

- 66.** A company is concerned with the high cholesterol levels of many of its employees. To help combat the problem, it opens an exercise facility and encourages its employees to use this facility. After a year, it chooses a random 100 employees who claim they use the facility regularly, and another 200 who claim they don't use it at all. The cholesterol levels of these 300 employees are checked, with the results shown in the file P09\_66.xlsx.
- a. Is this sample evidence “proof” that the exercise facility, when used, tends to lower the mean cholesterol level? Phrase this as a hypothesis-testing problem and do the appropriate analysis. Do you feel comfortable that your analysis answers the question definitively (one way or the other)? Why or why not?
  - b. Repeat part a, but replace “mean cholesterol level” with “percentage with level over 215.” (The company believes that any level over 215 is dangerous.)
  - c. What can you say about causality? Could you ever conclude from such a study that the exercise *causes* low cholesterol? Why or why not?

## CASE

## 9.4 REMOVING VIOXX FROM THE MARKET

For years, the drug Vioxx, developed and marketed by Merck, was one of the blockbuster drugs on the market. One of a number of so-called Cox-2 anti-inflammatory drugs, Vioxx was considered by many people a miracle drug for alleviating the pain from arthritis and other painful afflictions. Vioxx was marketed heavily on television, prescribed by most physicians, and used by an estimated two million Americans.

All of that changed in October 2004, when the results of a large study were released. The study, which followed approximately 2600 subjects over a period of about 18 months, concluded that Vioxx use over a long period of time caused a significant increase in the risk of developing serious heart problems. Merck almost immediately pulled Vioxx from the American market and doctors stopped prescribing it. On the basis of the study, Merck faced not only public embarrassment but the prospect of huge financial losses.

More specifically, the study had 1287 patients use Vioxx for an 18-month period, and it had another 1299 patients use a placebo over the same

period. After 18 months, 45 of the Vioxx patients had developed serious heart problems, whereas only 25 patients on the placebo developed such problems.

Given these results, would you agree with the conclusion that Vioxx caused a significant increase in the risk of developing serious heart problems? First, answer this from a purely statistical point of view, where *significant* means statistically significant. What hypothesis should you test, and how should you run the test? When you run the test, what is the corresponding  $p$ -value? Next, look at it from the point of view of patients. If you were a Vioxx user, would these results cause you significant worry? After all, some of the subjects who took placebos also developed heart problems, and 45 might not be considered that much larger than 25. Finally, look at it from Merck's point of view. Are the results practically significant to the company? What does it stand to lose? Develop an estimate, no matter how wild it might be, of the financial losses Merck might incur. Just think of all of those American Vioxx users and what they might do.