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Report on Research Compliance Volume 15, Number 6. June 30, 2018 Moffitt Shares Strategies for Reducing Complicated Research/Clinical COIs

By Theresa Defino

Last year, the Food and Drug Administration (FDA) approved lenalidomide, sold under the name Revlimid by Celgene Corp., for multiple myeloma patients who require a maintenance drug after a stem cell transplant. FDA first approved the drug in 2006 "for use with dexamethasone in patients with multiple myeloma who received at least one prior therapy," and it's said to have set the standard of care for certain multiple myeloma patients.

The medication was developed due to the "pioneering work" of Alan List, M.D., president and CEO of the Moffitt Cancer Center, whose efforts spanned "from the laboratory to clinical trials," according to Moffitt's website.

Although the success of List's research was a "very big deal for Moffitt," it also "created an institutional conflict" for the organization, according to Donnetta Horseman, Moffitt's chief compliance officer.

List's "technology" was licensed by a pharmaceutical company with which the Tampa, Florida, center was "already doing multiple research projects" and which had "donated significant funding to our foundation. We purchased drugs from that pharma company. They sponsor educational events," Horseman said. As CEO, List "would normally be the person in the organization who would negotiate such an agreement with" a pharmaceutical company, but he could not be "involved in the process at all," she added.

An additional wrinkle was that "[a]ll of the other people who would have taken over for him, report to" List, Horseman explained. Given these activities, "pretty much just about every way that you can imagine…there could be a conflict."

But Moffitt successfully managed those complicated issues, as well as individual conflicts of interest (COIs) List potentially faced, Horseman explained in a recent talk at the Health Care Compliance Association's (HCCA) Compliance Institute in March. The talk, "Strategies for Managing Conflict of Interests in the World of Innovation," was to have been presented by Moffitt official Cheryl Byers, who Horseman said had previously served as the cancer center's conflict of interest officer. Horseman used slides created by Byers, who was unable to attend.

Moffitt implemented a comprehensive management plan for oversight of List's research, seeking input from other organizations because this "was really kind of the first of its kind for us," said Horseman, adding that the situation "really does talk to all of the types of conflicts" that can be triggered.