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Lack of Security Leads to Theft of Investigational Drugs, Prompts FDA Warning Letter

More than 100 kits of Schedule III investigational drugs or placebos a South Florida cardiologist received in December 2021 were improperly stored and reported stolen three months later, according to a May 2 warning letter from the Food and Drug Administration (FDA) to Kevin R. Bender, M.D. The letter also indicates that FDA is not satisfied with Bender's new security measures and is seeking more information. According to FDA, 110 metered dose pumps containing either an investigational drug or a placebo were "stored outside the designated locked cabinet in a locked room following receipt; and the room was accessible to individuals other than staff designated to oversee investigational drug[s]."

Bender reported the theft to the study monitor in March 2022 and the Drug Enforcement Administration a month later. Although Bender conducted an investigation, no culprit was found; the items were deemed "missing because of customer/nonemployee theft." In December 2022, nearly a year later, an FDA official inspected Bender's clinical site and found that he violated requirements for secure storage and failed to ensure the study plan was followed. Bender responded in January 2023, outlining a series of security measures he had or planned to implement, including installing an electronic keypad and a video camera; conducting a weekly inventory; and constructing a larger room, with a closet, that is "secure and inaccessible to all non-study staff." In the May 2 letter, FDA called these actions "inadequate because you did not include sufficient details about your corrective action plan." Within 15 days of Bender's receipt of the letter, FDA requested "details concerning how you will ensure access is limited to the appropriate personnel," as well as regarding "planned or completed training on the responsible conduct of clinical trials or compliance with FDA regulations."

Link to warning letter