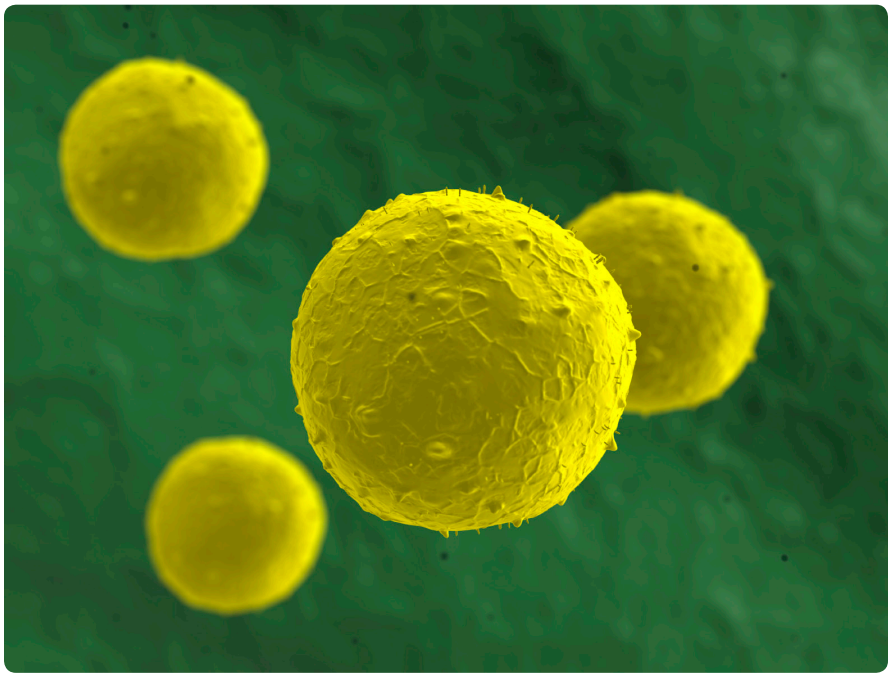
FDA Warns About Stem Cell Claims

Stem cell therapies offer the potential to treat diseases or conditions for which few treatments exist.



Researchers hope that stem cells will one day be effective in the treatment of many medical conditions and diseases.

Stem cells, sometimes called the body's "master cells," are the precursor cells that develop into blood, brain, bones and all of your organs. Their promise in medical treatments is that they have the potential to repair, restore, replace and regenerate cells that could then be used to treat many medical conditions and diseases.

But the Food and Drug Administration (FDA) is concerned that the hope that patients have for cures not yet available may leave them vulnerable to unscrupulous providers of stem cell treatments that are illegal and potentially harmful.

FDA cautions consumers to make sure that any stem cell treatment they are considering has been approved by FDA or is being studied under a clinical investigation that has been submitted to and allowed to proceed by FDA.

FDA has approved only one stem cell product, Hemacord, a cord blood-derived product manufactured by the New York Blood Center and used for specified indications in patients with disorders affecting the body's blood-forming system.

Regulation of Stem Cells

FDA regulates stem cells in the U.S. to ensure that they are safe and effective for their intended use.

"Stem cells can come from many different sources and under the right conditions can give rise to many different cell types," says Stephanie Simek, Ph.D., deputy director of FDA's Office of Cellular, Tissue and Gene Therapies.

Stem cells that come from bone marrow or blood are routinely used in transplant procedures to treat patients with cancer and other disorders of the blood and immune system.

Umbilical cord blood is collected from a placenta with the birth mother's consent. Cord blood cells are then isolated, processed, and frozen and stored in a cord blood bank for future use. Cord blood is regulated by FDA and cord blood banks must follow regulatory requirements.

But there are many other stem cell products, including other cord blood-derived products, that have been reviewed by FDA for use in investigational studies, says Simek. Investigational products undergo a thorough review process as the sponsor prepares to study the safety and effectiveness of the product in adequate and well-controlled human studies (clinical trials).

As part of this review, the sponsor must show how the product will be manufactured so that FDA can make certain that appropriate steps are being taken to help assure the product's safety, purity and potency. FDA also requires that there be sufficient data generated from animal studies to aid in evaluating any potential risks associated with the use of these products.

Consumers need to be aware that at present—other than cord blood for certain specified indications—there are no approved stem cell products.

"FDA will pursue perpetrators who expose the American public to the dangers of unapproved stem cells."

Advice for Consumers

- If you are considering stem cell treatment in the U.S., ask your physician if the necessary FDA approval has been obtained or if you will be part of an FDA-regulated clinical study. This also applies if the stem cells are your own. Even if the cells are yours, there are safety risks, including risks introduced when the cells are manipulated after removal.

  "There is a potential safety risk when you put cells in an area where they are not performing the same biological function as they were when in their original location in the body," says Simek. Cells in a different environment may multiply, form tumors, or may leave the site you put them in and migrate somewhere else.

- If you are considering having stem cell treatment in another country, learn all you can about regulations covering the products in that country. Exercise caution before undergoing treatment with a stem cell-based product in a country that—unlike the U.S.—may not require clinical studies designed to demonstrate that the product is safe and effective. FDA does not regulate stem cell treatments used solely in countries other than the United States and typically has little information about foreign establishments or their stem cell products.

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Thwarting a Stem Cell Scheme

In December 2011, three men were arrested in the United States and charged with 15 counts of criminal activity related to manufacturing, selling and using stem cells without FDA sanction or approval.

According to the criminal indictment, one of the accused, a licensed midwife who operated a maternity care clinic in Texas, obtained umbilical cord blood from birth mothers, telling them it was for "research" purposes. Instead, the midwife sold the cord blood to a laboratory in Arizona which, in turn, sent the blood to a paid consultant at a university in South Carolina. The owner of the laboratory in Arizona was convicted in August 2011 of unlawfully introducing stem cells into interstate commerce. She faces up to 3 years in prison and a fine of up to $10,000.

The consultant, an assistant professor, used university facilities to manufacture stem cell products. He then sent the products back to the lab, which sold them to a man representing himself as a physician licensed in the U.S. The man then traveled to Mexico to perform unapproved stem cell procedures on people suffering from cancer, multiple sclerosis and other autoimmune diseases.

The three defendants allegedly received more than $1.5 million from patients seeking treatment for incurable diseases.

"Scammers like these offer false hope to people with incurable diseases in order to line their own pockets with money," says Special Agent in Charge Patrick J. Holland of FDA's Office of Criminal Investigations (OCI), Kansas City Field Office. "FDA will continue to aggressively pursue perpetrators who expose the American public to the dangers of unapproved stem cells and ensure that they are punished to the full extent of the law."

FDA's OCI worked the case with the Federal Bureau of Investigations and the Internal Revenue Service's Criminal Investigations Division.