FBI raids Silicon Valley microbiome startup

Federal Bureau of Investigation (FBI) agents [searched uBiome headquarters](#) on 26 April, reportedly investigating questionable billing practices, according to the *Wall Street Journal*. The California Department of Insurance is also conducting an investigation into billing practices at the microbiome startup. uBiome uses machine learning and high-throughput sequencing of the 16S ribosomal gene in bacterial DNA to profile the gut and vaginal microbiome and provide information with clinical utility. The tests identify microbial species purported to correlate with irritable bowel syndrome, chronic fatigue, diarrhea, weight gain and other conditions. Before the FBI raid, uBiome had already accumulated [28 complaints](#) filed between 2017 and 2019 with the Federal Trade Commission. These complaints, revealed through a Freedom of Information Act request, included a person billed for a test taken by their spouse; after flagging the mistake, the couple were charged about \$3,000 more for a test they never took. Another customer was billed over \$2,000 after the insurance company covered only part of the costs.

uBiome was founded in 2012 with \$350,000 from a [crowdfunding campaign](#) and later raised up to \$105 million from investors. The biotech [launched SmartGut](#) and [SmartJane](#), doctor-ordered sequencing tests for the gut and vaginal microbiomes, respectively, that are intended to be covered by insurance, and a Gut Explorer kit, which is available directly to the public online at \$89. On 1 May uBiome founders Zac Apte and Jessica Richman were [placed on leave](#), and five days later uBiome [withdrew SmartGut and SmartJane](#).

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“We are just wasting time discussing GM technology. We have capacity and brains to deploy the technology,” Florence Mutua, a member of the Kenyan parliament, comments on a proposal to allow local farmers access to genetically modified maize seed, as the country faces a food and water crisis due to drought. (*Cornell Alliance for Science*, 30 April 2019)

“Rather than picking up a pipette and doing a Series A as your strategy for solving the problem, I would spend five years in D.C. cultivating the right politicians to make sure that we have the right circumstances.” Serial entrepreneur Ned David explains why his antibiotic company failed while his company that treats chin fat succeeded. (*STAT*, 14 May 2019)

bad for the environment, eating a lot of red meat isn't healthy, and replacing meat with plant-based alternatives solves both of those problems. “The way to save the planet is to make a delicious plant-based food,” says David Lipman, CSO at Impossible Foods.

The company's first product—the Impossible Burger—consists largely of soy protein, but looks, tastes and even bleeds like beef. The key ingredient giving the burger the singular, ‘bloody’ taste of meat is heme, a molecule found abundantly in animal muscles bound to the protein myoglobin.

Heme can be sourced from soybean root nodules, where it occurs in the protein leghemoglobin. Impossible Foods' founders determined that sourcing heme from soybean plants didn't make sense environmentally or economically, so the company found a way to produce it using fermentation of bioengineered yeast. Company scientists modified *Pichia pastoris* yeast with a gene encoding soy leghemoglobin, along with other genetic modifications related to the yeast's metabolic pathways.

When fermented with sugars, amino acids and vitamins, the yeast synthesizes heme-bound soy leghemoglobin. A separation process breaks open the yeast cells, extracting the protein, filtering away solids and concentrating the liquid, which is blood red in color. The liquid is then mixed with soy protein and a few other food ingredients to make what looks like raw meat and cooks like a burger.

The final recombinant product is indistinguishable from leghemoglobin isolated from soybean and is not labeled genetically modified. Its [status as a non-GMO product likely stems from the precedent](#) set decades ago by the fermentation production of chymosin, an enzyme commonly used in cheese making. To produce chymosin, microbes transformed with a [bovine gene that encodes the enzyme](#) are fermented, releasing the enzyme, which is then separated and [added to milk as a coagulant](#). The final cheese product is not considered bioengineered.

With a splashy media launch, the Impossible Burger debuted in 2016 at the hip restaurant Momofuku Nishi in New York. Since then it has expanded to hundreds of specialty restaurants and launched in fast-food chains, such as White Castle in the United States and Beef & Liberty in Hong Kong, as well as (intriguingly) ‘organic’ and ‘all natural’ specialty chains, such as Bareburger in the United States.

The new deal with Burger King, with its 7,200 locations in the United States, will more than double the number of restaurants serving Impossible's product, once the rollout is complete, and puts plant-based

burgers in front of a massive number of meat lovers. “It was a strategic goal of ours to go right to the most burgery burger place you could imagine,” says Lipman, whose father was a butcher. “We'd love to be able to satisfy vegetarians and vegans and people who are health conscious. But really our goal is to make a product that everybody is going to want.”

In another corner of agbiotech, seed developer Calyxt, formerly Collectis Plant Sciences, has used TALEN gene editing to develop what it calls “products with purpose.” The company angles itself as focusing on crops that benefit both consumers and farmers. “The consumer is asking: ‘What's in it for me?’ And that's where we think we're able to tell a story,” says Sahoo at Calyxt.

The company's first commercial product, a soybean oil high in oleic acid, contains no trans fats and has a longer fry and shelf life than traditional soybean oil. Calyxt achieved the effect by knocking out the fatty acid desaturase genes *FAD2-1A* and *FAD2-1B* in soybean. That dialed down the production of linoleic and linolenic acids in the plant, while increasing oleic acid to ~80% of the fatty acids (commonly 18%), according to the company. With that kind of fatty acid profile, the oil doesn't have to be partially hydrogenated—a process that creates trans fats—to retain its flavor for an extended period on the shelf and in the fryer. Calyxt markets the oil to the food service industry for frying, salad dressings and sauces.

Pioneer, now part of Corteva Agriscience, developed a similar high oleic acid soybean oil, and now markets it under the brand name Plenish. It too has a longer shelf and fry life, contains about 75% oleic acid and no trans fats, and was generated with alterations to the same gene family (*Nat. Biotechnol.* **28**, 769–770, 2010).

But Plenish soybeans were modified using transgenic technology that triggers regulatory oversight and results in a product largely considered a GMO—a term that carries negative connotations in some circles. By contrast, Calyxt altered the genomes of its plants using TALEN, a type of gene editing. As a result, Calyxt's crops don't require regulatory oversight from the US Department of Agriculture. And it's possible that such gene-edited crops won't have to be labeled as GMOs, says Deepti Kulkarni, a partner at the law firm Sidley Austin, on the basis of her interpretation of the USDA's [bioengineered food disclosure standards](#), which were finalized in December.

Being a gene-edited crop tends to kindle some street credibility. “There's been a lot of popular press about the benefits of gene editing” particularly in medical applications, says Arnot at the Center for