**Frank Rivas** is vice president of NSF Becker & Associates’ compliance and integrity programs. He has represented industry in interactions with the HHS Office of Inspector General (OIG) on a broad range of topics, including compliance with the parameters of corporate integrity agreements (CIAs).

**WDL:** How does NSF Becker’s 360 Corporate Compliance Program differ from its other consulting services?

The program offers enterprise risk management (ERM) tools to conduct gap analysis. NSF Becker has a broad range of experience in the industry to draft procedures to help companies meet the 2003 OIG guidance on establishing an effective compliance program. We have hired former senior level FDA personnel and executive-level industry veterans who have specific experience in tailoring ERM tools to a company’s needs.

**WDL:** What are the seven compliance elements established by the OIG?

The guidance states that at a minimum, industry must establish the following elements:

- Implementing written policies and procedures;
- Designating a compliance officer and compliance committee;
- Conducting effective training and education;
- Developing effective lines of communication;
- Conducting internal monitoring and auditing;
- Enforcing standards through well-publicized disciplinary guidelines; and

The finalized document provides considerations applicable to all injectors. But it also provides general content and format information for injectors that are reviewed under 510(k) submissions as well as injectors reviewed under an NDA or BLA submission for the combination product.

Injectors intended for use with a specific drug/biological product are typically considered combination products and their regulatory pathway is based on the primary mode of action (PMOA). Combination products with a drug or biological product PMOA are assigned to CDER or CBER for review. For combination products comprising an injector and a drug/biological product, one marketing application is generally sufficient, the guidance states, adding that the application is usually an NDA or a BLA.

The final guidance also contains some editorial and terminology changes to improve clarity and readability, the agency says. The guidance can be viewed at [www.fdanews.com/ext/files/06-06-13-injectors.pdf](http://www.fdanews.com/ext/files/06-06-13-injectors.pdf). — Melissa Winn
Responding promptly to detected problems and undertaking corrective action.

**WDL:** What sort of monitoring program, internal or external, must exist to maintain compliance?

The extent of monitoring will vary depending upon the risk profile of the company, which depends in part upon the therapeutic class, risk appetite of management and board, as well as prior enforcement activity. The OIG and Department of Justice have demonstrated little patience for companies deemed as being involved in recidivist behavior. Therefore, it is important for every company to continually assess their compliance programs to determine if they are adequate to effectively monitor activities.

**WDL:** How commonplace are CIAs in the pharmaceutical industry these days? And what is the intended outcome of one?

Companies that settle claims brought against them by the OIG or other regulatory bodies typically enter into a CIA, a contract with the government to establish certain standards and metrics for adherence to those standards for a period of time — usually five years. While the majority of companies in the U.S. operate without a CIA, the best practice is to evaluate other companies’ CIAs as models of the OIG’s expectations. The intended outcome of a CIA is to create validated procedures that are regularly monitored and audited once personnel are trained. The goal is to ensure compliant behavior across all disciplines within the organization.

**WDL:** What are the consequences of being noncompliant with your CIA?

Typically, CIAs have language that stipulates to liquidate damages for failing to adhere to the CIA. Moreover, the regulatory bodies, including DOJ, the FDA, CMS and OIG may impose new civil and criminal fines and penalties upon a company or individuals, as well as new or an extension of existing CIAs. Senior-level OIG officials have stated that they will consider individual prosecution as part of a campaign to reduce recidivist behavior.

**WDL:** Some drugmakers have recently come under investigation, or are in litigation, for business practices that appear to violate CIAs. What happens next for these companies?

History has shown that fines and penalties for repeat offenses have been considerably higher than for the first-time penalties. The governmental entities have also imposed some significant changes to CIAs. An example is the GlaxoSmithKline CIA, which requires considerably greater action across all levels of the organization to avoid activities similar to what was the subject of the enforcement action. This included radical changes to the manner in which sales-based personnel are measured for bonus compensation; claw-back provisions for management and executive personnel for improper actions that take place in their reporting structure; and embedding compliance monitors into the business functions, among other means, of monitoring activities. The cost of compliance in general is considerable, and this type of structure to the organization can be staggering. This, of course, must be measured against the direct (fines and penalties) and indirect (loss of market capitalization, reputation, morale) cost of non-compliance.