

# ROY SNELL HEALTH CARE REGULATORY & COMPLIANCE WRITING COMPETITION

## 2022 PROBLEM

*This Competition Problem is purely fictional and prepared solely for this educational purpose.*

### Introduction – Winter Arrives

Winter had arrived in Youngstown, Ohio and a raw January wind cut like a hot knife through butter as Jack Smallen, Quality head for MOSS Laboratories, shuffled towards the blue corrugated steel building that seemed miles away instead of mere yards. Even from a distance, Jack could see the dark green MOSS Laboratories logo on the sign on the side of the building that housed part of the once proud and mighty Youngstown Sheet and Tube Company.

Shaking his head, Jack remembered that MOSS, too, was once proud and mighty, but now he and a team of three quality engineers were all that was left at the facility. “How did we ever get here,” Jack mused as he stepped up the pace to get out of the wind.

### Chapter 1 – Youngstown’s Favorite Sons

MOSS Laboratories was the vision of the Moss brothers, Wilbur and Oliver, venture capitalists who grew up in Youngstown and witnessed the collapse of the steel industry. The brothers made a fortune from skillful investments in the likes of Theranos and Purdue Pharma. But they were the lucky ones, exiting right before the two companies crashed and burned.

Always ones to see opportunity within chaos, the brothers recognized that the rapid onset of climate change, coupled with the COVID-19 pandemic, created a need for simple, in-home diagnostic test kits for dengue fever and malaria especially in the southern states, and for the U.S. military. Partnering with the University of Notre Dame, which had support from the Bill and Melinda Gates Foundation, MOSS Testing, a separate corporate subsidiary of MOSS Laboratories, worked to develop inexpensive dried bloodspot (DBS) test kits for consumers.

Taking a leaf from Apple’s playbook, MOSS Testing controlled the entire supply chain. The company manufactured the laboratory reagents, shipped the DBS card kits to consumers, and performed the analysis all from their state-of-the-art Youngstown facility. It also controls the web portal for consumers to order their kits and receive their results from a company contracted physician. It was a welcomed boost to a community short on jobs and tax revenue and the brothers were hailed as Youngstown’s favorite sons.

### Chapter 2 – A Dry Well

While initial interest in MOSS’s test kits for dengue fever and malaria was high, kit orders were well below expectations. Even covered reimbursements from Medicare and Medicaid were lagging. Thus, MOSS launched an aggressive educational and marketing campaign with physicians, clinics, and group practices.

The campaign was the brainchild of Dr. Jonthan Ross, noted infectious disease specialist and the paid chairman of MOSS Laboratories' Scientific Advisory Board. Dr. Ross also collaborates with NIH and sits on the FDA's infectious disease advisory board.

Prior to the pandemic, the program consisted of targeted in-person events involving lavish dinners, lots of alcohol, and a physician speaker, who would give a short presentation. One favorite venue for these programs was Mama Rossa's Steakhouse in Cincinnati. In a two-year period from 2018-2019, MOSS held over 275 events there. Mama Rossa's is co-owned by Dr. Ross and his sister Melody, although Dr. Ross is a silent partner in the restaurant.

Since the pandemic, MOSS has shifted its educational and marketing programs to an entirely virtual format. To accommodate the shift, MOSS now provides \$250 gift cards for meals and drinks to participants with no expiration date. Thus, they could be used once inside dining became safe again. In 2020 alone, MOSS distributed 100 gift cards to Momma Rossa's.

Despite these efforts, sales of the test kits continued to struggle prompting the Moss brothers to eliminate all but Jack and his team working on the test kits right before the Christmas shut down. Company insiders referred to it as the Christmas Mugging.

## Chapter 3 – Moss & Mold

Declining kit sales were not MOSS's only problem. To keep costs low, the brothers decided to house all MOSS operations in a single, abandoned steel mill that they acquired in a foreclosure sale. Although it was an efficient way to keep costs low, problems soon emerged. Several batches of the DBS cards were found to be contaminated with reagent particulates that triggered false positives.

Upon a more detailed investigation, Jack's team determined last year that the reagents themselves were contaminated with mold from the outdated ventilation system and this mold triggered the false positives. Based on their investigation, it appeared that the mold entered the building via the shipping department. From there it spread to the entire building because of inadequate partitioning between the shipping department, reagent department, testing department, and the offices.

Worse still, it affected MOSS Pharmacy, another MOSS Laboratories subsidiary, that provided the rest of the company with a stable and sizable cash-flow for operations and expansion.

MOSS Pharmacy compounded drugs for patients, hospitals, and clinics. It also compounded drugs for small animals distributed by veterinarians. It was completely separated from the rest of MOSS's operations, occupying a remote corner of the building. However, the compounding operations shared the same ventilation system as the rest of the building.

## Chapter 4 – Spoiling the New Year

As he entered the doors to the darkened facility, Jack replayed the urgent call he received last night. It certainly had put a damper on his New Year's Eve celebration.

Jack was celebrating with family and friends when his cellphone rang. As he pulled the phone from his pocket, Jack saw it was Oliver Moss calling.

“Well, this can’t be good,” he mused since Moss had left two weeks ago for his private Bahamas island. Waving aside the look of concern from his wife, Jack excused himself and went into the bedroom for some privacy.

Dispensing with any pleasantries, Moss got right to business telling Jack that Dr. Ross had received a tip from a friend in the Ohio Department of Health that the Justice Department, supported by the FBI, FDA, and the Ohio Attorney General’s Office planned to launch a dawn raid on the Youngstown facility right after the holidays.

According to Ross’s friend, the government was investigating an anonymous tip about product contamination involving both MOSS Testing and MOSS Pharmacy. “Jack, I don’t have to tell you how serious this is. We’ve got to make this go away.”

Moss then ordered Jack and his team to go to the facility on New Year’s Day and destroy any remaining DBS cards, reagents, test results, as well as all documents and reports detailing the contamination investigation. He had ended the short call with, “I know I can count on you.”

Stepping into the foyer, Jack disabled the building’s alarm system and internal security cameras and sat down to await the rest of his team, and brief them on their task. By nightfall, the team had destroyed the test kit materials and the paper documents. They also wiped all the office computers’ hard drives.

Punching in the building’s alarm code and locking the front door, Jack reflected on how his team had worked quickly and efficiently to remove all traces of the product components and documents. They even went so far as to load everything into giant garbage bags that were now headed to the city landfill. Jack was proud of his team and just before leaving the building, he stopped to text Moss, “What you asked is done. Mission Accomplished.”

Hustling to his car to head home and get some sleep, Jack muttered to himself, “Boy, the temperature sure dropped,” and he hoped it was not an omen.

The next morning, FBI Special Agent-In-Charge Bryan Connor from the Cleveland field office and his team of twenty-five agents all wearing classic blue windbreakers arrived at the facility and presented Jack with a search warrant. As the agents got to work, Connor toured the facility with Jack.

Passing a locked door on the second floor, Connor asked Jack what was in the room. Hesitating at first, Jack finally stammered, “It’s the company server room where the mainframe and backup servers are kept.”

“I’ll need the master key for this room,” Connor told him. When Jack replied he didn’t have the key, Connor snapped, “Well, I’m sure the janitors have master keys, so get them or we’ll break the lock.” As Jack left to track down the master keys, he realized with a sinking feeling that he and his team had failed to destroy everything and he immediately texted Oliver Moss, “We have a problem here.”

## Chapter 5 – Shifting Through the Rubble

Back in Cleveland, Connor and his team began meticulously sifting through the MOSS Laboratories backup files. It was all there in black and white.

The investigators uncovered Jack's original investigation report and Oliver's email response about it to Jack.

TO: Jack Smallen  
FROM: Oliver Moss  
CC: Wilbur Moss  
SENT: November 23, 2021  
RE: Quality Contamination Investigation

Jack,

This is getting tedious. While I don't doubt your expertise, I'm not convinced that the problems you highlighted in your report are that serious or that we need to worry about MOSS Pharmacy. Merely stating that the ventilation system serves the entire facility does not mean we have a problem.

We have seen nothing to suggest that MOSS Pharmacy products are contaminated, and as you noted, there have been no new contamination issues with the test kits. Thus, I'm sure that mold problem has gone away. The company is in a precarious financial position, and we cannot afford any more time on this, and we certainly are not going to spark a customer panic by notifying them or the regulators. And I am certainly not bringing this crap to the Board. WE ARE DONE WITH THIS.

They also uncovered an email from John Pope, Jack's environmental specialist, written just two weeks before he was terminated in the Christmas Mugging.

TO: Jack Smallen  
FROM: John Pope  
CC:  
SENT: December 7, 2021  
RE: Management Denial

Oliver's statement that MOSS Pharmacy is not impacted by the ventilation issue is nuts! As we both know, the ventilation system is 1970s technology and was never properly maintained. The ductwork is one massive loop running between all the departments and areas in the building. There is simply no way that MOSS Pharmacy is not affected by the mold problem.

All I can conclude is that MOSS Pharmacy has not seen or reported contamination because they are not looking hard enough or even at all. Even a green inspector is going to figure this out unless we get Moss to approve the \$2M retrofit program and get it corrected **BEFORE** they set foot into the facility. If he doesn't, we all are going to be wearing orange – and I don't look good in orange!

Digging further, they unearthed an email from Wilbur Moss to Ross about the test kit educational programs.

TO: Jonathan Ross

FROM: Wilbur Moss  
CC: Oliver Moss  
SENT: March 11, 2020  
RE: Pandemic Commitment

Jon,

I cannot thank you enough for all your efforts to make our educational programs a success. And what a success they've been! Your efforts in 2018 and 2019 to line up speakers and host educational events have been instrumental in staving off disaster! We've seen an excellent return on our investment.

Therefore, I wanted to make it clear that we are committed to continuing the programs in 2020 despite this pandemic. Since we cannot hold in-person programs at this time, we are going to shift to a virtual format. However, we need to reward attendees for showing up by giving them gift certificates to Mama Rosa's that they can use when the pandemic inevitably burns itself out.

Is that something you and your sister would consider? We figured that it is a way that we can support Mama Rosa's during the pandemic and would allow you to recoup customers when you can reopen. If so, I talked with Oliver, and we are increasing your compensation as chairman by \$10,000 so that in 2020 you'd receive a total of \$100,000. It's just our way of showing how much we value your friendship and support.

## Chapter 6 – A Mossy Pickle

After receiving Jack's cryptic text message, the Moss brothers began to realize they and the company could be in serious trouble. Racking his brain, Oliver remembered that he met Orrin Bachman, managing partner of the Bachman Law Group, two years ago at a trade association dinner where Bachman presented on strategies to avoid government investigations and prosecutions. He recalled Bachman was a bald, heavy-set man, who exuded a quiet air of authority and confidence.

Two days after Connor's "visit" and learning the extent of the bad news from Jack, the brothers boarded their private Gulfstream jet and flew directly to New York to meet with Bachman and his legal team at the Group's flagship offices in Times Square. It was not a pleasant meeting.

Bachman was aware of the raid on MOSS Laboratories and that the government had gathered a mountain of evidence, made worse by the fact that the company had no established records retention policy. After three grueling hours, during which Bachman probed for facts and weaknesses, he concluded by saying, "Gentlemen, this is one heck of a pickle you've gotten yourselves into. We need to do some research and we'll get back to you shortly."

## The Ask

As Bachman's right-hand senior associate, he has tasked you with preparing a memorandum for him that highlights and discusses all potential legal, regulatory, and compliance issues involving FDA and/or federal healthcare laws facing the Moss brothers and their company, including any additional investigation or review needed.

He also asked you to synthesize the memo in a PowerPoint slide deck for him to present to Oliver and Wilbur stressing that they both hate what they refer to as legal “mumbo jumbo”, and that the presentation must be clear and concise, but comprehensive.