INSIDE THE MINDS™

HEALTH CARE LITIGATION STRATEGIES

LEADING LAWYERS ON ANALYZING RECENT HEALTH CARE LITIGATION TRENDS, DEVELOPING SUCCESSFUL CASE STRATEGIES, AND PROTECTING CLIENT RIGHTS

ASPATORE

Greg Luce, Skadden, Arps, Slate, Meagher & Flom LLP
Gregory N. Pimstone, Manatt, Phelps & Phillips LLP; Thomas G. Smith, Harter Secrest & Emery LLP
Kirk S. Davis, Akerman Senterfitt LLP; Jeffrey Clark, McGuireWoods LLP
Kevin E. Raphael, Pietragallo Gordon Alfano Bosick & Raspanti LLP
George B. Breen, Epstein Becker & Green PC; Geoffrey E. Webster, Chester Willcox & Saxbe LLP
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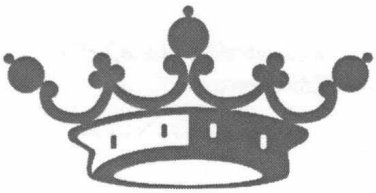

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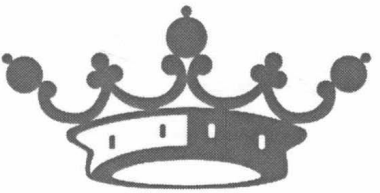

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Defending the Health Care Industry Against the Government's Expanding and Novel Theories of Liability

Greg Luce

Partner

Skadden, Arps, Slate, Meagher & Flom LLP

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Introduction

Far from focusing on conduct that would be viewed as fraud by an objective observer, the majority of the current government civil "fraud" cases against mainstream health care providers seem to rely upon technical violations and recordkeeping lapses urged by private "whistleblowers" as proof of false claims submitted to government health benefits programs such as Medicare. The "whistleblowers" account for over 80 percent of the government's enforcement docket, which increasingly relies on widespread and routine practices that may or may not meet prevailing agency interpretations of compliance, but that are alleged to violate some legal or regulatory standard. Often such standards are not required terms of payment by the health program, but are conditions of participating in such programs as providers or suppliers. The alleged regulatory lapses are typically numerous because they reflect routine practices by providers, not preconceived fraud schemes. Yet their numerosity is held out as evidence of a reckless disregard for the accuracy of the claims or certification of compliance with prevailing regulations. Finally, some courts are refusing to accept such sweeping claims as stating allegations of objective fraud on the federal fisc, however, and providers are securing dismissal of these specious or hyper-technical applications of agency regulations. This chapter discusses the ways in which such defenses have prevailed and the importance of considering the long-term effect on a provider and on the industry by acceding to "convenience" settlements that may only encourage more spurious claims intended to secure a recovery under the False Claims Act.

Modern Trends in Health Care Litigation

A Focus on Enforcing the False Claims Act

The main trend in current health care litigation right now is private and governmental enforcement of the False Claims Act. Use of the False Claims Act in the health care arena has continued to increase even by the Department of Justice's (DOJ) own estimation. Virtually 80 percent of the government's cases in this arena have been generated by False Claims Act cases filed by whistleblowers, or relators, as they are called in the law. These *qui tam* relators have effectively flooded the DOJ with their various claims

of fraud in the hope of collecting a large bounty. Many of the largest cases have resulted in settlements in which relators have made substantial amounts of money, and some of them have made False Claims Act litigation almost an enterprise in itself.

For example, a small Florida-based pharmacy has gone full time into becoming a whistleblower by mining data and determining where it thinks it can bring a False Claims Act case. It is very aggressive and has been very successful in engendering significantly large settlements, particularly against pharmaceutical companies and in claims under both the Medicare Law and under state Medicaid programs. The trend has clearly been an increase in the number and size of settlements by pharmaceutical and medical device manufacturers, but hospital systems are similarly intertwined in government and private False Claims Act enforcement.

Medicare Billing Requirements

Another trend worth noting is that many of these cases founded upon allegations of fraud deal with very technical considerations of Medicare billing and coding requirements. Some are based on the government's rules by which providers are to operate their facilities, or upon the particular code or description providers are to employ for a certain type of claim. Minor regulatory violations are frequently alleged to be fraud in these large-scale False Claims Act cases. This is having an impact on what is actually occurring in almost every aspect of health care company operations. Defensive responses by providers, pharmaceutical manufacturers, or device manufacturers must take into account not only the large amounts paid in settlements, but also a subsequent amount that may go to addressing a "corporate integrity agreement" (CIA), which is essentially an administratively enforced compliance program paid for by the company but enforced by the government. In addition to the typically large expense of the settlement itself, a CIA often results in additional expensive mandatory compliance measures that may impose further risk of regulatory penalties if their terms are not met. In light of these heightened settlement costs and risks, more companies are starting to reconsider how and whether to settle their cases with the government, or whether to proceed to litigation.

Prosecuting Corporate Executives and In-House Counsel

One of the more disturbing trends in recent years has been the effort of the Office of Inspector General (OIG) to exclude corporate executives from federal health care programs. The OIG sought to exclude an eighty-three-year-old CEO of Forest Labs for activities that had nothing to do with that individual's own particular conduct or activity, but simply as a by-product of a settlement against Forest Labs in a civil False Claims Act case. This was widely reported, including on the front page of the *Wall Street Journal.* Contrary to its intended deterrent effect, this action by the OIG was largely regarded as mean-spirited and attention grabbing. It offended many people who feel that this type of exclusion has little to no deterrent effect.

The government also recently sought to indict the in-house counsel for GlaxoSmithKline, claiming that her efforts in defense of the company and her production of documents and representations regarding the company's conduct relating to a government investigative matter were fraudulent. They sought to indict her, but a federal judge cited the prosecutors for continuing a baseless case intruding on the attorney-client privilege and the ability of corporations to secure and rely upon the advice of their counsel. The judge dismissed all counts in federal district court in Maryland only a few weeks ago.

Overall, the government has vastly overreached in both its personal exclusion efforts and in criminal prosecutions of in-house counsel assisting companies in response to federal investigations. It is unclear whether this will limit the government's enthusiasm for these types of prosecutions, but it has had a certain hardening effect on the industry, which now realizes that it can push back and resist such overreaching and overly zealous enforcement.

Parallel Civil and Criminal Investigations

Another interesting trend in this area of law is the use of parallel civil and criminal investigations, particularly under the Food & Drug Administration's (FDA) misdemeanor criminal authority to investigate and prosecute off-label promotion of drugs or devices. The government

enforcement trend has been to take technical billing, coding, or reimbursement issues and add a layer of criminal enforcement for matters in which there are allegations that a pharmaceutical or medical device company inappropriately encouraged the use of a drug or device for a use or purpose that has not been approved by the FDA. These so-called off-label issues become factually complex because physicians are not bound by the labeling that the FDA approves if, in their professional judgment, a drug or device can have a clinical beneficial effect for their patient, regardless of the safety and efficacy determinations in the FDA's labeling decision. However, in this sort of gray area, the companies that manufacture the drugs and devices may not promote a use that a physician might choose for a drug or device if it is not within the strict labeling terms that the FDA has approved for purposes of sale and introduction into interstate commerce.

The Implications of Settling Cases

In these areas of prosecutorial discretion, there are no particular rigid rules. Instead, the government applies a look-and-feel test, which has the potential of leading to criminal liability and program exclusion for corporate officers who may have been generally charged with the operations of the company and who generally comply with laws. They may not have had any particular personal involvement in the targeted activity, but they still face personal liability. This is all part of the government's efforts to punish individuals for what are perceived to be corporate failings. Some of this is in response to the congressional pressure that comes from major companies paying big fines. The officers and directors allegedly responsible for the conduct that led to the fine are settling cases rather than going to court because the risks are so high. In a settlement, each party has agreed that settling on certain terms is better than proceeding to trial, and most importantly, settlements do not include admissions of guilt. However, they often are viewed as admissions of guilt in the public eye, and the effect of trying to settle cases has led to a generalized view that the industry is entirely corrupt. In reality, the industry is facing an unprecedented amount of civil and criminal enforcement in arcane and technical areas of activity that probably never rise to the level of fraud.

The Impact of Trends on Clients

All of these trends have forced companies to consider whether they should do something more than try to expeditiously resolve matters with a settlement because the collateral damage of settlements has become so great. Notwithstanding the risk of litigation, companies are now considering alternatives. For example, some are refusing to execute corporate integrity agreements. This could result in the executives being excluded from Medicare, but in all likelihood, a major pharmaceutical company with a drug that is required by millions of Medicare beneficiaries will simply not allow such exclusion to happen. This is yet another reason why the Office of the Inspector General has tried to revert to personal liability attacks in order to force companies to yield to its demands.

Understanding Health Care Litigation

Changes in Client Demographics

My practice focuses on litigation and compliance advice to avoid regulatory liability largely premised on the False Claims Act or on the Food Drug and Cosmetics Act. Our clients are major international pharmaceutical companies, medical device manufacturers, and major health care systems. Some are owned by investors and some are not-profit organizations.

Our representation of large companies has grown partly as a consequence of the higher stakes in today's regulatory arena. Large firms with a deeper bench and highly specialized litigators and regulatory counsel can address the concerns of these companies. My partners have added to our collective expertise, so we are now one of the larger and better recognized defense firms in this area, and we are seeing a migration to our practice. This migration has partially come from clients who are tired of the old routine of getting a government subpoena and spending significant funds in trying to satisfy the government's inquiries and demands for documents, e-discovery, and interviews, only to pay a large settlement and sign a corporate integrity agreement. Instead, these companies are looking for counsel that wants to offer an alternative to rolling over or engaging in extraordinarily expensive internal investigations and document productions, particularly where the government's theories of potential liability are thin or attenuated.

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