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# THE RISE OF CONSUMER PHARMACEUTICALS

Empowered with new data about chronic health concerns, consumers and scientists are seizing the opportunity to remake medicine.

by Ysette Witteveen and Teymour Boutros-Ghali



# “Let thy food be thy medicine and let medicine be thy food.”

This quote, attributed to Hippocrates more than 2000 years ago, underscores the importance of nutrition and supplements to prevent or cure disease. It has taken on a new significance in this age of the empowered consumer—a time when we don’t just have access to more choices but to more relevant, targeted information about the world and about ourselves.

The impact on consumer goods has been apparent for some time. The impact on health and medicine is less appreciated. Increased education and awareness have given consumers revolutionary amounts of confidence in their ability to navigate health decisions. We have more data than ever about our complaints and chronic conditions, and we’re intent on curating solutions that are hyper-customized to our needs.

At the same time, scientists have gained a deeper understanding of how our metabolism and the microbiome impact our health. This, in turn, has spurred the development of more personalized formulations, and novel delivery channels.

In other words, good health isn’t just in a pharmaceutical pill. It’s in a personalized diet, a specific herb or strain of bacteria, or specially formulated foods and drinks.

This has led to the rise of a market we call **Consumer Pharmaceuticals**. This category, powered by **novel data sets**, encompasses pre and probiotics, vitamins, supplements, and even clinically tested medical foods that people use, often without a prescription, to improve their health and manage chronic conditions. It starts with increased access to our genetic and molecular profiles—as well as those of the trillions of microbes our bodies host. Coupled with feedback loops from low-cost wearables and at-home testing devices, and the analytical power of Artificial Intelligence, science has brought us far more targeted, effective, non-pharmaceutical healthcare solutions while creating multi-billion-dollar investment opportunities.

**Here we explore what’s driving the trend and describe some of the most promising opportunities.**

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# Understanding Consumer Pharmaceuticals

## WHAT ARE CONSUMER PHARMACEUTICALS?

We eat food for energy, but we also eat it to manage high blood pressure and prevent heart disease. We use St. John's wort to fight depression and probiotics to maintain gut health; we take Lutein extract, a carotenoid that's typically extracted from Marigold flowers, to prevent eye disease.

In short, there's a whole spectrum of things, from probiotics and food to supplements and nutraceuticals to so-called "medical foods," that people consume because of their impact on health and well-being; we're calling them **Consumer Pharmaceuticals**.

Consumer Pharmaceuticals range from **functional foods** like garlic or green tea—which are said to provide health benefits beyond their essential nutrients—to **medical foods** like infant formula that satisfy scientifically recognized nutritional requirements for the prevention and management of disease.

Not all of these "remedies" are new; indeed, many of them aren't. What is new are the data we now have about our genetics and our microbiome, combined with a more sophisticated analytical understanding of when, why, and how these "old school" remedies are effective.

That means the effects of Consumer Pharmaceuticals—once anecdotal—are now supported by real clinical research. What's more, this research has delivered a very personalized view of which bodies will respond to which treatments. Sometimes, it can accelerate the development of conventional pharmaceutical compounds. Other times, Consumer Pharmaceuticals are sold directly to the market, with or without specific guidance from a physician.

Science has made a broad range of Consumer Pharmaceuticals more personalized, precise, and effective.

- **Prebiotics:** Substrates in food that target and stimulate the growth of certain microorganisms in the body
- **Probiotics:** Specialized "good" bacteria and strains of yeast, many of which already inhabit our bodies and can be isolated from food, stool, soil, or skin
- **Postbiotics:** The metabolites of probiotics, or the components that result from probiotic activity in the gut, like fermentation
- **Synbiotics:** A combination of pre and probiotics that synergizes probiotics and the specific fiber they feed on
- **Functional foods:** Foods that have a positive effect on health that transcends their nutritional value by, for example, reducing the risk of disease
- **Vitamins and minerals:** Organic compounds that are present in many foods and support normal cell function, growth, and development
- **Nutraceuticals:** Bioactive compounds, like fish oil, that are extracted from foods and provide medical or health benefits
- **Medical foods:** Specially formulated foods that are designed to satisfy scientifically recognized nutritional requirements for the prevention and management of a disease or condition



# What's behind the rise of Consumer Pharmaceuticals?

Demand and supply-side drivers are converging to spur the development of the market for Consumer Pharmaceuticals. Technology has democratized access to information about human health. It's given consumers a more precise understanding of their ailments and treatment options—and enabled scientists and start-ups to develop, assess, and adapt products to meet their needs more nimbly.

**IN THIS SECTION, WE'LL UNPACK THE FORCES AT WORK.**

## The medical toolkit is expanding

Scientists have access to more data than ever before—and better tools for making sense of it. The human microbiome is [now being sequenced](#) as tenaciously as the human genome, and huge advances have been made in understanding how that ecosystem works. This, in turn, has powered the discovery of numerous health-impacting substances that, ingested separately or together, offer formidable, [scientifically supported benefits](#).

The bacteria in the microbiome help digest our food, regulate our immune system, protect against other disease-causing bacteria, and produce vitamins. Autoimmune diseases like diabetes, rheumatoid arthritis, muscular dystrophy, multiple sclerosis, and fibromyalgia are associated with dysfunction in the microbiome. Scientists are using this knowledge to expand consumer pharmaceutical treatments with food and stool derived prebiotics, probiotics, and postbiotics—as well as a new category known as **synbiotics**, which synthesize probiotics and prebiotics to provide more advantageous outcomes.

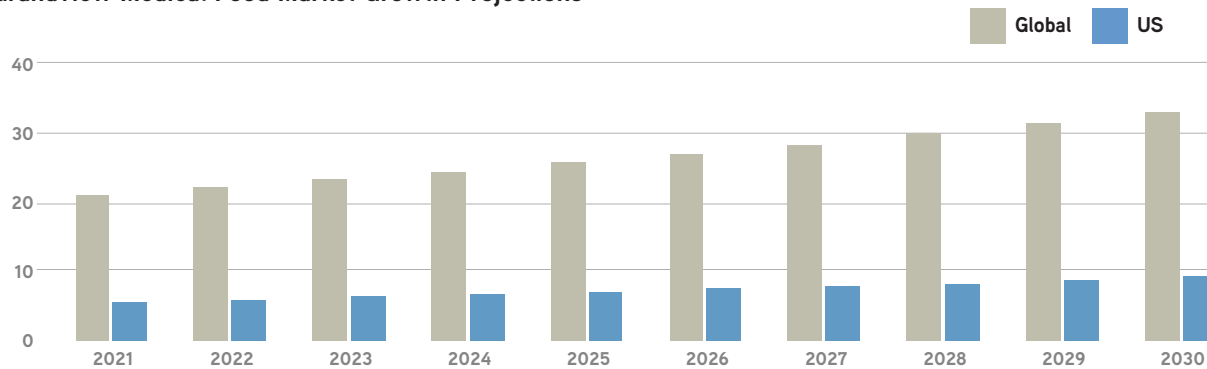
## Food is medicine

Much of the science behind Consumer Pharmaceuticals revolves around the gut, whose effects are now understood to extend [far beyond digestive health](#). That, in turn, has led to the development of more convenient, shelf-stable delivery formats like pills and liquids that are easy to distribute in retail pharmacies and even direct-to-consumer.

To make **medical foods**, for example, natural ingredients are used to formulate foods that are easy to ingest, have minimal side effects, and are clinically proven to manage chronic diseases and metabolic disorders. Data and AI is driving the dramatic improvements in the design and effectiveness of these solutions.

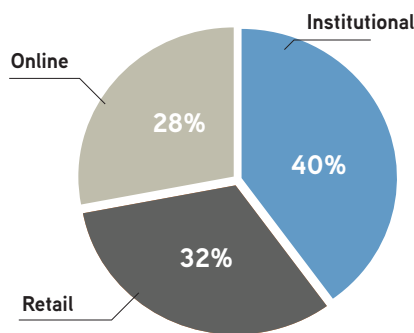
Indeed, the medical food market is growing fast, and it's projected to top \$30 billion annually by 2028.

#### Grandview Medical Food Market Growth Projections



Source: BOLD Analysis, Grand View Research

Medical foods are unique among Consumer Pharmaceuticals because they are considered both food and drugs and are regulated by the FDA. They are subject to clinical trial requirements and, in the U.S., must receive Institutional Review Board (IRB) approval. Though institutional sales currently dominate their distribution, trends are shifting, and ecommerce and retail pharmacy sales are expected to grow in the future.



#### Grandview Market Channel Breakdown

Personalized vitamins and supplements, meanwhile, are already widely available through direct-to-consumer channels—some based on genomic tests that identify individual nutritional needs and deficiencies. According to Nutrition Business Journal, the market for personalized supplements is [expected to grow](#) from an estimated \$281 million in 2019 to \$4.3 billion in 2023, or 6.4% of all U.S. supplement sales.

Source: BOLD Analysis, Grand View Research

### Science is accelerating

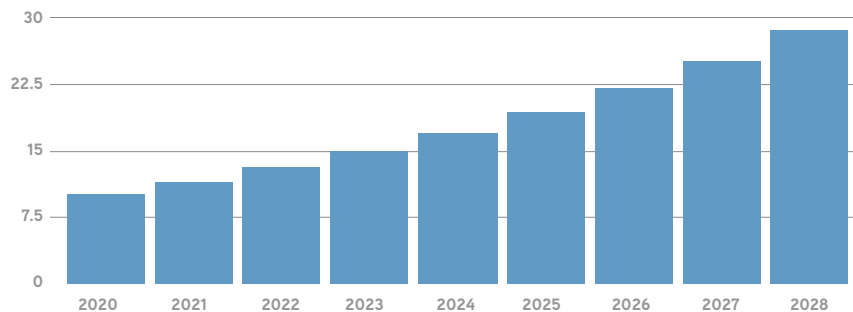
The science behind Consumer Pharmaceuticals is exciting not just for what it can accomplish on behalf of the new category, but for its potential to impact other areas of research. It is significantly faster to bring a medical food to market than it is a conventional drug. Moreover, companies can center their initial R&D efforts around medical foods as a means of accelerating the Rx path—giving them greater control and flexibility about development timelines.

### Consumers are empowered, and they're concerned about their health

Consumers, meanwhile, are able to navigate this landscape thanks to increased education—and increasingly

accessible diagnostic technologies that help monitor and make sense of the reams of data our bodies generate. According to Pew Research, a majority of Americans say that they [do their own research](#) when making decisions about healthcare treatments. More than three-quarters [want to do more](#) to stay healthy in the future. And the growth of the market for wearable diagnostics is [well-documented](#), both among mainstream brands like Apple and Fitbit and newer players like Oura Health. This is also evidenced by the rapid growth in sites like Stuff That Works, where consumers use crowd-sourced knowledge to deal with chronic conditions.

### Grandview/BOLD Wearable Health Tech Market Growth Projections

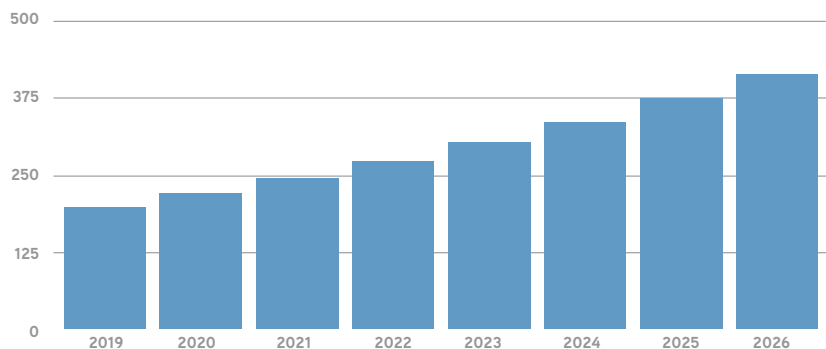


Source: BOLD Analysis, Grand View Research

Yet access to information is only the beginning. We are constantly reminded, both by conventional physicians and alternative providers, that an ounce of prevention is worth a pound of cure. We need more treatments for preventing and managing diseases, thanks to the rising prevalence of lifestyle-associated and chronic conditions like obesity, hypertension, and IBS. According to the CDC, 6 in 10 adults [have a chronic disease](#); 4 in 10 have two. More than 40% of people around the world have .

Small wonder that the market for preventive healthcare technologies and services—valued at \$179.95 billion in 2018—is projected to reach \$414.84 billion by 2026, growing at a CAGR of 11.0% from 2019 to 2026.

### Verified Market Research Preventive Healthcare Technologies and Services Growth Projections



Source: BOLD Analysis, Verified Market Research

### Interest in personalized, holistic treatments is growing

Of course, if managing and treating our chronic conditions means putting up with expensive medications and inconvenient side effects, we're increasingly not interested. 77% of Americans believe that the [price of drugs](#) is unreasonably high. More than half have tried some form of [alternative medicine](#), both instead of and in conjunction with conventional medical treatment. Nearly 60% of adults [use dietary supplements](#).

And we've been trained to expect solutions that are tailored to our needs, both by "mass customization" in the consumer goods space and by conventional medical practitioners, who are leveraging developments in genomic sequencing and AI to develop more [personalized and precise treatments](#) for their patients.

### Trust in conventional medicine is declining

The conventional healthcare industry has not ignored the preventive care market. The 2010 Affordable Care Act (ACA) mandated that insurers provide preventive care at no additional cost to patients, and preventive interventions are widely recognized to be the most effective and least expensive when it comes to managing chronic disease.

Yet conventional providers have struggled to translate this awareness into action. Financial incentives in the medical system [do not align](#) with a focus on preventing chronic diseases, and public trust in the medical establishment is at an all-time low. In 1966, more than 75% of Americans had [great confidence](#) in medical leaders. Today, [only 34% do](#). This trust gap opens big opportunities for other types of health solutions providers.

### Consumers want and need control

Today's consumers expect to be the CEOs of their own health. They want to navigate a landscape of user-friendly, science backed products that put them in control of the way they prevent and manage diseases.

## Where the Opportunity Lies

Investment opportunities have emerged among companies that are harnessing new biological data to create non-pharmaceutical solutions that help people prevent and manage disease—and have the potential to reach billions more simply and effectively than ever.

**IN THIS SECTION, WE’LL EXPLAIN WHY WE BELIEVE THIS TO BE SUCH AN ATTRACTIVE CATEGORY FOR INVESTORS.**

### Why invest in Consumer Pharmaceuticals?

The need for Consumer Pharmaceuticals is as big as the opportunity. The world is aging quickly, and chronic disease is on the rise. Home diagnostics have made people ever more aware of the need to proactively manage their health. Furthermore, the market is young, and, though a few established players like Nestlé and Abbott Nutrition have invested heavily in the area, no dominant players have emerged.

The product landscape is broad and diverse. Enteral nutrition formulas help patients manage fat malabsorption. Beverage thickeners reduce the risk of aspiration for people with swallowing difficulties. Specially formulated low-protein foods help people manage inborn errors of metabolism. Capsules containing stool-derived bacteria and prebiotic fibers lower blood sugar spikes in people with type 2 diabetes.

Distribution channels are diverse, too. Many products, like Fiber Choice—prebiotic fiber supplements that help people manage IBS and functional dyspepsia—are available in retail pharmacies. Direct-to-consumer supplement providers have raised hundreds of millions of dollars and are widely seen as the industry’s next frontier. Viome, for example, analyzes people’s blood and stool and formulates personalized supplements that support gut, cellular, and immune health.

Medical foods, on the other hand, must be consumed under the supervision of a physician. Health insurance coverage varies across states and plans, and patients must work with their insurance carriers to obtain coverage and/or reimbursement. Increasingly, advocacy groups have been formed to assist them with this process. Many medical food companies have their own patient assistance programs; some even offer physician referrals. As the health insurance landscape continues to expand its focus on preventative care and wellness, products that help people maintain good health, manage chronic disease, and reduce the cost of care will win.

Consumer Pharmaceuticals bring rigor to an area that’s of enormous interest to consumers—wellness—which has often been derided as vague and pseudoscientific. Capitalizing on ever-more sophisticated lab and data analysis techniques, it is accelerating science and powering discoveries whose implications transcend categories. Indeed, there’s no clearer signal than the growing interest among traditional pharma companies in investing in the space: Alfasigma, Italy’s fifth largest pharmaceutical company, has invested in companies that developed probiotic medical



food for brain and metabolic health. Nestlé Health Science, meanwhile, has an extensive portfolio of science-based consumer health, medical nutrition, and supplement brands that address the needs of newborns to senior citizens.

### Areas of interest

Investors should look for companies that are harnessing sophisticated science to deliver clinically tested solutions—using formulations that are easy for people to access and consume, from food and drink to pills and powders.

Traditional indications that are targeted by Consumer Pharmaceuticals include:

- **Metabolic health:** Products that help manage metabolic disorders such as in-born errors of metabolism and hypoglycemia
- **Pediatric malnutrition:** Specific nutrient profiles aid the growth and development of infants and children with inborn errors of metabolism
- **Digestive health:** Compounds targeted for malabsorption help manage gastrointestinal and renal diseases such as IBD, leaky gut syndrome, and renal disease

Newer uses leverage increased understanding of the role that our microbiome plays in regulating other areas of the body. This is where the most exciting opportunities are, encompassing:

- **Oncology health:** Products that target different types of cancer and help patients manage the treatment process and gain better results
- **Cognitive and central nervous system health:** Products that help prevent, reduce or manage symptoms such as depression, Alzheimer and neuro-degenerative diseases.
- **Immune health:** Products targeted to prevent and manage immune system disorders and auto-immune disorders
- **Cardiovascular health:** Products targeted to prevent and manage cardiovascular diseases such as hypercholesterolemia and peripheral artery disease
- **Musculoskeletal Health:** Products for the prevention and management of bone, muscle and joint health and musculoskeletal disorders such as osteoporosis, sarcopenia, and fibromyalgia

The scale of the opportunities is enormous as they bridge consumer and pharmaceutical markets: the consumer side means the number of potential buyers is massive—the pharmaceutical side means price realizations can be significant.

# BOLD Investments

## INNOVATION SNAPSHOT

In this section, we highlight some of the exciting paths pursued by BOLD companies as they harness data to create personalized, effective, and consumer-friendly treatment options:

- **Seed** has leveraged clinical research from leading university research programs to create a proprietary line of pre- and pro-biotics that are sold directly to consumers.
- **Viome**, leveraging its proprietary RNA molecular testing, has built the largest dynamic microbiome and host response database in the world. Machine learning and AI are driving the development of their wellness, diagnostic, and therapeutic products.
- **SolareaBio** is at the forefront of creating microbe derived medical foods to target chronic disease.

All three companies are tackling the “Consumer Pharmaceutical” opportunity through a different, but highly effective, data lens.

## Seed

[Seed](#), in collaboration with leading scientists and research partners around the world, has developed a line of research-backed probiotics targeting outcomes across gastrointestinal, dermatological, oral, pediatric, and nutritional health in a prebiotic outer capsule.

Bringing many of the techniques of classic pharmaceutical research, Seed has developed a systematic process to identify, culture, validate, simulate, and test different probiotic strains. Their strain bank consists of probiotics generated at academic institutions and research partners around the world and is supported by extensive clinical data. An optimized biofermentation process, followed by further clinical research—the company validates its formulations in double-blind, randomized, and controlled trials—simulation, and testing ensures product quality and efficacy.

In 2020, Seed began conducting two trials, the first to assess the clinical effects of its DS-01™ formulation in treating irritable bowel syndrome (IBS), and the second under Health Canada approval to study the DS-01™ and its impact on post-antibiotic recovery. In parallel with its research efforts, Seed has developed a vibrant direct-to-consumer business supported by an active content and community strategy.

In Seed, we see the marriage of classical digital consumer marketing with data-driven pharmaceutical R&D, very much a reflection of the co-founders: Ara Katz and Raja Dhir.

Ara, an experienced consumer marketer, co-founded and served as CMO of mobile commerce marketplace Spring and was on the founding team of social commerce company BeachMint, where she launched six direct-to-consumer, influencer subscription brands.

Raja, a life sciences entrepreneur, brings unique expertise translating scientific research for product development with a track record that includes patented inventions to stabilize sensitive compounds to improve alpha-diversity of the gut microbiome.

The combination has resulted in a highly successful data-driven probiotic business.

## Viome

If Seed is focusing on probiotics, Viome is taking a broader look at the drivers of wellness with a holistic approach that's focused on food, probiotics, and supplements. Through its proprietary molecular testing platform, which measures gene expression, Viome identifies the trillions of active bacteria in a human's gut as well as host (human) response. The latter allows Viome to identify biomarkers, examine disease states, and investigate immune responses. This data set is continually augmented by phenotypic data.

Viome's platform includes data from over 300,000 people (and growing) and measurements over multiple testing periods, enhanced by extensive clinical trials spanning over 4 years. AI is used to analyze this cross-sectional and longitudinal data to discover what foods and supplements are ideal for an individual, their cellular health and gut microbiome.

From these insights, precision supplements and prebiotics + probiotics are specifically formulated for an individual from over 250+ premium ingredients optimized to restore health. The basis for a thriving and growing wellness business, Viome is poised to disrupt the more than \$100 billion supplement business with its precision Consumer Pharmaceuticals.

Interestingly, while the consumer business provides tremendous value in its own right, the Viome data set is also reshaping the more traditional pharmaceutical business. AI and machine learning, coupled with clinical trials, are paving the way for FDA approved diagnostics and therapeutics.

Today, Viome Life Sciences has become a global healthcare company, developing precision nutrition, precision drugs, and precision vaccines to help people live a disease-free life.

## SolareaBio

Finally, [SolareaBio](#) is at the forefront of using food to develop microbiome-based Consumer Pharmaceuticals to target chronic disease.

The company has developed innovative technologies to harness the power of microorganisms to modulate inflammatory processes in conditions such as osteoporosis in humans, leveraging their extensive capabilities in data science and microbial product development. Using AI, SolareaBio has identified new probiotics from microbes derived from over 200 fruits and vegetables to combine with prebiotics to develop Defined Microbial Assemblages™ (DMAs™). DMAs are dosed at 5-10 billion cells per dose (equivalent to >10 Kg of fruit or vegetable). DMAs provide transient functionality agnostic of engraftment; they don't need to attach and grow in the gut—they get passed and, in the process, enhance the signaling in the gut to the rest of the body. For example, DMAs produces anti-inflammatory short chain fatty acids and vitamin K2 to promote bone health.

The company has launched clinical trials to assess the effectiveness of their products in preventing and managing osteoporosis—an underdiagnosed disease and high health risk for postmenopausal women.

In the meantime, the Archer-Daniels-Midland company [recently announced a](#) partnership for the use of SolareaBio strains in food and beverage solutions—yet another version of Consumer Pharmaceuticals.

## What's Next?

The science behind Consumer Pharmaceuticals is accelerating quickly, powered by access to more data, more sophisticated analytical techniques, and more targeted delivery mechanisms.

It meets a world whose needs are accelerating just as rapidly, marked by increasing rates of chronic disease, growing concerns about the cost of managing those conditions, and heightened interest in finding personalized, data-driven treatment options.

As understanding and awareness deepen on both sides, Consumer Pharmaceuticals are well positioned for further growth and innovation. We expect these innovations to come not just in the form of novel targets and delivery mechanisms but in stronger feedback loops that empower consumers to more precisely target individual health needs and goals. With more information than ever about what ails us, and a more sophisticated option set, we'll continue to grow more confident in our ability to take control of our own outcomes.

It's an opportunity we predict will have both investors and traditional healthcare companies—and even tech giants who make connected health and lifestyle devices—raising a glass or a fork to good health at each step of their nutritional journey.

## About

BOLD Capital Partners is a venture capital firm that seeks entrepreneurs and companies who share a fierce vision of a brighter tomorrow. We identify emerging science and technologies that will disrupt and democratize massive markets, creating innovative solutions to humanity's greatest challenges.

Ysette Witteveen is a Venture Partner at BOLD and a Senior Principal Life Sciences Lead at Business Talent Group (recently acquired by Heidrick and Struggles.) She has an extensive background in commercializing life sciences and technology products, expanding relationships with the F1000, and investing in and growing start-ups

Teymour Boutros-Ghali is co-founder and Managing Partner at BOLD. He is particularly interested in businesses at the intersection of software and biology as well as business at the intersection of the virtual and physical worlds