

Scientists slam Italy's untested stem cell therapy (Update)

March 28 2013, by Nicole Winfield

European scientists are criticizing a decision by Italy's government to allow a handful of children to be treated in public hospitals with an experimental stem cell therapy.

The adult stem cell treatment was halted in May by the Italian Pharmacological Agency. But the government last week overruled the regulator after parents went to court to demand that the therapy be continued. The health ministry, citing ethical and compassionate concerns, said the therapy shouldn't be interrupted since it hadn't shown any "grave collateral effects" in the children, some of whom are terminally ill.

In a letter to Italy's health minister, Renato Balduzzi, more than a dozen scientists criticized the decision, saying it "seems to be dictated by emotions raised by public opinion rather than scientifically based reasons."

The decision to allow the unproven therapy by the Stamina Foundation, which is based in Italy, came despite findings from a police search, including inspectors from the Italian Pharmacological Agency, at the laboratory where the stem cell treatments were being prepared.

In May, the agency ordered all work at the Stamina Foundation laboratory to stop after finding that conditions were "absolutely inadequate." The inspectors said there were "terrible maintenance and cleanliness conditions" that couldn't guarantee the cells weren't

contaminated. The agency also said the doctors administering the adult stem cell treatment weren't aware of what they were injecting and the patients' medical records didn't detail the therapies.

Adult stem cells can maintain and repair tissues within a person, but there is no known benefit of removing such cells and using them to treat patients.

Most research into stem cells concerns embryonic stem cells, often considered controversial because they involve the destruction of embryos. Embryonic stem cells can produce a wide variety of specialized cells, and scientists are working to harness them as repair kits for diseases, including Parkinson's and diabetes.

By comparison, adult stem cells have a more limited ability to turn into other types of body tissue and are more likely to contain abnormalities than those derived from embryos.

Balduzzi defended the decision to allow the treatment and described it as a "compassionate" ruling. He said it would only continue in public hospitals or research clinics under strict monitoring with the consensus of an ethics committee.

The government ruling covers patients already receiving the Stamina Foundation treatment, those who had begun preparatory procedures such as the cultivation of cells, or those who by court order had been authorized to begin the treatment.

"The decision of the government to authorize the continuation of therapies ordered by judges was necessary to prevent discrimination, based on autonomous decisions by judges, between patients who had begun treatment with the Stamina Method," Balduzzi said.

Several British scientists said the Italian decision set a dangerous precedent and could even encourage desperate patients to seek treatment abroad.

"If politicians, doctors or patient organizations ignore the facts, they may unwittingly become party to exploitation of the most vulnerable members of society by approving meaningless 'treatments,'" Austin Smith, director of the Cambridge Stem Cell Institute, said in a statement.

Steve Dunnett, a stem cell expert at the University of Cardiff, said it was worrying that no details on the experimental procedure or its results in patients had been published.

"Our starting position has to be that the marketing is a scam to which the correct response should indeed be to refuse a license and certainly not pay for a spurious treatment out of the public purse," Dunnett said in a separate statement.

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