

US agency suspends clinical trials after contamination risk discovered

Two NIH facilities that manufacture products for use in patients have been shut down because of safety violations.

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The US National Institutes of Health (NIH) has suspended two of its manufacturing facilities that were found to be at risk of contaminating materials intended for use in patients, the agency announced on 19 April. Several clinical trials that use products made by those facilities are also on hold and will not be recruiting new patients until the issues are resolved.

Oncologist Steven Rosenberg's lab at the National Cancer Institute (NCI) in Bethesda, Maryland, is one of the two facilities affected. Rosenberg is developing cancer therapies using [immune cells called T lymphocytes](#), which he engineers to attack a specific patient's cancer. After discovering problems with Rosenberg's cell-manufacturing lab, the NCI suspended 13 trials that used materials from the facility.

The second lab, at the National Institute of Mental Health (NIMH) in Bethesda, manufactures molecules used in brain imaging. The NIH has identified 15 studies with a total of 92 patients that have received injections of material from this lab.

The safety violations came to light during a sweeping NIH-wide review that began last year. It was prompted by the [discovery of widespread contamination](#) by the US Food and Drug Administration (FDA) in a facility at the NIH Clinical Center in Bethesda that manufactures customized drugs for use in clinical trials. A whistleblower's tips led FDA investigators to fungal contamination in materials intended for injection into patients, lab workers with uncovered hair, and insects in the light fixtures.

The NIH later formed a working group to develop remediation plans. The group will present these in a report to director Francis Collins on 21 April.

Clean sweep

To find out whether its other labs might have similar problems, the NIH hired two consultancy groups, Working Buildings in Atlanta, Georgia, and Clinical IQ in Madison, New Jersey, to perform independent evaluations. "It was to reassure ourselves that every other place that was manufacturing things to be infused into patients was up to snuff," says Kathy Hudson, NIH deputy director for science outreach and policy.

The latest violations do not appear to involve contamination, she says, but rather problems with the labs such as airflow and workers' clothing. "We are working very hard and very collaboratively with [Rosenberg] and NCI and others across NIH to identify a path forward so that we can have him continue his research," Hudson says.

The NIH says that it does not believe that any patients have been harmed by the safety lapses. The patients in the 13 cancer trials had already received their one-time injection of T cells and are being monitored. The NIMH says that it is following the people who received injections of a radioactive molecule that helps researchers to see the brain's structure under a scanner. About three-quarters of these people were healthy volunteers.

Rosenberg declined to comment on the matter. NCI spokesperson Cynthia Vitelli says that the institute suspended the cancer trials on 6 April after identifying problems.

Looking ahead

Kite Pharma in Santa Monica, California, which collaborates with Rosenberg and plans to commercialize some of the T-cell therapies, broke the news about the NCI findings on 16 April at the annual meeting of the American Association for Cancer Research in New Orleans, Louisiana. Kite's executive vice-president, David Chang, says that the company was unaffected by the suspended trials, and the company's future trials will use cells and materials manufactured at its facilities in Santa Monica.

Another Rosenberg collaborator, Lion Biotechnologies in New York City, said on 17 April that several trials it had been involved in were

also unaffected.

Contractors — who are still inspecting several NIH labs in Frederick, Maryland — discovered the contamination risk at the NIMH facility and alerted the NIH on 19 April. The agency announced that it had suspended operations at the NIMH and NCI facilities the same day. NIH spokesperson Renate Myles says that Working Buildings and Clinical IQ plan to file a systematic review of their findings by 29 April.

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