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2014

Life Sciences Legal Forecast: 2014 Compliance Issues Keeping Executives Up at Night

Written by

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A report from ALM Legal Intelligence

PREFACE

Life Sciences Legal Forecast: 2014 is a white paper published by ALM Legal Intelligence (ALI) and sponsored by Foley Hoag LLP. ALI conducted the survey and gathered the data. Philippa Maister wrote the report and Jessica Abela edited the report along with Jasmine Trillos-Decarie from Foley Hoag LLP. We would like to thank all of those who participated in the survey.

– December 2014

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FOREWORD

FOLEY HOAG LLP SPONSORED THIS SURVEY, WHICH WAS CONDUCTED BY ALM Legal Intelligence, to better understand how general counsel at life science companies perceive their industry's unique compliance issues and are preparing to deal with them. As a firm with strong focuses on the biotechnology, medical device and healthcare industries, we are pleased to share these results to contribute to the understanding of these important issues, and hope you find the information useful.

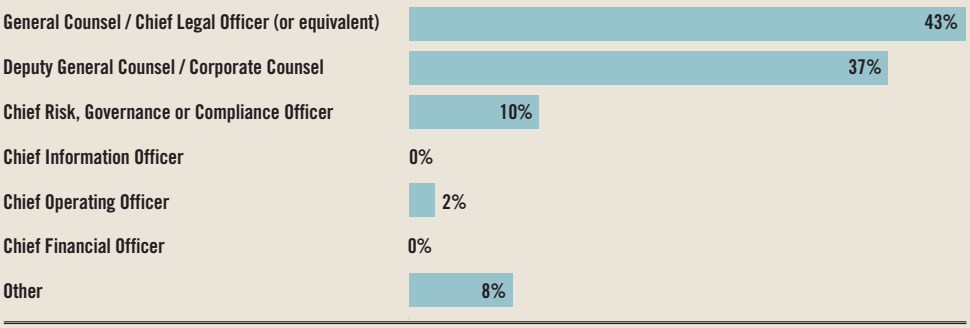
About this Report

The findings and conclusions detailed in this report are based on a survey that assessed the most important compliance issues facing general counsel in the life science industry, and how they are responding. The survey was conducted by ALM Legal Intelligence in association with Foley Hoag LLP.

ALM sent questionnaires to general counsel and compliance counsel of U.S. biotechnology, medical device and healthcare companies across the country in August 2014, and received 49 responses. The majority of respondents (57%) represented companies with annual revenues of less than $1 billion, while the remainder reported income ranging from $1 billion to more than $10 billion.

Respondents consisted primarily of general counsel or equivalent (43%), deputy general counsel (37%) and compliance officer or equivalent (10%). They were from a wide range of companies across the life science industry, including pharmaceutical, biotech, medical device and healthcare providers such as long-term care facilities, health plans, or health information companies.

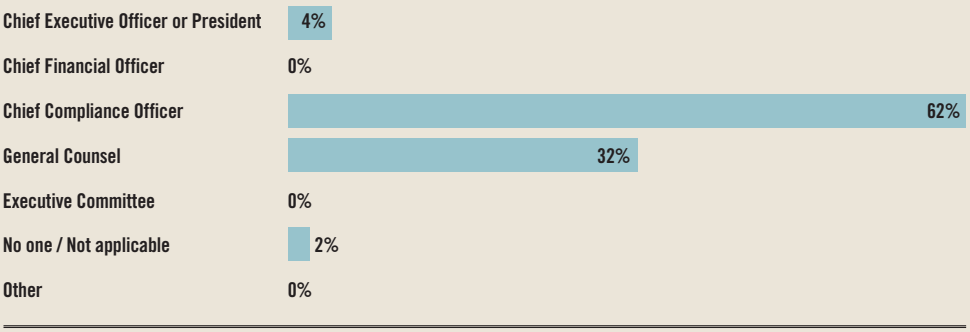
Please check the option that most closely identifies your title



Responsibility for compliance at 62% of the companies that responded to the survey rested primarily with chief compliance officers. Compliance was assigned to general counsel (GCs) in 32% of companies, and the chief executive officer at 4% of companies.

Who has primary responsibility for compliance in your organization?

Please choose the most appropriate response.



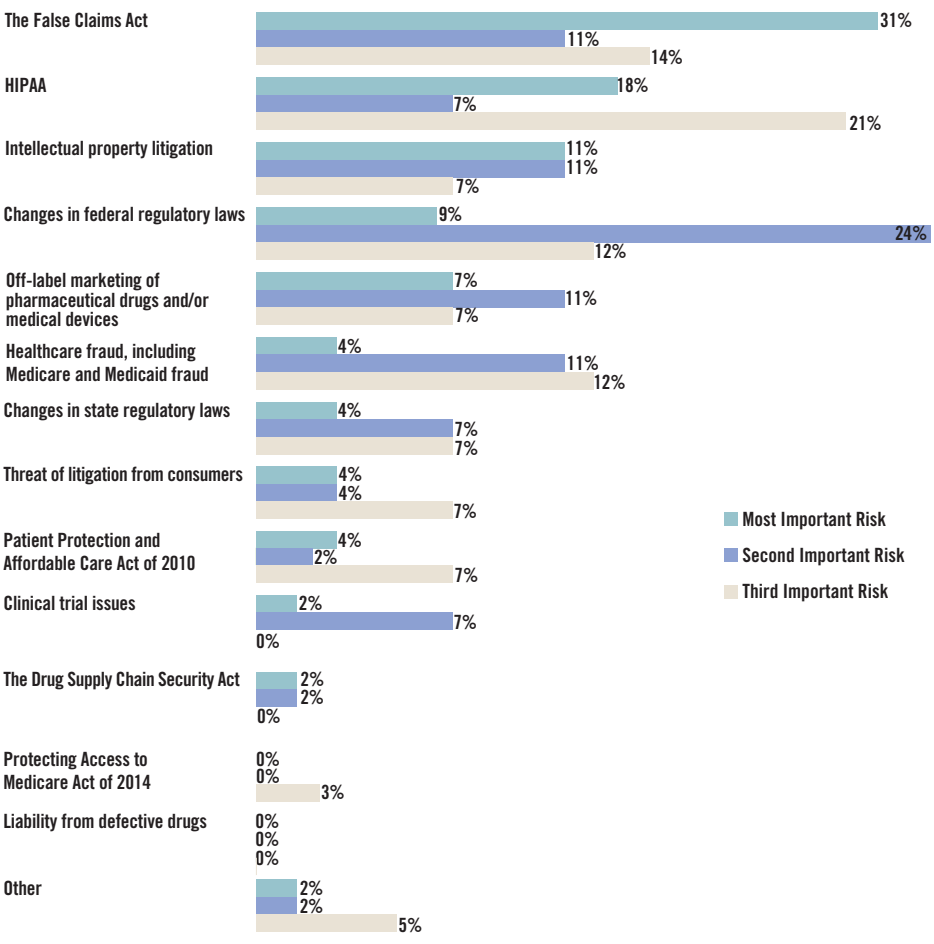
EXECUTIVE SUMMARY

AS EXPECTED, COMPLIANCE RISK WEIGHS HEAVILY ON THE MINDS OF GENERAL counsel ("GC") in the life science industry. This report's findings fall into two broad categories:

1. **What keeps life science general counsel up at night?**
2. **What protections they are implementing to reduce their exposure to damages?**

In the first category, the False Claims Act (FCA) outpaced all other concerns by an almost 10 percent margin. The FCA was a concern for 56% of respondents. HITECH-HIPPA rules and changes to federal rules were cited by 46% and 45%, and off-label marketing of drugs and/or medical devices concerns were cited by 25%.

What are the three most significant risks that are top of mind for your business? Please rank the risks below from 1 to 3, where 1 is the biggest risk. Only rank three of the following.



The concern over FCA investigations is well founded. One in three of the respondents' companies had been subject to an FCA investigation in the past five years—half of them in the last 12 months. In FY 2013, the Department of Justice ("DOJ") recovered $3.8 billion from False Claims Act Cases. $2.6 billion related to federal health care fraud recoveries of which $1.8 billion were from alleged false claims for drugs and medical devices under federally insured health programs including Medicare, Medicaid and TRICARE.

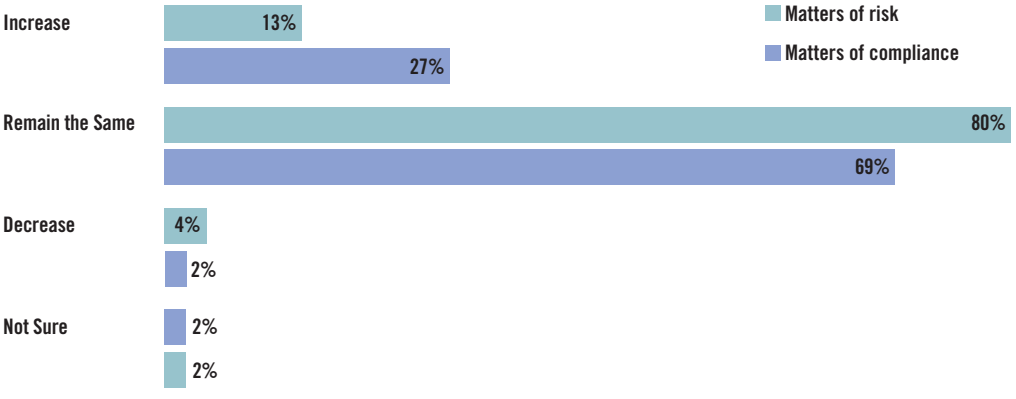
Whistleblowers are a significant factor in FCA cases. In FY 2013, DOJ recovered $2.9 billion in lawsuits under the *qui tam* provisions of the False Claims Act. The results that general counsel most fear from FCA investigations are: damage to reputation; exclusion from Medicare, Medicaid and other federal healthcare programs; vicarious liability and joint employer claims; and risk of losing their licensure, accreditation, or tax-exempt status.

In the second category—what protections they are implementing to reduce their exposure to damages?—there were some outwardly contradictory findings. Surprisingly, given the concern over FCA complaints, only three of four companies had FCA compliance policies or procedures in place. Among companies that did have FCA policies, most were developed in-house, often in consultation with outside counsel.

Even in the absence of specific FCA policies, there was significant awareness of other compliance issues. Virtually all respondents offer compliance or ethics training to executives and senior managers with 86% reporting the training as mandatory. Almost all GCs were aware of the need to prevent retaliation against corporate whistleblowers, and most have implemented training of supervisory personnel and company policies forbidding retaliation.

Survey respondents demonstrated a willingness to bring in outside resources to supplement their compliance programs. Most training of compliance professionals is done internally, though 37% of companies surveyed use external training resources, including training provided by trade associations. In response to the growing crackdown on healthcare fraud and whistleblower cases, 13% of respondents plan to increase their use of outside law firms to advise them on risk, and 27% plan to do the same on compliance issues.

Within the next 12 months do you plan to increase or decrease your overall use of outside counsel as it relates to...



FINDINGS

WHAT KEEPS GENERAL COUNSELS AWAKE AT NIGHT

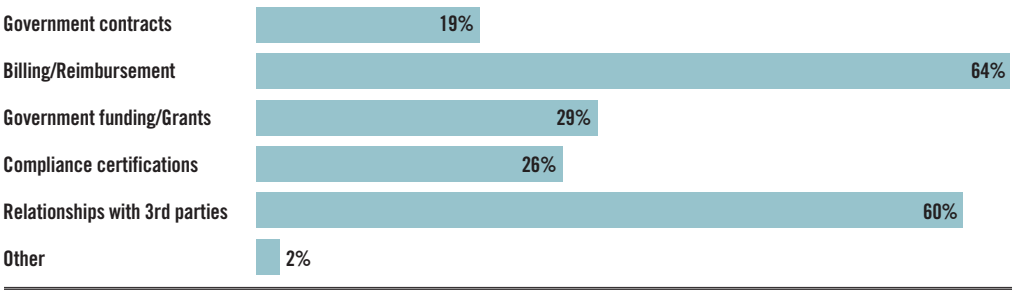
THE FALSE CLAIMS ACT (FCA) IS THE NUMBER-ONE COMPLIANCE CONCERN CITED BY 56% OF GCS IN OUR SURVEY. A key reason for this concern is the role of whistleblowers under the FCA, which the Department of Justice (DOJ) describes as the federal government's primary civil remedy to address false claims for government funds.

Individuals with knowledge of fraud in connection with federal healthcare programs, such as fraudulent billing of Medicare, who come forward as *qui tam* relators, or whistleblowers, may receive 15-25% of the amount recovered if the government intervenes to take over prosecution of the case. If the government does not intervene, the relator may receive 25-30% of a successful recovery. Of the $3.8 billion in total FCA claims that DOJ recovered in 2013, $2.9 billion related to lawsuits filed under the *qui tam* provisions of the FCA. In 2013, DOJ paid out more than $345 million to whistleblowers.

Overwhelmingly, most whistleblowers turned out to be former or current employees. Less frequently, whistleblowers were customers or competitors. In only one investigation was the whistleblower a physician. In half of the cases reported by those surveyed, DOJ chose to intervene on the side of the whistleblower.

In addition to remuneration costs, 64% of respondents were also concerned about the impact an FCA investigation would have on their business model, especially billing and reimbursement.

What areas/issues are of concern to your organization's FCA liability?



"Billing is a difficult area and honest mistakes can occur," says a vice president and associate general counsel for a large healthcare system in the Midwest who participated in the survey. This respondent contends that under the FCA, billing mistakes can be considered criminal violations by the DOJ. In his view, federal regulators are going for every dollar they can collect, and "they have created a piggy bank with all these regulations."

After this survey was distributed, a federal policy emerged that has legitimized this respondent's fear of criminal charges arising from civil FCA allegations. In September 2014, U.S. Assistant Attorney General Leslie R. Caldwell of the DOJ's Criminal Division announced that the division's Fraud Section—which includes a 40-attorney Health Care Fraud Unit — would immediately review *qui tam* cases as they are received to determine whether to open parallel criminal investigations. She also urged lawyers for whistleblowers to reach out to criminal authorities at the same time that they contact civil counterparts when filing cases.

In addition to the potential financial penalties from FCA investigations, 60% of respondents also worried about the implications an FCA investigation would have on their relationships with third parties. About 30% of respondents were also concerned about its impact on government funding or grants and compliance certifications. A smaller number (19%) was concerned about the impact on their government contracts.

HITECH-HIPAA IS THE NUMBER-TWO COMPLIANCE CONCERN CITED BY 46% OF GCS IN OUR SURVEY. The Health Insurance Portability and Accountability Act (HIPAA) of 1996 protects individually identifiable health information held by covered entities and their business associates. It also gives patients an array of rights to protect the privacy of that information.

In 2009, HIPAA was supplemented by The Health Information Technology for Economic and Clinical Health Act (HITECH). Most recently, in January 2013, the Department of Health and Human Services (HHS) issued the HITECH-HIPAA Omnibus Final Rule that expanded the requirements for business associates of covered entities to safeguard personal health data and also made them liable for civil penalties if they failed to do so.

"Some of the largest breaches reported to HHS have involved business associates."

—HHS SPOKESPERSON

The HITECH-HIPAA Omnibus Final Rule also recognizes a role for whistleblowers if one of two conditions are met: a "workforce member or business associate believes, in good faith, that the covered entity has engaged in conduct that is unlawful or otherwise violates professional or clinical standards" or that the covered entity has endangered patients, workers or the public.

The concern among GCs about HIPAA and HITECH is well placed. In 2012 alone (the most recent data available), the HHS Office of Civil Rights (OCR) received 222 reports of breaches of patient protected health information (PHI), each affecting more than 500 individuals. In total, the breaches affected approximately 3.3 million individuals. Leading causes of the breaches were:

- Theft of portable devices or paper containing PHI
- Unauthorized access or disclosure of PHI
- Loss of electronic or paper records
- Hacking
- Improper disposal of PHI

Also in 2012, OCR received 21,194 reports of breaches each affecting fewer than 500 individuals, with a total of 165,000 individuals affected. At the time of the (undated) report, the agency had over 500 open cases.

Breaches like these represent huge liabilities for life science companies. Penalties associated with HITECH-HIPAA can be substantial. In May 2014, OCR reached a $4.8 million settlement with New York and Presbyterian Hospital and Columbia University following their 2010 joint report of a breach of electronic PHI for 6,800 individuals. The breach was first discovered after an individual reported finding personal information of a former hospital patient online.

CHANGES IN FEDERAL REGULATIONS ARE THE NUMBER-THREE CONCERN CITED BY 45% OF GCS. Life sciences and healthcare are among the most heavily regulated industries.

Changes in regulations require companies to rethink their established procedures and implement new ones. Changes can also increase the risk of federal investigations and penalties for compliance failures.

Pharmaceutical and biotechnology trade associations are closely following proposed federal regulations. These proposals include changes to Medicare prescription drug benefit programs and clinical pharmacology labeling requirements for drugs and biological products.

Among the top concerns of the American Hospital Association (AHA) is the proposed Protecting the Integrity of Medicare Act, which aims to further clamp down on waste and abuse. The AHA also worries about "value-based purchasing," which in 2014 based payments to hospitals on how they scored on three sets of measures related to clinical care, patient satisfaction and mortality rates. Value-based purchasing will be introduced for physicians in 2015 on a "voluntary" basis.

Drug manufacturers, physician and hospital associations are also closely monitoring the implementation of the Physician Payments Sunshine Act (the Open Payments Database). The act requires manufacturers of drugs, medical devices and biologicals that participate in U.S. federal health care programs to report payments and valuable items given to physicians and teaching hospitals.

In 2014, U.S. Department of Health and Human Services' Office of the Inspector General (OIG) also began to address for the first time the operation of health insurance marketplaces and the expansion of Medicaid under the Patient Protection and Affordable Care Act. OIG reviews will focus on payment accuracy, eligibility systems, contract management, and security of data and consumer information. OIG's 2014 work plan also noted a number of new areas for review of hospitals, including criteria for new inpatient admissions, Medicare costs associated with defective medical devices, and cardiac catheterization and heart biopsies. Medical equipment and supply makers were affected by new review of Medicare payments for certain equipment, and supplier compliance with requirements for nebulizer payments and related drugs, among others. OIG also initiated new reviews of drug prices and uses. Indeed, no sector of the healthcare industry was omitted from the 101-page work plan, validating respondents' concerns about the impact of new laws and regulations.

ANOTHER CONCERN CITED BY 25% OF GCS ARE ISSUES RELATED TO THE MISBRANDING OF DRUGS AND MEDICAL DEVICES. This issue concerns drugs or devices that have been approved by the Federal Drug Administration for specific uses and at specific dosages that are promoted or sold by the manufacturers for other unapproved uses, or at dosages not approved by the FDA.

Civil and criminal charges concerning illegal off-label promotion often result in substantial penalties. Abbott Laboratories, Inc. settled with the DOJ in May 2012, agreeing to pay $1.5 billion in a landmark settlement to resolve allegations that it illegally promoted the drug Depakote. In February 2014, Endo Health Solutions, Inc. and its subsidiary Endo Pharmaceuticals, Inc. agreed to pay $192.7 million to settle allegations of misbranding its drug Lidoderm. And in September 2014, Shire Pharmaceuticals, LLC became one of the latest victims of the crackdown. It agreed to pay $56.6 million related to illegal off-label marketing of various drugs, including Adderall XR.

The rewards for whistleblowers in these cases can be huge. The *qui tam* whistleblower in the Shire case received $5.9 million. The Abbott whistleblowers were awarded $84 million.

There are signs, however, that drug makers are fighting back. The Pharmaceutical Research and Manufacturers of America (PhRMA) have submitted an amicus curiae brief in a whistleblower case against Millennium Pharmaceuticals, Inc., Schering-Plough Corp. and Merck & Co. The whistleblower suit alleges that the companies promoted unapproved uses of the drug Integrilin by distributing reprints of medical studies published in reputable journals with accompanying letters summarizing the clinical results of the unapproved uses of the drug. PhRMA contends that the claims against the manufacturers amount to an unlawful restraint on their commercial freedom of speech under the First Amendment.

WHILE THE RISKS CITED ABOVE ARE THE MOST SIGNIFICANT, THE SURVEY ALSO SHED LIGHT ON OTHER RISKS THAT WORRY GCS. These risks include potential exposure to criminal charges of healthcare fraud, especially in Medicare and Medicaid; intellectual property litigation; litigation by consumers; and compliance with the Affordable Care Act.

Individual respondents noted other challenges. One cited the risks that could be created by third-party partners. Another pointed to the Anti-Kickback Statute, which bans rewarding referrals with anything of value and is another fertile source of FCA claims.

"Anyone would agree that going out and buying referrals is criminal," said the Midwestern healthcare executive. "But we have functionally criminalized a lot of normal business procedures and given people a lot of financial incentives to go forward with whistleblower suits. There are a lot of ordinary procedures that are not intended to buy referrals, such as signing an exclusive agreement for pharmacy services or an exclusive arrangement with a radiology group. That's why there are safe harbors." The problem is determining the fair value of these agreements, the executive added.

"Just Because You're Paranoid Doesn't Mean They Aren't After You."

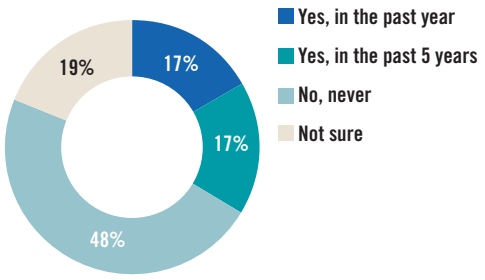
—JOSEPH HELLER, AUTHOR, "CATCH-22"

The FCA poses immediate risks for life science and healthcare companies. One in three of the companies represented in our survey have been subjected to an FCA investigation in the past five years. These investigations originated in a number of different ways:

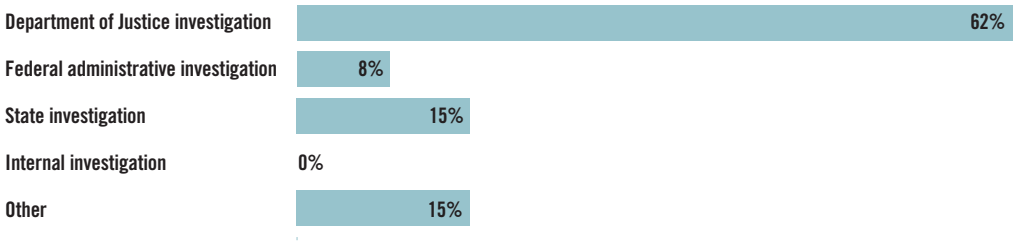
- 62% as a result of a DOJ investigation
- 15% by a whistleblower claim
- 15% by the relevant state's attorney general
- 8% from a federal administrative inquiry, such as an HHS investigation

In slightly less than half the cases, no formal enforcement action or government litigation resulted from the investigation or *qui tam* complaint. However, 23% of cases wound up in private civil litigation, and 20% in a settlement. In 3% of cases, criminal prosecutions, civil enforcement actions and administrative actions were the outcome.

Has your company been subject to an FCA investigation?



How did the problem come to light?



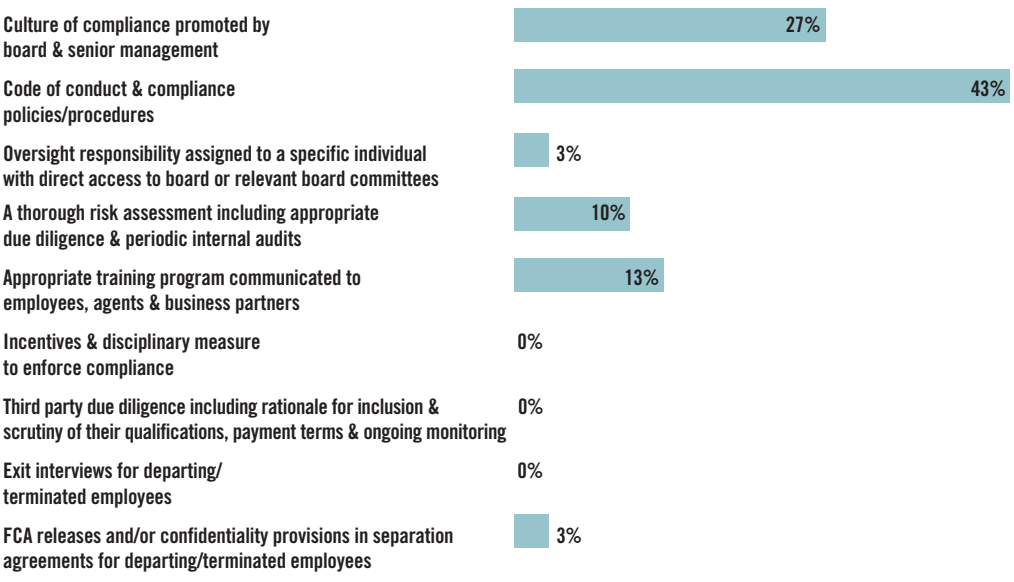
HOW THE INDUSTRY MANAGES RISK

DESPITE THE CLEAR RISKS, ONLY THREE OUT OF FOUR RESPONDENT COMPANIES HAD FCA COMPLIANCE POLICIES OR PROCEDURES IN PLACE. None of the respondents reported having a policy regarding incentives and disciplinary measures to enforce compliance, third-party due diligence, or exit interviews for departing or terminated employees.

Companies with compliance policies usually developed them in-house, often in collaboration with outside counsel. At some companies, the chief financial officer, risk management personnel or the chief operating officer had input. In a few cases, compliance officers or facilities managers also played a role. The most common elements of the resulting compliance policies are:

1. Code of conduct and compliance policies and procedures (43%)
2. Culture of compliance promoted by board and senior management (27%)
3. Appropriate training program communicated to employees, agents and business partners (13%)
4. Risk assessment including appropriate due diligence and periodic internal audits (10%)
5. FCA releases or confidentiality provisions in separation agreements for departing or terminated employees (3%)
6. Oversight responsibility assigned to a specific individual/s with direct access to board or relevant board committees (3%)

Which elements does that policy include?



GCs were clearly aware of their companies' potential exposures in cases of possible FCA violations, or even investigations coming to light. The most potentially damaging exposures they cited were:

- Damage to the company's reputation
- Exclusion from Medicare, Medicaid or other federal healthcare programs
- Vicarious liability and joint employer claims
- Risk of losing their licensure, accreditation or tax-exempt status

As a result of these potential outcomes, one respondent noted that companies "need to settle regardless of liability due to cost of defense."

GCs were similarly aware of the substantial costs of failing to prevent an FCA violation, including fines and the cost of an investigation. Others worried about a decline in the company's stock price, losing their position as a preferred provider or a system interruption.

"The cost (of an FCA investigation)" is higher to this smaller company because it can "prevent research and investment funds, interfere with clinical trials and distributorship, or caused it to suffer blacklisting of the products," one respondent wrote.

Yet surprisingly, in view of their clear perception of the risks, only 44% of GCs said they have a readiness plan in place for handling whistleblower claims.

Among those that do not have a plan is the Midwestern hospital company, which has faced a whistleblower complaint that was dismissed, according to its GC. "We have a lot of lawyers. We would handle a whistleblower case like a lot of our litigation," says the GC. "We always use outside lawyers for litigation." The company does have in place a business conduct compliance program that is regularly updated.

Of those companies that do have whistleblower readiness plans, some have no more than general guidance to no more than "appropriately handle issues when they arise," or "GC and board of directors decide what to do." Several respondents said they would launch an internal investigation or turn to outside counsel to work with in-house lawyers, possibly in collaboration with corporate communications to develop "internal and external messages."

One plan called for "early evaluation of potential case" and "efforts to enter a dialogue with the Assistant U.S. Attorney making intervention decision." Another was more specific: "Immediate meeting with the board, executive members including President & CEO, CFO, CIO, GC, chief compliance officer, and VP and director of HR; conducting litigation holds and discussions with targeted custodians; conducting internal investigation/audit; conducting interviews within the company and with third-party vendors; bringing in and collaborating with outside counsel; and possibly dealing with any governmental inquiries."

Almost all GCs were aware of the need to prevent retaliation against corporate whistleblowers. Many cited training of supervisory personnel and company policies forbidding retaliation. A few respondents also took steps to mitigate employee dissatisfaction by promoting a culture of openness and information-sharing among supervisory staff that would encourage employees to share their concerns. "We also do direct confidential disclosure inquiries at low supervisory staff levels about their knowledge of potential bad acts," commented one respondent.

COMPLIANCE TRAINING AS A KEY TOOL

VIRTUALLY ALL RESPONDENTS SAID THEIR COMPANIES OFFER compliance or ethics training to executives and senior managers, and most (86%) said this training is required. Most training of compliance professionals is done internally, though 37% use external resources including training provided by trade or professional associations.

Where compliance training is offered internally, it is often done using online or web-based programs, sometimes with the participation of the GC and/or chief compliance officer. In one case, training is provided by legal, human resources and finance staff. In another, it is conducted by the chief compliance officer, compliance director and regulatory counsel. One company offers training by telephone, video and in-person by the assistant general counsel.

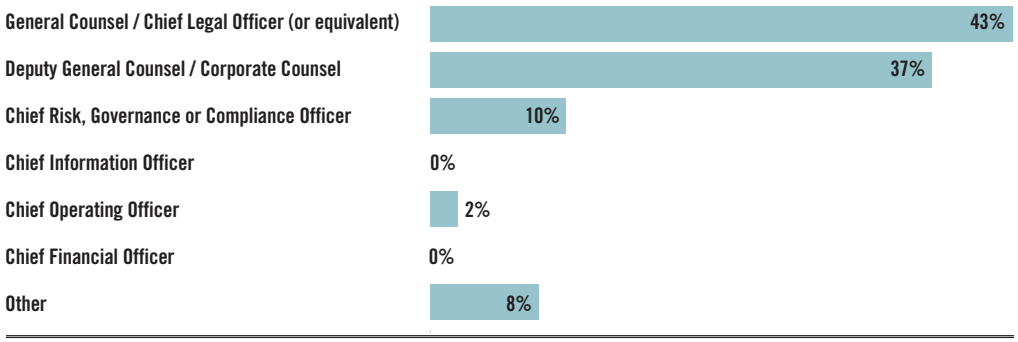
In most cases, internal training is offered onsite, though some companies use offsite locations.

CONCLUSION

THE FCA'S *QUI TAM* PROVISIONS AND WHISTLEBLOWER PROVISIONS IN other laws present a growing threat to many sectors of the life sciences and healthcare industries. Most GCs are well aware of these risks. It is not clear, however, that all have adequate policies and procedures in place to minimize the risks of FCA allegations and efficiently manage claims arising from potential whistleblower filings.

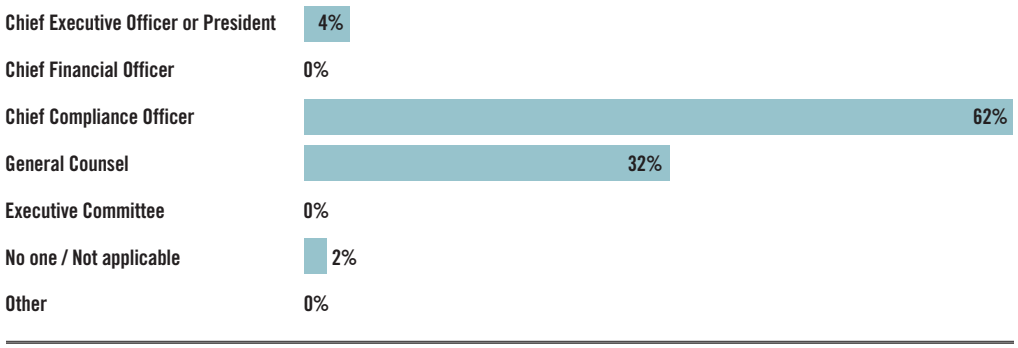
APPENDIX: SURVEY RESULTS

1. Please check the option that most closely identifies your title



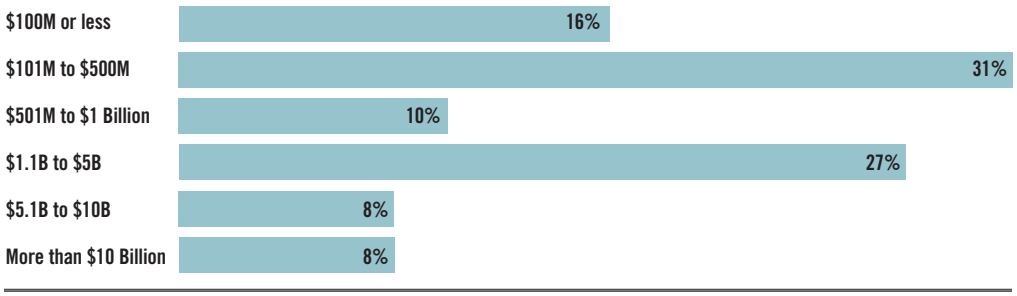
2. Who has primary responsibility for compliance in your organization?

Please choose the most appropriate response.

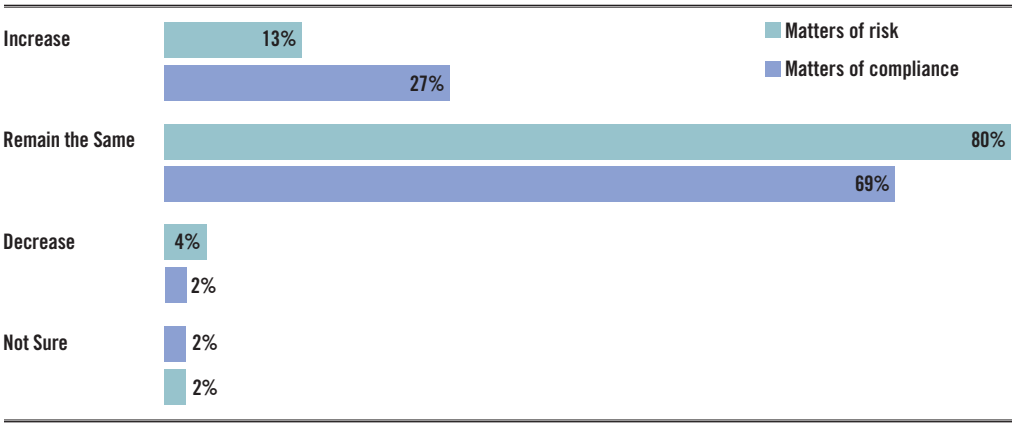


APPENDIX: SURVEY RESULTS

3. What is your company's annual revenue?

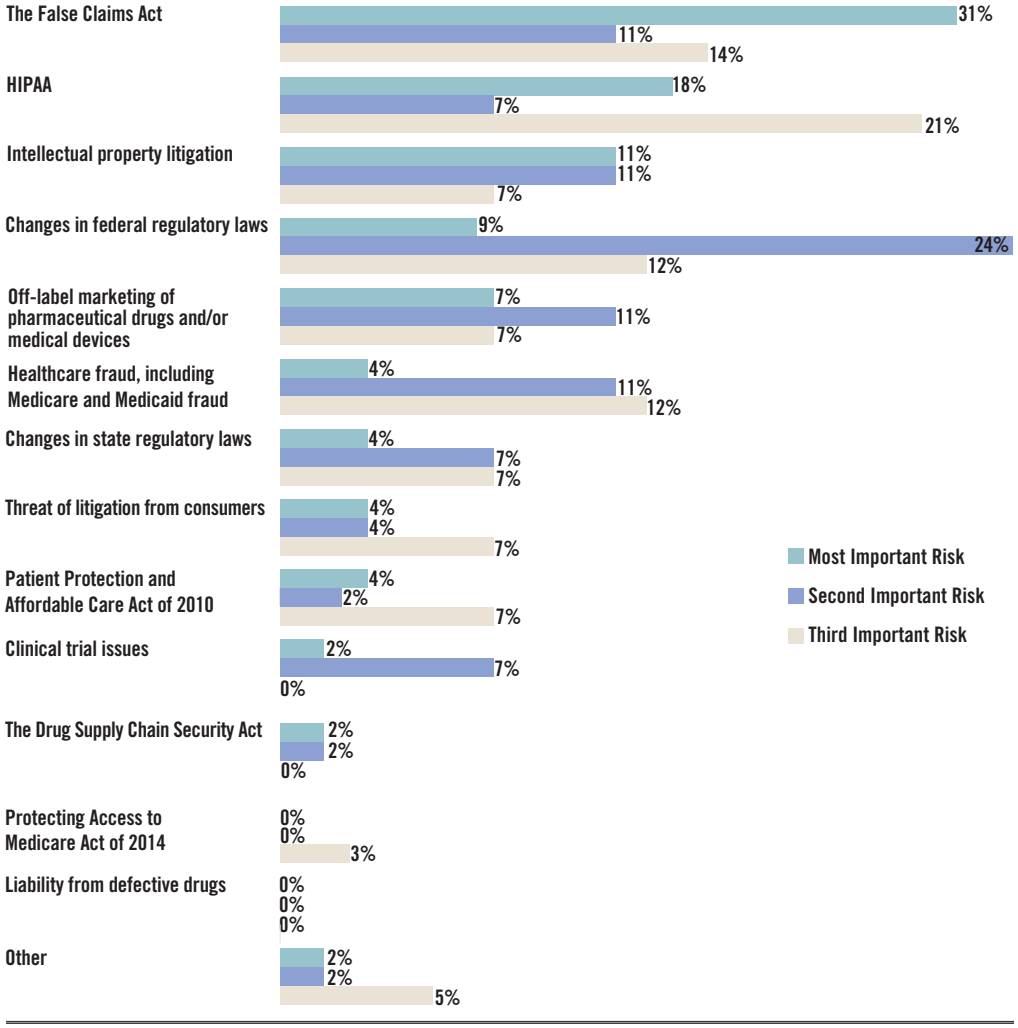


4. Within the next 12 months do you plan to increase or decrease your overall use of outside counsel as it relates to...



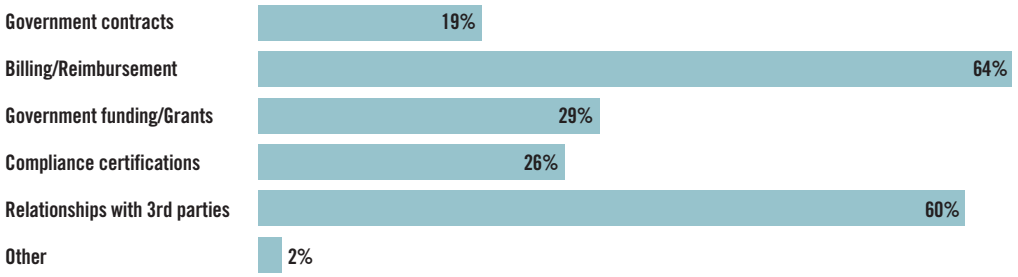
APPENDIX: SURVEY RESULTS

5. What are the three most significant risks that are top of mind for your business? Please rank the risks below from 1 to 3, where 1 is the biggest risk. Only rank three of the following.

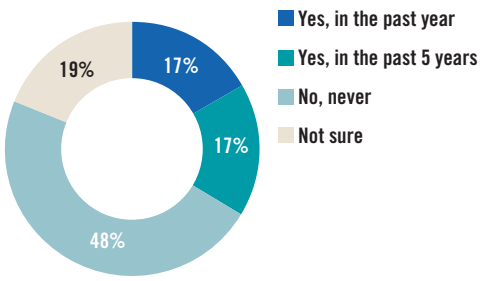


APPENDIX: SURVEY RESULTS

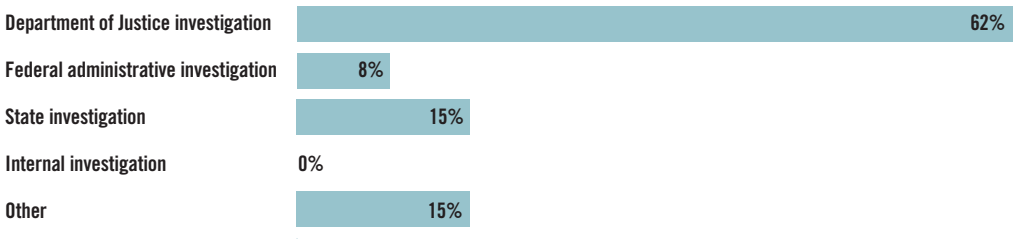
6. What areas/issues are of concern to your organization's FCA liability?



7. Has your company been subject to an FCA investigation?

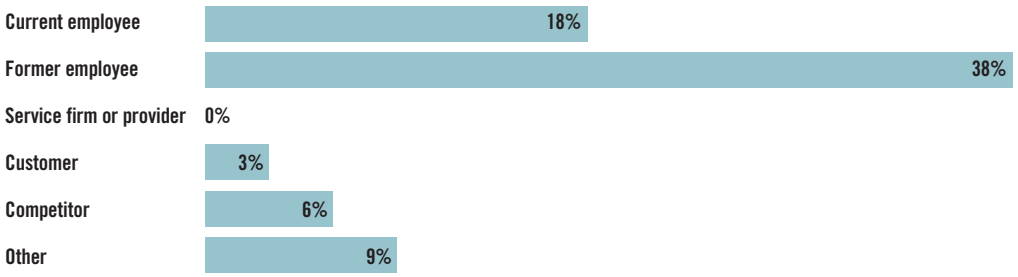


8. How did the problem come to light?

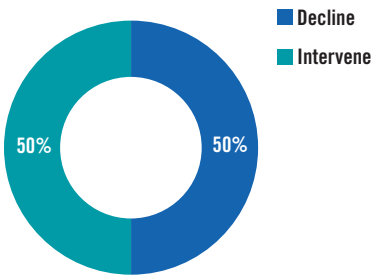


APPENDIX: SURVEY RESULTS

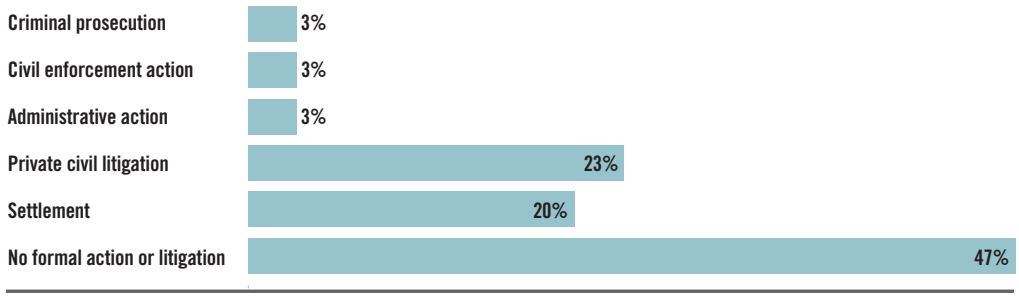
9. Have you ever had a qui tam (or, outside) whistleblower from...



10. Did the Department of Justice intervene in the qui tam action (or decline to participate)?

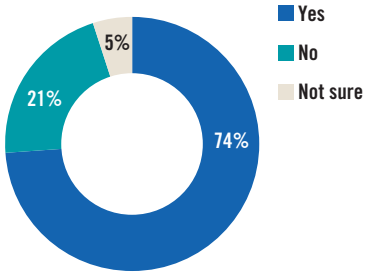


11. What was the result of the FCA investigation and/or qui tam complaint?

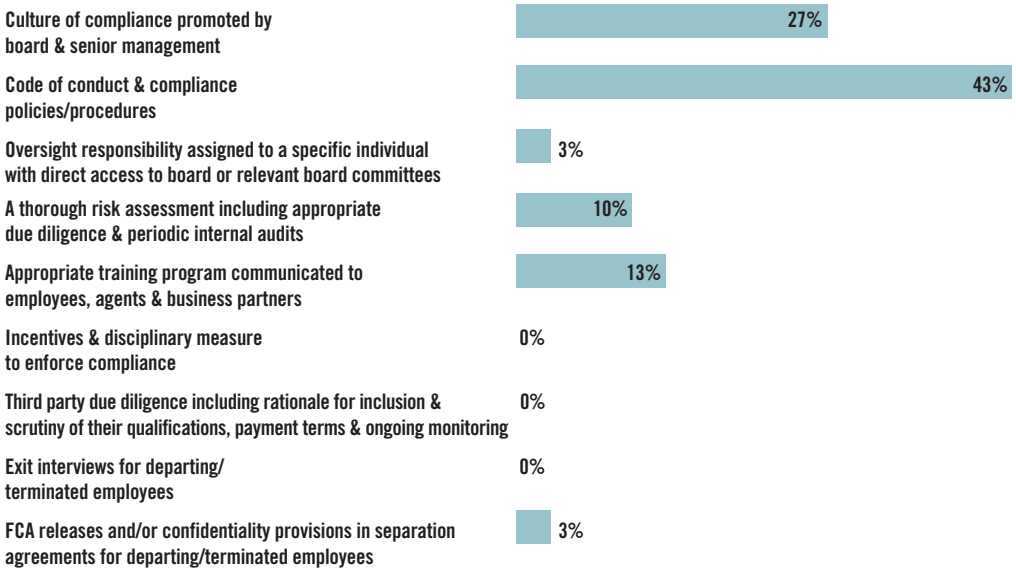


APPENDIX: SURVEY RESULTS

12. Has your company instituted a FCA compliance policy and/or procedures?

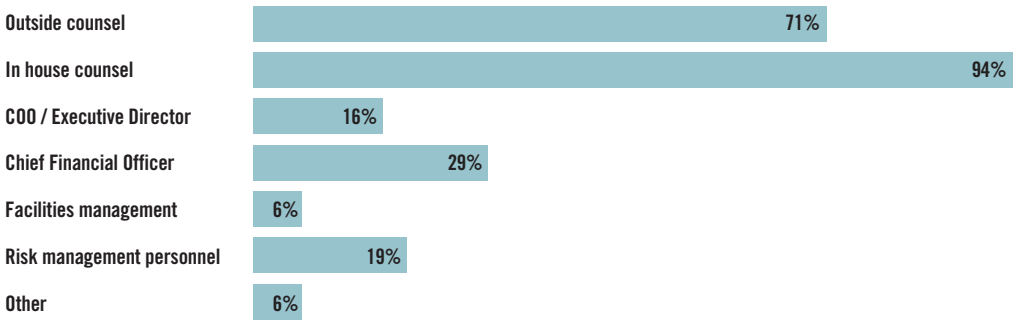


13. Which elements does that policy include?

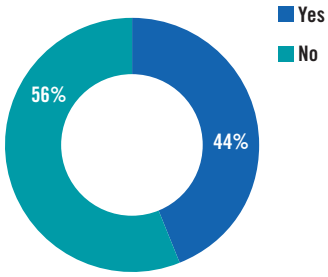


14. Who has developed or aided in the development of your FCA compliance policy?

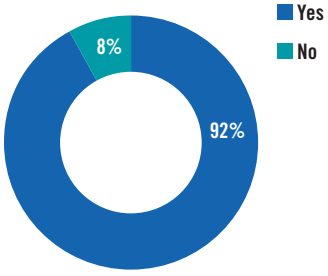
Please select all that apply.



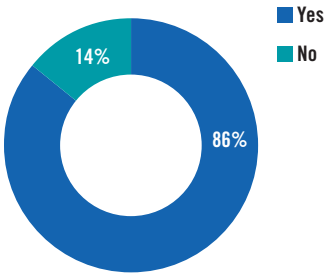
15. Do you have a readiness plan in place for handling whistleblower claims?



16. Does your organization offer compliance or ethics training to executives or other top management in the organization?



17. Are these executives required to complete compliance/ethics training?



18. Where do you send your compliance professionals for education on this topic?

Please select all that apply.

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