

Life Sciences Due Diligence: A Reference Guide for Your Life Sciences Corporate Transactions

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Key Points

- Life sciences companies are subject to rapidly changing regulatory obligations, government enforcement, and increasing public scrutiny.
- Conducting effective legal and regulatory due diligence can mean uncovering risks and other obstacles that impact how you value a corporate transaction, the terms on which you will enter a transaction or the timing to close the transaction.
- For example, recent revisions to the AdvaMed Code and the Sunshine Act as well as anticipated regulatory changes intended to address value-based arrangements could require companies to update their internal compliance programs.
- Recent litigation demonstrates the use of the False Claims Act as an avenue for holding private equity and venture capital firms liable for portfolio companies' activities.

To access and download Akin Gump's Life Sciences Due Diligence Checklist, click [here](#).

As the life sciences industry experiences a boom in corporate mergers, acquisitions, and financing and lending arrangements, due diligence efforts need to account for the latest changes in the legal landscape.

Two recent False Claims Act cases (*United States ex rel. Martino-Fleming v. South Bay Mental Health Center*¹ and *United States ex rel. Medrano v. Diabetic Care*²) have highlighted the continued need for investors and acquiring companies to closely examine their due diligence processes and post-close obligations. This is especially important when valuing and weighing deals in the life sciences industry.

First, in *Martino-Fleming*, the False Claims Act relator alleged that South Bay Mental Health Center violated the False Claims Act by billing Medicaid for mental health services performed by individuals lacking appropriate licensure, educational background and supervision. Importantly, the trial court determined that the private equity investors of South Bay—H.I.G. Growth Partners and H.I.G. Capital—could be

Contact Information

If you have any questions concerning this alert, please contact:

Matthew Wetzel

Senior Counsel
mwetzel@akingump.com
Washington, D.C.
+1 202.887.4221

Nathan Brown

Partner
nabrown@akingump.com
Washington, D.C.
+1 202.887.4245

Howard Sklamberg

Partner
hsklamberg@akingump.com
Washington, D.C.
+1 202.887.4055

Taylor Jones

Senior Counsel
tjones@akingump.com
Washington, D.C.
+1 202.887.4278

Gene Elder

Senior Counsel
gelder@akingump.com
Washington, D.C.
+1 202.887.4149

Jo-Ellyn Sakowitz Klein

Senior Counsel
jsklein@akingump.com
Washington, D.C.
+1 202.887.4220

defendants (and, therefore, presumably, could be found liable) given their direct involvement in the facility's operations and their majority stake on the board.³

Similarly, in *Medrano*, the False Claims Act relator alleged that defendant Patient Care America (a compounding pharmacy) engaged in a kickback scheme that involved hiring outside marketing companies to generate patient referrals. As alleged, the marketers would refer patients for compounded drug prescriptions to the defendant; reimbursement claims for these drugs were then sent to and paid for by the government (here, TRICARE); and the defendant then allegedly paid 50 percent of the profit to the marketing agents. The court in *Medrano* found that the defendant's private equity owner—Riordan, Lewis & Haden, Inc. ("RLH")—could be a defendant in this case due to RLH's controlling interest in as well as its knowledge, approval and even funding of the marketing arrangements.⁴

These two discrete matters may not signal a new government enforcement strategy to hold private equity and venture capital investors liable under the False Claims Act, as some law firms and other observers have indicated. But, they do illustrate the general concept that the False Claims Act can be a potential avenue for relators and others to pursue recoveries from investors for the actions of the investors' portfolio companies. As a result, these cases serve as timely reminders of the importance of comprehensive due diligence and understanding post-close obligations.

Layered on top of these False Claims Act cases are other changing legal and regulatory requirements. Enhancements and revisions to FDA's approval and clearance processes, changes to OIG's safe harbors for discounts and rebates, updates to industry codes of ethics, the expansion of the Sunshine Act, and increased press and plaintiff's bar scrutiny on life sciences companies' product pricing and customer interactions highlight the need for careful attention to due diligence and post-close obligations.

Akin Gump Strauss Hauer & Feld LLP has prepared a due diligence checklist to help ensure that your life sciences transactions—whether private equity or venture capital investments, mergers or acquisitions—continue to include a strong, effective review of your target company's or portfolio company's health care regulatory risk profile.

To access and download Akin Gump's Life Sciences Due Diligence Checklist, click [here](#).

¹ United States ex rel. Martino-Fleming v. South Bay Mental Health Center, No. 15-13065-PBS, 2018 WG 4539684 (D. Mass. Sept. 21, 2018).

² United States ex rel. Medrano v. Diabetic Care Rx LLC (d/b/a Patient Care America), No. 15-CV-62617, 2018 WL 6978633 (S.D. Fl. Nov. 30, 2018).

³ See *id.* at *5.

⁴ See *Medrano* at *11.

akingump.com

Contact Information

If you have any questions concerning this alert, please contact:

Christin Carey

Counsel
chcarey@akingump.com
Washington, D.C.
+1 202.887.4257

Daniel Graver

Counsel
dgraver@akingump.com
Washington, D.C.
+1 202.887.4562

Marlee Gallant

Associate
mgallant@akingump.com
Washington, D.C.
+1 202.887.4252