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◆ **The Food and Drug Administration (FDA) is seeking strategies from Jeffrey W. Taub, M.D., to prevent future violations of human subject regulations the agency said were documented during site visits in September and October 2022.** In a Dec. 19, 2023, warning letter posted online, FDA officials said that a six-year-old participant in a trial run by Taub, chair of pediatric cancer research at Wayne State University and a pediatric hematologist/oncologist at Children's Hospital of Michigan, received three additional dosages of an unidentified treatment, causing the child to be "exposed to an increased risk of these toxicities." Additionally, institutional review board (IRB) approval for a study lapsed for a 10-day period in January 2022, but one subject received the study drug, and bone marrow and blood samples were taken during this period, according to FDA.

Taub told the agency by letters in October 2022 and January 2023 "that these additional treatments occurred because a physician subinvestigator misinterpreted the drug administration plan" and that the IRB was notified, FDA said. Taub said the lapse in IRB approval was "attributable to a multitiered review of the continuing review, which delayed the continuing review from being addressed at a timely, regularly scheduled IRB meeting, as well as to staff turnover after submission of a continuing review." FDA was unsatisfied with corrective actions Taub told the agency were or would be, taken, saying the "response is inadequate because you did not include sufficient details about your corrective action plan. For example, you did not provide sufficient details about the policies and procedures that you would institute at your site to ensure compliance with study protocols and to ensure that ongoing and future clinical investigations will be conducted in compliance with applicable FDA regulations." FDA requested, "given the significance of the protocol violation involving a pediatric subject... follow-up documentation regarding the policies and procedures being implemented at your site to ensure compliance with study protocols, including randomization assignments." FDA asked Taub for a response within 15 days of receipt of its letter. He did not respond to a request for comment from *RRC.* (*1/18/24*)