

# Holistic Primary Care

• NEWS FOR HEALTH & HEALING® •

NUTRITION & LIFESTYLE

## “Clinically Validated Daily Intake” (CVDI™) - An Antidote to Supplement Fairy Dusting

BY JANET GULLAND  
*Contributing Writer*

There is a troubling yet common practice in the nutritional supplement industry known as “fairy dusting:” a manufacturer includes a tiny amount of a popular herb or nutrient in a product, then lists the ingredient on the product label, even though the dose is far too small to be effective.

In many cases, no one would ever know that the doses are minuscule because supplement companies are not required to disclose the levels of a particular ingredient if it is part of a “proprietary blend.”

Federal regulations do require dose declarations for basic vitamins and minerals for which the Institute of Medicine has established Recommended Daily Allowances (RDAs). But those rules do not apply to a wide range of herbs and specialty nutrients for which there are no RDAs.

The RDAs are an imperfect system, to be sure. Many nutritional experts consider

them to be too low for a lot of key nutrients. But the RDAs at least provide some basis for making informed choices. For a large number of supplement ingredients, even this basic level of guidance is lacking.

It is the supplement manufacturers themselves who are determining the recommended doses, and you either have to trust their judgments about efficacy and safety or conduct your own extensive research.

Consider turmeric, for example. There is no RDA or any other federal standard to define how much of this bright yellow herb would probably give health benefits. Both whole turmeric and curcumin — one of the plant’s main bioactive compounds — have been shown in human clinical trials to confer health effects: inflammation reduction, lipid regulation, and eye health, among them.

In these studies, the benefits were obtained at specific doses ranging from hundreds to thousands of milligrams. Whole turmeric products, which typically contain 2%-5% curcumin, have clinically validated health benefits at

daily doses of 1000 mg and above. Concentrated curcumin extracts have been validated at doses as low as 100 mg. Yet one popular, widely available natural multivitamin includes just 6 mg of turmeric extract per serving: a prime example of fairy dusting.

In many cases, the fairy dusting is intentional. It reflects economic or practical considerations: Smaller doses are cheaper and fit better into fewer capsules.

Even companies that try to do the right thing sometimes use ingredients at doses far below those validated in human studies. It may be because they are selecting their doses based on animal or even in vitro studies. Or, in the case of some herbal products, it may be due to reliance on “traditional use” rather than on human trials.

For many ingredients, there are no large clinical studies; historical or traditional use may be the only dosing guidance.

Whatever the reason, supplements that contain minute amounts of key ingredients are less likely to deliver the expected benefits.

Suboptimal dosing leads to suboptimal health outcomes, which can erode consumer and practitioner confidence in ingredients that would otherwise be helpful if taken at the correct dose.

### **CVDI: A New Standard**

Rather than waiting for the government to step in, one nutritional supplement company is taking matters into its own hands.

“It’s time to change the current industry practices and embrace transparency in order to reassure consumers that they are getting effective doses of the ingredients they take,” says Dan Lifton, CEO of Quality of Life Labs.

The company, best known for AHCC®, a product derived from shiitake mushrooms, has been working with several physicians and nutrition experts to develop a new reference standard for dietary supplements: Clinically Validated Daily Intake (CVDI™). The CVDI is the minimum daily amount of an ingredient that has been found to produce a positive health effect in human studies.

For example, the CVDI for whole turmeric is 1000 mg, because that is the lowest dose at which turmeric has been shown to benefit health in human research.

While the RDA specifies the lowest amount of an essential nutrient needed to prevent basic deficiency, the CVDI provides guidance on the lowest amount of an ingredient (essential or otherwise) needed to match clinically validated therapeutic doses.

The CVDI works on a percentage basis, just like the RDA. A supplement that supplies 1 gram of turmeric per day provides 100% of CVDI, while one that supplies 4 grams daily provides 400%.

The CVDI Guide, available online at [www.CVDIguide.org](http://www.CVDIguide.org), not only specifies the minimum clinically validated levels but also provides the full dose range at which an ingredient has been tested in humans.

For example, the CVDI for turmeric is 1,000 mg, but the highest dose tested in reputable published clinical research is 6 grams. Knowledge of the dose range is relevant not only for evaluating efficacy but also for confirming safety. Clinicians can use this information to advise patients on staying within dose ranges shown in studies to be safe and free from adverse events.

Quality of Life has committed to including at least 100% of the CVDI for every single

ingredient in every one of their products. The company now hopes to inspire the entire supplement industry to adopt the same level of integrity and transparency.

### Clinical Validation Is Essential

Consumers are constantly bombarded with claims that supplements are “evidence-backed,” “research-driven,” and “science-based.” But what do these claims really mean? A nutritional ingredient supported by a single in vitro study can qualify for all three of these claims.

Adding to the confusion is the fact that many consumers are unfamiliar with the precise definition of the term “clinical,” which means “relating to the observation and treatment of actual patients rather than theoretical or laboratory studies.” Therefore, the term “clinically validated” – unlike the terms mentioned previously – is actually somewhat more meaningful because it indicates that a compound was shown to be effective in humans.

Animal studies and in vitro experiments are essential steps in the scientific method, but they are simply unreliable indicators of efficacy in humans. One research review on active pharmaceutical ingredients found that 90% of compounds shown to be effective in animals did not demonstrate a benefit in human clinical trials! Dose selection based on in vitro or animal studies is dubious, since animals differ from humans in their anatomy, physiology, and metabolism.

This is why the dose of an ingredient should ideally be in line with the doses used in valid clinical studies.

### “Clinically Proven” vs. “Clinically Validated”

It is important to be aware that the Federal Trade Commission (FTC) has challenged the use of the term “clinically proven.” Until a few years ago, the FTC ruled that in order to claim a product is “clinically proven,” the marketer had to produce two well-designed, independent, double-blind, placebo-controlled human studies.

Subsequently, the company behind POM Wonderful pomegranate juice challenged the FTC in court. In 2015, a Washington, DC, circuit court upheld an FTC ruling that POM Wonderful – which has spent millions of dollars on clinical research – was making unsubstantiated disease claims for its pomegranate products. However, the court also ruled against the FTC’s two-study standard, insisting that this was not justified.

Despite this apparent victory for the nutrition industry, many responsible supplement companies have come to see using the term “clinically proven” as a regulatory risk.

Some companies, including Quality of Life, have chosen instead to use the term “clinically validated,” which has a different connotation.

The power of the CVDI reference standard is that it informs consumers of the minimum dose of each ingredient that has been shown to be effective in humans. Patients will no longer need to guess and hope for the best.

Quality of Life’s leaders hope consumers and practitioners will embrace the new CVDI, and that it will help ensure that people aren’t wasting their money on products that are practically guaranteed not to work well because they contain insufficient levels of active ingredients.

### Words Matter.

How to read between the lines of supplement marketing claims:

<p><b>An ingredient backed by just 1 <i>in vitro</i> study can be described as:</b></p> <ul style="list-style-type: none"> <li>- Evidence-backed</li> <li>- Research-driven</li> <li>- Science-based</li> <li>- Extensively studied</li> </ul> <p><i>Ask to see copies of human clinical studies.</i></p>	<p><b>Look for ingredients that are validated by one of the following:</b></p> <ul style="list-style-type: none"> <li>- Clinical studies</li> <li>- Clinical research</li> <li>- Human studies</li> <li>- Human clinicals</li> </ul> <p><i>They mean the same thing: “clinical” means “human.”</i></p>	<p><b>There is no such thing as “animal clinical studies.” That’s an oxymoron.</b></p> <p><i>Please remember and share with others: “If it’s clinical, it was studied in humans.”</i></p> <p><i>If it doesn’t say either “clinical” or “human,” its efficacy is unproven.</i></p>
---	--	---

*For more information, please visit [www.CVDIguide.org](http://www.CVDIguide.org)*