United States Senate
COMMITTEE ON THE JUDICIARY
WASHINGTON, DC 20510–6275

April 13, 2018

VIA ELECTRONIC TRANSMISSION

The Honorable Alex Azar
Secretary
Department of Health and Human Services
200 Independence Avenue SW
Washington, D.C. 20201

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

Dear Secretary Azar and Dr. Gottlieb:

According to a Washington Post article published in March of 2017, three women became permanently blind after undergoing unproven stem cell treatment that was touted as a clinical trial at a South Florida clinic, which was later revealed to be U.S. Stem Cell Clinic.[1] The article raises serious concern that this clinic was able to list its study on ClinicalTrials.gov, and that at least one of the patients believed she was taking part in a government-sanctioned study. At a public workshop held by the FDA on September 8, 2016, Dr. Thomas Albini, who treated two of the patients, detailed several egregious missteps taken by U.S. Stem Cell Clinic, from injecting into both of each patient's eyes simultaneously to conducting the entire procedure without proper oversight. Dr. Albini stated that the patients were under the impression that the study being posted on clinicaltrials.gov lent some credibility to it.[2]

On August 28, 2017, the U.S. FDA issued a press release, detailing a warning letter issued to U.S. Stem Cell Clinic. The letter cites numerous issues, ranging from "evidence of significant deviations from current good manufacturing practices in the manufacture of at least 256 lots of stem cell products by the clinic," to U.S. Stem Cell Clinic's efforts to impede the

[1] Laurie McGinley, Three Women Blinded By Unapproved Stem-cell 'Treatment' at South Florida Clinic (2017), https://www.washingtonpost.com/news/to-your-health/wp/2017/03/15/three-women-blinded-by-unapproved-stem-cell-treatment-at-south-florida-clinic/?utm_term=.9bc3e3eb3846

[2] Transcript from United States Food and Drug Administration Public Workshop on Scientific Evidence in Development of HCT/Ps Subject to Premarket Approval, p. 306 (September 8, 2016) https://www.fda.gov/downloads/BiologicsBloodVaccines/NewsEvents/WorkshopsMeetingsConferences/UCM530238.pdf

FDA's investigation – which the press release itself notes is a violation of federal law.[3] Despite the harm this clinic has already caused, this clinic is apparently only at risk of "additional enforcement action" if it does not correct itself.[4] I am writing to follow up on these issues and to request an update on the FDA's investigation. Accordingly, please answer the following:

1. Has the FDA completed its investigation into U.S. Stem Cell and any related entities? If so, please provide a copy of the final report.
2. What was the FDA's response to U.S. Stem Cell when it tried to impede the investigation?
3. Has the FDA referred U.S. Stem Cell and any of its employees to the Justice Department for potential prosecution? If so, when did that referral take place?
4. It appears that the listing of a trial on ClinicalTrials.gov has created for some the impression that a trial is government-approved. The website has since posted disclaimers to stress that "[l]isting a study does not mean it has been evaluated by the U.S. Federal Government." Please explain what benefits are presented by the website that outweigh the risk that patients will still incorrectly assume the trials are more credible because they are listed on a government website.
5. Please explain the process by which a clinical trial goes through before placement on the ClinicalTrials.gov website.
6. What steps have been taken to ensure that the trials listed on ClinicalTrials.gov are actually trials and not fee-for-service treatments or mere advertisements? What precautions are taken to educate potential research participants that the listed "trials" may not be an approved clinical trial?
7. In what specific ways did U.S. Stem Cell Clinic fail to meet federal regulations? What plan did they implement to correct these deviations? Were they permitted to continue conducting treatments in the interim, and are they permitted to conduct treatments still?

Thank you in advance for your prompt attention to these matters. Please respond in writing to the list of questions no later than April 27, 2018. Should you have any questions, please contact Josh Flynn-Brown of my staff at (202) 224-5225.

Sincerely,

Charles E. Grassley
Chairman
Committee on the Judiciary

[3] United States Food and Drug Administration. *FDA warns US Stem Cell Clinic of significant deviations* [Press Release] (August 28, 2017). Retrieved from https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm573431.htm
[4] *Id.*