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November 20, 2018

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

Re: Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank; Docket Number: FDA-2018-D-0787-0001

Dear Commissioner Gottlieb,

On behalf of the International Society for Stem Cell Research (ISSCR), I write to share our comments regarding the FDA's proposed industry guidance for "Civil Money Penalties Relating to the ClinicalTrials.gov Data Bank." The ISSCR is the leading professional organization of stem cell scientists and represents more than 4,000 members in the United States 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 are concerned that unscrupulous clinics marketing unproven stem cell-based interventions abuse the ClinicalTrials.gov database to appear legitimate and to promote their treatments to patients. Advertising from these companies often seeks to create the impression of FDA approval, even though they have not been tested for safety or efficacy, and we believe that registering unproven therapies on ClinicalTrials.gov is one step that helps these companies blur the distinction between FDA approved and non-FDA-approved products. We believe this poses a threat to the public's health; therefore, we encourage the FDA to use the new guidance for ClinicalTrials.gov to prioritize enforcement against unproven stem cell clinics that submit false and misleading promotional information to the database.

For many years, the ISSCR has expressed concern with the commercialization of unproven stem cell-based interventions outside the context of regulated clinical trials. Last year, we applauded the FDA's new regenerative medicine guidance that clarified the FDA's role in regulating stem cell-based interventions as biologics under Section 351 of the Public Health Service Act. In May, we were delighted to see the FDA seek permanent injunctions against stem cell clinics for marketing unapproved stem cell treatments whose safety and efficacy had not been verified

through peer-reviewed clinical trials. While we are grateful for the FDA's recent attention to this challenge, we believe the agency can further protect the public's health by strengthening the ClinicalTrials.gov database.

Unscrupulous clinics marketing unproven therapies as legitimate stem cell treatments have a history of abusing the ClinicalTrials.gov database by submitting promotional or false and misleading information. Last year, it was reported in the New England Journal of Medicine that one of the patients blinded by an unproven and scientifically implausible stem cell treatment found the clinic providing the treatment through the ClinicalTrials.gov database. It is common for these clinics to use the database to refer patients to sensational news stories that suggest their treatments can cure serious health conditions. It is also common for these clinics to make spurious claims that their interventions provide a therapeutic benefit for a wide range of serious and incurable conditions. While we understand the challenge of scrubbing the internet of these dubious health claims, we believe that the ClinicalTrials.gov database should be a safe place for patients and physicians searching for accurate information regarding clinical trials.

We encourage the FDA to revise Section III C of the draft ClinicalTrials.gov guidance to prioritize enforcement under Section 402(j)(5)(D) and Section 402(j)(3)(D) of the Public Health Service Act, which prohibits the submission of promotional or false and mislead information to the ClinicalTrials.gov database. Furthermore, we believe the guidance could be improved by providing examples of the types of promotional information that will be a priority for enforcement, including links to sensational news stores or patient testimonials. Finally, we encourage the FDA to provide examples of the types of information that would be considered false and misleading, including claims that are scientifically implausible or claims that a single intervention can treat multiple unrelated health conditions.

Thank you for considering these recommendations regarding the draft guidelines for the ClinicalTrials.gov database. 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.

Sincerely,

Doug Melton

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Xander University Professor, Harvard University
Co-Director, Harvard Stem Cell Institute