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FDA warns psychiatrist who treated dead foster child

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Seven-year-old Gabriel Myers hanged himself with a shower cord in a Margate foster home.

A South Florida psychiatrist who was treating a 7-year-old foster child before the boy committed suicide last year has received a warning from federal drug regulators who say he failed ``to protect the rights, safety and welfare'' of children enrolled in clinical drug trials.

In a strongly worded letter dated Feb. 4, regulators at the U.S. Food and Drug Administration said Dr. Sohail Punjwani over-medicated children who were enrolled in clinical trials for undisclosed drugs. One girl, the letter said, slashed her wrists while hallucinating.

Another, a 13-year-old, ``experienced sedation and dizziness during the study,'' the letter said.

The warning letter, a harsh and rare form of discipline by the agency, says Punjwani failed to ``adhere to the applicable statutory requirements and FDA regulations governing the conduct of clinical investigations.''

``Your failure to conduct the requisite safety measures contributed to the unnecessary exposure of pediatric subjects to significant overdoses, which jeopardized the subjects' rights, safety and welfare,'' the letter says.

Punjwani did not return calls from The Miami Herald seeking comment.

Punjwani, who practices in Tamarac and has offices elsewhere in South Florida, was treating 7-year-old Gabriel Myers when the boy hanged himself with a shower cord in a Margate foster home. The boy's death prompted a yearlong probe by a Department of Children & Families task force, as well as proposed legislation before the Florida Senate.

Before Gabriel's death, Punjwani had prescribed several powerful mental health drugs -- some of which had not been approved by the FDA for use on children and had been linked to dangerous side effects, including an increased risk of suicide among children.

Punjwani also was sued last summer by a Tamarac mother who claims her son, 16-year-old Emilio Villamar, died after being over-medicated with a group of mental health drugs at a Fort Lauderdale psychiatric hospital.

The letter mailed to Punjwani does not specify the names or types of drugs the doctor was testing, and a spokeswoman for the FDA, Sandy Walsh, said such details are kept confidential to protect drug companies.

Walsh said the FDA does not send out such warning letters often, and the agency considers breaches of its regulations to be ``very serious.'' The letter was signed by Leslie K. Ball, a doctor who heads the compliance office of the Division of Scientific Investigations, and Constance Cullity, a doctor who is also a compliance officer.

For years, drug makers did not study most medications on children, largely due to ethical concerns over using kids as test subjects. More recently, however, Congress passed laws to encourage pharmaceutical companies to test their drugs for safety and efficacy with children by extending patents on drugs approved for adults.

In a trial for one drug that was not identified, Punjwani gave one child dosages ``in excess of... specified limits,'' the letter says.

The child was discontinued from the trial before it was completed, the letter says, ``due to worsening auditory hallucinations that apparently caused the subject to lacerate her wrists.'' The girl was ``overdosed'' on the drug for more than two weeks.

The letter says Punjwani submitted a corrective action plan to the FDA and revised his procedures to better protect his research subjects from dosing missteps. ``However,'' the letter says, ``we are concerned that the response is not adequate to prevent future recurrence of the violation.''

The clinical trials for a different drug were to adhere to a series of protocols that specified what dosage of the drug was to be used, depending on the child's weight, the letter states. But for six of seven children -- chosen at random -- who received one of the tested drugs in Punjwani's study, the dosage exceeded what was spelled out in the protocol.

One child who weighed 103 pounds, for example, ``was overdosed on study medication for 20 consecutive days while participating in the study,'' the letter states. The child is identified only as ``Subject 1001.''

A child identified as ``Subject 1003,'' who was 15 at the time of the trials, ``was overdosed on study medication for 21 consecutive days while participating in the study,'' the letter says. ``Subject 1004,'' a 16-year-old, ``received doses in excess of the maximum target dose for 3 consecutive days while participating,'' the letter says.

A 10-year-old, identified as ``Subject 1007,'' was ``overdosed'' for nearly two weeks while on the study, the letter states.

Department of Children & Families Secretary George Sheldon, who appointed a task force last year to study Gabriel's death, said Monday he is asking the FDA to compare a list of Florida foster children with lists ofchildren enrolled in Punjwani's clinical trials. Sheldon

said he was acting on concerns that children in state care may have been involved in clinical trials, which is against state law.

The FDA letter, Sheldon said, ``raises clear ethical issues and judgment issues that we need to clearly understand.'' If foster kids were enrolled in clinical trials, he said, ``we will need to take it to another level.''
