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ANSWER BOOK

2019 Edition

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HOLLAND & KNIGHT LLP

Edited by
Christopher A. Myers
&
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Practising Law Institute
New York City

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Timothy D. Belevetz is a partner in Holland & Knight's Washington, D.C. and Northern Virginia offices. A former assistant U.S. attorney and U.S. Securities and Exchange Commission attorney, he focuses his practice on white collar criminal defense, SEC enforcement matters, internal investigations, government investigations, and compliance matters. He has extensive trial and investigative experience,

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Eric Crusius is a partner with Holland & Knight who focuses his practice on a wide range of government contract matters, including bid protests, claims and disputes, compliance issues, and sub-prime issues. Mr. Crusius has extensive experience in government contract litigation, including successfully prosecuting and intervening in numerous bid protests before the U.S. Court of Federal Claims, Government Accountability Office (GAO), boards of contract appeals and other federal agencies. He counsels clients regarding the Service Contract Act (SCA) and other labor issues, trade agreements, export controls,

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William F. Gould is a partner in Holland & Knight's National White Collar Defense and Investigations team and co-chair of the firm's Healthcare & Life Sciences Industry Team. He represents corporations and individuals in civil and criminal matters, with a focus on responding to government investigations, litigation, and negotiations, particularly in heavily regulated industries such as healthcare and government contracts. Prior to joining Holland & Knight, Mr. Gould was a federal prosecutor with the Department of Justice and on the faculty of the University of Virginia School of Law, where he taught trial practice and criminal law. He also served as a law clerk for federal District Court Judge Morton A. Brody. He graduated from the University of Virginia School of Law.

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Shannon B. Hartsfield is board-certified in Health Law in Florida, advising clients on state and federal healthcare regulatory matters, including compliance, data privacy, licensure, prescription drug distribution, and fraud and abuse. She is a past Chair of the eHealth Privacy

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Chapter 23 Food Safety

Richard T. Williams

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Gregory Baldwin

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Chapter 38 Institutions of Higher Education

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Chapter 40 Anti–Human Trafficking and Forced Labor

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Introduction

> "We are a good company. We don't need a compliance program. What is a 'compliance program' anyway?"
>
> "I am sure we have a compliance program, I just can't tell you where it is."
>
> "We would like to have a compliance program; we just don't have the resources right now. Our financial performance last quarter wasn't so good."

These are just a few of the variations on the common theme frequently heard from companies we speak with about compliance and ethics programs. Many companies instinctively react negatively to the suggestion that they spend time and often scarce resources on a compliance and ethics program. They initially don't see a positive and direct impact on their bottom line. But this attitude is short-sighted and potentially disastrous, as corporate debacles too numerous to count can attest.

Frequently, however, when corporate executives see the fallout from an Enron, a WorldCom, or any one of hundreds of multi-million-dollar fraud settlements with healthcare organizations, government contractors, financial institutions, and others, they often disassociate their companies from the "bad" companies that commit fraud and other offenses. The reality, however, is that bad things happen to "good" companies too. Despite the best intentions on the part of boards, management, and employees, many companies involved in heavily regulated industries are easily tripped up by one or more of the complex regulatory regimes that govern their operations. This includes, among numerous others:

- public companies, which must comply with the Sarbanes-Oxley Act and the Dodd-Frank Act;
- government contractors, which must comply with the Federal Acquisition Regulation and other procurement regulations;
- health and life sciences companies, which must comply with Medicare, Medicaid, FDA, the Affordable Care Act ("Obamacare"), and a host of many other federal and state regulations; and
- financial institutions, which must comply with the Bank Secrecy Act and now must deal with the investigations and regulations flowing out of the financial system meltdown.

Sometimes companies make the same mistakes over and over again because they misunderstand a government requirement. The impact of such mistakes often depends on the "intent" or mindset of the individuals involved. Did they misunderstand a complex regulation despite a good-faith effort to comply and thus make an honest error? Did they fail to pay attention to the regulations that they knew governed their operations, and thus commit "reckless disregard" and subject themselves to civil penalties? Did they intentionally violate a known regulation in an effort to cheat the government, the investing public, or others to whom they owed a responsibility to be honest, and thus commit a criminal violation? What is inside the heads of the key actors, management, and sometimes the board, is the crucial determining factor in whether the company simply has to repay any overpayment it has received, or whether it is hit with crippling penalties, damage to reputation, and possible suspension, debarment, or exclusion from future government business.

Often it is government investigators, prosecutors, or plaintiff's lawyers who must make judgments about the company's intent or state of mind. Gleaning a corporation's intent from documents and witness statements is a process that involves judgment and sometimes guesswork. The persons making those judgments and guesses often don't have the best interests of the corporation as their top priority. Investigating agents are trained to be skeptical; prosecutors sometimes seek

the thrill of bringing down a big industry player. For example, an Assistant U.S. Attorney in a healthcare fraud investigation of one of our clients once said, "Anyone who is making money in the Medicare system is committing fraud." How does an organization respond and prove something government agents and prosecutors are programmed not to believe?

The one thing that has proven to be most useful in persuading regulators, prosecutors, and judges of the good faith and good intent of companies is an "effective," fully implemented and supported compliance and ethics program. Recent studies have demonstrated empirically that, in addition to the ability to deflect investigations into possible regulatory and other violations, companies with good systems of governance and compliance have numerous financial advantages in terms of access to capital, lower insurance costs, and higher stock prices.

This *Corporate Compliance Answer Book* provides information intended to help busy corporate counsel and compliance officials understand what an effective compliance and ethics program is, how it should operate, and what issues and risks it must address in a variety of heavily regulated industries. Most importantly, it helps make the case to management and the board as to why your company needs to have such a program.

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