FDA Warns About Stem Cell Claims 111

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

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.

"Scammers ... 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."

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