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ISSUE BRIEF

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Lumina - the self-spreading and super-competing GM probiotic

A genetically modified microorganism engineered to outcompete natural mouth bacteria

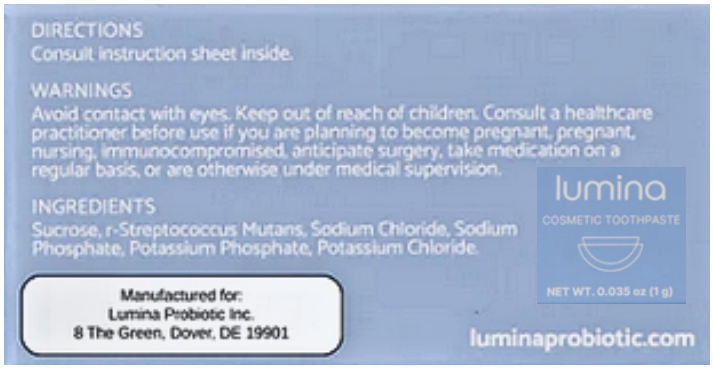
- A super-competing genetically modified bacteria designed to permanently colonise the human mouth is currently available for sale in the United States and Honduras.
- The modified strain continuously produces ethanol - a known carcinogen - in place of the lactic acid it would naturally produce.
- Spreading of the genetically modified bacteria (GM) between people, including infants, is highly likely based on established transmission pathways for this bacterial species.
- Advances in AI-assisted biological design could greatly compress development times for self-spreading super-competing genetically modified microorganisms capable of permanent establishment in natural microbial communities (microbiomes).
- The producer of this high-risk GM microbe has taken great lengths to avoid scrutiny by regulatory authorities.

What is the issue?

BCS3-L1 is a genetically modified strain of a bacterium called *Streptococcus mutans*, developed as a one-time treatment to permanently prevent tooth decay. The strain was engineered to incorporate a gene from another bacterial species, enabling it to produce ethanol instead of the lactic acid naturally generated by this species - which is the primary acid responsible for cavity formation [1].

In addition to its genetically altered metabolic pathway, BCS3-L1 was isolated to be a 'super-competitor' with the capacity to outcompete other bacteria in the oral microbiome through the production of a naturally occurring antibiotic (mutacin). The product is intended as a single topical application that permanently replaces a consumers' native oral bacteria with the modified strain and is currently priced at USD 250 [2].

Commercialisation was first attempted by Oragenics, Inc. in the early 2000s. This included two applications for Phase I clinical trials under the supervision of the USA Food and Drug Administration (FDA). However, direct commercialisation was ultimately abandoned by Oragenics prior to 2015 [3]. In 2023, Lantern Bioworks acquired the rights and began marketing the organism as 'Lumina Probiotic', repositioned as a cosmetic product rather than a drug [4]. The product's initial commercial launch reportedly took place in Próspera, Honduras - a private charter city with minimal regulatory oversight [4]. According to the original developer and the current producer, colonisation of the human mouth with the modified microbe persists for more than 20 years [2].



Back of the toothpaste package containing genetically modified bacteria, Source: Lumina

The self-spreading and super-competing probiotic

Why does this matter?

Self-spreading 'super-competitor'

The engineered strain's enhanced colonisation capabilities, combined with its native antibiotic production that eliminates competing bacteria, could facilitate even more efficient spread than most wild-type strains.

It is well established that mother-to-child transmission of unmodified *S. mutans* occurs at extremely high rates, with studies demonstrating that virtually all children acquire their oral *S. mutans* strains from their mothers through routine contact such as kissing and shared utensils [5, 6, 7]. Substantial transmission of unmodified *S. mutans* between household members is also very well documented [8, 9]. The magnitude of the transmission concern (see also next section) led the FDA to impose significant but proportionate conditions on the Phase 1a clinical [10, 11]. Having reviewed the results of the first trials, for a subsequent phase 1b trial, the FDA demanded "a plan to eradicate the modified organism in subjects' children, along with mandatory pregnancy testing for partners of subjects" [12]. The Phase 1b trial was never conducted [12], and Phase 1a data are not generally public.

Continuous carcinogenic ethanol production

A fundamental safety concern stems from BCS3-L1's continuous ethanol production directly within the mouth. Ethanol has been classified as a Group 1 carcinogen by the International Agency for Research on Cancer (IARC), with specific evidence linking it to oral cavity cancers [13]. While the quantity of ethanol produced by the bacteria would be small compared with that from consuming alcoholic beverages, the continuous and permanent nature of this novel exposure is likely to be the reason for the FDA clinical trial restrictions mentioned above (see also [14]). Despite obvious concerns, shared by competent regulators, there is no public human data available on the risks associated with BCS3-L1 as a novel, continuous source of ethanol production in the mouth (see also [15]).

What might be the consequences?

The history of Lumina Probiotic shows that certain companies [16] are ready to go a long way to exploit weaknesses in regulatory frameworks for genetically modified microbes. Consequently, a self-spreading and super-competing genetically modified organism has been released into the environment without adequate safety assessment.

Despite being sold as a "cosmetic", the product carries a prominent warning on its packaging: *"Consult a healthcare practitioner before use if you are planning to become pregnant, pregnant, nursing, immunocompromised, anticipate surgery, take medication on a regular basis, or are otherwise under medical supervision."*[17] While the development of BCS3-L1 spanned more than 20 years, advances in AI-assisted biological design will greatly compress the development timeline for similar super-competing genetically modified microorganisms [18,19]. The regulatory gaps exposed by this case highlight the pressing need for safety regulations that effectively protect both the environment and the society at large.

Where can I get more information?

For sources cited in this text and additional notes go to:

www.saveourseeds.org/briefings/issue-brief-lumina-gm-probiotic/