A Pill Filled with Bacteria Instead of Drugs

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Delivering healthy bacteria in a pill could help patients harboring out-of-balance microbial communities.

Yogurt eaters already know that not all bacteria are bad for you. They may not realize that some bacteria are so important that one day people may fight off disease with pills filled with bacteria instead of drugs.

<u>Seres Health</u> hopes to develop the first regulated, clinically approved bacteria-filled pill to treat diseases associated with disruptions to the microbes inside the human body. The company launched last month with \$10.5 million in investments; its founders have been working on the bacteria pill for two years and say they're already testing one candidate treatment in patients.

A new understanding of the microbiome—the collection of microbes inhabiting a body—has led a wave of companies, from startups to large pharmaceutical companies, to look at bacteria as a new area of focus. While some companies plan to develop drugs to "reset" the microbiomes of sick people, Seres is one of a few planning to use live bacteria to do the same job.

In recent years, large-scale studies by the National Institutes of Health and others have shown that the healthy human body is home to 10,000 or so species of microbes—outnumbering human cells 10 to one (see "Researchers Catalogue Your Microbial Zoo"). At the same time, medical researchers have shown that the microbiome can affect health, and that swapping bacteria can cure gastrointestinal infections and potentially treat conditions such as inflammation and obesity (see "Transplanting Gut Microbes to Treat Disease"). Bacteria have even been shown to protect against diabetes in mice (see "Transplanted Gut Bugs Protect Mice from Diabetes").

"People are just now starting to appreciate how big a role it plays in our life, health, and disease," says Seres Health CEO <u>David Berry</u>, a <u>2007 MIT Technology Review Innovator Under 35</u>.

The company will examine the differences between microbiomes in healthy patients and those with a particular condition, says Berry. That comparison requires more information than just a list of "who's who" of microbes living in a patient's gut; Seres Health also uses molecular analyses to understand how the members of a microbiome interact with each other and with the human body.

Even in two healthy people, there can be a lot of variation in the exact species of microbes, but there is a lot of consistency in what types and patterns of genes are on and off when the full microbiome ecosystem is considered, says Berry. So when considering how to rebalance an unhealthy microbiome, Seres Health researchers will look at which functional roles of microörganisms are out of balance and then try to restore balance by delivering microbes capable of producing or regulating those functions.

If successful, Seres Health could create a new kind of medicine. "We aren't talking about new chemical entities made in vats," says Noubar Afeyan, a cofounder of Seres and a partner at the venture-capital firm Flagship Ventures, which has invested in Seres. "We are talking about living organisms that colonize the human gut naturally."

Although the company is not describing in detail the number or types of bacteria it plans to include in its treatments, Berry says the company will try to keep the number low.

The treatment will be more advanced than fecal transplants, which involve transplanting diluted stool samples from a healthy person into a sick patient. Such transplants have been shown to cure patients afflicted with *Clostridium difficile*, a gastrointestinal infection that kills some 14,000 Americans each year. *C. difficile* infections usually take hold after a patient is given antibiotics for another condition. However, while fecal transplants have helped patients, doctors don't know what bacteria are in the transplanted microbiome, and some fear that a dangerous microbe could be delivered along with the

beneficial microbes. The Seres Health pills will contain reproducible, controlled collections of bacteria.

Seres Health is already testing a live-bacteria pill treatment for *C. difficile* in patients. "We know what organisms we are adding," says Berry. "We make them in ways deemed appropriate for making drugs," which enables reproducibility, he says. The company is also developing microbe-based treatments for two inflammatory and metabolic diseases, conditions less obviously connected to disruptions in gut microbes.