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June 18, 2013

“The view of the American College of Gastroenterology is that this decision by FDA to clarify IND requirements and enforcement in relation to fecal microbiota transplantation to treat refractory *C. difficile*-associated diarrhea is an important step in right direction. ACG sees the move toward an informed consent model for use of this therapy as essential to assure that patients in need of this extremely promising therapy for an intractable public health problem have unimpeded access to treatment as recommended by their physicians.

We will continue to work with the FDA to ensure that the implementation of this agency recommendation is the least burdensome to clinicians who aim first to do no harm while at the same time responding in timely and appropriate way to the needs of their patients.

The College has been working with the FDA and has convened a task force of experts to sort through the challenges related to this paradigm-shifting treatment which transplants beneficial microbes to re-establish the gut microbiome and reverse a potentially life-threatening gastrointestinal disorder.”

Ronald J. Vender, MD, FAGG
ACG President 2012-2013
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Annual Scientific Meeting and Postgraduate Course
October 11 – 16, 2013, San Diego Convention Center, San Diego, California
acgmeetings.gi.org