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Stop Rushing Headlong into the Same Mistakes

Compliance and Ethics

One morning last spring, as I was having breakfast, I heard knocking on the sliding glass door to the back porch. When I went to see who was banging on my window, I saw a male red-breasted robin angrily fighting his own reflection. Time and again he flew headlong into the window. Despite the fact he was taking quite a beating, and the many times I chased him away, he came back day after day to do battle with his imagined adversary. For decades, the US healthcare industry has engaged in the same kind of repeated self-destructive behavior.

It all started in 1965 on a hot July day in Independence, Missouri. Sitting at a desk in the Truman Presidential Library, President Lyndon Johnson signed into law the Social Security Act amendments that created the Medicare and Medicaid health insurance programs for the elderly and the poor. These programs have since benefited millions of Americans by saving lives and relieving suffering. They also created a multi-trillion-dollar pot of gold that healthcare companies cannot resist.

Shortly after the Medicare and Medicaid programs went into effect, the US government discovered that the healthcare industry was awash in kickbacks and fraud. Medical device and pharmaceutical companies were routinely paying kickbacks to hospitals and physicians to induce them to use their products. Doctors not only took the bribes but they also engaged in self-dealing by referring patients to ambulance services and diagnostic facilities in which they had a financial interest.

To curb these corrupt practices, which increased healthcare costs and compromised the quality of patient care, Congress passed the Anti-Kickback Statute (AKS) in 1972. The AKS has been

amended many times since its initial passage, but its essential tenets have remained unchanged. The AKS essentially criminalizes garden-variety marketing practices. Specifically, with the exception of enumerated safe harbors, the AKS makes it illegal to provide anyone gifts, meals, entertainment, rebates, discounts, payment for services, or anything of value with the intent to induce another to purchase or refer to a patient a drug or medical device that might be paid for in whole or in part by a government-funded healthcare program.

The False Claims Act (FCA) further compounded the healthcare industry's compliance risks. The FCA was enacted during the US Civil War to combat rampant fraud. At the time, fraudsters were selling the Union Army moldy blankets, empty boxes meant to contain rifles, and other defective war-related materials. One fraudster was said to have sold the same horse to the Army multiple times.

The FCA has been, and continues to be, a potent weapon against government fraud, primarily because it contains a citizen suit provision also referred to as a "qui tam" provision — short for the Latin phrase, "*qui tam pro domino rege quam pro se ipso in hac parte sequitur*," which means "he who brings an action for the king as well as for himself." Today whistleblowers, referred to in FCA parlance as "relators," can receive a bounty of up to 30 percent of any settlement or penalty paid to the government in resolving a case brought pursuant to the FCA.

In 2010, the Affordable Care Act amended the FCA by expressly tying it to the AKS by providing that "claims that include items or services resulting from a violation of the AKS also constitute a false or fraudulent claim for purposes of the FCA." States have their own versions of the AKS and FCA and frequently join the United States in actions against healthcare companies.

Combined with vigorous enforcement, the AKS and FCA have netted thousands of criminal convictions and record fines, many of which have been paid by the biggest names in healthcare, such as Pfizer, Glaxo Smith Kline, Eli Lilly, Merck, Johnson & Johnson, Novartis, Smith & Nephew, Medtronic, and Allergan. These firms, and many others, have been compelled to enter into multi-year corporate integrity agreements mandating stellar compliance and ethics programs and oversight by outside watchdogs.

As a compliance officer practicing in the pharmaceutical and medical device industry for over 10 years, I have both witnessed and participated in a grand, multi-billion-dollar experiment to find the cure to the industry's apparent compulsion to engage in corrupt business practices. This experiment involved the creation and implementation of stacks of policies, procedures, controls, and training programs designed to compel and induce compliance with the law and high ethical standards. The results of this experiment are in. This approach has been and continues to be an utter failure. If it had any potency whatsoever in driving ethical behavior, we would not witness so many firms like Johnson & Johnson, Allergan, Pfizer, and Novartis, with textbook compliance and ethics programs, be repeat offenders. In 2017 alone, the healthcare industry paid US$2.7 billion in FCA penalties.

Despite these data, like the robin who kept banging his head against my window, we compliance professionals and corporate counsel continue to focus our efforts on creating new policies and training programs with the hope that they will lead us to the promised land. We do this because it's easy and the real solution is hard. It is past time to recognize the primary root cause of corruption — a failure of top leadership.

We are powerless to pick our leaders. But, perhaps we should try something new. Instead of tossing more policies, procedures, and controls on the heap, let's focus all our energies on coaching our board of directors and senior leaders on how they can and must stop passing the buck to the

compliance and law departments and take personal responsibility for driving ethical behavior. Specifically, tell your leaders that to create and sustain a strong ethical culture they must:

- Understand and master the rules well enough to teach them and expect that every other leader in the company to do the same.
- Put compliance and ethics at the top of every business meeting and expect every other leader in the company to do the same.
- Fire any leader in the company who cannot or will not meet the first two expectations.
- Get their head out of their spreadsheets for a while and remind everyone the reason the company is in business with the objective of becoming a purpose-driven organization.

This approach is risky. But, so is repeating the mistakes of the past. The robin on my back porch had an excuse for its futile behavior. What's yours?

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