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Short Communication

The Medical Food Category: The Food that Delivers Health Promises through Science

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The Medical Food category evolved from the growing need to manage health conditions with a specifically formulated nutrition, including a range of delivery forms consumed, as advised by a physician or health practitioner. There are three categories of healthcare products: dietary supplements, Medical Food, and prescription drugs.

A dietary supplement is for healthy individuals, based on safety and efficacy guidelines governed by the DSHEA act (The Dietary Supplement Health and Education Act of 1994), the United States Federal legislation statute that defines and regulates dietary supplements. The Medical Food category is for a population with specific health problems or risk of a particular health condition. It requires standardized active ingredients supported by evidence of safety and efficacy recognized among qualified experts. The GRAS status (Generally recognized as safe) under sections 201(s) and 409 of the Federal Food, Drug and Cosmetic Act usually determines the safety of Medical Foods.

The popular Medical Food is in the form of drinks addressing the aging population with conditions like muscle wasting and osteoporosis. An example of a commercial nutritional application is Beta-hydroxy-β-methyl butyrate (HMB), a leucine metabolite that helps counteract muscle loss-launched by Abbot company under Ensure brand of a drink providing a quality muscle-building protein.

The emerging Medical Food is a multitasking vitamin K recognized for supporting bone and cardiovascular health, especially in the form of long-chain menaquinone-7 (MK-7) occurring abundantly in traditional Oriental foods like fermented soybeans in conventional Japanese natto. Our 2021 published pilot randomized, placebo-controlled double-blind study provided, for the first time, evidence linking the increased levels of circulating vitamin MK-7 to improvement in the debilitating pain, cramps, and symptoms of peripheral neuropathy in diabetes type 2 and vitamin B12 deficiency [1]. The MK-7 may involve vitamin K activating a family of proteins, including the growth arrest-specific gene 6 (GAS6) protein for oligodendrocytes and myelin sheet repair [1,2].

The versatile profile of MK-7 led to a growing number of Medical Food applications, with one of the recent ones in the form of olive oil-based drops combined with the antioxidant alpha lipoic acid as developed by India's Synergia Life Science Pvt., Ltd. The MK-7 formula resulted in a preliminary study evaluating nutritional support for special needs children with neurological disabilities [3]. In a physician-approved and monitored case study of a 10-year boy with global developmental delay due to Bohring Opitz Syndrome (BOS) [3], the MK-7 drops in a custom preparation with alpha lipoic acid (240 mcg/ml MK-7 and 6 mg alpha lipoic acid) used to provide approximately 80 mcg of MK-7 daily for three years. In the pre-supplementation, the BOS patient with diagnosed retinal dystrophy had to wear glasses prescribed for myopia and reduced glare. A recent ophthalmologist report showed an improvement in the patient's eyesight, with corrective glasses no longer necessary for near work.

This promising outcome of the preliminary study requires further follow-up of the case and additional validation of the result. There were no side effects associated with the three years of MK-7 in the BOS case study.

Next to vitamin K, probiotic bacteria emerge as a promising category of Medical Food. Specifically, the unmet need for nutrition to help combat infections, whether stand-alone or in combination with antibiotics. The application quickly gains popularity, especially among elderly patients and patients with disabilities. Spore-forming, room-temperature stable probiotics like *Bacillus subtilis* are vital in Medical Food applications [4]. The spores of these *Bacillus* species being heat-stable, have several advantages over the non-spore-formers like *Lactobacillus* spp., which are not stable at room temperature and in the low pH of the gastric environment [5]. The spore-formers stimulate innate immunity, competitively excluding pathogens but not probiotic microorganisms, secrete unique antimicrobials and produce beneficial nutrients, e.g. digestive enzymes assisting gastrointestinal tract functions and body homeostasis in combating the infection [5]. *Bacillus subtilis* in Europe carry a QPS (Qualified Presumption of Safety) status designated by the European Food Safety Authority (EFSA) [6]. It is safe at a dose of up to 10 to power ten spores daily.

The *Bacillus subtilis* strain HU58, studied extensively at Royal Holloway College, the University of London, is particularly suitable for Medical Food category applications [7]. The HU58 is more stable than other spore-formers in an acidic stomach environment, able to sporulate efficiently in the gastrointestinal tract, and produces biofilms and surfactants, which enhances gut adhesion, colonization and probiotic performance.

Bacillus subtilis sp. make four types of antimicrobials: three ribosomal antibiotics, 31-kDa protein with TasA abbreviation, subtilosin, and sublancin, four nonribosomal antibiotics, bacitracin, bacilysin, plipastatin and surfactin, the phospholipid antibiotic bacilysocin and an amino-sugar antibiotic, neotrehalosadiamine [8]. The HU58 strain has a confirmed safety profile for human use as a probiotic, with its genome structure selectively excluding potentially toxic bacitracin. It meets EFSA recommendations for the minimum inhibitory concentrations (MIC) with the EFSA-identified eight antibiotics of human and veterinary importance. The safety profile predisposes HU58 in Medical Food, for example, in synergy with conventional antibiotics against a broad spectrum of bacterial and fungal infections safeguarding against dysbiosis developed with long-term antibiotics [9,10].

Bohring Opitz Syndrome provides an example of a childhood disability exposed to an ever-present risk of infection and the need for a supportive treatment with probiotic-based Medical Food. A childhood disability like BOS requires continuous antibiotic therapy to prevent recurring urinary tract infections (UTIs) due to neurogenic bladder conditions [11]. The neurogenic bladder results from an anatomic and physiological abnormality of the bladder, poor bladder control, urinary reflux to kidneys, infection and scaring of kidneys with a progressing renal failure. The need for intermittent catheterization of a patient further aggravates bacterial contamination of the urinary tract. The exemplified form of UTI necessitates frequent use of antibiotics leading to multidrug-resistant microorganisms. There is a growing medical consensus that the continuous use of antibiotics in those patients is unsustainable [9]. The alternative approach may require the supportive use of spore-forming probiotics to prevent, treat and control UTIs. The described characteristic of spore-formers like *Bacillus subtilis* HU58 in Medical Food applications may diminish and even avoid the need for antibiotics in the neurogenic bladder UTI.

The objective of Medical Food development should be a continuous innovation that features delivery forms supported by science-based safety and functionality. The ultimate goal is to develop products with good compliance and proven management, like discussed childhood disabilities. If a child has to take the juice/smoothie/etc. that doesn't taste good or if their doctors' tests are not showing the product's measurable benefit, most consumers and health practitioners will abandon it.

The increased demand for Medical Food trend started approximately 15 years ago, and since then, the body of peer review papers on the subject has grown substantially. However, the growing body of science on Medicinal Foods has yet to translate into practical knowl-

edge and availability of Medical Foods. The next decade will likely bring health providers a better understanding and recognition of Medical Foods.

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