

August 29, 2017

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

Delivered by email to: CommissionerFDA@fda.hhs.gov

Dear Dr. Gottlieb,

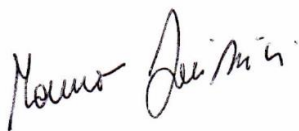
This letter is a message of appreciation for your public statement on August 28, 2017 describing the FDA's current stance regarding Stem Cell and Regenerative Medicine regulatory enforcement. The International Society for Cellular Therapy (ISCT) is a leader in educating the range of stakeholders affected by this issue. We strongly applaud these media announcements.

In 2016, the ISCT Presidential Task Force (PTF) on the Use of Unproven Cellular Therapies published a comprehensive [Reference Guide](#), authored by 23 leading experts in the cellular therapy field. The document details ISCT's stance and provides concrete guidelines on the characteristics of proven versus unproven cellular therapies.

The Task Force continues to be a prominent and leading voice in the industry. ISCT PTF landmark [publications](#) and [initiatives](#) are driven by our international [experts](#). Several PTF members are highly involved with regulatory aspects of cellular therapy. ISCT has a long-standing collaboration with the FDA, leading the [Cellular Therapy Liaison Meeting](#), which represents the interests of over 20 stakeholder groups.

We would be delighted to work with the FDA in its continuing efforts to ensure safe and effective treatment for cellular therapy patients. Please contact us if there is an opportunity for ISCT's involvement.

Best Regards,



Massimo Dominici, MD
Chair, ISCT PTF on the Use of Unproven Cellular Therapies (2016-2018)
University Hospital of Modena & Reggio Emilia -
Modena Policlinic
Modena, Italy



Catherine Bollard, MBChB, MD
ISCT President (2016-2018)
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About the International Society for Cellular Therapy

Established in 1992, the International Society for Cellular Therapy (ISCT) is a global society of clinicians, regulators, researchers, technologists and industry partners with a shared vision to translate cellular therapy into safe and effective therapies to improve patients' lives worldwide.

ISCT is the global leader focused on pre-clinical and translational aspects of developing cell-based therapeutics, thereby advancing scientific research into innovative treatments for patients. ISCT offers a unique collaborative environment that addresses three key areas of translation: Academia, Regulatory and Commercialization. Through strong relationships with global regulatory agencies, academic institutions and industry partners, ISCT drives the advancement of research into standard of care.

Comprised of over 1,300 cell therapy experts across five geographic regions and representation from over 50 countries, ISCT members are part of a global community of peers, thought leaders and organizations invested in cell therapy translation. For more information about the society, key initiatives and upcoming meetings, please visit:

www.celltherapysociety.org