

Position Statement on Stem Cell Therapy

Stem cell therapy for unproven indications is proliferating in the Philippines and posing serious safety issues to unknowing clients. Alarmed by these uncontrolled practices which may include false claims, misinformation and exorbitant fees,

We, the undersigned presidents of medical professional organizations, push the Food and Drug Administration (FDA) to issue stricter regulations on stem cell therapy and declare the following to serve as guidelines for the general public:

1. Presently, stem cell therapy has been proven beneficial in very few medical conditions:
 - cancers of the blood and bone marrow, and
 - some primary immune-deficiencies treated by autologous or allogenic stem cell transplants.

Stem cell therapy, as treatment for these conditions, should only be administered by trained professionals working in FDA accredited facilities.

2. The effectiveness and safety of stem cell therapy have yet to be proven in the following conditions ("unproven indications"): heart, lung, neurologic, skin, rheumatologic, kidney and gastrointestinal diseases, diabetes mellitus, hypertension, autism, cancer, aging and aesthetics, HIV AIDS and other conditions.
3. *The use of stem cell therapy for these conditions should be confined to clinical studies, that is, properly designed studies that have been screened and approved by a duly constituted technical review board and ethics committee. Such studies should in fact be encouraged so that the potential benefits of stem cell therapy in these conditions can be documented.*

When stem cell therapy is given under a clinical study, it is unethical to make patients pay for the treatment. The cost of treatment should be shouldered by the sponsor of the study.

4. Finally, we recognize and support Republic Act (RA) No. 3720, as amended by RA No. 9711, which mandates the FDA: "to conduct appropriate tests on all applicable health products prior to the issuance of appropriate authorizations to ensure safety, efficacy, purity, and quality" (Section 4h); and "to develop and issue standards and appropriate authorizations that would cover establishments, facilities and health products" (Section 4m).

We urge the Department of Health through the Philippine FDA to strictly enforce its legal mandates and issue clearer regulations for stem cell therapy for practicing clinicians to safeguard the health of Filipinos. We urge the public to help stop those who seek to profit from the desperation and ignorance of others.

Please report immediately to the FDA any of the following:

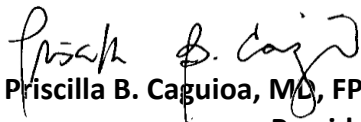
- 1) practice of stem cell therapy by persons or institutions not accredited by the FDA,
- 2) promotion and use of stem cell therapy for unproven indications (as listed above), and
- 3) acceptance of payments for stem cell therapy when used for these unproven indications.

Please report the above to (02) 910-2253 or on the website: report@fda.gov.ph

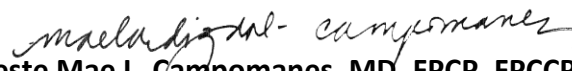
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Signed by:





Priscilla B. Caguioa, MD, FPCP
President
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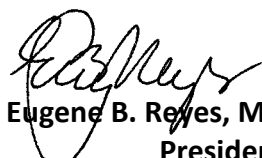



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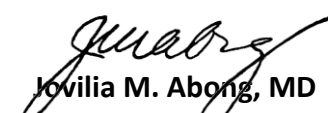



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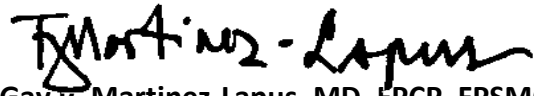


Philippine Society of Hematology & Blood Transfusion


Ma. Angelina L. Mirasol, MD, FPCP
President



Philippine Society of Medical Oncology



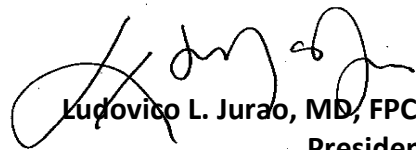
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