SAMPLE SURVIVOR LETTER

Peter Marks, M.D., Ph.D.
Director of the Center for Biologics Evaluation and Research
Food and Drug Administration
10903 New Hampshire Avenue
Silver Spring, MD 20993-0002

RE: Official Comment to FDA-2020-P-1633

Dear Dr. Peter Marks,

As a survivor of a *Clostridioides difficile* infection *(C. diff),* I am writing to advocate for increased research and development activities to identify safe treatments for this life-threatening disease.

C. diff is estimated to kill 15,000 people in the United States every year. I can personally attest to the deadly power of this disease, but additionally, I want to emphasize the story behind the numbers. *C. diff* uprooted and nearly destroyed every facet of my life, and if it were not for clinical trials, I fear I would not be alive today.

While suffering from *C. diff*, I was unable to leave my house since I was plagued with painful diarrhea. I needed to use the restroom 10-15 times a day, and I was rapidly losing weight. My social life and economic health suffered, and this greatly impacted my family's well-being. I was nauseated, dehydrated, fatigued, and without answers. As I continued to suffer, my family prepared for the worst possible outcome.

As we endure the COVID-19 epidemic, I am greatly concerned about the additional stressors on those suffering from recurrent *C. diff*. These stressors can include financial restraints, cancelled physician visits, and an inability to purchase hygiene products such as toilet paper. It is reasonable to think the increase in COVID-19 hospitalizations may result in more patients suffering from hospital-acquired *C. diff*, already considered a public health threat due to antibiotic resistance.

Therefore, I encourage the U.S. Food & Drug Administration to clarify the available treatment options for *C. diff*. This disease is largely unknown to the public, and it's easily misdiagnosed by providers. Unregulated FMT adds to this confusion since it's not an approved treatment, and the long-term effects of FMT are unknown.

As a *C. diff* survivor, I am hopeful future patients will have a safe and effective *C. diff* treatment, but this can only take place if research and development flourish. I don't want anyone else to experience the nightmare that befell my family.

Please keep the whole patient experience in mind as you decide how to regulate FMT. I am grateful for the opportunity to share my story.

Sincerely,