FDA resumes trial using genetically engineered cancer-killing cells two days after patient deaths

The GLP aggregated and excerpted this blog/article to reflect the diversity of news, opinion and analysis.

Federal regulators on [July 12] gave Juno Therapeutics the all-clear to resume testing an experimental cancer treatment, just days after shutting down the trial because of three patient deaths.

The Food and Drug Administration put [Juno's oncology] study on hold…after three young leukemia patients who had received Juno's experimental therapy developed fatal brain swelling.

Juno blamed the deaths on an unforeseen interaction between those reengineered blood cells, called CAR-Ts, and a chemotherapy drug used to prepare patients for treatment. It proposed resuming the trial without using that chemotherapy drug.

The FDA completed the review with startling speed, apparently accepting Juno's explanation[.]

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The deaths spurred widespread questions about the future of CAR-T therapies, which have led to lasting remissions for some seriously ill patients but have been tested only in small trials.

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The FDA's speed in letting Juno restart its trial is notable for an agency that tends to be conservative when it comes to drug safety. Juno had said…it hoped to get an answer within 30 days. It took just two.

Read full, original post: FDA lets cancer trial resume after three patient deaths