Nutritional Genomics: Field Is Growing, But Commercial Success Remains Elusive

Experts say consumer mistrust, lack of science and fuzzy regulatory environment are hindering progress

In the brave new world of nutritional genomics, the pursuit of the perfect diet might go something like this: You'd drag a cotton swab across the inside of your cheek, send a saliva sample off to a lab and, within days, get an analysis of a few dozen genes that influence how you process certain nutrients and, consequently, what your risk for certain diseases is. Perhaps you'd learn that you have a hard time processing B vitamins and flushing out toxins, that you are prone to inflammation or that fatty foods take an unusually tough toll on your cholesterol levels.

Armed with your genetic profile encoded on a credit-card-like chip, you'd head to the supermarket, slip your chip into a "gene-smart" interface and receive a customized shopping list, complete with functional foods and supplements geared toward your gene type—such as high-folate orange juice, omega-3s to combat inflammation or broccoli extracts to help you detoxify. On the way out, you might even slip your chip into a vending machine, which would mix you up a healthy drink based on your unique DNA.

Sound like science-fiction? Perhaps. But researchers, nutritionists and CEOs in the burgeoning field of nutritional genomics insist that such a day will come. The burning question now is: How long will it take? Or, in the minds of some early pioneers trying to stay in business in a field that has yet to make much of a commercial splash: Why is it taking so long?

"[Nutritional genomics] is in its infancy right now, but I believe it is going to explode," said Ruth DeBusk, PhD, RD, a Florida-based nutritionist and geneticist who serves as a consultant to food and supplement companies, including **Alticor**'s *Nutrilite* business. "Ultimately, it is going to have a major impact on food and supplement choices from a consumer standpoint."

From Obscurity to Notoriety

Nutritional genomics hinges on the notion that different gene variants prompt people to respond differently to certain nutrients, and that certain nutrients, in turn, can alter the way our DNA expresses itself. A relatively obscure science for decades, the field broke into the spotlight in 2000, with the announcement of the completion of a working draft of the Human Genome Project—a scientific milestone that piqued unprecedented interest in genetic testing. Today, more than 30 gene variants have been shown to impact lipid metabolism alone, and dozens more have been linked to the way we process toxins, respond to caffeine, handle inflammation and metabolize sugar—all critical risk factors for diseases such as heart disease, diabetes, osteoporosis and cancer.

Armed with this information, a few companies—including **Sciona Inc.**, **Interleukin Genetics** and **Genova Diagnostics**—emerged early on, providing nutrigenomic testing paired with nutritional advice for consumers. Today, more than a dozen such companies are in existence, with service prices ranging anywhere from a few hundred to several thousand dollars, and industry experts estimate that the DNA testing industry alone is worth between $30 million and $50 million annually. A few other companies, including **Metagenics**, now produce supplements geared toward people with certain common genetic variants. And several large food companies are quietly exploring what all this may mean for business. But, for the most part, the broad commercial acceptance many predicted has yet to materialize.

So why not? Experts point to everything from consumer fear about misuse of their genetic information to a lack of science to a fuzzy regulatory environment. But hopes are still high—as long as nutrigenomics is done right.

"There is a concern about the integrity of the field. The messaging has been very confusing to people and healthcare professionals are—for the most part—not on board with this yet," said Patrick Hanaway, MD, chief medical officer for Genova Diagnostics Inc. "To succeed, we have to simplify the message and stay true to what the science says."

What Does the Science Say?

Researchers say that while hundreds of possible gene-diet interactions have been identified for study, only a few dozen have solid science behind them. For instance, studies show that people with a certain variant of the MTHFR gene tend to have excess homocysteine (a risk factor for heart disease) in their blood—a problem that can be easily addressed by boosting intake of B vitamins. Other people have a variation of the vitamin D receptor gene that makes them particularly susceptible to caffeine's adverse effects (such as accelerated bone loss). Some have variants of the interleukin family of genes, which make them more prone to inflammation (a problem that can be addressed with omega 3 supplementation). And some people are missing a gene called GSTM, which is critical for purging the body of toxins (eating lots of broccoli can help compensate for this).

While the science is young and unfinished, many believe that sharing what we know up to now could save lives.

"From the scientific point of view, I would say the fruit is not ripe," said researcher Jose Ordovas, PhD, director of the Nutrition and Genomics Laboratory at **Tufts University**. "But from a practical point of view, it may provide some benefit."

Testing Comes First

Eager to bring the fruits of the Human Genome Project to the general public, Sciona Inc. broke into action in Europe in 2000. "We put together our business plan. Within six months we had our first million dollars in seed funding. And six months later we were running our beta tests," said Sciona Chief Science Officer Rosalynn Gill, a longtime genetic

researcher who helped bring the first consumer nutritional genomics test to market nearly eight years ago.

Today, Sciona (now based in Boulder, Colorado) offers the $299 *MyCellf DNA* nutrition program (which includes analysis of 24 genes, a lifestyle questionnaire and dietary recommendations), via the Web, select retail stores, health practitioners and spas. It has also partnered with product broker **Market America**, which also sells complementary supplements aimed at addressing gene variants revealed within the tests. In April, Sciona launched a new *MyCellf DNA* fitness program (available only online for $299), which looks at genes associated with body composition, exercise recovery and cardio fitness.

Initially, some consumer watchdog groups vocally opposed Sciona taking the direct-to-consumer route so early in the game, alleging that the tests "mislead consumers," that they wouldn't have a physician on hand to help them make sense of the results and that the information gleaned could someday be used to exclude them from insurance or employment. Under pressure from consumer advocacy group **GeneWatch UK**, which has been particularly vocal about the potential misuse of nutritional genetic testing, 13 retail stores in London pulled the Sciona tests from their shelves in 2002.

Despite such roadblocks, Gill stands by her company's products and its decision to bring the tests directly to the consumer. "That was a very important business decision for us," she said, stressing that her company does not diagnose disease, but rather helps people promote better health. "We felt it was important to share with consumers their own genetic information—to give back to the public some of the huge private and public investment in the Human Genome Project." Sciona is a privately held company, and Gill declined to share revenues or number of tests sold. However, she did say the company is growing.

Interleukin Genetics also took a direct-to-consumer approach for its products, partnering with its major shareholder Alticor (parent company to multi-level marketer **Amway**, online seller **Quixtar** and supplement maker **Nutrilite**). Alticor sells Interleukin's Gensona General Nutrition Genetic Test and Gensona Heart Health Genetic Test through its multi-level marketing arms, as well as dietary supplements aimed at compensating for genetic flaws found in those tests. The company also sells a genetic test, through health practitioners, aimed at predicting propensity for periodontal disease. Tests range from $100 to $250.

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Interleukin reported a net loss of $1.9 million in the first quarter of 2008, and revenues of $2.7 million. The company hasn't posted a profit in several years, acknowledged CEO Lew Bender, and many independent sellers have stopped offering it's products.

Bender points to consumer confusion over Interleukin's test results as a major culprit. "If you get our test results and look at the report, you won't know what the heck it means, because it hasn't been written well," he said. To help overcome this problem, the company is overhauling its Website, re-writing its genetic results reports to make them more reader friendly and exploring ways to sell its products via other sales channels, including retail. It is also trying to distance itself from Alticor's supplement arm somewhat. "We do not want to have the appearance of a conflict of interest, so we are not going to push any one therapy over another," said Bender.

Genova Diagnostics, which has offered genetic testing since 2002, has taken a different approach, providing its tests (priced anywhere from $200 to $500) exclusively through health practitioners and keeping a distance from supplement and functional foods companies eager to come up with solutions to problems found in the tests.

"That is the one thing that has differentiated us from the start," said Hanaway, who would not disclose the company's sales figures. "We have been against direct-to-consumer testing, particularly when it is tied to particular supplements. We believe a physician should be there to help people understand what their risks are. And when the genetic testing is used as a loss leader to help sell a product, it totally compromises the integrity of what is being done."

In recent months, other Web-based genetic testing companies have also hit the market, including **23 and Me**, **Navigenics** and **DeCode Me**, to name a few. These companies test for predisposition to everything from lactose intolerance to obesity to type 1 diabetes.

But just how nutritional genomics testing should be sold—direct-to-consumer; through practitioners only; in collaboration with supplement companies, or not—remains a big debate, and the U.S. federal government has not been shy about chiming in.

In 2006, the **U.S. Government Accountability Office** issued a scathing report, concluding that direct-to-consumer genetic tests "mislead consumers by making predictions that are medically unproven and so ambiguous that they do not provide meaningful information." It also suggested that "personalized supplements" based on genetic testing (some costing as much as $1,200 per year) contained the same ingredients as "typical antioxidants that can be found in any grocery store for about $35 per year."

Industry executives and longtime researchers decried the report as misinformed and poorly conducted. But the damage to the field's public image was

done. That, combined with a lack of regulatory oversight for testing facilities, has further slowed progress, industry experts say. "One key issue has been lack of regulatory clarity. That has led to some confusion in the marketplace and in the investor space," said Sciona's Gill, who is working with the **U.S. Food and Drug Administration** (FDA) to figure out just how to regulate the testing industry, without lumping companies like hers that provide nutritional advice alongside those that test for more serious genetic diseases.

Beyond Testing

Testing aside, several companies have begun to take the discussion a step further, asking not only what picture our genes paint for us, but also how we can change that picture with specific products.

Metagenics, a company founded 25 years ago "to help patients achieve their genetic potential through targeted nutrition" has long used nutrigenomics in product development, helping the company formulate nutraceuticals that address common "nutrigenomic expression patterns," the company reports. In essence, Metagenics works off of the second principal of nutrigenomics—that nutrients can alter the way DNA is expressed—to develop products such as *Kaprex*, a plant-based joint relief product said to modulate prostaglandin production, and *Insinase*, which targets cells to promote healthy insulin function. Chief Scientific Officer Jeffrey Bland stresses that his company does not create products to "neutralize bad genes."

"We evaluate the most common forms of genetic uniqueness that relate to specific health conditions and we design our product to address those," he said. Metagenics sells only through healthcare practitioners. In 2007, the company grew its revenues 21% and is on track to finish 2008 with more than $200 million in revenue, Bland told *Nutrition Business Journal*.

Brian Meshkin, president and CEO of **Salugen Inc.**, believes consumers want something more. Thus far, the three-year-old San Diego, California-based company has launched two pilot programs to test what it bills as "customized individual solutions based upon genes." First came *GenoTrim*, which used genetic testing to create a *Made For Me* formulation to "address your body's specific roadblocks to optimal weight." Then came *Spa Gen*, which used genetic testing to create "a one-of-a-kind supplement" to promote wellness. Now, the company is reviewing its data from the pilots, is working to bring down the cost of its supplement packets (which reached into the hundreds of dollars) and is planning its distribution strategy, Meshkin said.

"No one does a lab test for the sake of doing a lab test," Meshkin noted. "When [people] take a lab test, they are doing it to treat [a problem], to do something about it. The customization model is the true promise of nutrigenomics."

That promise could require a wait though. Products like Salugen's tend to make research pioneers like Ordovas queasy. While the science behind the genetic testing is sound, Ordovas said, the link between specific supplements and changing the trajectory of certain diseases is tenuous at best.

"I am very concerned about those companies that have taken that route of pairing simple genetic analysis with a solution in the end that doesn't have a scientific basis."

Meanwhile, many investors simply aren't up to speed on what nutrigenomics is.

Another entrepreneur, Fredric Abramson, had the idea in 2000 of creating a vending machine that mixed your soft drink based on your DNA. He pulled together a distribution plan and enjoyed some early, positive press, but has been shocked at the lukewarm response since.

"We just haven't been able to break away from early stage," said Abramson, who teaches biotechnology at **Johns Hopkins University**. "The food companies and dietary supplement companies don't understand genetics. We haven't found anyone interested in funding it." The tide may be turning, however. In May, President George Bush signed the Genetic Information Nondiscrimination Act, which aims to protect people from discrimination in the workplace or by their insurer due to genetic information. That single piece of legislation alone could have a powerful impact on consumers once leery of any kind of genetic test.

"People were worried that their genetic information was this powerful stuff that their employer or insurance company could get a hold of and that was a major barrier from a consumer standpoint," said DeBusk. "I feel like that barrier has now been erased."

And food giants **Nestlé** and **Uniliver** are already exploring ways they can consider genes when creating new foods. In 2001, the companies jointly hosted a nutrigenomics conference in the Netherlands. And scientists at the Nestlé Research Centre in Switzerland have made nutrigenomics a research priority for several years.

Given all of this activity, maybe—come a few years from now—that supermarket of the future might not seem so sci-fi after all.

The *NBJ* Bottom Line

The nutritional genomics movement holds great potential for the U.S. nutrition industry. In fact, we believe that nutrigenomics could be the force that drives mature supplement categories back into double-digit growth rates, as consumers search for proven ways to prevent disease and live healthier, longer.

But before more companies are able to make good on this potential and begin moving out of the start-up phase with their products—as Metagenics has been able to do—they must develop a clearer and unified message about the science behind nutrigenomics, its potential and its limitations. They also must invest in further high-quality research to convince regulators of nutrigenomics' efficacy and safety.