

complaints surfaced? How many lives would have been saved if the executives took corrective action at the first signs of problems? How many infections could have been averted if the board provided proper governance and incentivized the right behavior of its executive team? The answers to these questions can range from none to all. I hope for the victims and their families that some of these answers were determined in the two years from the outbreak of the infections to the settlement.

Leaders are defined by how they guide companies through a crisis. I previously described how Johnson & Johnson responded to the Tylenol tampering—and it wasn't even an issue under their control! However, it involved patient safety and brand protection. Today, in a number of MBA schools, the Johnson & Johnson response to the Tylenol tampering is taught as a case study on how to properly lead a company through a crisis.

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## SUMMARY

We defined *pharmacy compounding* at a deeper level. We also showed examples of nonsterile compounding solutions and compounded medicines that are sterile for office use. We introduced the Drug Quality and Security Act and Title I: Compounding Quality Act, and proceeded to discuss the Food and Drug Modernization Act of 1997 as a prelude to the Drug Quality and Security Act. We quickly revisited Section 503A and went through why its exemptions (if earned and qualified) are so important by showing the extensive process of FDA trials for new drugs. We then looked at Section 503B and outsourcing facility registration and reporting.

We discussed some issues to be resolved, such as a few gray areas to be defined and inspections of compounding facilities. We then did an in-depth look at governance and leadership, and how there were breakdowns in these areas with the NECC.

Going back to my introduction, I mentioned that there are close to 2 million people employed in the pharmaceutical drug industry. People make mistakes. There are also people who do bad things, either by accident or intentionally. With the NECC, it appears that negligence and an absence of governance and leadership contributed to the fungal infections and loss of life. Regulations to compensate for bad governance and bad leadership will prevent bad situations from getting worse. There must be additional measures and innovations to prevent such situations from