

# Botched French drug trial leaves 1 brain dead, 5 in hospital

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French Health Minister Marisol Touraine, left, and Professor Gilles Edan, the chief neuroscientist at Rennes Hospital, address the media during a press conference held in Rennes, western France, Friday, Jan. 15, 2016. Six previously healthy medical volunteers have been hospitalized—including one man who is now brain dead—after taking part in a botched drug test at the Biotrial lab in western France, the French Health Ministry said Friday. (AP Photo/David Vincent)

One man was brain dead and three others faced possible permanent

brain damage after volunteering to take part in a trial for a painkiller and anxiety medication based on a natural brain compound similar to the active ingredient in marijuana, French authorities said Friday.

The Paris prosecutor's office opened an investigation into what French Health Minister Marisol Touraine called "an accident of exceptional gravity" at a clinical trial lab in the western French city of Rennes.

The drug trial involved 90 healthy volunteers who were given the experimental drug in varying doses at different times, she told reporters at a news conference in Rennes.

Six male volunteers between 28 and 49 years old have since been hospitalized, including one man now classified as brain dead, Touraine said, adding that the other 83 volunteers were being contacted.

Calling the case "unprecedented," Touraine said she was "deeply moved" by the suffering of the victims, who she met with earlier Friday, along with their families. "We'll do everything to understand what happened," she said. "I don't know of any other event like this."

The drug trial for the six hospitalized men began on Jan. 7 and was halted Monday, a day after the first volunteer fell ill.

The chief neuroscientist at the hospital in Rennes, Dr. Gilles Edan, said in addition to the brain-dead man, three other men could have "irreversible" brain damage. A fifth man is suffering from neurological problems and a sixth man is being kept in the hospital but is in less critical condition, he said.



French Health Minister Marisol Touraine gestures as she arrives to address the media during a press conference held in Rennes, western France, Friday, Jan. 15, 2016. Six previously healthy medical volunteers have been hospitalized—including one man who is now brain dead—after taking part in a botched drug test at the Biotrial lab in western France, the French Health Ministry said Friday. (AP Photo/David Vincent)

Edan said there's no known way to reverse the effects of the experimental drug, which was given orally to health volunteers as part of a Phase 1 trial by Biotrial, a drug evaluation company based in Rennes, on behalf of the Portuguese pharmaceutical company Bial.

Touraine said that in addition to treating pain, the drug was intended to ease mood and anxiety troubles as well as motor problems linked to neurodegenerative illnesses by acting on the endocannabinoid system. In this system, natural brain compounds act on specific receptors to exert their effects. The experimental drug is based on a natural brain

compound similar to the active ingredient in marijuana.

Touraine said the drug was not based on marijuana itself, as some media reports had claimed.

"This drug is not cannabis. It is not derived from cannabis. It works on the natural system that helps fight pain, that's what is called the endocannabinoid system," she said, adding that no drug currently on the market was implicated in the failed trial.



French Health Minister Marisol Touraine, left, and Professor Gilles Edan, the chief neuroscientist at Rennes Hospital, address the media during a press conference held in Rennes, western France, Friday, Jan. 15, 2016. Six previously healthy medical volunteers have been hospitalized—including one man who is now brain dead—after taking part in a botched drug test at the Biotrial lab in western France, the French Health Ministry said Friday. (AP Photo/David Vincent)

Bial, the Portuguese drug producer, said Friday that 108 healthy people had already taken part in trials involving the drug and had no moderate or serious reactions. Bial added that initial testing for the drug started in June following toxicology tests.

For the French volunteers, it was meant to be a way to earn extra money and help develop a drug to treat people with pain and anxiety. Adults volunteering for Biotrial tests can earn between 100 euros and 4,500 euros (\$110 to \$4,920).

It's rare for volunteers to fall seriously ill during Phase 1 trials, which study safe usage, side effects and other measures on healthy volunteers, rather than drug effectiveness. Researchers generally start with the lowest possible dose after extensive tests in animals, and Touraine said the drug had previously been tested on chimpanzees and other animals.

Biotrial, which has headquarters in Rennes as well as offices in London and Newark, New Jersey, says it has over 25 years of experience in clinical trials and uses "state-of-the-art facilities."

In 2006, Britain saw a similar incident, when six previously healthy men were treated for organ failure only hours after being given an experimental drug targeting the immune system. That prompted a review of procedures and resulted in the U.K. regulatory agency imposing new testing standards, including recommendations to use the lowest possible dose and to test new drugs only on one person at a time.

The six men in Britain now apparently have a higher risk of cancer and autoimmune diseases tied to their exposure to the experimental drug.

Dr. Ben Whalley, a neuropharmacology professor at Britain's University of Reading, said standardized regulations for clinical trials are "largely the same" across Europe.

"However, like any safeguard, these minimize risk rather than abolish it," Whalley said in a statement. "There is an inherent risk in exposing people to any new compound."

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