

## **FifthFluor Medical Part 1: Bold Moves**

*Joyce Baker had no trouble with confrontation. Growing up in a family with five successful collegiate athletes, there had never been a question of Joyce's ability to hold her own when challenged. Joyce felt that the competition that pervaded her parent's home had taught her how to pursue her own objectives while maintaining a healthy respect for her rivals. She was certain the environment provided the motivation she had needed to succeed both on the lacrosse field and in her undergraduate and graduate biochemistry studies.*

*Her competitiveness had a companion, however; one that periodically proved less helpful. Joyce had little patience for colleagues who either failed to share her goal orientation or pursued their own agendas in a manner that Joyce judged to be devious. Facing such a situation now, Joyce knew it was going to take every bit of control she could muster to remain focused on the big picture.*

### **Pursuing a New Antibiotic**

FifthFluor Medical had been established to build on an exciting discovery made by Dr. Alexander Audax at the University of Iowa. In the mid 1990s, Dr. Audax had received a grant from a large Japanese manufacturer of amino acids. The grant had funded research that might improve the purity of fermentation processes used to manufacture amino acids. In the course of the work, Audax had identified opportunities to improve the performance of fluoroquinolones. Distinct from the other rapidly developing innovations in the field, products based on Dr. Audax's approach were soon termed the "fifth generation fluoroquinolones."

Investment in a new antibiotic was controversial. Some analysts had concluded that a combination of limited treatment windows and low pricing undermined the ability to gain returns for the high costs of clinical development. However, government programs including the Biomedical Advanced Research and Development Authority (BARDA) and the Generating Antibiotics Incentives Now (GAIN) Act were subsidizing investment and providing extended periods to capture returns.

Accessing capital from a group of angel investors who normally focused on the AgChem sector, Dr. Audax had formed the company and initiated early research. The company had originally been named Audaxtious Innovation.

### **Time for a New CEO**

Three years later, Joyce received a call from John Cooper. The two had met when John was a junior associate at one of the venture capital firms that had invested in Joyce's last company. At the time, Joyce had felt substantially out of her comfort area leading Business Development for the genomics focused biotech. John supported and mentored Joyce as she became acquainted with the finance and market understanding aspects of her job.

John explained that his firm had been the single traditional biotech focused VC that invested in Audaxtious Innovation. He told her that the science had progressed nicely, but the CEO role was now far beyond the

capabilities of Dr. Audax. Speaking in a tone that conveyed a smile on his face, John told Joyce that he had only one candidate to replace Audax and he was on the phone with her.

Joyce's first months at the company were a whirlwind. In quick succession, she established a new headquarters for the company in Boston's Seaport, she secured a substantial BARDA grant, and she changed the company name. It had struck Joyce at the time that Dr. Audax was helpful in all areas except the last. Despite his obvious unhappiness with the name change, Audax continued to make valuable contributions to the company. While he maintained his residence in Iowa, he worked two to three days a week in Boston and stayed in a local, company financed apartment.

## **Progress in the Clinic**

In the clinic, FifthFluor was making great progress. Preclinical studies had progressed nicely and the Phase 1 study, funded by the BARDA money, offered strong support for progressing to Phase 2. Joyce was further encouraged by the knowledge that products with positive early clinical results in infectious disease have a much higher probability of later success than compounds in other categories. She worked that information along with a discussion of the implications of the GAIN act into a pitch presentation that had attracted an enviable group of investors.

The company was preparing to pivot quickly to a Phase 3 study as soon as the Phase 2 program read out. A plan for the pivotal trials had been established and consensus had been reached regarding the anticipated budget. Naturally, Dr. Audax had taken an active role in designing the trial and he was leading the effort to vet contract research organizations (CROs) who would conduct the study. The initial commitment to the CRO was anticipated to land somewhere near \$20 million.

## **Picking a CRO Without Even Knowing the Choice Had Been Made**

Until this morning, Joyce had thought that all of this was progressing smoothly and professionally. Then, she arrived in her office to find the company's controller, Jackson Feefirst. Jackson alerted Joyce to the fact that he had received an initial invoice from Pivotquest, one of the CROs being considered for the work. Jackson told Joyce that there was no paperwork supporting the selection of Pivotquest and went on sardonically, "of course, no one has followed the Purchase Order process that has been suggested."

Learning that Dr. Audax was working from Iowa this morning, Joyce made an immediate call to his mobile phone.

"Andrew, what is going on with the selection of Pivotquest? We received an invoice from them and we haven't even completed the selection process."

Audax calmly replied, "Don't worry Joyce, I haven't signed anything yet. Richard told me that he could put people to work right away on our program and that if we didn't jump on this chance, we will likely lose the opportunity to work with some of his best people. So I told him to go ahead and get started. I figured if we have to unwind this, we can."

Joyce felt the same surge in adrenaline she had experienced when she had witnessed competing players taking cheap shots on her teammates ankles. “Are you kidding me, Andrew. When did you make these arrangements?”

Sounding a little agitated, Audax replied, “Early last week. Tell me, am I in charge of the selection process or not?—No, wait a minute, don’t tell me now. I’ve got a small emergency occurring outside. I’ll call you back.”

The phone went dead. Joyce was nearly beside herself with rage.

*Joyce put the phone down. How could anyone at his age act as unprofessionally as Audax? She didn’t even know whether she was currently at contractual risk or even if there was a financial compliance breach. The company hadn’t established Standard Operating Procedures for these types of decisions, but she had never anticipated that Audax would think he could proceed as he had independently. First, she needed to address the current situation, then she needed to determine how to get better controls in the company.*