

## 6. Risk and Reward

John Jones: Good Afternoon, Ms Smith. I understand that you are the new Vice President for Quality Control at DRUGSARE US, Inc.

Jane Smith: Yes, it's a pleasure to meet you. My boss asked me to see you to obtain your opinion about an ongoing situation as our outside counsel.

Jones: So, tell me what is going on.

Smith: As you know, we manufacture anti-viral vaccines and medications for world-wide distribution.

Jones: Yes, we have done legal work for DRUGSARE US for over fifteen years and I am quite familiar with your operations.

Smith: During the past year, we have manufactured 240,000 units of medication that have been shipped to various suppliers in Africa and Asia.

Jones: What was the cost to you of this medication?

Smith: About \$ 2.4 million.

Jones: What have the suppliers done with the medication?

Smith: As far as we can tell, about 12,000 units have already been dispensed to patients in Burma and Rwanda. The rest remain in inventory of the suppliers, but I have no doubt that the medication will all distributed during the coming year.

Jones: So far, I don't see why you need our services.

Smith: We did after we discovered a defect in the manufacturing process that will result in as much as 1% of this medication likely denaturing. That will not only cause it not to work, but it is then likely to contain a serious defect that could lead to the death of patients who take the defective medication.

Jones: Is there any way DRUGSARE US can identify the defective units?

Smith: Not without examining virtually every carton of the medication or undertaking a thorough and expensive examination of each patient who takes the medication.

Jones: What is the worst case scenario if you do nothing?

Smith: If nothing is done, some 2,400 people are at serious risk of death.

Jones: Let me look into this and get back to you in a few days.

2 DAYS LATER

Jones: Ms. Smith, our research indicates that DRUGSARE US has not violated any law or regulation in the United States or any of the foreign countries involved. Further, if you fail to take any corrective action, you may be subject to tort liability, but not to criminal prosecution. Finally, since we believe there will be real difficulties in potential plaintiffs bringing successful lawsuits in this country, DRUGSARE US's liability exposure appears to be less than the costs of a recall of the remaining medication.

Smith: Thank you for that analysis and advise. Given this, it is the position of DRUGSARE US that we will not take any corrective action and we expect you not to disclose these facts to anyone.