Kit to be tried

Home test kits bring personalized nutrition home while technology promises more accuracy

By Marc Brush

The synthetic form of folate is called folic acid, a common supplement ingredient with widespread application in fortified foods. For about 20 percent of the U.S. population, it's also a methylation nightmare. "In individuals who have methylation issues, folic acid would be just about the worst supplement they could take," says David Perlmutter, celebrated neurologist and author of the bestselling **Grain Brain**. "It actually binds up the folate receptors otherwise activated by methylated folate."

Are customers of B vitamins being hurt by the supplements they take to feel better? That's just one biochemical question mark in an avalanche of questions that the supplement industry faces.

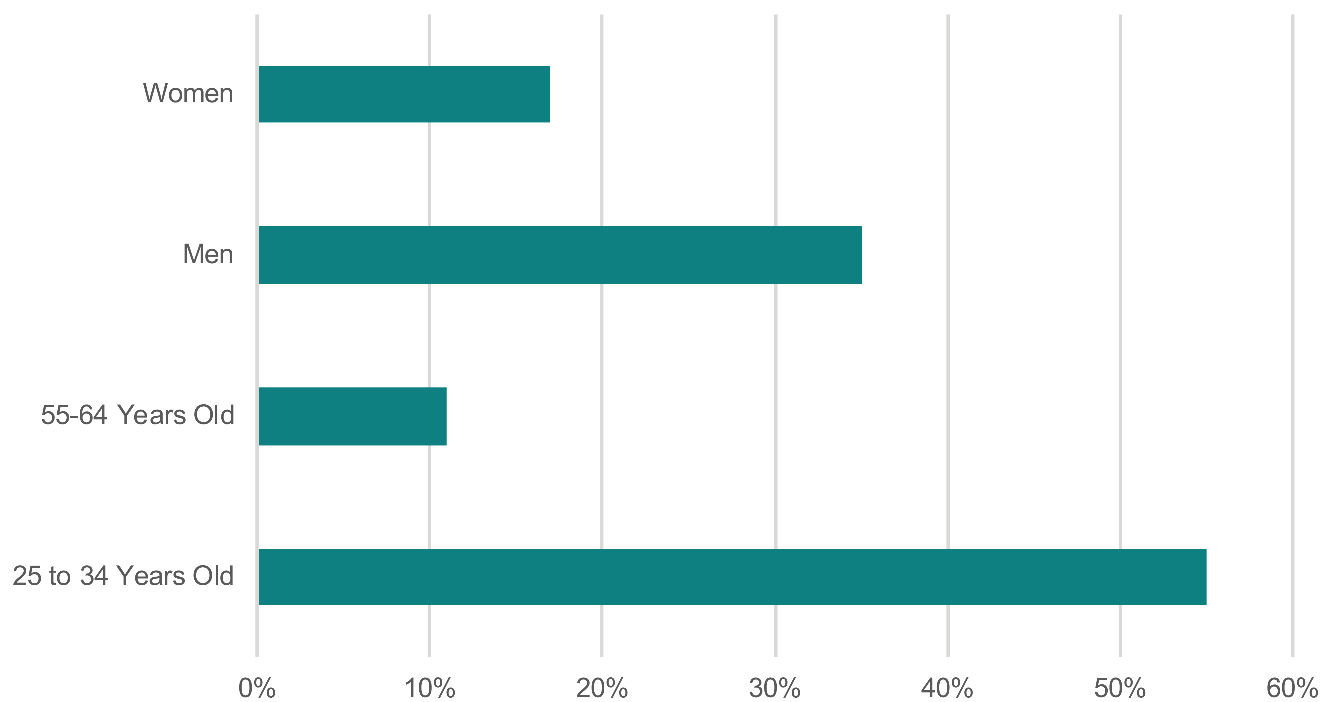
And now, with home test kits becoming both available and cheap, it's consumers asking the questions.

Methylation is a simple biochemical process in the body that helps regulate everything from cardiovascular function to liver detoxification and neurotransmitters in the brain. It's one of the clearest, earliest indicators of the opportunities in personalized medicine and nutrition, but it's still just one arrow in the quiver. "There are lots of tools we leverage these days to understand what

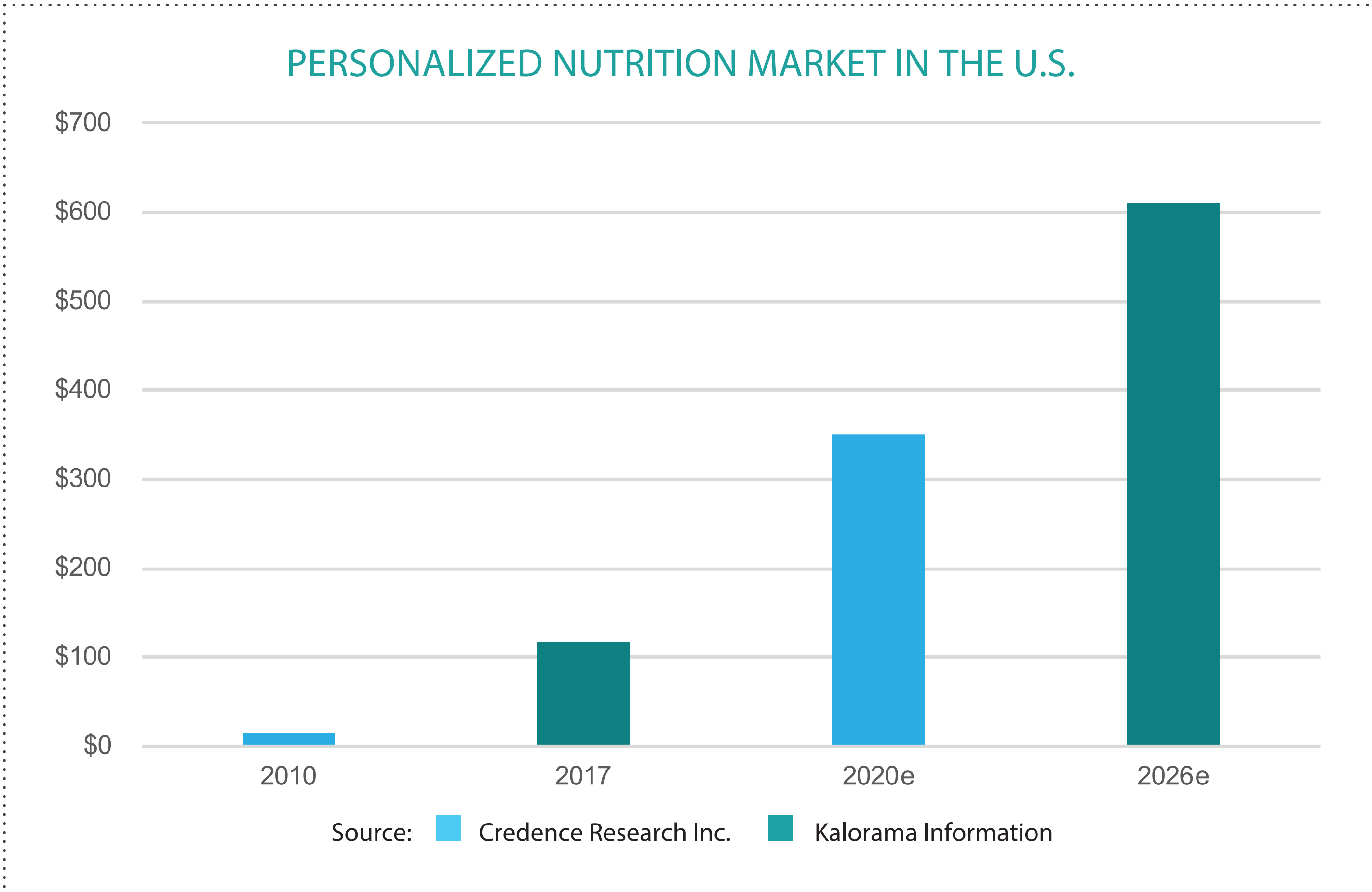
NBJ Takeaways

- Home tests kits are allowing personalized nutrition to leapfrog the practitioner's office and go straight to consumers
- Blood, feces and urine all have potential in nutrient monitoring
- Legal and regulatory ramifications of in-home test kits are complicated
- Silicon Valley is driving the technology, largely indeendently of the nutrition industry

CONSUMER INTEREST IN PRODUCTS CUSTOMIZED TO THEIR OWN DNA



Source: GlobalData



an individual might need in the area of nutritional supplementation," says Perlmutter. "It's not just measuring the levels of certain vitamins and nutrients in the blood." Mark Pedersen, SVP of R&D at **Capstone Nutrition**, sees a similar future on the horizon. "Take those 23 vitamins and minerals we go to all the time in supplements," says Pedersen. "You may be a super-absorber or you may be a non-absorber. This is going to take five, maybe ten years to play out, but the trick is to figure out what you don't absorb well and find a way around it. That's when you'll see better health outcomes, more longevity, better energy."

To get there, the supplement industry will need to incorporate emerging technologies—genomic sequencing; microbiome sequencing; metabolic testing through blood, saliva, stool, and urine; big data sets coming from wearables for sleep and exercise—and prepare to talk about efficacy in entirely new ways. What's ultimately at stake with the personalization trend is a more definitive answer to the critic's question about whether supplements actually work. It's a double-edged sword, of course. The answer could be *yes*, or in some cases *no*, but the smart players are positioning now to answer deeper questions around *how* to get to that yes or no. The nuance around *how* might throw whole segments of consumers off a company's radar, but the ones who remain will be more dedicated and loyal than ever before.

The concept of personalized nutrition has long evoked an image of a consultation in a practitioner office, but what happens when the consultation comes in a box that the consumer ordered on the internet? What happens when consumers start asking questions based on answers they found on their own?

In the here and now

The genomics wave kickstarted by **23andMe** has matured to a point where secondary markets are spinning off from that primary data set. Startups like **Habit** now offer plans that allow consumers to import 23andMe data and save $100. Others, like **StrateGene**, let customers upload that data for immediate and novel interpretations that speak to the latest-and-greatest thinking about individual ability to metabolize neurotransmitters, the presence of vitamin D receptor polymorphisms, or those key methylation pathways mentioned above.

Innovation is on display at every link in the personalization chain. Companies like **Vitamin Packs** are taking the health questionnaire to new heights with customized supplements built-to-order from customer responses. The diagnostic game is seeing dramatic advance swith a proliferation of sample media, from blood draws and finger pricks to saliva swabs, stool samples, and even urine strips. This speaks to some maturity in personalization as a marketable attribute with companies on the hunt for convenient, at-home solutions that connect an appropriate test to the right biomarker and any supplement that might then come into play.

More players working more tests equals more potential to finally put the pieces of the supplement puzzle together. Habit has abandoned its meal-kit platform for now but still offers DNA analysis combined with biomarkers off finger pricks around its nutrition challenge shake. **Orig3n** does a saliva swab for condition-specific DNA that speaks to absorption potential for all the major letter vitamins. **WellnessFX** still does blood draws, but that's just the tip of the iceberg for **Thorne**'s investment in this area. **BIOHM** and **DayTwo** are looking at stool samples to assess customer's microbiomes, or, in BIOHM's case, the "mycobiome" that includes gut fungi with the bacteria.

Closer to home in the supplement industry, several brands have begun to offer kits directly off their websites that tie to the ingredients they offer. **HumanN** and **Berkeley Life** have a nitric oxide saliva test to complement their beetroot powders, and **Vital Choice** sells a HUFA test for omega-3/6 balance to go with their seafood subscriptions and fish oils. As the **Organic & Natural Health Association** pushes for a vitamin D health claim linked to premature births, a partnership with **Grassroots Health** for at-home blood-spot testing of D and omega-3s promises to amass a large data set from citizen scientists that bolsters the lobbying effort.

"Blood collection is the single biggest pain point to scaling health and wellness."

- Paul Jacobson, Thorne

Is urine the holy grail?

Blood is not the only bodily fluid in the personalization crosshairs. "The problem with blood for some of our specific markers, like systemic inflammation and oxidative stress, is that you're trying to stop a working machine," says Andrew Dahl, CEO of **WellMetrix**, a startup looking to urine as the lab-free, inexpensive, convenient solution to wellness tracking via a bluetooth analyzer and app. "Oxidative stress is very dynamic, *so* dynamic that by the time you draw a blood sample from the body it's almost useless. Urine is end state. The byproducts come in like a detective after the crime's been committed, and they're stable and easy to measure." Dahl wouldn't look to urine to measure glucose, as an example, but for the metabolic markers in his mix, "urine is better than blood."

It's certainly more consumer-friendly. At $11 per disposable test strip, and an app that tracks eight biomarkers—with a concentration around inflammation and oxidative stress, two key sets of data for aging well—the consumer proposition begins to make more sense. The gear comes at about the price of a **Fitbit**, then $11 per quarter pays for nutrition, exercise, and supplement regimen efficacy tests. "The market for consumer health tracking and wearables has had a great run, but do you know if you're getting any healthier?" says Dahl. "We want to look at the things that age you and square the curve. After age 50—those are the big consumers of dietary supplements—how do you assess key metabolic biomarkers to slow down that parabolic decline in function and vitality?"

Consumer's capacity to tweak their regimen with various diet and supplement protocols over time creates a recurring revenue stream the likes of which 23andMe and **uBiome**, the pioneer in consumer sequencing of the microbiome, have yet to figure out. This leads Dahl to see the supplement industry as a natural home for his tech, which is one way the personalization trend might play out for adventurous brands looking to align with a future built around kits and product efficacy. "We're not entirely married to the idea of bringing this technology to market ourselves," says Dahl. "We're scientists, engineers, designers, so I can see the value in partnering with an established wellness brand name, preferably with a line of nutraceuticals that could benefit from this technology."

The path to true personalization

Thorne is the kind of company Dahl might be envisioning.

NBJ spoke with CEO Paul Jacobson as he prepared to move his entire company from Idaho to Charleston, SC, to accommodate growth. After the acquisition of WellnessFX in 2013 and a rebrand last year that clearly positions the company along two lines—supplements and at-home kits— Thorne has already distanced itself from core players in the professional channel by embracing the personalization trend. But this is just the beginning. Think of those direct-to-doctor and direct-to-consumer test kits as personalization light, given what Thorne's up to with its investments in **Pillar Health** and **Drawbridge Health**.

With Drawbridge, Thorne aims to break the blood barrier, pun intended. "Blood collection is the single biggest pain point to scaling health and wellness," says Jacobson. By investing in Drawbridge, a Silicon Valley start-up developing a "people-friendly system for collecting and stabilizing blood samples," Thorne aims to lead the market for blood biomarker analytics before that market has even developed.

Pillar Health, co-founded by Thorne and Drs. Joel Dudley and Chris Mason, is set to debut later this year, with early signs indicating that it will take the at-home kits offered through Thorne for common concerns like sleep, stress, fertility, thyroid, and heavy metals to a whole new level. Pillar aims to put all of the pieces together; pieces Thorne has been collecting and developing for years now. Microbiomics is in there, as are metabolomics and genomics. The analysis will be driven by AI and machine learning to build "multi-omics profiles" that optimize health and wellness in personalization made real for the consumer.

All of this raises a host of business concerns not often found inside the wheelhouse of a traditional supplement brand. There are federally-mandated privacy issues concerning the health data and CLIA and CAP certified labs to manage. "Should every supplement brand do this?" says Jacobson. "No. We're becoming a prevention and wellness tech company to do this. You have to invest a lot of money. The regulatory infrastructure you need to put in place is quite substantial. The legal infrastructure is quite substantial as well." Thorne is taking the long view on a long haul. "Don't forget that we bought WellnessFX five years ago to start this learning process," Jacobson says.

"There are lots of tools we leverage these days to understand what an individual might need in the area of nutritional supplementation."

- David Perlmutter, M.D.

"You may be a super-absorber or you may be a non-absorber. This is going to take five, maybe ten years to play out, but the trick is to figure out what you don't absorb well and find a way around it."

- Mark Pedersen, Capstone Nutrition

With so much of the innovation in personalized medicine and nutrition emerging from Silicon Valley, perhaps the supplement brands that want relevance in this space need to partner up with the technologies and tech brands disrupting toward a healthier future. "If you look at all of the new angles coming to prevention and wellness, we're the only supplement company involved here," says Jacobson. "Everyone else is from Silicon Valley. We think we have a jump on the market because of our institutional knowledge, our customer base, our in-house manufacturing expertise, and our relationships with companies like Drawbridge."

The decision to enter the diagnostic kit business rises to the scale of redesigning the business plan from the ground up. It becomes a decision to move more aggressively toward a future in which efficacy has real teeth for supplements and nutritional interventions that change lives become more possible. Will there be fallout? Perhaps, or maybe just increasing complexity. Take those healthcare practitioners, the obvious home for leading-edge diagnostics wedded to supplements. "We strongly support the practitioner—and in the testing business with Pillar Health we think we can improve their capabilities and capacities with patients—but we're also big believers that individuals have the right to their own health," says Jacobson. "The genie's out of the bottle. If you fight that trend, your business will suffer."