Roy Snell Health Care Regulatory & Compliance Writing Competition

2024 Competition Problem

Although inspired by actual cases, this problem is fictional and prepared solely for educational purposes.

Introduction

The blizzard's gale-force winds howled like a banshee as Terrence Scott sat before the cabin's stone fireplace. As often happened, Scott thought about his grandfather, Wilbur, as he listened to the Lake Superior maritime report on Wilbur's WWII vintage radio. Wilbur volunteered with the Royal Air Force in 1940 and later became a Colonel with the Army Air Corps, listening to the same radio broadcasting updates from the European theater between bombing missions. Scott sadly reflected that Wilbur would be 101 this year had drug-resistant sepsis not killed him, which motivated him to establish Lockwood Pharmaceuticals.

Founded in 1995, Lockwood Pharmaceuticals, Inc. is a small biotech company headquartered in Rochester, Minnesota, focused on developing new antibiotic treatments for drug-resistant gram-negative bacterial infections. Lockwood is seeking FDA approval for its new product, Ambastin CR.

Ambastin is a new version of an old compound, Amoxystin. Discovered in 1965 by Smith Kline and French Laboratories (SKF), Amoxystin is derived from a naturally occurring fungus. However, development was discontinued due to potential toxicity concerns discovered during a University of Pennsylvania study.

Lockwood acquired the rights to Amoxystin in 1996. Since acquiring the asset, the company has worked tirelessly to address the toxicity concerns and finish the development process started by SKF chemists. Lockwood is pioneering an oral, controlled-release version of Amoxystin, called Ambastin, as part of the development process. Unlike other high-powered antibiotics for drug-resistant infections, because Ambastin (Amoxystin) is an oral medication, it does not need hospital or clinic administration. Moreover, with its controlled-release formulation, Lockwood can avoid the toxicity issues seen earlier with Amoxystin.

Confident that the FDA will recognize Ambastin's benefits and approve it shortly, Scott's bigger challenge is convincing hospitals and clinics to use it instead of other established intravenous antibiotics, especially for Medicare and Medicaid patients. Thus, Scott pondered his call the day before with Jason Kelso as he threw another log on the fire.

A Tale of Two Friends

Although Scott and Kelso met as college undergraduates and became firm friends, their paths radically diverged after Harvard. After graduation, Scott went to Wharton to pursue an MBA. Kelso went to MIT to study Computer Engineering and Machine Learning.

Kelso's call was a surprise because the two friends had not spoken in years. Kelso told Scott that after MIT, he joined several failed Silicon Valley startups, including Theranos. Having gained experience but little else to show for his efforts, Kelso recently formed his own company, Hercules Health Records, Inc. (HHR). He told Scott he planned to use AI to revolutionize the world of electronic healthcare records. Thus, HHR's motto is "We do the heavy lifting, so you don't have to."

However, despite its promising proof of concept, HHR needed additional funding to finish the system, known as ClinLIFTAI, and secure customers. Thus, he told Scott, "Terry, I think there is an opportunity to help each other. You have the cash I need, and with our system, I can guarantee HHR's clients will prescribe Ambastin." Kelso told Scott he was looking for a $5 million unrestricted grant from Lockwood and needed Lockwood's decision by the end of the following week because he had other companies interested in partnering with HHR, "Besides, the Christmas Holidays are right around the corner."

Lockwood Goes All In

Upon returning to the office, Scott summoned his CFO, Travis Grant, and Jay Simpson, Vice President of Regulatory and Clinical Affairs, to his office to discuss HHR's proposal. During the brief meeting, Grant and Simpson indicated they had concerns with what Kelso proposed. Because of the short decision timeline given to Lockwood, Scott requested that both men summarize their thoughts in emails sent to him. To maintain confidentiality, he asked that they simply refer to the topic as "Project Record" and not use Kelso's or HHR's name. Instead, they would use "K" for Kelso and "H" for HHR.

After the meeting, Grant wrote to Scott:

> December 14, 2021
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> To: Terrence Scott
>
> From: Travis Grant
>
> CC: Jay Simpson
>
> Subject: CONFIDENTIAL – Project Record
>
> After our meeting, I reviewed our current funding and projected expense forecasts. We can support K's request for $5 million without negatively impacting our clinical development and commercial plans. However, we need to be careful. Clearly, K passionately believes in H's solution but has no experience delivering such a product. In addition, we have no evidence of the "promising proof of concept," he claims. Thus, H's solution is a "black box" as far as we are concerned.
>
> Consequently, if we decide to proceed, I recommend creating a formal contract with milestones between us and H instead of making a simple, unrestricted grant as we do for independent medical education. K is asking for a lot of money, and we need protection.

Simpson responded to the group:

> December 15, 2021
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> To: Terrence Scott
>
> From: Jay Simpson
>
> CC: Travis Grant
>
> **Subject: RE: CONFIDENTIAL – Project Record**
>
> I just learned from my contact at the FDA that we can expect our Ambastin approval letter by January 15, 2022. That's the good news. The bad news is that despite our positive data, they will require a boxed warning about potential toxicity, and we are restricted only to third-line therapy after the failure of two other drugs. My contact told me that we need additional clinical studies if we hope to make Ambastin first or second-line therapy.
>
> These restrictions really complicate insurance reimbursement and will make it even more difficult to penetrate the market than we thought. Therefore, I agree with Travis that we need a formal contract from H in exchange for this large investment.

Based on the input received from Grant and Simpson, Scott wrote to Kelso:

> December 16, 2021
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> To: Jason Kelso
>
> From: Terrence Scott
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> **Subject: CONFIDENTIAL – Your Proposal**
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> Jason, I wanted to inform you that Lockwood will provide HHR with the requested $5 million. However, things got more complicated because we learned that the FDA intends to require a boxed warning for Ambastin and to restrict us to third-line therapy. Nevertheless, I assume your guarantee that HHR's clients will prescribe Ambastin if they use ClinLIFTAI still stands.
>
> If it does, we will create a contract between our two companies and provide the $5 million requested. I am sure you will agree that, given these developments, Lockwood cannot provide an unrestricted grant for such a large sum. Please let me know if this approach is acceptable. I look forward to hearing from you at your earliest convenience.

Although disappointed, Kelso immediately called Scott and agreed to his demand for a contract.

The Agreement

On January 5, 2022, two days before the FDA approved Ambastin with the restrictions Simpson told Scott about, Lockwood and HHR signed an agreement. Under the terms of the agreement, Lockwood agreed to provide $5 million to HHR to finish the system development of ClinLIFTAI and secure clients.

As conditions for receiving the funding, HHR agreed to the following timeline:

1. Complete the development of ClinLIFTAI, including any necessary Health and Human Services (HHS) certifications, by May 15, 2022.
2. Launch the final system by June 1, 2022.
3. Have 50 active client users of the system by September 1, 2022.

The agreement also specified that if HHR did not meet the timeline, HHR must repay the $5 million to Lockwood with 10% interest or $5.5 million.

However, just having client users was not enough for Lockwood. Therefore, separate from the written agreement, Kelso and Scott agreed in a series of text messages that ClinLIFTAI users had to generate at least 50 Ambastin prescriptions by the end of 2022.

Kelso's Plan

Before first guaranteeing Ambastin prescriptions to Scott, Kelso had formulated a plan to achieve that. Kelso and his team had included code within the ClinLIFTAI that would automatically notify physicians what medications to prescribe based on the patient's diagnosis, their clinical data (e.g., laboratory test results, concomitant medications, etc.), and insurance coverage. These supposedly evidence-based notifications were called Clinical Decisions Support Alerts or CDSAs.

Since HHR controlled the coding behind the CDSAs, Kelso knew he could manipulate them for patients with drug-resistant gram-negative bacterial infections so that the system would recommend Ambastin as the drug of choice instead of the older, intravenous drugs. Kelso also realized that busy physicians were unlikely to scrutinize the CDSA recommendations closely and that hospital and clinic administrators would support the CDSA recommendation because it would free up scarce outpatient resources for more lucrative activities such as chemotherapy or dialysis.

When Scott informed Kelso of the boxed warning and third-line designation, Kelso knew that meeting his agreement with Scott to generate 50 Ambastin prescriptions by the end of 2022 was almost impossible. However, ever the problem solver, Kelso sent the following email to his Chief Coder, Joshua Nicholas:

> December 17, 2021
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> To: Joshua Nicholas
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> From: Jason Kelso
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> **Subject: URGENT – Recoding the Ambastin CDSA**
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> Josh, I learned from Terrence Scott over at Lockwood that the FDA plans to approve Ambastin with a boxed warning (toxicity) and only as a third-line therapy. We need to recode the CDSA ASAP so that it ignores the boxed warning and will recommend Ambastin regardless of its third-line status. Can you do that? Thanks, Jason

Nicholas told Kelso that, of course, he could do that, after all, he was the company's Chief Coder. The following week, Nicholas met with Kelso in HHR's empty offices to review the system changes. Thrilled by what he saw, Kelso ordered Nicholas to put the revised code into production without further testing immediately.

Challenges & Solutions

As part of the January 2022 agreement, HHR agreed to hold monthly joint progress meetings (JPMs) with Lockwood to update them on ClinLIFTAI's status. At the JPM on February 1, 2022, Grant and Simpson, whom Scott tasked with representing Lockwood, raised concerns about the negative impact of the FDA's approval restrictions.

Kelso told them that the system was already configured to account for those restrictions, and they should not pose any problems. While skeptical about Kelso's overly positive response, neither Grant nor Simpson inquired further and simply responded that Scott would be pleased.

In late February 2022, Nicholas told Kelso that although the Ambastin CDSA issue was resolved, ClinLIFTAI's software still lacked the necessary functionality to pass the Health and Human Services certification. Nicholas told Kelso that because of the continuing effects of the COVID-19 pandemic, he felt it was "nearly impossible" that HHR would achieve certification by the June 1 deadline. Kelso told Nicholas, "Do whatever it takes, but that deadline must not slip."

At the same time, Sandra Ludeman, HHR's Vice President of Sales and Marketing, told Kelso that potential customers were extremely reluctant to purchase ClinLIFTAI "sight unseen." Thus, she only had five verbal commitments for the new system and no signed contracts. Kelso responds, "Well then, we will have to give them something to look at."

After he met with Nicholas and Ludeman, Kelso sent the following email to Nicholas and Ludeman:

> February 4, 2022
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> To: Joshua Nicholas, Sandra Ludeman
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> From: Jason Kelso
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> **Subject: Meeting the ClinLIFTAI Deadlines**
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> Josh and Sandra, as you both know, HHR must meet the timelines in our agreement with Lockwood. If we don't, we must repay the funding with interest. That will bankrupt us. Thus, FAILURE IS NOT AN OPTION.
>
> Since we already have a prototype with limited functionality, let's rebrand it as a finished product called ClinLIFTAI, v. 1.0, and show it to prospective clients. We also can submit the prototype for HHS certification if we play our cards right. If we don't mention it, nobody will ever know it's only the prototype, not the finished product.
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> Josh, I need you to ensure that the prototype will work sufficiently to make it appear to be the finished product.
>
> Sandra, I am doubling your marketing budget with some Lockwood money. We need to design an incentive/referral program for early adopters, especially those who will prescribe Ambastin. Let's meet to discuss.

In May, the JPM minutes reflected the following:

Minutes – Joint Lockwood/HRR Progress Meeting – May 9, 2022

Attendees: T. Kelso, J. Nicolas, S. Ludeman (HHR). T. Grant and J. Simpson (Lockwood)

1. ClinLIFTAI, v. 1.0, has been submitted for HHS certification. Certification is expected by May 30. Lockwood agrees that the 15-day delay is acceptable and will not consider it a contract breach.
2. HHR now has contracts with 35 customers for the system. HHR expects to have 30 more by September 1.
3. HHR has identified no significant issues with the system.
4. HHR is on track to deliver 50 Ambastin prescriptions from client users (clinics, hospitals, physician practices) by the end of 2022.
5. Next meeting will be August 2022.

House of Cards

In February 2023, Kelso, Nicholas, Ludeman, Scott, Grant, and Simpson met to review the Lockwood/HHR relationship. HHR received certification for ClinLIFTAI, v. 1.0, and was developing version 2.0. HHR also revealed that it had 75 active clients who were generating an average of one Ambastin prescription per month. Thus, based on this early success, Kelso projected that HHR would sign another 75 within the next six months.

Right after the celebratory meeting, Nicholas, familiar with the success of other healthcare whistleblowers, contacted Marsha Black, a partner with Foley, Ashbridge, Kanter, and Ellis, saying he wanted to file a whistleblower lawsuit. He told her Kelso recently rejected his requested 10% salary increase and "was treating him worse than a dog."

He outlined Kelso's manipulation of the CDSA and the certification process, telling her he had "hacked the system to pass" at Kelso's direction. However, by the end of 2022, many of HHR's customers threatened to cancel their ClinLIFTAI, v. 1.0 contracts because they had discovered that the system did not work as promised. For example, the system would inexplicitly delete crucial patient data such as concomitant medications. Moreover, some customers also discovered that the CDSA was generating inappropriate Ambastin prescriptions.

Nicholas told Black that HHR responded to the "mutiny" by giving the complaining customers rebates of 25% off the original purchase price, not to cancel their contracts. HHR further increased the rebates to 35% for those customers who agreed to keep prescribing Ambastin using the "gerrymandered CDSA." In addition, HHR sometimes provided an additional 10% in the form of cryptocurrency directly to key decision-making customer employees for their silence and continued support.

Finally, he told Black that Ludeman and Kelso also instituted an Adopter Referral Program (ARP) that paid existing customers a bonus of up to $10,000 for referrals when the referrals resulted in new customer sales of the system. HHR provided the ARP bonus as a credit for future HHR upgrades, products, and services.

The Ask

Legal Memorandum

You are Marsha Black's senior healthcare litigation associate. She has asked you to prepare a memorandum outlining the legal issues Nicholas presented and identifying who should be included in the complaint she plans to file in federal court.

Slide Deck

Black also needs you to prepare a slide deck based on the memo for her to present to the U.S. Attorney's Office when the case is filed under seal. The case will be stylized as *U.S., ex rel. Joshua Nicholas v. Hercules Health Records, Inc*., *et al.*, Case No. 24-cv-00xxx (D. Minn.).

She stressed that the presentation must be concise because the government reviews many whistleblower claims. Moreover, she emphasized that a goal of her presentation is to avoid government intervention simply to dismiss the matter and suggests you review the U.S. Supreme Court case *U.S., ex rel. Polansky v. Executive Health Resources, et al.*, No. 21-1052 (June 16, 2023).