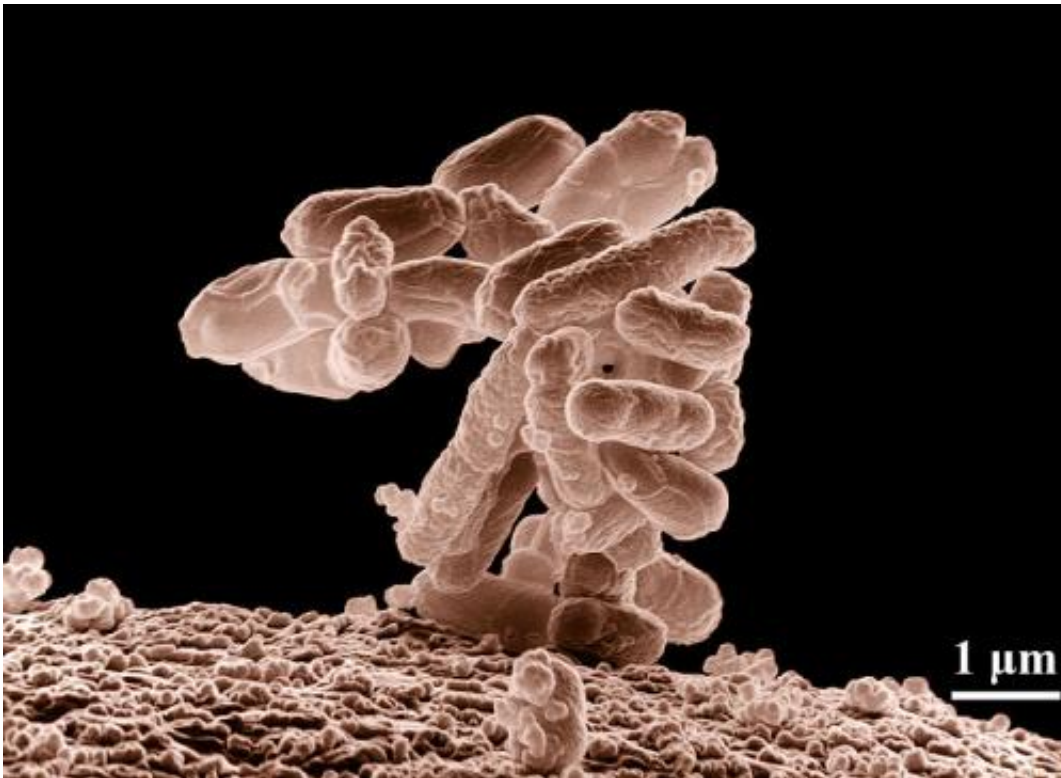


Researchers suggest fecal transplants should be regulated as tissue not drug

February 20 2014, by Bob Yirka



Low-temperature electron micrograph of a cluster of *E. coli* bacteria, magnified 10,000 times. Each individual bacterium is oblong shaped. Credit: Eric Erbe, digital colorization by Christopher Pooley, both of USDA, ARS, EMU.

(Medical Xpress)—A trio of researchers are suggesting in a Comment piece in the journal *Nature*, that the FDA should cease regulating fecal transplants as drugs and should instead begin treating them as tissue

product procedures. In their article, Mark Smith, Colleen Kelly and Eric Alm suggest that treating fecal material as a drug is inhibiting research into its beneficial possibilities and is preventing its use in many instances by physicians unwilling to undergo the bureaucratic process needed with unapproved drugs.

Capturing fecal matter from one person and placing it into another for medicinal purposes has been investigated for over half a century, but its only in the past several years that it's become a much higher profile therapy—due mostly to research that has uncovered more details about the gut biome. Scientists now know that bacteria in the gut plays a critical role in human health—and some studies have suggested that various types of [gut bacteria](#) can be healthy, others unhealthy, and the absence of others a detriment, leading to such ailments as Irritable Bowel Syndrome, Crohn's disease, etc. Unfortunately, there is still a lot scientists don't know about the gut biome and how it operates, and for that reason, research is continuing. In the meantime, doctors and patients that are convinced that biome changes made using fecal transplants can provide relief want to move ahead with giving it a try. In their comment piece, the researchers note one study found that improvement rates for patients with *Clostridium difficile* infections was close to 90 percent using fecal transplants—it's currently the only pre-approved fecal transplant therapy authorized by the FDA.

What makes fecal transplants different from other procedures is that patients, if they so choose, can do it themselves. All that is required is collecting a stool sample from someone, mixing it with water, and then using it as an enema. While that may seem to make the matter moot, the researchers note that in reality, [fecal transplantation](#) is far more complicated when prescribed or performed by a doctor or other licensed medical professional—for two main reasons. The first is that no one really knows if there are negative side effects from fecal transplants, and the other is that other diseases (hepatitis, HIV, etc.) can be passed from

host to recipient. For that reason, they believe fecal matter should be treated (and regulated) as tissue, or given its own classification as has been done with blood. That they say would free researchers to do their work, while also allowing doctors and patients some sort of safety net when considering the use of fecal transplants as therapy for unapproved ailments.

More information: Policy: How to regulate faecal transplants:
[www.nature.com/news/policy-how ... -transplants-1.14720](http://www.nature.com/news/policy-how...-transplants-1.14720)

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