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Scott Gottlieb, MD
Commissioner of Food and Drugs
U.S. Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993

Dear Dr. Gottlieb:

On behalf of the American Thoracic Society (ATS), I would like to thank you for the release of the new FDA Regenerative Medicine Policy framework in the form of draft guidelines. We believe that the regulatory changes introduced by this framework will resonate with regulatory agencies worldwide and in the long run will rein in the proliferation of direct-to-consumer, unproven stem cell-based interventions.

We are particularly pleased to see in the finalized guidelines that the "minimal manipulation" and "surgical exception" criteria do not apply to processed adipose tissue, according to the FDA's updated interpretation of existing regulations. In previous publications, we have extensively argued against the problematic, unregulated use of adipose tissue fractions in clinical interventions aiming patients with respiratory diseases (The Global Emergence of Unregulated Stem Cell Treatments for Respiratory Diseases, Ann Am Thorac Soc. 2016 Aug; 13 (8) and Unproven Stem Cell Treatments for Lung Disease- An Emerging Public Health Problem (http://www.thoracic.org/patients/patient-resources/resources/stem-cell-therapy.pdf)). We hope that the new framework will be accompanied in the near future by enforcement action against organizations that continue to place themselves outside the FDA's purview.

We look forward to working with the FDA as the new Regenerative Medicine framework is implemented.

Sincerely,

Marc Moss, M.D.
President
American Thoracic Society