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FDA's Sharpless: We Will Be 'Vigilant' Against Data Fraud

By Theresa Defino

The topic took up just the last four minutes of his talk, but Acting Food and Drug Administration Commissioner Ned Sharpless' words were clear about the value of data integrity: If you bring "bad" data to the FDA, we will go after you.

Speaking at the close of a day-long conference hosted by Research!America, Sharpless never mentioned what prompted his warning, namely the scandal that unfolded in August. The FDA revealed then that months prior to FDA approval in May, a subsidiary of Novartis AG knowingly submitted falsified animal research data in support of a medication for a sometimes-fatal pediatric spine condition. The drug was already under fire because of its high price tag—$2. 1 million.

FDA learned of the falsifications from the firm two months after approval; some terminations were triggered, but overall, both Novartis and FDA ultimately said no safety concerns have arisen as a result, and the drug, Zolgensma, is staying on the market for now ("FDA: Some Animal Research Data Behind New $2.1M Gene Therapy Drug Were 'Manipulated,'" *RRC* E-Alerts: August 8, 2019).

Quest for Quick Approval a Factor?

Still, FDA's Aug. 6 announcement of the fraud was stunning and unprecedented, as was its response to the disclosure. FDA released a trove of internal documents, including emails and inspection reports, and warned the firm that investigations were continuing. "The agency will use its full authorities to take action, if appropriate, which may include civil or criminal penalties," FDA's statement said.

In his remarks, after cataloguing the progress of cancer treatments (Sharpless, an oncologist, is on loan to FDA from his post as head of the National Cancer Institute (NCI)), Sharpless spoke of the "need for more biomedical research and yielding the best data." He recounted his surprise at discovering the level of data fraud in papers submitted to the *Journal of Clinical Investigation*, where he was an editor.

He began by drawing a distinction between "good as opposed to bad data."

"Every day there's research that offers great promise, but some of the rapid desire for progress can translate into the potential for taking a shortcut with the FDA, i.e., not collecting good data, but rather collecting bad data and then submitting this bad data to us in support of a medical product application, for example," said Sharpless.

Two "important causes" of bad data "are that it's sloppy, slipshod research or that there's actual data falsifications," said Sharpless. He added that it "can be difficult for the FDA to tell these two things apart, as really, they differ [in] terms of intent. But in one sense, [the distinction] doesn't matter that much to the agency" because both types cause damage and are unacceptable practices.

Saying he wanted to "comment on the problem of data fraud," Sharpless recalled that when he was with the *Journal of Clinical Investigation*, "we decided we'd wanted to see more of the primary data from the authors when

they submitted their papers. And I thought this was sort of an unnecessary endeavor. I thought it was a nicety. And then we rapidly appreciated that many authors were submitting, frankly, fabricated [Western] blots to the journal, at a degree that really surprised me and that I had not expected."

After he joined NCI, "I similarly saw that people would mislead us in grant applications. So it's probably not surprising that if someone will use bad data or data manipulation to get their paper published or they will do that to get their grant funded, then they will also consider doing that to get their billion-dollar medical product approved," Sharpless said.

The FDA, Sharpless said, "cannot tolerate deception of any kind."