

So Close and Yet So Far

It's a Big Setback

You are the project leader for one of the company's most promising drugs that was close to receiving final approval from the FDA. Instead, you have just been notified that the company has received a warning from the FDA related to safety requesting a clinical hold on the product release. You immediately call a team meeting. The group is somber and stunned by the news.

But they immediately plan a full review of the requirements from the FDA to develop a recommendation for senior management about the implications of the delay. After several fast and creative meetings, the team has determined that this will delay the launch of this promising product for at least one year. While the company has not fully staffed the sales force, the Commercial infrastructure (Business head, Directors, Marketing, and Sales Operations) have all been staffed. Some technical sales specialists have been hired. In addition, the manufacturing department has also ramped up for production, and there will now be significant excess capacity.

The Operations members of the team have met with manufacturing to plan a strategy for dealing with the excess capacity. The Commercial team is meeting to decide how to manage the sales and marketing issues. Given everything that has happened you feel the team is handling the setback unusually well. Several people have mentioned to you that they still believe in this drug and believe it is important to meet the FDA's additional requirements because of the positive impact this drug could have for patients.

Wouldn't It Be Nice If Everyone Felt the Same Way?

Unfortunately, not everyone on the team is reacting the same way. Most disappointing is the reaction of the Clinical Project Manager, Clay Gustain. On some level, you understand how Clay feels. He was one of the people who worked hard to accelerate the Phase 3 Clinical trials. He has put off vacations and other time off and made this work his most pressing priority – not only at work, but in his life. At first, you were patient and understanding with his bitter disappointment. You could understand why he might have the strongest reaction of anyone on the team. That patience is now starting to wear thin because at each team meeting, Clay can't seem to get past what happened and his perception of how unfair it is. He wastes time in meetings complaining about the unfairness of the FDA's decisions instead of focusing on how the clinical team can address the FDA's concerns. Instead of leading the project forward, he is increasingly becoming an obstacle.