

NUTRACEUTICAL STRATEGY

No Need to Compete: Mental Wellness Naturals

Natural ingredients can complement what drug companies offer and use their campaigns build awareness and demand for products.

by Volker Gallichio

From autism to dementia, well-funded drug companies use sophisticated marketing tactics to build visibility for their new portfolio of mental wellness products. As they do, their campaigns dramatically expand awareness of the mental health conditions. This trend also creates profitable opportunities for natural ingredient makers to expand into these same markets – and to do so without entering into direct competitions with drug makers (pharma).

Natural ingredient products can be positioned to complement drug-based solutions on the market.

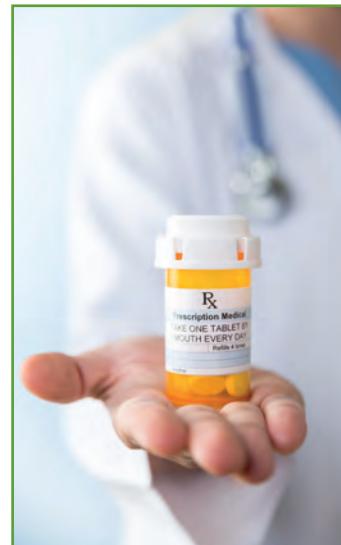
This is a “tailwind” strategy that focuses not on capturing the entire market category, but rather a subset of that category: breakthrough symptoms.

To leverage this strategy, it's important to evaluate your specific opportunities within these expanding markets.

There are four steps to this process: assess the potential

growth of particular mental wellness markets; determine how your product fits within the market by assessing unmet needs; examine the markets and new medical research to identify your own best tailwind approach; and finally, assess how to reach your market – even with a very modest, limited marketing budget. Let's walk through these steps.

1. Assess the Potential Growth of Mental Wellness Markets: The figure shows six high-poten-



tial mental wellness categories: migraine, autism, Alzheimer's dementia, insomnia, general anxiety disorder (GAD) and depression. Expanding successfully into any market requires making certain there is sufficient market size and growth to justify the investment. Clearly, all six of these categories satisfy this objective, with depression as the largest market at US\$14.5 billion in 2018 and migraine as the growth leader, projected to expand by 18 percent through 2025.

MENTAL WELLNESS MARKET TRENDS

	RX OPTIONS <i>Most popular</i>	2018 MARKET SIZE	GROWTH THROUGH 2025	AVERAGE COSTS*	CAM OPTIONS
MIGRAINE	Triptans, Topiramate CGRP (Small And Large Molecule), Egrot Alkaloids	\$7.8 bn	18%	\$9 - \$558	Butterbur, Feverfew, Magnesium, Riboflavin, Coq10
AUTISM	Selective Serotonin Reuptake Inhibitors, Sertraline, Fluoxetine	\$3.1 bn	17.9%	\$9 - \$587	L-carnosine, Fish Oil, Vitamin D3, L-carnitine, Ayurveda
ALZHEIMER'S/DEMENTIA	Cholinesterase Inhibitors, Memantine, Monoclonal Antibody-based Immunotherapies, ACE Inhibitor	\$3.8 bn	17.5%	\$5 - \$263	Lutein, Zeaxanthin, Turmeric, Sage, Pumpkin, Gingko, Vitamin E, Fish Oil
SLEEPLESSNESS	Benzodiazepine, Zolpidem, Eszopiclone, Zaleplon, Belsomra	\$4.1 bn	4.2%	\$9 - \$370	Melatonin, Magnesium, Valerian, Ashwagandha, California Poppy
GENERAL ANXIETY DISORDER	SSRI, SNRI, Benzodiazepine Alprazolam, Buspirone	\$7.5 bn	2.5%	\$7 - \$399	Kava, Rhodiola Rosea L, Passion Flower, Lavender, Lemon Balm
DEPRESSION	Selective Serotonin Reuptake Norepinephrine Reuptake Tetracyclic Monoamine Oxidase Benzodiazepines	\$14.5 bn	2.5%	\$9 - \$166	Sam-e, Probiotics Bacillus, B Vitamin, St. John's Wort, Saffron

* Does not include cost of doctor's visits.

2. Assess How Your Product Can Answer Unmet Needs: Looking at the chart, you see the most popular prescription drug options. To determine your possible entry strategy, assess what needs the drugmakers are already answering. Then, determine what needs remain unmet which your ingredients can help address.

In the migraine category, for example, triptans, topiramate, ergot alkaloids and the new CGRP injectables all focus on migraine

prevention. Do complementary and alternative products have any power to capture a share of the market? They do for instance: supplements like butterbur, feverfew, magnesium, riboflavin and CoQ10 are increasingly used for migraine by consumers and recommended by physicians. This is because they fill several unmet needs:

- **Side Effects and Tolerability:** Compared to prescription drugs, supplements of-

fer fewer and milder side effects, have long-term safety data making them attractive to children, the elderly and those with other health conditions.

- **Cost:** The monthly cost of supplements can be lower than the insurance copays for Rx drugs.
- **Effectiveness:** Supplements such as butterbur and feverfew have shown effectiveness that is competitive with prescription drugs.

Using migraine as an example, the sidebar examines how to assess differentiators you might use to position products in your own market niche.

3. Assess Your "Tailwind" Strategy Within the Market Category: All six of the high-potential mental wellness markets previously mentioned are major markets. While major drugmakers have budgets sufficient to compete for market leadership, there is a smarter, more efficient approach for the makers of natural ingredient products. This is the "tailwind" strategy.

There are prescription-drug leaders in each of the six mental wellness categories – but there is no "silver bullet" cure in any category. Furthermore, even if symptoms are well controlled, there are still breakthrough symptoms.

This is where your opportunity exists. General Anxiety Disorder (GAD), for example, might be fairly well controlled by SSRIs (selective serotonin reuptake inhibitors). During a particularly stressful time, however, patients may experience breakthrough anxiety. Do they increase the dosage of their SSRI and also increase their risk of the drugs' toxic side effects? Or, might they complement their SSRI with a proven natural product that can ease the breakthrough anxiety without risk them of additional serious health consequences?

Clearly, there is a market for such complementary products.

The tailwind strategy is not to ask consumers or physicians to replace prescription drugs with your product, but to add those products to a care regimen.

Another example of the tailwind strategy is to capitalize on research already getting exposure in the mental wellness community.

Recently, medication Overuse Headache (MOH) has emerged as an important issue. This is where frequent use of prescription or even non-prescription painkillers creates a dependence that, when use of the painkillers is reduced, triggers the condition – headache – they were

► Migraine: An Example of Assessing Market Opportunity

State of the Market: Episodic or chronic migraine affects more than one billion sufferers worldwide. A number of clinically credible alternative therapies can effectively and safely help prevent migraines. Recently, a breakthrough in understanding the mechanism particularly has led to the discovery of a new neurotransmitter involved in migraine – a peptide named CGRP. Novel monoclonal antibody drugs that block CGRP are proving effective at preventing migraine. Multiple CGRP products were recently approved by the FDA. Studies presented for the approval process show a 50 percent responder rate (the number of patients who experience a 50 percent or greater drop in migraine frequency) of 43-62 percent. The drugs require injection (from monthly to once every three months). The treatment cost is US\$6700/month and getting insurance to cover these drugs can be challenging.

Cost of Therapy: CGRP-blocking drugs cost US\$6,700/year. Some insurance companies do not include these drugs in their formularies. For insurers who do provide coverage for these drugs, co-pays and other restrictions often apply. Compare this to the relatively modest monthly cost of supplements.

Effectiveness: The 50 percent responder rate for a purified butterbur preparation was 68 percent in one published placebo controlled clinical trial and 45 percent in another. This is competitive with the anti-CGRP data. In fact, given these responder rates, butterbur is arguably the best-in-class product for migraine based upon efficacy alone.

It is the demonstrated efficacy and safety of butterbur – and of feverfew, magnesium, riboflavin and CoQ10 supplements – that have previously led to their inclusion in evidence-based treatment guidelines for episodic migraine prevention published by both the prestigious American and Canadian neurology associations.▼

LEADING NATURAL INGREDIENT FOR MIGRAINE

	Diener et al Eur Neurol 2004	Lipton et al Neurology 2004	Pothmann et al Headache 2005
SUBJECTS	N=60, 18-60 yrs	N=245, 18-65 yrs	N=108, 6-17 yrs
DESIGN	RCT	RCT	open
DOSING	2x2 25 mg (100 mg)	2x 50 mg (100 mg) 2x 75 mg (150 mg)	50 – 150 mg depending on age
DURATION	12 weeks	16 weeks	16 weeks
RESULTS	Mean attack frequency/month reduced from 3.4 to 1.8 (p=0.0024) 45% responders*	48% attack reduction (150 mg) (p=0.0012) 68% responders* (150 mg)	63% reduction of migraine attacks 77% responders [†]

Responder = improvement of migraine frequency $\geq 50\%$

intended to treat. Two key research findings have created major opportunities for natural ingredient migraine products: First, that the majority of these rebound headaches were actually migraines; and second, that just using migraine prevention on its own improved MOH. Migraine research is a key aspect of the tailwind strategy.

Knowing how to mine research is a key aspect of the tailwind strategy. Here is just one more example of the role it can play in expanding your products into a new market.

4. Assess How You Will Reach Your Market: Drugmakers use major marketing budgets to reach consumers and physicians. You probably have a much vastly smaller budget for expanding into new markets. That's why it's critical to understand how to reach your targets by deploying unconventional tactics.

Start with data on what prescriptions are being written in your category and who exactly is writing them. There are a variety of processes for obtaining this information.

In the United States, this information is available from a prescription database, and available for purchase. With this data, you can identify which physicians within a particular market are

➤ Research Snapshot: Lutein and Zeaxanthin

Lutein and zeaxanthin are now well-known as ingredients in eye supplements. This is the result of a key study: the Age-Related Eye Disease Study (AREDS2). This research was designed to determine if daily intake of certain vitamins and minerals reduced the risk of cataract and advanced age related macular degeneration. The positive results – particularly for lutein and zeaxanthin – created widespread awareness of supplementation's value for eye health, and lead to a lucrative growing market for lutein and zeaxanthin-based eye vitamins.

But that's not where the research ends: college students taking these supplements reported better grades, better sleep and higher energy levels. Studies are also showing impressive improvements with seniors and Alzheimer's patients. Clearly, the market potential for lutein and zeaxanthin continues to grow. Makers of products with these ingredients have the opportunity to use the tailwind strategy as physicians and consumers become ever more aware of the benefits.▼

prescribing which drugs. Narrow your focus and assess how many specialists you can reach. In Canadian and European companies, where a database is not publicly available, information on specialists is available as a starting point.

Emphasizing specialists such as neurologists, gerontologists, OB/GYNs, etc., lets you hone in on the physicians likely to have the greatest interest in the complementary product you offer – and who are most likely to recommend it to patients.

Once you know the size of your audience, determine the costs for reaching it. The average field sales pharmaceutical rep makes 1,870 physician calls per year at an average cost (plus

expenses) of \$110,000. With an unconventional approach (a dimensional mailing, for instance, packed with research) you can reach ten times that many – 18,700 physicians – for the similar cost of US\$112,200. In our experience, this kind of campaign builds awareness (and results) faster than traditional sales calls.

In terms of reaching consumers directly, digital communications and social media play important roles in engaging and sustaining your target audience. As you launch, however, reaching consumers also means creating an Amazon strategy.

Amazon is critical and can be made to work for you even with a small budget and margins

(which is a topic all on its own).

What's Next?

From regulatory realities to creating materials that speak credibly to your new audience, challenges remain. But by going through the steps above, you will have a solid understanding of your opportunities for expanding into one of today's profitable mental wellness markets – and the differentiators and research you can use to support your success.▼

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