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Research Article

Proving the Value of Nutritional Supplements: The Good, the Bad, and the Ugly

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Abstract

Human nutritional supplements are increasingly popular but information about effectiveness is sparce. We live in the information age, so it may seem surprising how little information consumers have traditionally demanded when buying nutritional supplements. The number of clinical trials testing these products is growing at 10% per year mostly sponsored by academia not the product manufacturers. However, results are most often ambiguous and generally unavailable to consumers. In this article, we examine the clinical trial data being generated to demonstrate safety and efficacy of nutritional supplements. Specifically, we highlight three different products, which we believe represent groups of products that a) have real demonstrated benefit, b) have no clinically demonstrated benefit but are generally safe and may have a placebo effect, and c) may be harmful and/or deceptively marketed.

Introduction:

Will eating nutritional supplements really make you heathier? The human nutritional supplements market is a $60-100 billion industry growing at 8+% per year and many people believe in their benefits [1]. As the ingredients are generally regarded as safe, manufacturers do not need to conduct rigorous clinical trials the same way pharmaceutical developers do; however, they also cannot make medical claims such as the power to cure a disease. In recent years, a growing number of clinical trials testing nutritional supplements have been conducted. Nevertheless, the results are not always readily available or easy to interpret, such that the value of these substances often remains unclear.

Clinical Trial Trends

Here we examine the trends from clinical trials testing nutritional supplements listed in the TrialTrove database from Pharmaintelligence from 2016 to 2021 [2]. Trialtrove is a comprehensive clinical trial database tracking trials throughout their life cycle, providing insights into trial timing benchmarks, enrollment successes and failures, accrual details and study results.failures, accrual details and study results.

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Number of clinical trials started per year

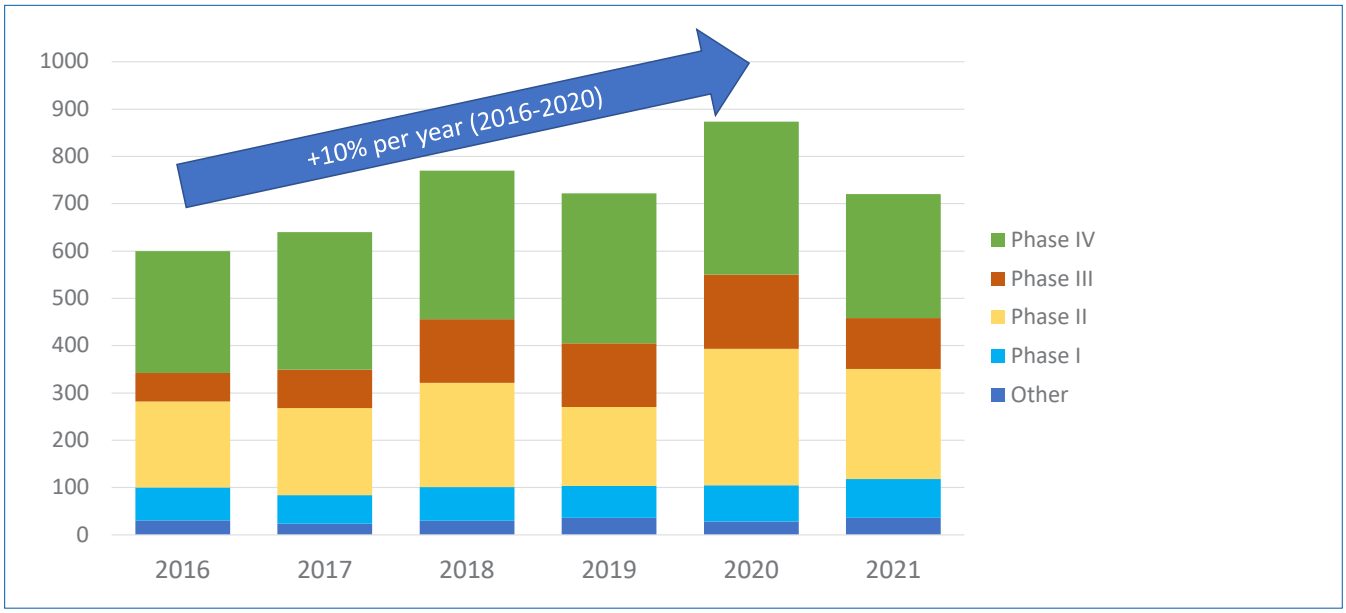

Figure 1: Number of clinical trials started per year

The number of clinical trials evaluating nutritional supplements has grown by about 10% per year from 2016 to 2020. This growth slowed during the Covid pandemic, but overall numbers have not fallen significantly. **Figure 1** shows the number of trials started in each of the last six years. Since a trial is planned well in advance of its start, many trials continued with little impact from the pandemic. Moreover, unlike clinical trials for drugs, nutritional supplements are mostly tested outside of the hospital setting, and as such, experienced fewer delays related to Covid. The findings within **Figure 1** demonstrate that relatively few trials test for safety (Phase I trials) since nutritional supplements are almost always *deemed generally regarded as safe* (GRAS). Phase II and Phase III trials test for efficacy of non-branded products (e.g., vitamin D) and are conducted with greater frequency. Interestingly, the largest proportion of trials are Phase IV which test for efficacy of marketed and branded products (e.g., Nature's Bounty Vitamin D3).

Clinical trials sponsors

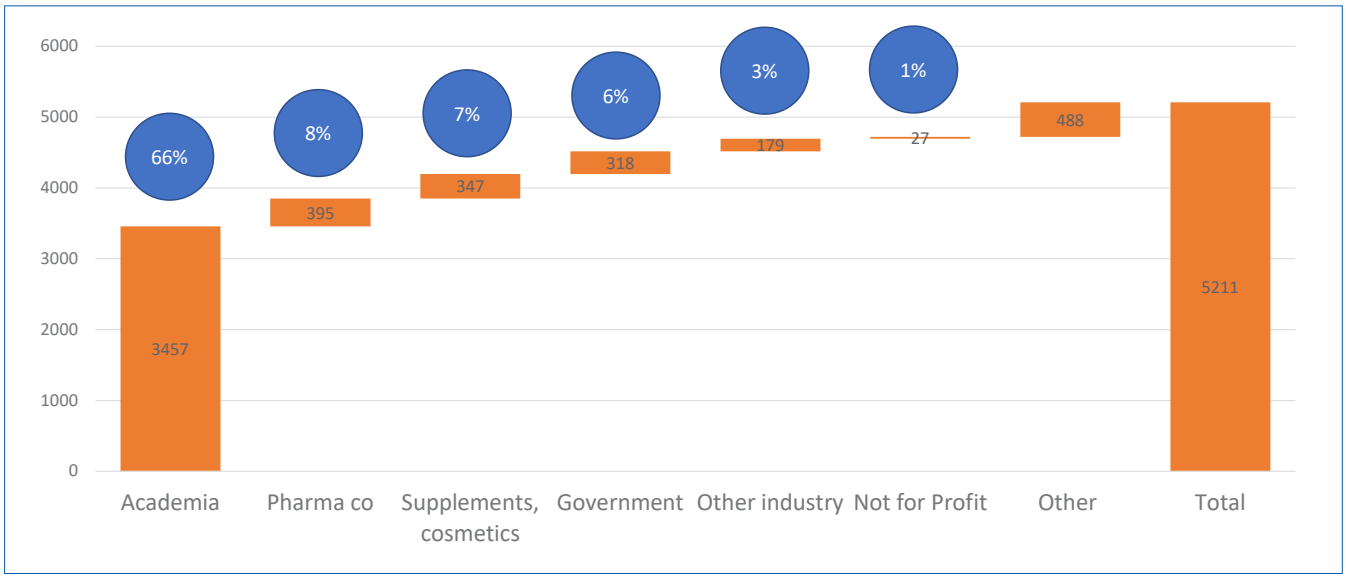

Figure 2: Clinical trial sponsors

The majority (66%) of clinical trials on nutritional supplements are carried out by academic researchers (**see Figure 2**). Only 15% of the trials are sponsored by the manufacturers of the supplements themselves (pharmaceutical companies and supplement and cosmetic manufacturers). Notably, very little from these manufacturer-driven studies is published. The authors tried to find publications from the trials listed in the TrialTrove database, but data is reported from only about 20% of these studies. The authors speculate that most trials are inconclusive and, as such, are neither interesting nor commercially valuable. Furthermore, there is likely a significant aversion to publishing findings which could be interpreted as negative or not beneficial.

Most studied nutritional supplements

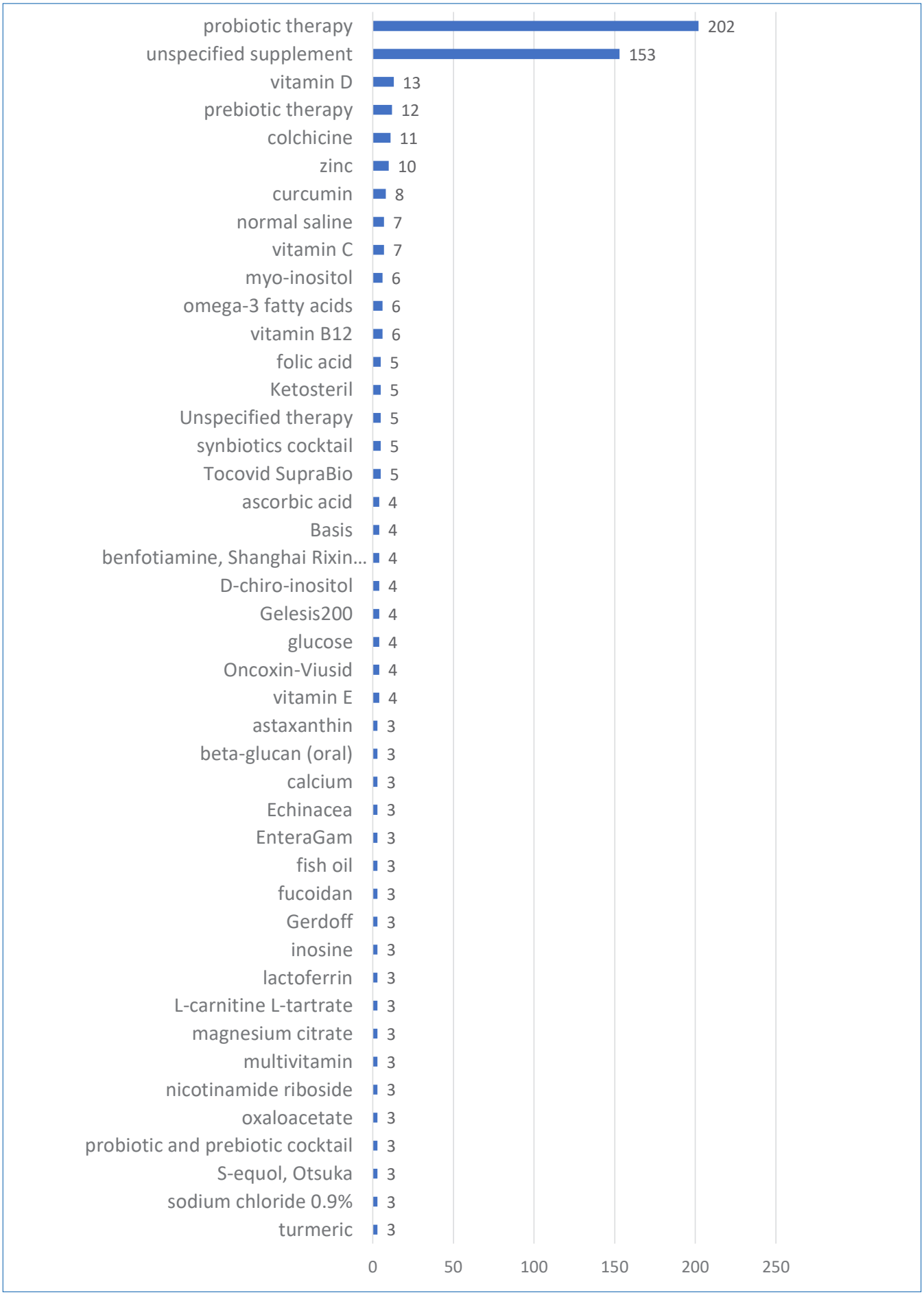

Figure 3: Most studied nutritional supplements

The most studied group of products are probiotics (**see Figure 3**). Probiotics are live microorganisms which have been promoted with claims that they provide health benefits when consumed, generally by improving or restoring the gut flora. However, substantive data to prove these benefits is very scarce [3]. One of the issues complicating the interpretation of existing results is that criteria for defining gut health and immune health are lacking [4]. Further, it is not always clear what the background diet is and clinical trial selection criteria. Finally and most importantly, available data is generally not translated into a message that can be easily accessed or understood by the consumer. In the following, we highlight three different examples of nutritional products and existing evidence for their safety and efficacy. These supplements have been chosen as representative of the spectrum of products which are currently available:

- Good - products which have solid evidence supporting their health benefit claims
- Bad - those with high prices tags, but little data to indicate benefit or harm
- Ugly - substances for which research indicates potential harm to those who consume

The Good: Biogaia

Biogaia is the brand name of family of products containing the live bacterium lactobacillus reuteri. The Swedish company by the same name manufacturers and markets several supplements; however, most primarily focus on building a healthier gut and gastrointestinal tract for people of all ages. The bacteria in these probiotics are directly responsible for the positive effects, as studies have proven their ability to benefit the human body in numerous places, in particular the digestive system [5]. While it is possible to attain lactobacillus reuteri through foods such as beans and yoghurt, these supplements serve as a safe and effective way to enhance an individual's natural array of bacteria (flora) and potentially contribute to a healthierhealthy intestinal tract. Revenues for these products are slowly increasing and are today 785 million SEK (77 million USD) [6].

The Bad: Neuriva

Neuriva is a supplement based on an extract from the Coffea Arabica plant, and claims to support brain health, focus, memory, accuracy, learning, concentration, and relaxation. While hundreds of high-rated reviews on Amazon and other sellers may suggest that the Neuriva works, very little hard evidence exists. The product comes in three simple forms: capsules, gummies, and liquid shots. Each formulation costs over 400 dollars a year for a yearly supply. The company has recently come under scrutiny due to a lack of sufficient scientific evidence to back their claims regarding the impact of coffee cherry extract on the brain. Interestingly, a recent study conducted by researchers unaffiliated with the company ultimately concluded that that primary ingredients found in Neuriva have little to no effect on the human brain [7]. Their speculation is that any appreciable benefit from the supplement is likely represents as placebo effect.

The Ugly: Jack3d

Jack3d was an incredibly popular pre-workout supplement which was supposed to contain a mixture of plant extracts and caffeine. Each container of the product was labeled claiming in bold lettering to be "University Studied" and was advertised as a safe supplement for all about 10 years ago. It was later discovered that Jack3d also contained DMAA, a sympathomimetic drug created in China, which has been shown to cause high blood pressure, strokes, and even death. After being exposed for their fraudulent claims, the manufacturers of Jack3d were fined $10.7m and two executives were sentenced to prison [8].

Discussion

Human dietary supplements constitute a rapidly growing market, but one that is unregulated, and as such is filled with many products with unproven benefits. The number of clinical trials seeking to elucidate these benefits is growing; however, the results are rarely published, and information about these products is not readily accessible to consumers. The U.S. Congress has introduced the Dietary Supplement Listing Act of 2022 to improve transparency and the availability of information regarding dietary supplements by empowering the Food and Drug Administration (FDA) to regulate this wild west market [9]. The authors are supportive of this proposed legislation and specific efforts to help inform potential consumers. Simple rating scales for safety and efficacy which are updated based on existing evidence (perhaps such as those used for rating the safety of medications for pregnant women) would help to guide individuals who are considering the expense and potential benefit of these substances.

Conflict of Interest

The authors have no conflict of financial interest.

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