

The Future of Pharma Compliance: An Interactive Quiz

Janet Rehnquist, Esq.
Co-Chair, Health Care Practice,
Venable LLP (Washington, DC)

Former Inspector General,
U.S. Department of Health and Human Services

1. It is more important for a pharmaceutical company to have a credible compliance program than a blockbuster drug.
 - A. True
 - B. False

2. What benefits will a credible compliance program provide?
- A. It can mitigate intent.
 - B. It can keep you in business.
 - C. It can create an environment of trust and integrity.
 - D. It will prevent whistleblowers from coming forward.
 - E. All of the above.
 - F. A, B, and C.

3. Can a company ever devote enough money and resources to its compliance efforts to satisfy the government?
 - A. Yes
 - B. No

4. The marketing department should track the impact of the Company's investment in CME activities to ensure that it is getting adequate value.
- A. True
 - B. False

5. A company uses a particular consultant regularly for research and training activities. The consultant is a well known expert in her field of medical research. The company's internal trend analysis indicates that it has paid this expert \$575,000 in the last year for many different projects. Can the company continue to use this expert?
- A. Yes
 - B. No
 - C. Maybe

6. Which of the following is relevant to your decision in #5 above?

- A. The Marketing Department does not track this arrangement.
- B. The arrangement is administered by the Medical Division and is separate from Marketing.
- C. Similarly situated experts typically earn \$250-\$300K per year in fees.
- D. Similarly situated experts typically earn \$500-700K per year in fees.
- E. The consulting agreement is written, signed and specific.
- F. All of the above.
- G. None of the above.

7. Compliance officers for hospitals, pharmaceutical companies, and other providers are sought increasingly by federal investigators to discuss internal wrongdoing because:
 - A. They are a good source of information.
 - B. They are a convenient focal point.
 - C. They have more global corporate responsibility.
 - D. They are sometimes lawyers.

8. In light of this trend, a compliance officer might wish to:
- A. Reconsider his or her career choice.
 - B. Advise senior management of this development.
 - C. Develop a game plan in advance for dealing with government investigators.
 - D. Practice being interviewed by government investigators.
 - E. All of the above.
 - F. B, C, and D only.

9. A government investigator calls your office unexpectedly and you are sitting at your desk. You should:
 - A. Take the call and be as cooperative as possible to show good faith. Then discuss the encounter with company counsel.
 - B. Duck the call and put the message at the bottom of your in box.
 - C. Take the call and get as much information as you can without volunteering anything then promptly report this encounter to company counsel.

10. It is important for a compliance officer to understand the company's philosophy on compliance when responding to the government so that:

- A. He or she can present the company's programs in the best possible light.
- B. The compliance officer and the company present a consistent message.
- C. It is not important.
- D. A and B.

11. As a compliance officer, you are charged with ensuring the company's compliance with the spirit and the letter of many federal rules and regulations. One day, you receive a call from the company hot line describing sales practices by a "top gun" district manager -- a call that has you reaching for the Tums. You should:

- A. Promptly respond to this situation according to your company's written protocol.
- B. Contact your internal auditors.
- C. Contact company counsel.
- D. Try to trace the call from the hot line.

12. If a compliance officer is contacted by a government investigator, he or she should call:
- A. Company counsel.
 - B. Your friend who is a former FBI agent.
 - C. Your mother.
 - D. Outside counsel.
 - E. It depends.

13. If a compliance officer is contacted by a government investigator, prior to meeting with the investigator, the compliance officer should:
- A. Prepare to talk to the government by launching an independent investigation of company policies that the regulators might not like.
 - B. Prepare to talk to the government by meeting with company counsel and conducting a “murder board.”
 - C. A and B.

14. If a compliance officer is interviewed by a government investigator, he or she should:
- A. Tell the truth.
 - B. Be as helpful as possible.
 - C. Provide detail and context to help explain the issues.

Congratulations