

15 May 2013

**FDA ADVISORY**  
No.: ~~2013-012~~ **2013-012**

**SUBJECT: PUBLIC HEALTH WARNING AGAINST RECEIVING  
UNAPPROVED STEM CELL PREPARATIONS IN NON-  
HEALTH FACILITIES**

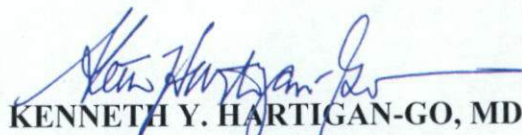
The FDA has been receiving complaints from the public and health professionals that stem cell therapies are conducted in non-health facilities, such as hotel rooms.

The public is warned against receiving stem cell preparations and therapies without prior regulatory application and approval from the Food and Drug Administration, Department of Health. The following stem cell preparations require FDA approval: a) genetically altered human adult and umbilical cord stem cells, b) adipose or fat cells derived human stem cell, c) human cells, tissues, and cellular and tissue-based products that are subjected to genetic manipulation, and d) live animal embryonic, fetal, or adult stem cells in parenteral form for human administration. The public is further warned that FDA-DOH does not allow the creation, importation, promotion, marketing and use of human embryos, human embryonic stem cells and their derivatives, aborted human fetal stem cells and their derivatives for human treatment and research, as well as plant parts labeled as stem cells.

Patients who might receive stem cell preparations and therapy without prior FDA-DOH approval run the risks of contracting infectious diseases and severe complications which may lead to permanent disabilities, physical deformities, serious iatrogenic harm, autoimmune diseases and worst death, and without the benefit of health insurance coverage.

All patients are advised to consult only with duly-licensed medical practitioners who practice stem cell therapy in health facilities that are approved by the DOH. Moreover, patients are highly encouraged to verify with the FDA, Philippines, before undergoing the procedures using our [info@fda.gov.ph](mailto:info@fda.gov.ph). This health warning and advice extend to all tourists who visit the Philippines for their leisure needs as well as medical needs.

In case of adverse event or complaints use our eReport facility at [www.fda.gov.ph](http://www.fda.gov.ph).

  
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