

*Guest commentary*

## **Be Proactive and Create a Culture of Compliance: Connecting the Dots between NASA and the OIG**

By Wendy Heckelman, PhD and Christina Garofano, PhD

**A**t the Pharmaceutical Regulatory and Compliance Congress and Best Practices Forum in Washington D.C., OIG Senior Counsel Mary Riordan and former astronaut Richard Mullane spoke on different topics. Riordan delivered an OIG update and Mullane talked about causes and lessons learned from NASA disasters. Although these were very different talks there was a fundamental connection between them that can guide companies to create a culture of compliance and avoid costly fines and prosecutions.

Riordan gave the audience a summary of recent OIG actions, areas of focus, and predictions and recommendations. Riordan said she was encouraged by companies under corporate integrity agreements (CIAs) looking to do more than the minimum requirements and encouraged this type of proactive behavior.

Mullane provided examples from the Challenger and Columbia disasters to caution biopharmaceutical companies that they need to guard against a “normalization of deviance.” This occurs when an otherwise good team of people deviate from best practices, and because there are no immediate consequences, they continue to do so until a “predictable surprise” occurs. He argued that both the NASA disasters and big corporate fines and CIAs are predictable surprises that occurred because of a normalization of deviance, which is another way of stating there was a flaw in the organizational culture of compliance.

### ***How can your company be proactive and guard against a “normalization of deviance”?***

By combining the recommendations Riordan and Mullane offered with additional best practices we have created the following list to help your company create a culture of compliance and avoid prosecutions and fines:

- **Identify and adhere to best practices and avoid deviating from agreed to practices.** Mullane stated that best practices were known at NASA but they were not followed when the group was under

pressure. He stressed the importance of adhering to established best practices. For biopharmaceutical companies, this means setting explicit expectations for behavior, especially in tricky situations such as handling off-label questions, and ensuring they are followed.

- **Perform and use risk assessment analyses to identify key areas of risk.** Perform a broad risk assessment to identify your areas of greatest vulnerability and address them. Riordan noted that there are new risk areas the OIG has begun to focus on, including dealings with physician owned distributorships which could violate anti-kickback rules. Mullane also noted the importance of listening to people with the most information on an issue because they can be your “canary in the coalmine” and provide warning early enough to take corrective actions.
- **Perform behavioral training to ensure behavior change occurs.** Traditional compliance training focuses on knowledge of regulations and policies, but the “normalization of deviance” described by Mullane is not based on a knowledge-deficiency. *It is a behavioral issue.* Companies need to ensure that all employees receive regular training and reinforcement on behavioral expectations to help create and maintain a culture of compliance. Behavioral training requires that learners have the opportunity to practice and receive feedback on observed behavior.

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- **Use effective auditing techniques to gain broader insights.** For auditing to be effective it needs to regular and broad to convey the notion that compliant behavior is an ongoing expectation. Riordan suggested that companies should look at all the ways they interact with HCPs and use other data, such as requests for medical information, to get a better picture of what is occurring in your organization and in the field. For sales, we also suggest that compliance monitoring be fully integrated with regular field ride observations and ongoing coaching efforts. Companies should define outstanding compliant selling behaviors for their products and train, monitor, and reinforce those expectations.
- **Respond to audit findings and ensure continuous improvement.** Ensure you have procedures in place to communicate and react to audit findings. Documentation and reporting needs to be real-time with automated procedures to share and follow-up on potential issues. Mullane also suggested that companies should have a formal process for retaining and reviewing prior organizational issues. This helps create and preserve organization memory, which can fade over time. He noted there were 17 years between Columbia and Challenger and many of the lessons learned were forgotten over time and repeated. Make sure consistent documentation occurs of key policies and practices.
- **Involve all levels of the organization to create a culture of compliance.** As stated by another conference keynote speaker, John Lechleiter from Eli Lilly, “the most important level of culture change in an organization is leadership.” To create a culture of compliance, the message needs to come from the top and be reinforced by all levels of the organization. Compliance training should be cascaded down through the organization. Combining this training with regular high-level reports from the field would also enable board members and other executives and managers with “signing authority” to certify with confidence that compliant behavior is occurring in their organization.

By proactively defining, training, monitoring, and following-up on compliant behavioral expectations, companies can create and maintain a culture of compliance and avoid what Mullane called the “predictable surprise” of large corporate fines and prosecutions. ■

Dr. Wendy Heckelman, president and founder of WLH Consulting, Inc. can be reached at [wendy@wlhconsulting.com](mailto:wendy@wlhconsulting.com). For more information, visit [www.wlhconsulting.com](http://www.wlhconsulting.com).

## What's Ahead in *Rx Compliance Report*

**Leading *qui tam* attorneys predict more rapid intervention decisions by DOJ and more traditional litigation.** The next issue of *Rx Compliance Report* will look at the changing enforcement environment from the perspective of several leading *qui tam* attorneys who say more rapid intervention decisions by DOJ will lead to more non-intervened cases moving forward, as well as more traditional litigation.

**Experts outline essential ingredients for an effective monitoring program.** Experts from Ernst & Young and Navigant explain how to build the necessary framework for an effective monitoring program.

**How to successfully use incentives in a compliance and ethics program.** Compliance veterans Joe Murphy and Dan Roach explain the best methods for using incentives in an ethics and compliance program.

## What's Ahead in *Disclosure Update for Drug & Device Companies*

The next issue of *Disclosure Update* will feature a recent update on the Sunshine Act regulations by CMS' Niall Brennan.

In addition, experts from Polaris suggest practical steps companies can take as they await the final rule.

## What's Ahead in *International Rx Compliance Report*

*International Rx Compliance Report* will feature coverage of last month's International Pharmaceutical Compliance Congress in Budapest, including discussion of emerging monitoring practices.

It will also feature an update on the changing global anticorruption landscape by experts from Deloitte and Touche and former DOJ attorney, Paul McNulty.