrative assistant Cindy Cooke. On March 15, 2018, Murphy wrote Brand,

"Sistrone has to go as he is no longer a team player. I don't care what you have to do, but I want him out of my company. Contact Jane Blaylock in Corporate HR and get her on it. If anyone can force someone out without repercussions it's Jane. She's always been my fixer."

As a result of that email, Sistrone was informed two days later that unless he agreed to resign, he would be terminated for "performance reasons and insubordination" thereby losing his previous year's bonus that was set to pay out in April. Sistrone agreed to resign and left CPSS's offices on April 3, 2018, although his last official day worked was reflected in his personnel file as July 3, 2018 so that he received his bonus. In the margin on the page in the WCG report discussing Sistrone's resignation, you see a single handwritten notation: "WHAT WILL HE DO?!"

Despite Sistrone's concerns, the CPSS ROI dashboard highlighting spending on HCPs together with their associated product purchases was being presented at CEMT meetings as reflected in various email threads. However, they were only presented at meetings where Chamberlain was not present. Nor were the dashboards distributed before the meeting or noted as an agenda topic in the CEMT meeting minutes.

## **Mini-Space Promotional Activities**

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The WCG report also detailed a number of issues surrounding CPSS's promotion of the Mini-Space product line. Specifically the report noted that when CPSS launched the product in January 2017, the Mini-Space marketing materials claimed that the spacers "have the flexibility of aluminum, combined with the carbon fiber strength of a fighter jet."

At the videotaped Las Vegas launch meeting, attended by the entire CPSS sales and marketing staff, as well as the MSLs from CPST and Storch, himself, Murphy announced the unveiling of the new Mini-Space line by saying, "Through the miracle of carbon fiber, we can now bomb our competition back to the stone age!" Furthermore, other marketing materials specifically developed for use by CPST's MSLs and nurse educators promoted the fact that the Mini-Space had unsurpassed "safety, efficacy and flexibility."



Despite the claims of superior strength and flexibility, WCG noted that CPSS could not locate any internal or external data on file to support these statements. At the same time, since the launch of the Mini-Space, CPSS had received feedback from numerous customers that the Mini-Space spacers were too rigid and therefore not flexible enough for the majority of their cases.

Although the fanfare surrounding the Mini-Space product line allowed CPSS initially to grab a 25% market share, within one year after the launch, sales had stagnated. An in-house market analysis prepared for Murphy and Brand determined that market share was derived largely from those surgeons CPSS used as speakers, instructors, or who were invited to attend a Silberstein Memorial Cadaver Lab.

In an effort to improve sales, CPSS launched a customer loyalty program in February 2018 via an email to the CPSS sales team, which provided a 15% discount to those surgeons who used CPSS products in at least 45% of their back surgery cases and who committed to increasing their usage level to 75% in three years. While the customer files contain no contracts outlining the loyalty program, “loyal customer” purchase orders merely contained the notation “CLP Member” and “15% discount” in the fine print at the bottom of each order.

During Murphy’s March 2019 ROI Dashboard review at the CEMT, he highlighted that “as a result of our customer loyalty program, Mini-Space now enjoys a 40% market share and is on track by year end to grow at least another 10%.”

## THE ASK

A week after your first meeting with Chamberlain where she gave you the “hot potato” file to review, you and Chamberlain meet once more to go over your impressions of what you saw in the files. During that meeting, Chamberlain reiterates her concerns over the circumstances of Sistrone’s departure.

At the end of that meeting, Chamberlain directs you to prepare two documents:

1. A memorandum for her to reference as she prepares her presentation to the CPS Board of Directors scheduled for their next meeting in a month and half’s time. Specifically, she wants you to highlight and discuss for her all potential legal, regulatory, and compliance issues involving FDA and/or federal healthcare laws facing the company as a result of what is contained in the WCG Report file she gave you to review. As she told you, “I am a details person and want to be sure I clearly address both the issues and the law in my presentation.”
2. A “do’s and do not’s” communication to the head of the CPSS field force (to be shared with the sales force) clearly outlining that CPS does not condone the types of problematic behavior seen here, including handling inappropriate requests from senior company executives. As a side note, Chamberlain tells you that CPS needs to get ahead of this and educate the field force involved with selling medical devices about the perils of engaging in the types of behaviors observed in the file. She also tells you:

“Now don’t ever repeat this, but our field force is like a bunch of teenagers. They don’t listen, are extremely literal and always are looking for the loophole. They also view Corporate as being stupid, especially Legal. I know that behind my back they call me ‘Comrade Niki’ and they view Legal as ‘the sales prevention department’. Thus, you will need to provide clear, specific, detailed, and above all pragmatic directives on what you want done. It’s a tall order but I know you are up to it. That’s why I hired you!”

## END OF PROBLEM

Please refer to: *Competition Guidelines, Section 7: Submission Requirements*, for important drafting considerations.