October 28, 2014

The Honorable Gene Green
2470 Rayburn House Office Building
Washington, DC 20515

Re: Support for H.R. 3742, the Antibiotic Development to Advance Patient Treatment (ADAPT) Act of 2013

Dear Representative Green:

The American Gastroenterological Association (AGA) is the trusted voice of the GI community. Founded in 1897, the AGA has grown to include 17,000 members from around the globe who are involved in all aspects of the science, practice and advancement of gastroenterology.

We are writing in support of H.R. 3742, the "Antibiotic Development to Advance Patient Treatment Act of 2013," and to encourage you to ensure that the legislation continues to address fecal microbiota transplantation (FMT). H.R. 3742 would address the use of antibiotics to treat unmet medical need by providing the Food and Drug Administration (FDA) with the authority to provide a separate approval pathway for certain antibiotics for a limited population.

As you are likely aware, in September 2014, the President released *A National Strategy for Combatting Antibiotic Resistant Bacteria.*[1] That report identified key priorities related to antibiotic resistance, including noting that *Clostridium difficile* (*C. difficile*) was a resistant pathogen which the Centers for Disease Control and Prevention (CDC) had recognized as an urgent or serious threat. The President's report built upon a CDC report released last fall, *Antibiotic Resistance Threats in the United States, 2013*, in which CDC for the first time ranked antibiotic-resistant bacterial disease agents according to threat level and outlined policy recommendations.

More than 90% of *C. difficile* infections, a bacterium that is listed in the highest threat category of the CDC report, occur in individuals over 65 years old. *C. difficile* is a serious infection that causes diarrhea.

[1] http://www.whitehouse.gov/sites/default/files/docs/carb_national_strategy.pdf

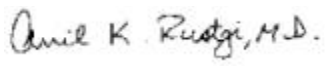
Approximately 75% of *C. difficile* infections begin in health care facilities. According to the CDC, the incidence of *C. difficile* infections rose by 400% from 2000-2007 and these infections now result in 14,000 deaths in the USA each year and $1 billion in excess medical costs.

C. difficile infections can be hard to eliminate, and recurrent *C. difficile* has high rates of mortality. Physicians have discovered that giving *C. difficile* patients microbes from the human gut can cure the infection. The key is transplant of fecal material, which contains a highly complex and dense community of microbes that include bacteria, fungi and viruses.

FMT is currently viewed by the FDA to be a drug or biologic,[2] and the agency has recognized FMT to treat an unmet medical need.[3] Therefore, it would appear that FMT is covered under the ADAPT Act's definition of an antibacterial or antifungal drug that is intended to treat a serious or life-threatening disease or condition in a limited population of patients for which there is an unmet medical need. **However, given the valuable potential to enhance the availability of FMT for patients in need, the AGA urges you to adopt report language to ensure the coverage of FMT by the ADAPT Act.**

AGA is committed to addressing the threat of antibiotic resistance and ensuring that patients receive effective treatment of their infection. We would be happy to discuss ways in which AGA may be of assistance in this endeavor, and would encourage you to contact Kathleen Teixeira at (240) 482-3222 or kteixeira@gastro.org if you have any questions.

Sincerely,



Anil K. Rustgi, MD, AGAF
Chair, AGA

[2] http://www.fda.gov/downloads/BiologicsBloodVaccines/GuidanceComplianceRegulatoryInformation/Guidances/Vaccines/UCM361393.pdf
[3] http://www.gpo.gov/fdsys/pkg/FR-2014-06-05/html/2014-13023.htm