White Paper

Claims substantiation in Southeast Asia

Generating claims that inform Consumer 2.0

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Significant needs, vast opportunities

The importance of data-driven, scientifically valid claims to gain consumer understanding and trust in the crowded me-too field of consumer health has never been greater. Gone are the days when endorsement by popular media personalities and well-made mass-media ads boasting of "Smoother skin!" "Whiter teeth!" etc. were enough to boost product uptake. Today's consumer is self-focused and digitally empowered. They want trustworthy information to compare and choose products for their individual needs to maintain wellness, prevent disease and treat illness.

The challenge is to uncover the secrets to the consumer's trust, such as:

- **What do consumers really think about a product vs. its competitors?** New technology is unlocking consumer secrets hidden in Big Data and social media – secrets they may be reluctant to otherwise reveal in surveys and focus-groups
- **How are consumers really using your product?** Read on to learn how the discovery of unexpected uses have yielded entirely new benefits that are then backed by scientific substantiation, creating lucrative new products
- **What are consumers really looking for when buying?** Not just a product. They want a solution to their specific problem; it must fit their lifestyle and deliver meaningful benefits

Unearthing these secrets is key to increasing value share and product innovation. The product must tell a story that consumers trust. The good news is that there are powerful new tools available to help select the right claims to substantiate – those that optimize trust – and to gather the evidence needed to secure regulatory approval.

These tools include deep consumer insights, real-world evidence, and secondary data from wearables and smartphones. Together these are transforming deep consumer insights generation, making it faster, more efficient, more accurate. These are truth detectors to uncover secrets buried in consumer data.

The foundation of excellent claims selection and substantiation, however, rests on two pillars:

- First is to approach claims strategically. Consumer Insights, Marketing, Medical, Regulatory, R&D and Legal must work as one to maximize the likelihood of success and avoid pitfalls.
- Second is to use a proven methodology that begins with a white space analysis – all possibilities explored and step-by-step claim concepts that resonate with consumers, clearly differentiate the product, can be substantiated at a cost commensurate with the value delivered and can pass regulatory approval.

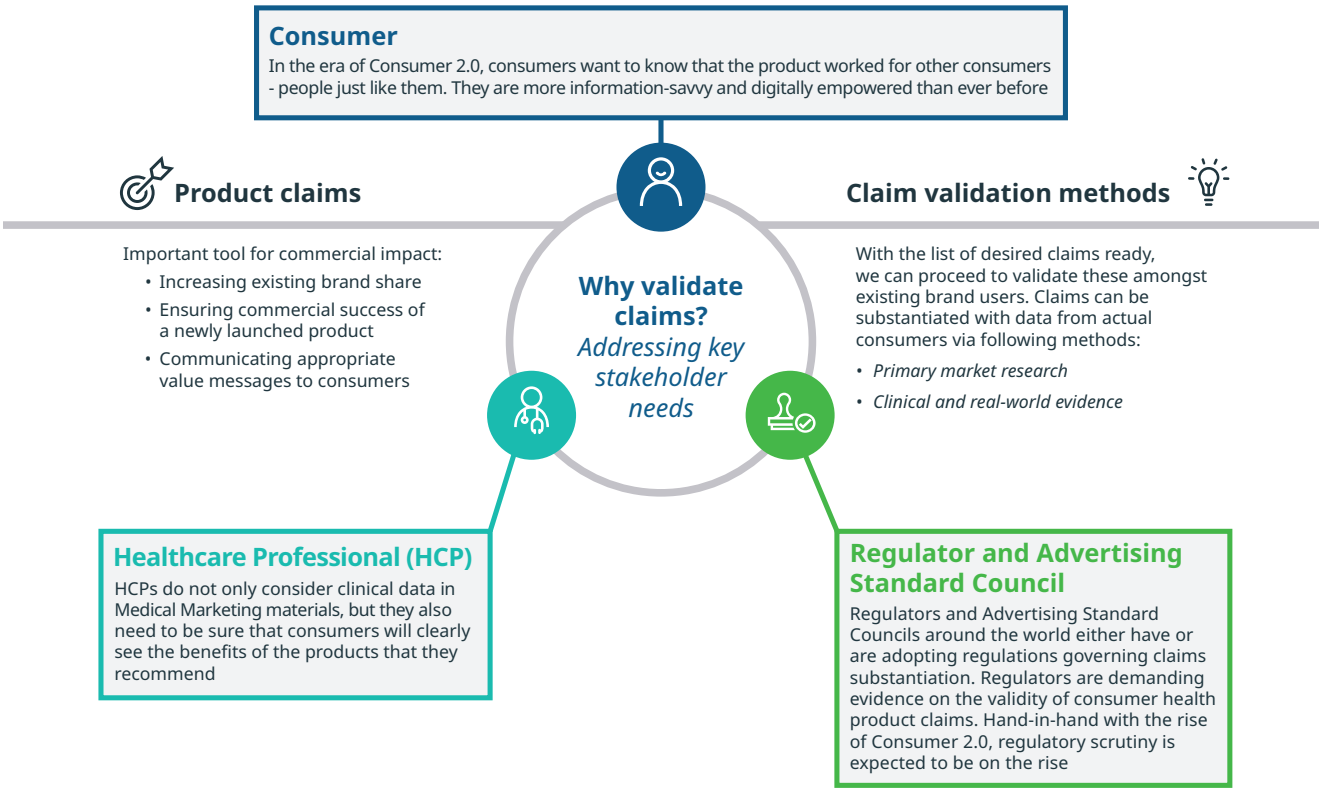
Southeast Asia's fragmented regulatory framework makes it especially important to tap into market-by-market knowledge of claims substantiation requirements. Thinking strategically, leveraging new technology, deep knowledge of markets and consumers: this is the magic elixir to success in the region.

Claim selection and substantiation

The rise of 'Consumer 2.0', in other words, consumers who are information-savvy and digitally empowered, represents changes in demographics and lifestyles worldwide. They are seeking prevention instead of treatment; they want improved product offerings and reliable data. In addition to the traditional claims derived via primary market research methodologies, consumer health brands are increasingly leveraging scientific claims[#] to educate and get buy-in from this new breed of consumer.

Every claim, regardless of the type, must be substantiated. Some regions of the world have adopted harmonized regulations governing claim substantiation; others have not, like here in Southeast Asia (the exception being cosmetics claims, where progress is being made in ASEAN guidelines harmonization). This makes local knowledge especially important to avoid costly re-working of substantiation research to meet local requirements. Do it once, do it right.

Figure 1: Testing consumer claim concepts



Having an overarching strategy is critical. Best practice is to have a company-wide claims strategy that crosses product categories and product lines. This creates a consistent methodology to choosing the best approach for each claim. Claims have multiple purposes and must satisfy scrutiny from distinct audiences, hence the need for a cross-functional team to oversee the process:

- **For consumer health companies:** differentiate the product, gain value share. Typically led by brand managers.
- **For consumers:** buy products that do the job. Typically led by Marketing & Insights.
- **For regulators:** empower consumers with credible claims appropriate for mass-media advertising, protect them from false and misleading claims, and prevent unfair trade practices. Typically led by R&D, Medical / Regulatory Affairs and Legal.

Claims substantiation approaches vary depending on the product and type of claim. *Table 1* shows examples suitable to clinical research the most scientifically rigorous and expensive approach and real-world evidence* and those suitable for market research (focus groups, surveys, etc.).

Claims generated through clinical and Real-world studies

Clinical trials generating scientifically robust data or evidence from literature are needed to support most health claims related to disease risk reduction.Real-world evidence (RWE) can be used support or complement clinical efficacy and safety in sub-populations and incorporating patient experience. Efficacy claims are carefully reviewed by regulatory authorities and therefore, it is important to carefully design the clinical trial or RWE end-points to obtain supporting evidence for substantiation.

Factors to consider include:

- Who is the target audience?
- Is the claim meaningful to consumers?
- Are you most interested in demonstrating efficacy, safety or effectiveness and quality of life?
- Is a pilot study the best way to go for an initial hypothesis or should you start with a large, definitive trial?
- What is the best study design? Open label? Randomized double blind? Others?

Table 1: Claims substantiation approaches

APPROACHED VIA MARKET RESEARCH	APPROACHED VIA CLINICAL AND RWE
• Consumer Testimonial Claims • Expert Endorsement Claims • Perceived Performance • Satisfaction Claims • Sensory Claims	• Comparative Efficacy & Effectiveness • Health Improvement Claims • Overall Health and Wellbeing • Safety and Tolerance Claims • Structure/Function Claims

* Section 505F(b) of the FD&C Act defines RWE as "data regarding the usage, or the potential benefits or risks, of a drug derived from sources other than traditional clinical trials" (21 U.S.C. 355g(b)).[1]

Real-world evidence provides another avenue to gain the validation needed. Data from consumer reported outcomes in the real world can complement clinical findings in a meaningful way as well integrate consumer insights gathered through traditional market research.

Claims generated through primary market research approaches

Claims appropriate for market research include consumer preference and satisfaction, e.g. "Mothers prefer…"; sensory claims, e.g. "less greasy", "improved taste" etc.; and consumer-claimed performance, e.g. "firmer skin", "less puffiness" etc. For market research the priority is to make sure there is a robust, geographically representative sample size in order to achieve a 95% confidence level, the usual target.

Regardless of the approach taken, it is vital that a cross-functional, company-wide team oversees the process, said GlaxoSmithKline's Sunitha Shanmugam, Regulatory Affairs Director, Consumer Healthcare Southeast Asia.

"For multinationals like GSK it's important for key messages to be consistent globally," Sunitha said. "You can't promote Panadol® in the UK for pain and say it's for fever elsewhere. Central control by a multi-disciplinary team ensures that every part of a claim is tight, especially for claims involving efficacy, health, function and safety. It's a sanity check."

Dr. Sheryl Tan, Head of Medical, ASEAN Consumer Health, Bayer, said that understanding the patient or consumer journey before and after they use the product is key.

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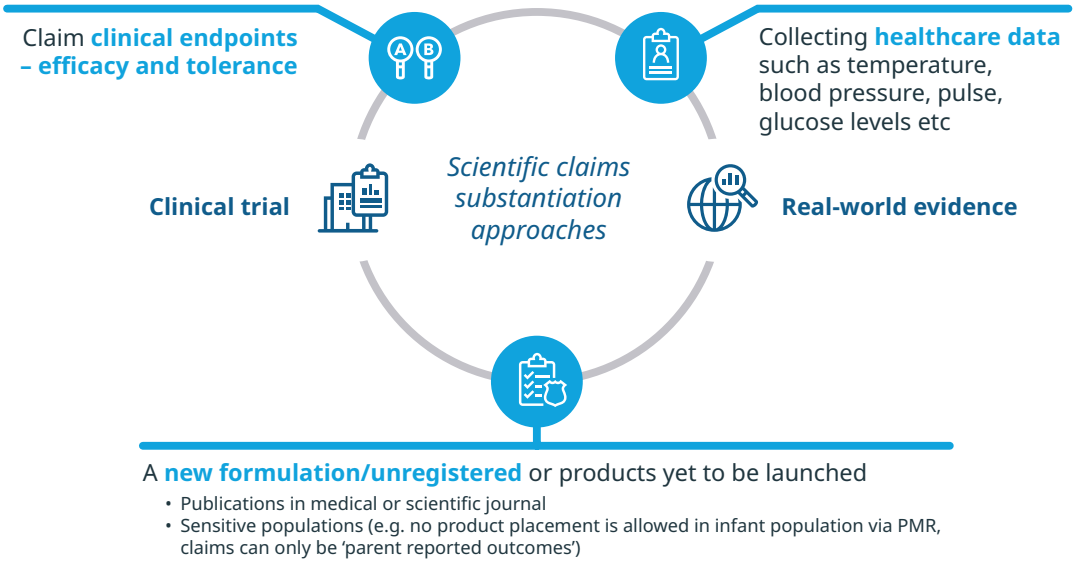
– Sunitha Shanmugam, Regulatory Affairs Director, Consumer Healthcare Southeast Asia, GlaxoSmithKline

In Bayer, said headquarter-generated strategy and consumer insights are augmented by market-level research, locally. Sheryl gave the example of how consumer market research in Vietnam resulted in Bayer enhancing its local advertising tagline for Berocca®, a B-vitamins rich multivitamin supplement.

Robust scientific evidence substantiates Berocca's benefits in mental alertness and physical energy, and this aligned with a consumer insight of a 2 p.m. power nap commonly practiced in Vietnam.

Utilizing this insight, Bayer enhanced the local tagline in Vietnam to "Have Your Berocca at 2 p.m." – positioning it as an alternative to daily power naps. "This campaign positively resonated with our Vietnam consumers", Sheryl said.

Figure 2: When to opt for scientific claims substantiation approach over primary market research



Claims derived from data collection involving any of the below are treated as Interventional studies. As a prerequisite ethics approval is sought before initiating such studies

Food & nutrition claims

Let's take a deeper dive into claims selection and substantiation in the food and nutrition category. There are no harmonized nutritional labeling and claims in Southeast Asia (whether harmonized or country-by-country, food and nutrition labeling regulations are informed by global Codex[$] guidelines). Here regulations vary at a country-level, making the process complex – trade barrier.

Nutrition labels convey information about the food's nutrition content and are designed to help today's health-conscious consumers make better choices. This creates opportunities for companies to introduce healthier alternatives to meet consumer demand – and to make nutrition and health claims that capture the consumers' attention and wallet.

The rise of Consumer 2.0 is creating opportunities for consumer health companies to develop and promote healthier products. However, there also are barriers. Nutrition labeling is expensive, especially if done incorrectly. It is complex and there is a lack of high-quality labs to provide analytical services, to name a few.

In Southeast Asia only Malaysia requires labeling for general foods at this point. There is, however, mandatory labeling for special dietary use foods, foods enriched or fortified, and foods making nutrient claims (Thailand requires labels for some snack foods, e.g. potato chips, popcorn, etc.). Voluntary labeling, if it follows a prescribed format, is allowed in some countries within Southeast Asia.

The region's regulatory agencies also face challenges. For example, some beneficial nutrients such as iron run the risk of being overused. Consumed in proper amounts iron is essential to preventing anemia. However, when overused or overfortified in food, it can cause hemochromatosis and other health problems[2].

Regulatory bodies and advertising councils in Southeast Asia put consumer safety and understanding first. They review evidence to ensure that claims are valid. Adding to the importance of advertising councils in the region, is the rise of digital promotion, with consumer health ads appearing on consumers' web browsers across multiple countries.

Despite the overall lack of regulatory rigor and consistency, health and nutrition claims are already common in Southeast Asia. The next step is to develop clear, consistent regulations at the regional level on labels and claims. IQVIA is joining industry associations and other organizations to facilitate discussion with governments and regulators to achieve that.

Table 2: Global view on nutritional and health claims

These claims refer to statements or suggest that a food or product has certain properties

TYPE	SUB-TYPES	EXAMPLES
Nutritional	Nutrient content	"Source of…", "High in …", "Free of …"
	Nutrient comparative	"Less than …", "Reduced …", "More than …"
Health	Nutrient function	"Calcium helps build strong bones and teeth." *Note: "Milk helps build strong bones and teeth" is unacceptable; claims can only be made for a nutrient (calcium) in a food, not the food itself.*
	Disease risk reduction	"Three grams of soluble fiber from oatmeal may reduce the risk of heart disease."

$ The Codex Alimentarius, or "Food Code" is a collection of standards, guidelines and codes of practice adopted by the Codex Alimentarius Commission. The Commission, also known as CAC, is the central part of the Joint FAO/WHO Food Standards Programme and was established by FAO and WHO to protect consumer health and promote fair practices in food trade.

ASEAN guidelines on health supplements[3] call for different levels of evidence for three types of health supplements:

- **General or nutritional claims** require general evidence from at least one authoritative text, scientific journal, scientific opinion from regulatory authorities, etc.
- **Functional claims** require a medium level of evidence, e.g. at least one piece of compulsory evidence from human studies, scientific papers etc. and an additional piece of evidence from scientific animal studies or documented history of use, etc.
- **Disease risk reduction claims** require the highest level of evidence: compulsory scientific evidence from human intervention study and additional evidence from authoritative papers, monographs etc.

Big Data & the big picture: Innovation in claims

In his book "Everybody Lies"[4] , author Seth Stevens-Davidowitz writes about how data can unveil hidden truths about consumers. He cites Peter Theil, an early investor in Facebook, who says that great businesses are built on secrets – either secrets about nature or people.

> *"Marketers and product developers focus too much on customer profiles and correlations unearthed in data, and not enough on what customers are trying to achieve in a particular circumstance."*
>
> *— "Know Your Customers' 'Jobs to Be Done", Harvard Business Review, September 2016.*

Blockbuster drugs are built on unlocking the nature's secrets to better therapies (imagine the value of understanding the biological pathway of Alzheimer's disease); the same holds true for discovering the hidden needs of consumers in nutrition, supplements, over-the-counter (OTC) products, cosmetics, etc.

Some of the biggest consumer-product success stories in recent years have arisen from discovering that consumers were using a product in unintended ways. For example, it was found that some consumers were taking

the long-established cold remedy from Vicks, NyQuil™, to help them sleep, even when they weren't sick. That led to ZzzQuil™, a formula clinically tested for occasional sleeplessness, offering consumers a restful night's sleep without the other active ingredients in the cold formula[5].

It's vital to focus on what consumers are trying to do when they purchase a product ("the job to be done") vs. just the product itself. For example, a mother packing her daughter's school lunches may buy boxed drink "A" because of its nutritional claims. Instead of just looking at why she purchased "A" vs. competing products, researchers should look at what the mother was really trying to accomplish – pack a healthy lunch for her daughter. That opens a rich new field for exploration.

Dr. Volker Spitzer, Global Principal R&D at IQVIA Consumer Health, gives a vivid example of what McDonald's discovered by looking at the job to be done vs. the product alone. McDonald's wanted to learn why drive-in customers were purchasing milkshakes vs. other types of drinks to take on long commutes. What they found was that it was not the taste of milkshakes, but rather the drivers' desire for a longer-lasting drink that wouldn't slosh out of the cup. The result: McDonald's focused on making thicker milkshakes to satisfy the commuters' real need.

It's not just about the function of the product; there are powerful social and emotional dimensions to customer preferences, and hence claims that resonate with them, as well. That is where starting with a "white space" analysis at the start of claims research can lead to big discoveries.

When claims go wrong: Consumer apathy, regulatory enforcement

How can claims go wrong? Several ways. Dr. Spitzer gives an example of FruitFlow®, the first European Food Safety Authority-approved natural cardio-protective functional ingredient. Despite strong scientific evidence supporting its claim "Clinically proven to promote healthy blood flow", products containing FruitFlow are still not very well known by consumers.

FruitFlow remains a niche ingredient after more than a decade on the market. Most consumers probably don't understand the link between blood flow and heart-health benefits, unlike claims for cholesterol-lowering ingredients, for example, which are well established and understood. In short, even world-class scientific evidence accepted by regulators is not always enough, on its own, to gain consumer trust[6].

Another way is by picking the right claim but doing the wrong type of research, resulting in substantiation that doesn't pass regulatory muster or ends up costing more than an alternative method that would have been cheaper and/or better.

And the most highly publicized and expensive way things can go wrong is by making and promoting claims that result in regulatory action and penalties. For example, in early 2019, the U.S. FDA accused 17 nutritional-supplement makers of selling more than 58 products with improper claims that they can prevent, treat or cure serious diseases, including Alzheimer's. The companies involved often marketed their products via websites and social media.

The future

The future of claims success lies in stronger scientific evidence that translates to meaningful and relevant claims mirroring Consumer 2.0's needs. The former can be developed by new technologies and techniques, especially through data and decoding derived from social media, personal devices and health apps.

In addition, claims and billing data and product and disease registries are important sources of evidence for Rx-to-OTC switches. Because real-world data is consumer-generated, it is de facto consumer-centric. It delivers insights essential to answering the vital question: "What claim should I focus on?"

The future is undoubtedly digital. Recognizing this, IQVIA has formed an exclusive partnership with ObvioHealth's proprietary platform to conduct clinical, real-world evidence, and market research studies digitally. Virtually any smart device can be linked to the IQVIA virtual research platform – smart watches; activity and sleep trackers; Bluetooth-enabled scales, blood pressure monitors, etc.

Recently IQVIA used a web-based quantitative survey in Thailand to help one of its clients extend the benefits of a baby skin-care product from "treatment" to "prevention." About half of the 300 participating mothers used the product after every diaper change, whereas the other half only used it to treat their baby's skin rash. The result: an enhanced understanding from consumers that regular usage offered better protection.

Social listening is providing valuable consumer insights unfiltered by research intervention. Monitoring what's being said online by regular consumers can reveal candid consumer insights in near real-time. The data can be used in multiple ways – competitive intelligence, the consumers' decision journey, brand perception, and influencer identification to name a few.

Keys to success

Best practice in claim substantiation begins with a "white space" analysis - the strategy, needs and resources. A full examination would include the competitive landscape evaluation - what are the competing products and their claims, regulatory approvals needed in each market, access to market-by-market consumer insights and need for additional research.

Both GSK's Sunitha Shanmugam and Bayer's Sheryl Tan said that understanding the consumers' needs is always the priority. Sunitha cautioned against the old-school approach of taking a product's key attribute and trying to "retrofit" it to meet a consumer need. Deeply understanding your consumers – their lifestyles and social, cultural and economic factors in addition to health needs – is essential. Sunitha also emphasized the importance of "consumerizing the language" used in a claim – taking the language of science and medicine and converting it to statements that consumers can easily understand and relate to. Sheryl described it as "giving the consumer a reason to believe" in your product.

New technologies can help companies quickly and efficiently gather the scientific and real-world evidence needed to gain regulatory approval and the consumer behavior and perception research to craft claims that resonate in the marketplace. The trick is to choose the right approaches from among many options.

Another key to success is to understand "how to talk" to regulatory authorities in each country. Sunitha said this goes beyond the dry guidelines about what authorities require. Practical experience in how to present substantiation research to authorities can significantly improve the odds of claim substantiation approval.

And finally, after all the work has been done and the product launched using the new claim(s), a new round of listening must begin – how are the claims impacting sales? What is being said on social media? What are the changes in consumer perception?

Listening...the key to uncovering secrets that lead to success.

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Airene Valencia heads the Primary Market Research practice for Consumer Health in South East Asia. She leads a team of highly experienced senior consultants in Singapore HQ, servicing Multinational Consumer Health clients for their consumer science and insight work in APAC, AMEA and LATAM. Airene has over 15 years of solid in-market and regional experience spanning new product development, market understanding, concept and communication development studies, brand health trackers, and claims testing. She is an expert in qualitative methodologies and techniques ranging from ethnography, in-depth interviews and focus group discussions, shop-alongs and virtual quals. Airene holds a Bachelor Degree in Social Sciences, Majoring in Behavioral Science from University of the Philippines, Manila.

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Swapna Kondapuram leads the Consumer health clinical strategy for APAC, across multiple categories particularly OTC & Nutrition. Her role involves engaging client R&D stakeholders for clinical studies linked to new product development, registration & claims substantiation. She has 12 years of in-market and regional experience spanning new business strategy, product lifecycle management, strategic marketing & post M&A commercial integration in Consumer Health, Pharma, Biologicals & Telecom in Europe & Asia. She brings with her Consumer health category expertise in VMS, OTC, Topicals, brand extension & innovation in Europe & Asia with leading CH MNCs such as Sanofi, Novartis & GSK Consumer Health. Swapna holds an MBA in New Market Development from HEC Paris, France. She has a BSc. Microbiology, Genetics & Chemistry with a Post graduate diploma in Bioinformatics.

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Dr. Volker Spitzer has over 27 years of R&D/Innovation and medical marketing experience in the consumer health OTC, natural ingredients industry, consulting and academia. After his career start as a university professor (pharmaceutical science) he continued in different leading global management roles in R&D, open innovation, licensing/M&A and scientific marketing at Roche, DSM Nutritional Products, Bayer Consumer Health and analyze & realize / Zaluvida. Since October 2017 he is Global Principal at IQVIA leading Consumer Health R&D/Innovation services. Volker has a background in chemistry/pharmaceutical sciences, holds a Ph.D. in Food Chemistry and is state-certified in food law. Volker documented his passion for science and consumer health also by more than 65 publications incl. text books and original research papers. He is also an experienced chairman and speaker at international conferences and acted for many years as a member of the board of directors of the German Association for Applied Vitamin Research.

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