# OpenBiome remains open to serve the medical community

**To the Editor:**

As the leadership team behind OpenBiome, a nonprofit stool bank dedicated to expanding safe access to fecal microbiota transplantation (FMT), we were pleased to see the discussion in your April issue of the complex and evolving regulatory environment surrounding this promising treatment[1]. However, we feel the article (entitled "Fecal transplantation poses dilemma for FDA") mischaracterized the impact of proposed guidance currently under consideration at the US Food and Drug Administration (FDA).


The article contained a box titled "Stool bank shut down," indicating that OpenBiome would no longer be able to supply processed stool from rigorously screened anonymous donors for FMT. We would like to clarify that this is not the case. Current FDA guidance allows clinicians to provide FMT for patients with recurrent *Clostridium difficile* infection (CDI) using material either from patient-identified donors or from stool banks, such as OpenBiome. Indeed, as of July 10, OpenBiome has provided material for >600 treatments to 65 hospitals and clinics in 27 states.

We believe the confusion arises from recent draft guidance released by the FDA for public comment. This draft guidance proposed that time-consuming Investigational New Drug (IND) applications become mandatory for the use of anonymous donors but not for the use of directed donors. As public comments on the proposed guidance illustrate, many physicians, patients and medical societies have noted that this approach would jeopardize public health because many patients are unable to identify a suitable directed donor. Moreover, even when donors are available, evidence from blood products suggests that anonymous, universal donors are safer than patient-identified donors[2,3]. Importantly, this controversial proposal was released for public comment only, and does not affect the existing FDA guidance that enables clinicians to proceed with FMT for patients with recurrent CDI.

The confusion associated with this proposal highlights a pervasive uncertainty about how best to regulate this unconventional, but lifesaving treatment. We have previously expressed our view that stool should be regulated like a tissue product, not a drug[4]. An especially worrisome consequence of regulating stool as a drug relates to how it interfaces with legislation that provides market exclusivity as an incentive for drug development. Rather than supporting the development of new medical therapies to combat the threat posed by antibiotic resistance, market exclusivity for ubiquitous human stool would allow a single provider to capture value from knowledge that already exists in the public domain. This would work against the public interest by inhibiting treatment choices for patients and raising prices across the healthcare system.

Nonetheless, we do appreciate the need to collect additional data on the safety profile of this emerging treatment. Toward this end, we are working with the FDA to initiate a long-term safety study under an IND that we hope will inform both policy discussions and clinical research.

Until further data are available, we believe that the standing policy does an enormous service to public health by enabling access to lifesaving care for patients with CDI who have few other treatment options. We have been deeply impressed by the sensitivity, responsiveness and care taken by the FDA to balance the needs for appropriate oversight and immediate care.

We feel that existing policy could be improved by instituting mandatory minimum screening requirements for all FMT donors to mitigate the risk of disease transmission. These screening guidelines could create a foundation around which to build rigorous, permanent standards for screening and processing human stool as a tissue product. We look forward to continued collaborative engagement with our partners at the FDA, the relevant medical societies and patient advocacy groups to ensure continued safe access to FMT.

COMPETING FINANCIAL INTERESTS
The authors declare no competing financial interests.

***Mark Smith[1,2], Zain Kassam[1,2], Carolyn Edelstein[1], James Burgess[1] & Eric Alm[1,2]***

*[1]OpenBiome, Medford, Massachusetts, USA.*
*[2]Department of Biological Engineering, Massachusetts Institute of Technology, Cambridge, Massachusetts, USA.*
*e-mail: mark@openbiome.org*

1. Ratner, M. *Nat. Biotechnol.* **32**, 401–402 (2014).
2. Dorsey, K.A., Moritz, E.D., Steele, W.R., Eder, A.F. & Stramer, S.L. *Transfus. (Paris)* **53**, 1250–1256 (2013).
3. Kruskall, M.S. & Umlas, J. *Arch. Surg.* **123**, 23–25 (1988).
4. Smith, M.B., Kelly, C. & Alm, E.J. *Nature* **506**, 290–291 (2014).

© 2014 Nature America, Inc. All rights reserved.
npg