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STEM CELL  
RESEARCH**

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24 June 2020

Professor Guido Rasi  
Executive Director  
European Medicines Agency  
Domenico Scarlattiiaan 6  
1083 HS Amsterdam  
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Dr. Martina Schussler-Lenz  
Chair, Committee for  
Advanced Therapies  
European Medicines Agency  
Domenico Scarlattiiaan 6  
1083 HS Amsterdam  
The Netherlands

Dear Professor Rasi and Dr. Schussler-Lenz,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to thank you for the EMA's recent [warning against the use of unproven cell-based therapies](#). The ISSCR is the leading professional organization of stem cell researchers and represents more than 4,000 members in Europe and around the world. Our members are scientists, clinicians, ethicists, and educators dedicated to the responsible advancement of stem cell research and its translation to the clinic. We support the crucial role for EMA and national regulators in protecting the public health by ensuring that new therapies are proven safe and effective before being sold to patients.

Businesses prematurely marketing unproven stem cell-based interventions are exploiting the COVID-19 pandemic and the absence of proven treatments to market unproven "regenerative therapies" and other stem cell-based interventions claiming to boost immune system function, prevent SARS-CoV-2 infection, or mitigate the effects of infection on tissue function. These businesses often cite unconnected and anecdotal findings as evidence that their products are safe and effective. They sell scientifically implausible products that are unlikely to provide any benefit and may pose serious risks to patients. Many of the cell-based interventions provided by unscrupulous business are non-homologous uses of the cells and require authorization from EMA or national regulators. Furthermore, all cell therapy products come with processing and contamination risks that should be assessed by regulators. We urge the EMA to coordinate enforcement activities with European regulators to prevent the premature commercialization of stem cell-based products.

Promoting excellence in stem cell science and applications to human health.

The role of regulators is also critical to protecting patients as experimental new therapies are evaluated in clinical trials. The pandemic has made that mission more challenging; however, regulators must continue to insist on robust and sound pre-clinical safety and efficacy data before allowing first-in-human clinical trials for experimental stem cell-based therapies. There have been many public claims from companies related to proposed cell therapies for COVID-19 that lack any credible basis in science. We know from experience with other products in this area that companies who are willing to sell therapies without regard to whether they are scientifically plausible are also often willing to ignore good manufacturing practices: there have now been many cases in which these products have been found to be contaminated by pathogens. Consequently, these products should only proceed to first-in-human clinical trials after developers have minimized safety risks by rigorously characterizing and assaying the toxicity and tumorigenicity of each product and showing they follow good manufacturing practices. These products should be required to have a plausible mechanism of action and plausible patient benefit before being tested in clinical trials.

The premature development of products that lack a plausible scientific basis puts patients at risk and wastes resources that could be used to develop more rational therapies. We urge you to work with regulators across the European Union to ensure that stem cell-based therapies are adequately tested in pre-clinical studies before allowing human trials.

Thank you for considering our concerns regarding unproven stem cell-based products and our recommendations regarding the development of new therapies. If the ISSCR can clarify any of these views or be of assistance, please contact Eric Anthony, ISSCR's Director of Policy at [eanthony@isscr.org](mailto:eanthony@isscr.org).

Sincerely,

A handwritten signature in black ink, appearing to read 'D. Srivastava', with a long horizontal flourish extending to the right.

Deepak Srivastava, MD  
President, ISSCR  
President, Gladstone Institutes