

Are products touted as supporting 'healthy gut-biome' scamming consumers?

"Fecal transplants saved my life!!!"

So [trumpeted a commenter](#) to an online Crohn's Disease discussion group on WebMD. The commenter continued: "I was very ill with Crohn's for years and finally tried Sky Curtis's protocol for doing fecal transplants at home."

Curtis is a Canadian author who began experimenting with protocols for fecal transplants, a method for using the microbiome to treat diseases, after her son was treated for Crohn's disease. She is the author of [The Fecal Transplant Guidebook](#), which directs readers through the process for setting up a fecal transplant at home. Today, however, she is no longer doing direct consultations herself, she said. "I don't usually help people anymore," according to [her Facebook page](#).

While Curtis may have started her business with the best of intentions, the discovery of the diversity of our microbiome — the bacteria and other microorganisms that live in our intestines — has spawned an industry of scam artists, purporting to cure a wide range of diseases, including Parkinson's disease, multiple sclerosis and lupus. At the very least, these sweeping treatment claims — and protocols for self-treatment — are being conducted without first being approved under U.S. Food and Drug Administration (and European Medicines Agency) regulations.

Scams worthy of an award

Jonathan Eisen, an evolutionary biologist at the University of California, Davis, began looking into claims made about cures, if not miracles, from somehow manipulating the microbiome. "I never realized how much crap was out there in regard to the microbiome," [he remarked](#) in a blog post. He also was inspired to institute an annual award, "Overselling the microbiome." He's had plenty of, well, material:

- [Stephen Barrie](#), ND, author and "Chief Science Office" of Lawke Health in Beijing, was the recipient of Eisen's first "[Overselling" award](#) in 2010, for making claims in the Huffington Post that "The health of your body and mind is largely tied to the health of your gut," and that "out of balance microbes can cause allergies, inflammatory bowel disease, eczema, arthritis, irritable bowel disease, obesity, autism and personality changes including paranoia, hostility, aggression and so on."
- Trevor Marshall, director of the California-based [Autoimmunity Research Foundation](#), won for [his claim that](#) the Marshall Protocol will treat chronic diseases (including Crohn's, type I diabetes, multiple sclerosis, psoriasis, rheumatoid arthritis, and celiac disease), that Marshall said "are the result of infection by an intraphagocytic, metagenomic microbiota of chronic bacterial forms."
- The site Curezone, which runs the range of alternative therapies to pure quackery, contains advice on how to be a fecal transplant donor, as well as the advantages of fecal transplants, [including this](#):

People with wide variety of health problems have experienced almost miraculous cures after fecal enema. Some of the health problems that responded to Fecal Microbiota Transplantation Enema are: chronic acne, cysts, unpleasant body odor, boils, Parkinson's disease,

inflammatory bowel disease, irritable bowel syndrome, chronic constipation, candidiasis, colon cancer, colon polyps, hemorrhoids, anal fissure, chronic diarrhea, prostate cancer, prostatitis, enlarged prostate, allergies, leaky gut syndrome, poor digestion, gallstones, MCS, multiple sclerosis, Fibromyalgia syndrome, chronic clostridium difficile infection, amoeba infection, protozoa infection, pinworms, ascaris infection, tapeworm infection, poor digestion, gas, abdominal pain, irregular menstruation etc.

The straight dope on the microbiome

There are many more examples beyond Eisen's award list. But microbiome research is valuable. It is not only providing unprecedented insight into how microorganisms in our gut and on our skin interact with us, studies are also showing that things like fecal transplants may provide some clinical value.

Microbiome studies showing the scale of population (and genetic influence) were first announced about seven years ago, though the interactions of host (i.e., us) and bacteria have been investigated for years. Until we are born, our intestinal systems are sterile, but upon the moment of birth, bacteria and other organisms begin taking up residence, and the proportion of microbiota depends on type of delivery, transfer from the mother, the environment, diet and antibiotics. Although initial studies on the scale of the microbiome claimed that bacterial cells outnumbered ours by 10 to one, a [more recent analysis](#) leveled that estimate to about even (though the report delicately points out that defecation can stack the human cells slightly above bacteria).

One of the first clinical trials of using the microbiome [appeared in 2013](#), in *The New England Journal of Medicine*. This trial, which was halted midway through the protocol because of its efficacy, showed that fecal transplants in the duodenum of patients suffering from *C. difficile* infections (also known as *C. diff*) were significantly more effective than the powerful antibiotic vancomycin.

Another study, however, showed a problematic side of fecal transplants. As reported by the Genetic Literacy Project and others, [a report earlier](#) in 2015 reported that a woman, suffering from a *C. difficile* infection, gained 40 pounds after a fecal transplant, prompting concerns over the relationship between the microbiome, body mass and disease.

Meanwhile, other studies are looking at the role the microbiome in general, and fecal transplants in particular, may play in a [number of diseases](#). Some of these relationships sound fairly clear, like with Crohn's Disease or irritable bowel syndrome, but other studies are looking at interactions with the [central nervous system](#). For example, one popular study from August attempted to show that participant's mood increased after taking a probiotic — a pill that contains “beneficial” bacteria. Others have attempted to show autism is caused by an “[unhealthy](#)” microbiome but none of the data on the central nervous system has shown anything more than correlations.

From the US government: it's a drug, maybe

However, these studies are not treatments. And the claims by many “practitioners” did attract the attention of the FDA, which [in 2013 announced that](#), as far as the agency was concerned, fecal microbiota for transplantation (FMT) “when used to prevent, treat or cure a disease or condition would fall within the definition of biological product.” This meant that anybody “helping” somebody with a fecal transplant would

first have to apply for an Investigational New Drug approval, to begin the process of pre-clinical testing and clinical trials required to approve any new treatment.

However, after objections from (more legitimate) healthcare providers, the FDA eased its stance, allowing for clinical applications of FMT in cases of *C. difficile* infections in certain cases, and as long as patients were allowed to give consent and the provider coordinated his or her treatments with the FDA.

Meanwhile, the cure-all claims continue.

In 2015, a Dr. Roizen conference on alternative and preventative medicine claimed that [attendees would finish](#) the conference loaded with “Smart tips about changing you and your patient’s microbiomes and what to do for your microbiome to promote weight loss and how it inhibits aging,” and “How you can affect the role of the GI tract in chronic disease.”

Just don’t try this at home.

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