FDA official: The risk of secondary cancer from CAR-T therapy is less than feared

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The risk of secondary cancer after CAR-T therapy, pioneered at Penn, is less than regulators feared last year, an FDA official said June 14 at cell and gene therapy conference in King of Prussia.

The FDA had announced in November that it was studying a handful of cases where patients developed lymphoma after being treated with chimeric antigen receptor T cell, CAR-T, therapies, hailed as a possible cure for some forms of blood cancer.

In January, the agency ordered the companies to put "black box" warnings on the six products that were part of the review.

"We were pretty concerned about this when we first saw it last year," Peter Marks, who heads the FDA's Center for Biologics Evaluation and Research, said at the conference sponsored by the Sino-American Pharmaceutical Professionals Association—Greater Philadelphia.

Most look to be secondary cancers affecting the T cells of patients who already have related cancers, he said.

"Luckily, the majority of these, it looks like are just secondary T cell malignancies that are occurring in people who have T cell malignancies. That's a known phenomenon," he said.

In a few cases, however, there are signs that patients developed secondary cancer in the type of white blood cells that were genetically modified as part of their treatment, Marks said. The risk is probably on the order of 1 in 10,000 people treated, he said.

That risk is "orders of magnitude" lower than the risk of malignancies from forms of chemotherapy that are given after cancer hasn't responded to standard treatments, Marks said during his opening keynote address at the conference, now in its third year.

About 500 people were registered for the 2024 @Philly Cell And Gene Therapy Annual Conference, a spokesperson for the conference organizers said.