



## Innovation without a home: Pharma-grade science in a restrictive regulatory landscape

[Functional Ingredients](#)

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Developing health products requires a unique combination of science and creativity. These days, the number and quality of minds involved in developing health products is greater than ever before. And when great minds get to it, great ideas come alive. I am fortunate to contribute to many of these exciting projects, and have had a front-row view of the challenge of turning a vision into a successful dietary supplement. I am not talking about the usual twists and turns of a normal product launch. Our industry presents a unique paradox: innovation that has outgrown the bounds of the regulatory framework.

A case in point: A biotech company generates some great, original science that opens up a new avenue for a preventative therapy that has never been used before. They know that a specific ingredient will work because of the biology involved (they discovered it!). The company has a choice to go for drug status, or to do something they never considered in the past - make a dietary supplement. The cost and time to market for a supplement is infinitely smaller than for a drug, and so this sounds like a good way to go. And the new offering is not even a luxury drug, it's something that can make a difference in people's health, so it fits in our neighborhood.

So the biotech begins to investigate what it will take to develop a dietary supplement, and starts developing their pitch. They can tell a great story to investors and manufacturers, but when it comes to consumer messaging they run into problems that may sound familiar...

"We discovered a complicated thing that happens in the body (sophisticated mechanism) that causes a harmful, degenerative process (ugh, so that's how it works...), and this ingredient will prevent it in this clever way (Ooo! I can see how that would really make a difference!), so in short, this ingredient PREVENTS [insert favorite Western disease here]."

ARRRGH!!

"In this industry sir, that's 'helps maintain a healthy heart,'"-- the same claim that can be made on at least a score of other products. There's no opportunity to use the packaging to communicate the ingredient's uniqueness and its powerful impact.

I've seen this obstacle become the deciding factor in a "no" from investors, cutting off funding that would have moved a highly promising venture forward.

At the [Next Innovation Summit](#), March 5-6 in Anaheim CA, I'll be presenting case studies of novel ideas and

the courageous people trying to push the envelope of the current landscape. [At my talk, "Innovation Without a Home: Pharma-grade Science in a Restrictive Regulatory Landscape,"](#) we'll include those coming from within and without the industry, discuss their stumbling blocks and share their attempts to overcome restrictions. We'll also leave time for a discussion of potential changes and future directions. Looking forward to seeing you there!



*Risa Schulman PhD, founder of Tap-Root, is a functional food and dietary supplement expert, professional speaker and writer. Our experience includes assisting prominent and pioneering food and dietary supplement companies, ingredient suppliers, and companies shifting into these spaces. Biotechs, investment bankers, law firms and design firms also use Tap-Root's services to further their activities in the industry. [www.Tap-Root.biz](http://www.Tap-Root.biz)*

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