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DOJ Targeting Healthcare for False Claims Act Enforcement

By Greg Freeman

Federal regulators and law enforcement are looking hard at healthcare organizations for False Claims Act (FCA) violations at the same time other sectors are enjoying less scrutiny. Healthcare leaders should take a hard look at their compliance programs to ensure they are doing all they can to avoid FCA enforcement actions.

The Department of Justice (DOJ) recently announced that its 2025 National Health Care Fraud Takedown resulted in criminal charges against 324 doctors, nurse practitioners, pharmacists, and other licensed medical professionals for their alleged participation in fraud schemes involving more than $14.6 billion in intended loss. (More information is available online at http://bit.ly/4lAJBzm.)

The DOJ reported $2.9 billion in FCA settlements and judgments in 2024, and more than $1.67 billion involved the healthcare industry. The DOJ report is available online at http://bit.ly/3G2DmVY. Health and Human Services (HHS) recently reported a $200 million settlement of an FCA lawsuit by Gilead Sciences. The HHS report is available online at http://bit.ly/3G9vMZD.

Current fraud investigations are spreading to some issues that healthcare organizations have not previously seen as compliance risks, says **Kurt Osburn**, a director with the risk management and governance team at NCC Group, a cybersecurity company based in Manchester, United Kingdom. He is based in the Orlando, FL, area.

Gender-affirming care is a hot topic for fraud investigations after the Trump administration announced that federal funds cannot be used to promote "gender ideology." The DOJ has said that they are prioritizing investigations against doctors, hospitals, pharmacies, manufacturers, and anyone else in the healthcare

Executive Summary

The Department of Justice is targeting the healthcare industry for False Claims Act enforcement even as it backs off on other industries. Risk managers should assess compliance programs for any points of vulnerability.

- Gender-affirming care and diversity, equity, and inclusion programs may be scrutinized.
- Speaker programs and vacations are another focus.
- Act quickly to address concerns of potential whistleblowers.

space who is involved in manufacturing drugs or devices that the government deems to be illegal in the context of gender care, Osburn explains.

"Some of the things that are specifically mentioned are puberty blockers, sex hormones, or — this is a quote from their guidance — 'any drug used to facilitate a child's so-called gender transition,'" Osburn says. "They're looking at it through the lens of the False Claims Act as well as the FDA (Food and Drug Administration) laws under the Food, Drug, and Cosmetic Act. So that's a very, very healthcare-specific policy."

Another issue that is not healthcare-specific involves what the government deems illegal diversity, equity, and inclusion (DEI) programming. Any healthcare organization involved with gender-affirming care or which has a DEI program should assess what specific business activities are involved, he says.

"They have to do an inventory of their exposure to begin with, and if they deem that they have exposure, even if they disagree with the policy or think the policy is unfair, then the next question is, how does our compliance program comply with the new policy?" Osburn says. "If it doesn't comply with the new policy, I think a business and legal judgment has to be made whether the company wants to get compliant with the policy or choose to continue business as usual and run the risk of having litigation with the government."

Pandemic-related issues also are spurring fraud cases, says **Jacquelyn Papish**, JD, partner with the Barnes & Thornburg law firm in Washington, DC. "We're now a couple of years out of the public health emergency and end of the primary pandemic, but we are continuing to see enforcement in that area. I think that's sort of just the nature of the False Claims Act. The False Claims Act is set up to permit and allow for cases to remain sealed during the investigation phase, when the government's investigating, and, sometimes, that can take quite a while," she says. "I think there are a number of civil false claims cases that we will see become public once they're unsealed after investigations are closed out. That will remain probably steady for the next few years."

Papish urges risk managers to remember that the focus of fraud investigations can change rapidly.

"In this new administration, we're seeing a variety of different executive orders issued and different priorities with different types of regulations," she says. "So just keeping abreast of the news of changes in policy, of priorities of the government, is number one."

In May, the DOJ put out priorities for white collar investigations and prosecutions, stating that healthcare is at the top of the list, says **Matthew G. Nielsen**, JD, partner with the Bracewell law firm in Dallas. "One of the themes of the administration is to combat fraud, waste, and abuse, and every year, healthcare is always the sector where the majority of that activity is and where the majority of that recovery is coming from," he says. "I see that continuing, if not, frankly, increasing."

The number of qui tam lawsuits has been increasing, Nielsen says, which makes it critical to facilitate internal reporting and act on potential problems. Whistleblowers almost always report problems internally before going to the government, he says.

"It really speaks to the need for companies to have a robust and effective internal reporting system so they can get the allegations and act appropriately to review them," he says. "You need to handle and remediate those before that person feels the need to go to the government or to go to the step of filing a qui tam."

Billing Services in Question

The government has expressed concerns about billing issues and fraudulent payments, including services not rendered or services rendered that were not medically necessary or worthless, **Bridget A. Gordon**, JD, partner with the Hooper, Lundy & Bookman law firm in Los Angeles.

"It's really difficult in the healthcare space because a lot of providers rely on external, third-party billing companies or billing consultants to help them with billing and coding. If there are errors on the billing side and they amount to a potential false claim, that is going to fall back on you as the provider," You really need to be setting up good checks and balances to determine that your bills are going out correctly, because often it will not be seen as just an inadvertent error, or that you relied upon an external billing company for guidance. The DOJ does not say providers can kind of offload that responsibility onto a billing company or consultants. They really need to be making the final calls on how things are billed."

The DOJ is continuing to conduct significant investigations into clinical laboratories and durable medical equipment providers, says **Paul D. Werner**, JD, attorney with the Buttaci Leardi Werner law firm in Princeton, NJ. Those sectors will always be at the top of the list because of their reimbursement levels, but specialty practices are now being targeted closely also, he says.

"You're not often going to see a general practitioner's office, or even a big group of general practitioners' office getting roped into a False Claims Act case. They just tend not to hit on the radar," Werner says. "But we certainly see them in specialties. Pain management, dermatology, ophthalmology, hospice, those are all areas where we see a lot of ongoing investigations."

The Trump administration's DOJ will continue focusing on obvious examples of fraud, says **Thomas H. Barnard**, JD, shareholder with Baker Donelson in Washington, DC.

"This administration's approach is, 'Let's get to our bread and butter of bad conduct and stop doing things that interrupt normal business,' things like the Anti-Kickback Statute. Private equity is going to continue to be of interest, and I think that the AI (artificial intelligence) use will be of interest," Barnard says. "I think the increased focus on Medicare Advantage might inspire some providers to get away from Medicare Advantage."

Cybersecurity and Reimbursement Issues

The public comments of senior DOJ officials within the Trump administration indicate that the FCA will continue to be vigorously enforced, and its application even further expanded, says **Geoffrey R. Kaiser**, JD, senior counsel with the Rivkin Radler law firm in Uniondale, NY.

He notes that comments by Deputy Assistant Attorney General Michael Granston at the Federal Bar Association's annual Qui Tam Conference earlier this year indicate that the DOJ will continue to focus on healthcare fraud, including Medicare Advantage fraud and fraud affecting the Patient-Driven Payment Model

(PDPM) for Medicare reimbursement of skilled nursing facilities (PDPM replaced the previous Resource Utilization Group reimbursement system).

"(The) DOJ will also continue to use the FCA to prosecute cybersecurity fraud and pandemic relief fraud. However, the Trump administration also has expressed an intention to expand FCA enforcement to new areas, including prosecution of efforts to avoid custom and tariff obligations, false certifications of compliance with civil rights laws (including through diversity, equity, and inclusion programs that unlawfully discriminate), and the submission of false claims for non-covered transgender-related medical services," he says.

Since data analytics are so important to DOJ enforcement decisions, Kaiser says one of the best ways for healthcare organizations to protect themselves is to continuously scrub the data underlying government reimbursement decisions for accuracy and, more generally, to avoid being viewed as an "outlier" among their industry peer groups.

"They also need to be mindful of (the) DOJ's expanded FCA enforcement efforts as they perform their compliance risk assessments, which should always be tailored to the unique characteristics of their business operations," he says.

The DOJ remains highly active in its enforcement of the FCA, particularly within the healthcare sector, says **Braden Perry**, JD, partner with the Kennyhertz Perry law firm in Mission Woods, KS, a former enforcement attorney at a federal agency and chief compliance officer of a financial firm.

A significant majority of FCA cases continue to originate from whistleblowers under the qui tam provisions of the statute, highlighting the central role whistleblowers play in surfacing alleged fraud, he says. The DOJ has further expanded whistleblower incentives through its new Corporate Whistleblower Awards Pilot Program, which rewards tips even beyond traditional FCA claims, including conduct by private insurers and representations involving civil rights and international trade, Perry explains.

"Recent enforcement priorities reflect this broadening scope. Notably, the DOJ has filed suits against major Medicare Advantage providers and insurance brokers over alleged kickbacks and improper steering practices," he says. "Other high-risk areas include upcoding and inflated risk scores, billing for non-covered services — such as certain transgender-related care — and misuse of federal funds in connection with diversity, equity, and inclusion certifications."

The agency also has begun scrutinizing representations made in relation to federal grant applications, tariff and customs compliance, and even pandemic-era reimbursement schemes, Perry says.

"For healthcare organizations, this presents a complex and evolving compliance landscape. The financial stakes are steep, with per-claim penalties reaching upwards of $28,000 and exposure to treble damages," he says. "Moreover, whistleblower complaints often trigger parallel criminal investigations, increasing both legal and reputational risk."

To mitigate these risks, healthcare providers should invest in robust internal controls and compliance programs, with particular focus on billing practices, referral arrangements, and DEI or civil rights representations tied to government programs, Perry advises. Internal whistleblower systems should be fortified to encourage early, internal reporting and minimize the likelihood of external disclosure.

"Organizations should also consider voluntary self-disclosure under DOJ policies that may allow for leniency or reduced penalties," Perry says. "Most importantly, healthcare entities must stay vigilant and adaptive as the DOJ continues to expand the reach of FCA enforcement across new domains."

The consequences for violating the FCA can be severe for practitioners and healthcare professionals, including significant fines for monetary damages incurred by the federal government, says **Richard F. Cahill**, JD, vice president and associate general counsel with The Doctors Company, a malpractice insurer based in Napa, CA.

Unforeseen collateral outcomes also may occur. Cahill says these may include program exclusions by Centers for Medicare & Medicaid Services, reports to state licensing boards prompting administrative investigations with possible regulatory sanctions and monetary fines for violations, dismissal from participation in federally funded payment programs, reports to private third-party payers with potential future bans as a network provider, negative actions by facility credentialing committees, and adverse publicity on social media sites (with adverse publicity causing significant damage to reputation and the continued ability to operate a clinical practice and even continue earning a commensurate living in the professional sector).

To prepare for worst-case scenarios, Cahill advises using these strategies:

- Evaluate existing office protocols as a baseline to determine whether federal and state regulatory guidelines are being properly interpreted and followed.
- Consider retaining independent healthcare experts from objective legal perspectives to improve policies and procedures consistent with evolving community standards.
- Ensure frequent clinical education programs for both professional and administrative support staff to promote uniform application of internal rules and avoid miscommunication on critical office expectations.
- Periodically re-evaluate practice guidelines to promote best practices, a culture of instilling processes compatible with due diligence, and helping to deliver optimum results with continuity of care.

Given the consistent recoveries yielded by whistleblower actions, the bipartisan support for fighting alleged fraud against the government, and the DOJ's public statements about its commitment to the FCA, healthcare leaders can expect a continued emphasis on FCA claims brought against healthcare organizations in 2025 and beyond, says **Selina P. Coleman**, JD, partner with the Reed Smith law firm in Washington, DC.

"Among other enforcement priorities, the DOJ has focused on alleged kickbacks to healthcare providers — a perennial risk area — such as physician speaker programs, as well as allegations related to Medicare Advantage and pandemic relief fraud," she says. "We also expect that the use of AI in billing or coding may give rise to scrutiny under the FCA."

Healthcare organizations should review proposed programs carefully and take compliance seriously, including any complaints raised internally, she says. Reviewing allegations of non-compliance, and, as appropriate, considering self-disclosures or refunds may mitigate FCA risks or support defenses.

"Healthcare companies should also be on the lookout for FCA enforcement involving peer companies, as we often see repeat causes of action brought by whistleblowers or the government against different players in the industry. Along those lines, we recommend that companies know their data. The government and potential whistleblowers may look for trends and companies that appear to be outliers through data analytics," Coleman says. "A proactive approach will help healthcare organizations identify and address risk areas, and ensure they are prepared to defend against any allegations brought under the FCA."

Much of the discussion around Trump administration FCA enforcement has focused on potential new bases, such as tariff-related theories and targeting

educational institutions with DEI programs, notes **Ty E. Howard**, JD, partner with the Bradley law firm in Nashville, TN.

"But make no mistake, healthcare is still the industry most at risk for FCA investigations, just as it has been for many years running. In many situations, that will involve traditional areas, like allegedly medically unnecessary services, upcoding or other billing errors, and arrangements tainted by the kickbacks," he says. "Larger jurisdictions and those with particular healthcare expertise are more likely to investigate and prosecute newer theories for FCA liability, such as those involving private equity in healthcare, Medicare Advantage (Part C) cases, cybersecurity, and data breach cases in healthcare."

Cases involving telemedicine, pandemic-related fraud, and areas like amniotic skin grafts and other emerging treatment options also have been identified by the DOJ as areas of focus, Howard says. For providers, Howard says the best protection remains these tried-and-true strategies:

- Implement and follow a robust compliance plan; train on it regularly and update it as the law and your practice evolves.
- Monitor your own claims data to assess your risk exposure and course correct as needed.
- Have a reporting system for internal reporting and would-be whistleblowers so matters can be quickly addressed internally before outside involvement.
- Foster a culture of compliance and transparency.
- Get outside counsel involved early on any issues to ensure they are handled properly and, in most cases, can be addressed under the cloak of the attorney-client privilege. (Remember that work performed by billing and audit companies that are retained directly by the healthcare organization, rather than through counsel, likely will not to be protected from later disclosure.)

"In FCA enforcement, as in medicine, an ounce of prevention is worth a pound of cure," Howard says.

DOJ Devoting Resources to Fraud

The United States has spent more than $1 trillion every year since at least 2023 in the two major healthcare programs, Medicare and Medicaid, notes **Jennifer A. Short**, JD, partner with the Blank Rome law firm in Washington, DC. Healthcare spending overall in the United States accounts for more than 17% of the country's gross domestic product.

"Those significant levels of spending mean that healthcare is ripe for fraud and abuse, and also that enforcement efforts are likely to yield more significant monetary returns to the U.S. Treasury compared to other areas of government spending," Short says.

The DOJ announced recently that it will be using the FCA as the means to investigate healthcare providers who are providing treatments inconsistent with the Trump administration's policy goals, particularly around treatments for transgender youth, Short says.

"While that is the stated policy objective, we can anticipate that the Civil Fraud section will pursue cases that look very much like what we have seen in healthcare enforcement in the past: Are doctors falsifying treatment codes or diagnoses to seek reimbursement for gender-affirming treatments that are not covered by federal healthcare programs?" she explains.

Beyond the administration's policy announcements regarding FCA enforcement in healthcare, the DOJ no doubt has a pipeline of preexisting healthcare

fraud investigations that it will continue to pursue, Short says. The DOJ has announced enforcement actions and settlements involving Medicare Advantage companies and entities that marketed or participated in the distribution of opioid prescriptions, she says.

"Other healthcare fraud investigations have been resolved against providers who are alleged to have overbilled federal healthcare programs or who reportedly were involved in improper kickback arrangements," Short says. "I do not see those types of cases going away, particularly because many healthcare fraud investigations are prompted by whistleblowers, who are not necessarily picking and choosing their allegations based on particular government enforcement priorities."

Short says she expects the DOJ section that is responsible for pursuing FCA cases and their counterparts at the U.S. Attorney's Offices across the country will continue to investigate and pursue healthcare fraud cases of all types with the same rigor and professionalism that they have exercised for decades.

"The current administration likely has raised the profile of the FCA as the government's preferred statutory tool for addressing fraud, waste, and abuse, and a number of policy directives and memoranda have put out a clear call to would-be whistleblowers to come forward and pursue FCA claims," she says.

Whistleblowers drive much of the DOJ's FCA docket, Short notes. Their insights can be incredibly valuable to the government's understanding of how an industry — and particular providers — work, she says. At the same time, it can be unsettling for healthcare organizations to be operating in the current environment of heightened awareness of whistleblower options, she says.

"Most healthcare organizations are well aware that they are operating in a heavily regulated environment and are doing their best to comply with a plethora of rules and procedures demanded of them," she says. "The idea that an employee who believes that an operational decision constitutes fraud — and decides to pursue an FCA claim, rather than reporting internally — is disconcerting."

Short advises healthcare entities to try to identify would-be whistleblowers early, through compliance training, reporting mechanisms, or other management communications. This allows a company to consider and respond to a concern before an employee decides to file an FCA action. More substantively, healthcare entities wrestling with ambiguous rules and regulations can seek guidance, often from the government or the contractors who administer Medicare and Medicaid payments.

"Seeking the advice of outside counsel is wise in certain circumstances," Short says. "Documenting these efforts and the rationale for making a decision on how to proceed can also demonstrate an entity's good faith in finding a compliant solution."

The last few months have seen increased enforcement activity as to conduct that the government believes violates the Anti-Kickback Statute, says **D. Jacques Smith**, JD, partner with the Arent Fox Schiff law firm in Washington, DC. One focus recently has been speaker programs.

"There's been a string of settlements relating to sham speaker programs, including a recent $200 million settlement with pharmaceutical manufacturer Gilead Sciences, Inc., which was allegedly hosting social gatherings for prescribers with little or no educational content under the guise of speaker programs," Smith says. "In light of these settlements, it would be prudent for life-sciences companies to re-evaluate how they structure speaker programs, and likewise, healthcare providers should be evaluating their policies for attendance at such programs."

The DOJ also remains interested in pursuing more traditional kickback theories, he says. "We're seeing a number of settlements that involve allegations of lavish meals, resort trips, and extravagant gifts in exchange for prescriptions. Finally, we are seeing an uptick in FCA activity tied to drug-pricing practices, particularly where companies are alleged to have manipulated or failed to report pricing data that feeds into government reimbursement formulas," Smith says. "All this signals that (the) DOJ is marrying classic (Anti-Kickback Statute) theories with the FCA's potent remedies, and it is not hesitating to demand nine-figure resolutions where it believes the facts support them."

The Trump administration has been steadfast in its intent to intensify curbing fraud, waste, and abuse, wherever it lies, Smith says. Since a significant portion of healthcare funding comes from federal and state programs, such as Medicare, Medicaid, and TRICARE, the government is highly motivated to protect these programs, and the FCA is the most successful tool in the government's toolbox for combatting fraud on the government, he says.

Attorneys at the DOJ have indicated that there will be an increase in customs fraud enforcement, particularly in light of recent tariffs, says **Nadia Patel**, JD, partner with Arent Fox Schiff in Washington, DC. She also anticipates that the DOJ's Civil Rights Fraud Initiative will result in the increased use of the FCA as a check on what the government views to be illegal DEI activities, she says.

"We cannot emphasize enough the importance of compliance," she says. "Healthcare providers should develop and maintain a robust compliance program that includes clear policies and procedures addressing speaker programs, consulting arrangements, and interactions with the industry."

Although recent civil rights fraud enforcement has focused on universities, healthcare providers are not immune to such actions, Patel says. Healthcare providers should review and update their policies and DEI programs to ensure compliance with anti-discrimination laws, conduct a detailed review and analysis of compliance certifications and conditions of payment required for receipt of federal funds, including medical research grants, and conduct risk assessments to identify areas of potential FCA exposure arising out of DEI programs, she advises.

Also, ensure compliance programs and hotlines are in place to capture and address complaints of discrimination. Healthcare fraud and abuse consistently has been the principal source of FCA recoveries, including recoveries from providers who allegedly improperly billed for medically unnecessary services and substandard care, kickback schemes, and Stark Law violations, says **Nora E. Becerra**, JD, partner with the K&L Gates law firm in Chicago.

"The trend of higher healthcare-related recoveries vis-a-vis other industries, has remained consistent despite a slight dip in the past years, and appears to be regaining ground, ticking up from 57% of total FCA recoveries in fiscal year 2024 to almost 65% in the first half of fiscal year 2025," she says. "This fiscal year 2025 uptick includes the DOJ's March 26 announcement of a $62 million settlement over Medicare Part C fraud against Seoul Medical Group, Inc., and others, on allegations relating to the submission of false diagnosis codes for two spinal conditions to increase payments from the Medicare Advantage program."

The healthcare industry can continue to expect heightened FCA scrutiny, with an observed focus in the first half of 2025 on Medicare Part C-related fraud, billing for medically unnecessary services and substandard care, kickback schemes, and Stark Law violations, along with other stated government priorities, such as cybersecurity and opioid-related enforcement, she says.

"Notably, qui tam lawsuits continue to be a stronger driver of healthcare recoveries under the FCA. Fiscal year 2024 marked the highest number of qui tam actions filed in a single year — at 979 qui tam actions filed by whistleblowers

— resulting in 558 settlements and judgments, which only slightly trailed the record set in fiscal year 2023," Becerra says. "This has understandably brought close attention to the recent challenges to the constitutionality of the FCA's qui tam provision."

Unlike other government enforcement priorities that changed with the new Trump administration, FCA enforcement will remain as the top priority for the DOJ, says **Brett W. Johnson**, JD, partner with the law firm of Snell & Wilmer in Los Angeles. This has been made clear in written guidance and emphasis by line assistant U.S. attorneys, he says.

In addition to continued criminal enforcement, the DOJ is expected to put significant emphasis on civil penalties, he says. Although the healthcare industry is banking on parallel DOJ guidance that it will provide mitigation for those entities that voluntarily report and fully cooperate with an investigation, it is clear that individual liability will remain a priority, he says.

"To ensure taking advantage of potential mitigations and beat any whistleblower to the punch, healthcare entities are expending resources on internal and external compliance programs," Johnson says. "This trend is expected to continue and adapt based on future settlements with the DOJ."

Healthcare is seeing a strong enforcement emphasis, which is publicly stated by DOJ officials as the number one priority because of the high-cost costs to the government in providing the case, Johnson explains. Between Medicare, Medicaid, Department of Defense, and Veteran Affairs, the government is the major payor for healthcare services, he notes.

"As such, the industry is rife with fraud, waste, and abuse opportunities — much of which is caused just by negligent actions or sometime weak compliance programs," he says. "Basically, if you are going to go fishing, you need to do it where the fish are easy to catch."

There has been an increase in investigation of sober living and developmental health areas, Johnson says. This may be the result of concentrating on networks of various providers and when you find one wrongdoer, it then leads to other wrongdoers in the network, he explains.

"It is expected that there will be more coordinated investigations between the various federal and state agencies. With the DOJ also highlighting tariff/import duty fraud as a high priority, there may be actual synergies due to the fact that so much of the medical equipment, supplies, and even medicines are imported," he says. "All industries have faced certain schemes associated with trying to avoid the Trump tariffs and the healthcare industry is no different."

While the healthcare industry is concentrating on the traditional issues related to billing inaccuracies that lead to FCA liability, they also should be looking at their supply chains and ensuring that they are not caught up in an FCA investigation because they were complicit with their suppliers to avoid the costs of tariffs, Johnson says.

Whistleblowers are essential to DOJ enforcement actions, Johnson notes.

"(The) DOJ does not need to advertise to recruit whistleblowers — the healthcare industry does it for them because of the mandated training programs," he says. "So, the whistleblowers are a force multiplier that is only enhanced not only for the financial benefit in reporting, but also avoiding the personal liability associated with an FCA claim."

What healthcare organizations can do to best protect themselves from possible FCA actions has not changed in the last 20 years, Johnson says. The solution is all about having a robust compliance program that includes senior management commitment to ensure the resources exist to support the program, he says. The

program includes regular updating policies and procedures, training, audits, and good internal reporting mechanisms.

Furthermore, when a potential false claim is reported or otherwise identified, healthcare organizations need an established plan to investigate the matter. This includes the retention of outside counsel as one of the first considerations, he says.

"A trend for the healthcare industry is to try to handle the investigations internally and, sometimes, without the assistance of a lawyer, internal or external. This trend eliminates the benefits of the attorney-client and attorney-work product privileges associated with having an attorney conduct the investigation," Johnson says. "The best way to protect against an FCA action is to plan ahead."

Sources

- **Thomas H. Barnard**, JD, Shareholder, Baker Donelson, Washington, DC. Telephone: (202) 508-3400. Email: tbarnard@bakerdonelson.com.
- **Nora E. Becerra**, JD, Partner, K&L Gates, Chicago. Telephone: (312) 807-4222. Email: nora.becerra@klgates.com.
- **Richard F. Cahill**, JD, Vice President and Associate General Counsel, The Doctors Company, Napa, CA. Telephone: (800) 421-2368.
- **Selina P. Coleman**, JD, Partner, Reed Smith, Washington, DC. Telephone: (202) 414-9220. Email: scoleman@reedsmith.com.
- **Bridget A. Gordon**, JD, partner with the Hooper, Lundy & Bookman, Los Angeles. Telephone: (310) 551-8175. Email: bgordon@hooperlundy.com.
- **Ty E. Howard**, JD, Partner, Bradley, Nashville, TN. Telephone: (615) 252-2376. Email: thoward@bradley.com.
- **Brett W. Johnson**, JD, Partner, Snell & Wilmer, Los Angeles. Telephone: (602) 382-6312. Email: bwjohnson@swlaw.com.
- **Geoffrey R. Kaiser**, JD, Senior Counsel, Rivkin Radler, Uniondale, NY. Telephone: (516) 357-3161. Email: geoffrey.kaiser@rivkin.com.
- **Matthew G. Nielsen**, JD, Partner, Bracewell, Dallas. Telephone: (214) 758-1039. Email: matthew.nielsen@bracewell.com.
- **Kurt Osburn**, Director, NCC Group, Manchester, United Kingdom. Telephone: +44 (0) 161-209-5200.
- **Jacquelyn Papish**, JD, partner with the Barnes & Thornburg law firm in Washington, DC. Telephone: (202) 831-6732. Email: jackie.papish@btlaw.com.
- **Nadia Patel**, JD, Partner, Arent Fox Schiff, Washington, DC. Telephone: (202) 775-5716. Email: nadia.patel@afslaw.com.
- **Braden Perry**, JD, Partner, Kennyhertz Perry, Mission Woods, KS. Telephone: (816) 527-9445. Email: braden@kennyhertzperry.com.
- **Jennifer A. Short**, JD, Partner, Blank Rome, Washington, DC. Telephone: (202) 420-2698. Email: jennifer.short@blankrome.com.
- **D. Jacques Smith**, JD, Partner, Arent Fox Schiff, Washington, DC. Telephone: (202) 857-6154. Email: jacques.smith@afslaw.com.
- **Paul D. Werner**, JD, Buttaci Leardi & Werner, Princeton, NJ. Telephone: (609) 799-5150. Email: pdwerner@buttacilaw.com.

Greg Freeman has worked with Relias Media and its predecessor companies since 1989, moving from assistant staff writer to executive editor before becoming a freelance writer. He has been the editor of Healthcare Risk Management *since 1992 and provides research and content for other Relias Media products. In addition to his work with Relias Media, Greg provides other freelance writing services and is the author of seven narrative nonfiction books on wartime experiences and other historical events.*