# **Pharmaceuticals Opinion Piece Sample**

# **Chapter 1: The Supplement Industry- An Overview**

How important is accurate knowledge when it comes to seeking and using natural healing methods for your body? Let’s start by using an analogy.

I want you to take out a piece of paper and fold it in an accordion style, alternating folds until the entire sheet is creased, then shape it into a fan by folding it in half lengthwise.. Then, I want you to open it up carefully and move it back and forth, causing air to move unevenly toward your body. Now, what have you created? Obviously, you’ve just created a hand fan.

A hand fan is nothing more than another way to cool the surface of your skin. Seems simple. Maybe even a bit silly. Yet, the reality is, with nothing more than a simple, folded piece of paper, you’ve created an 100% all natural way to take an overheated section of your body and cool it down. It requires nothing more than manipulation of the air being pushed toward the area of your choice.

This works because the pushed air *supplements* your skin with a cooler force that does its job naturally, even though it is using the same hot air that caused the overheating in the first place.

Effective consumable supplements work in a similar way. They have to be manufactured (concocted) of materials (chemical elements) that will force (cause) *a desired reaction in* a particular part of a human body.

The purpose of this book is to bridge what supplement users think they know versus what they actually know. Most people don’t know a thing about how supplements really work or even what they are even made from, yet they use them anyway. And sometimes they overuse them.

Could that action be Deadly? Possibly. Dangerous? Of course. So, what does a user need to know to remove those unwanted elements from the equation?

## The Promise and Peril of Supplements

First off, you need to realize that the consumable supplement industry as a whole operates under a ‘***profits before people’*** mentality. There are countless stated cases of some companies being caught red-handed, putting profits before people. Some of which I will share with you shortly.

To combat this mentality, government agencies have listed the bare minimum standard practices at which various goods are accepted or rejected for human consumption.

This baseline is called the GMP (***Good Manufacturing Practices)*** and it seeks to conform to the guidelines recommended by the relevant agencies. Those agencies control the authorization and licensing of the manufacture and sale of food and beverages, cosmetics, pharmaceutical products, dietary supplements, and medical devices, etc.

One of the most shocking offenders of this statement is a company known as Blackstone Labs. Blackstone Labs was indicted in March of 2019 for selling dietary supplements containing numerous illegal ingredients, including, but not limited to SARMS: an acronym for ***selective androgen receptor modulators***. Better known as *steroid alternatives[[1]](#footnote-0)*.

Blackstone Labs has been selling products in supplement retailers and nutritional health stores across America, not counting the addition of their own online sales. The indictment alleged that the owners of Blackstone Labs *knew* that their products contained illegal ingredients, yet despite this, they were still promoting sales through a distribution network covering the entire country.

The most surprising part is that Blackstone Labs had been in business for seven years prior to this indictment. That means for seven years they were willingly placing products that could do great harm to people into homes throughout the entire country.

The indictment, which you can readily find online, shows that they knew exactly what they were doing from the get-go. Seven years should be more than enough time to catch their mistakes and stop their illegal activities[[2]](#footnote-1).

Wouldn’t you think that, at some point in time, someone in the company would have asked *why*? Someone had to know that what they were doing was 100% illegal and wrong.

Perhaps they figured it was a victimless crime. While that’s hard to imagine, the amount of time involved illustrates they had plenty of opportunities to correct the course. Opportunities they ignored at all costs in the pursuit of profit .

People who want to get bigger, faster, and stronger will buy nutritional supplements religiously. In theory, Blackstone Labs provided something that would give them that result. However, as they did so, they took away the most important thing that you as a consumer have: *the power of choice.*

The power of choice comes from knowing what's in the product. At that point, you can then make an educated decision if it is for you. My issue with Blackstone Labs is not that they adulterated their product. It’s that they didn't inform consumers what they had done.

Look, I'm not here to judge if someone wants to chemically alter their body. That’s their choice. But when you, as a manufacturer, spike your product with additives that are on the bounds of legality and you don't let someone know you're doing it, you're causing someone undue harm without them even knowing.

## The Regulatory Landscape and Transparency

Most supplements available for sale today are nothing more than expensive samples. The products aren't tested. There's no scientific research conducted. There's no open source third-party studies. Instead, they rely on “legacy data” that is old and grossly out of date. Legacy Data exists from prior to 1994. On October 14, 1194, the Dietary Supplement and Health Education Act, known as the DSHEA Act, was passed. This federal law defined and regulated the sale of dietary supplements. The most impactful part of this law is that it allows manufacturers to make general health claims about their products without going through the Food and Drug Administration to prove safety or efficacy. In other words, you can say whatever you want about the benefits your product can provide, *without having any evidence to actually prove it.*

What that means is any supplement you find online or that you see as you walk through a store that has vitamins, minerals, and various ingredients that were in commerce prior to 1994, can make claims about the efficacy of the product *without any level of required confirmation from third party studies or human trials.* This is a prime example of no transparency!

Let’s use coffee as an example of what I mean. Coffee is about as harmless of a “supplement” as you can get, right? Imagine that you are at your local Whole Foods. You open up your favorite coffee brand and give it a nice deep breath to smell those beans. And when you put that coffee bag into your shopping cart, you’ve decided to vote with your dollars. You’re telling that brand they’re doing a good job and you’re rewarding them for that.

Here’s the thing with coffee: it has caffeine. And caffeine is habit-forming. If you're a coffee drinker, there's a good chance you know what I mean. You wake up in the morning, hurry to get your day started, head toward the kitchen, and immediately begin to brew a pot or a cup of your favorite coffee.

If you’re out and you’re forced to start your day without it, you may avoid talking to your coworkers as you get to the office. You might even start getting a headache. Chances are high you might not feel like you're even ready for the day.

Getting back to label transparency: Was there anywhere on the bag or label that specifically warns you about what could happen if you ingest caffeine? Does it say anywhere that you should not consume caffeine for two consecutive days? Not at all. In fact, nowhere on or around that coffee bag does it mention the words’ “habit-forming”.

Taking it a step further, it also doesn’t say anywhere on the bag or box from where the beans were sourced or with the specificity of the testing that it went through. From the very moment the beans were collected (harvested), to the moment it ends up in your coffee cup, there has been absolutely no transparency or sharing with you of the dangers or the negative elements of drinking coffee.

Yet, you never even consider this. Afterall, this is most likely a coffee that you’ve enjoyed for years. And besides, your retailer is a store you trust and you have shopped there for many years. You trust the fact that it's safe simply because it’s on the store shelf. You trust the fact that it's good for you and most likely feel that there is nothing wrong with it.

All of those thoughts (excuses, really) are nothing more than false statements or feelings with *absolutely no truth backing them up.*

To the contrary, there are endless numbers of printed and/or reported claims to the exact opposite. Take five minutes on Google and search for “coffee beans + mold.” You’ll quickly be overwhelmed by the number of lawsuits against coffee brands that contain such high levels of mold that they are causing serious, long-term health issues.

That's just one of thousands of examples regarding the lack of transparency surrounding this topic. Since there are zero requirements for a company to provide a *certificate of analysis* from start to finish, there are zero requirements for a company to provide a *chain of custody* on what any of those products went through.

A certificate of analysis is a document that provides detailed information about the composition and quality of a product, typically conducted through laboratory testing. It verifies that the product meets specified criteria and regulatory standards.

Chain of custody refers to the chronological documentation or paper trail that records the handling, transfer, and storage of a product from its origin through to its final destination. This ensures accountability and traceability throughout the supply chain, especially important in regulated industries like pharmaceuticals and food supplements.

A deeper element of what is missing around transparency is the fact that there are no pictures available of the manufacturing facilities involved. Consider this: Have you ever seen a photo or video from *inside the facility of where your favorite supplement is made?*

There is also a good chance you can’t find who the owners of those companies are. Who actually owns what you are consuming? What do they stand for and what are their manufacturing *mission statements*? Isn’t it odd that someone who owns products that supposedly improve people's health is completely anonymous? After all, shouldn’t the owners be concerned about customers' health and welfare using their products? And shouldn’t the owners of companies be held accountable for any infractions of the manufacturing process that causes harm to the people consuming their products?

I recently researched fifteen of the largest health supplement companies in the world. And I was not able to find the owner list on the corporate website for *any* of those brands. All those things are part of the overall lack of transparency. And even more importantly, at least on my side of the equation, I have to ask those hard questions of why? Why aren't there *certificates* *of* *analysis* from start to finish? Why isn't there a transparent *chain of custody*? Why won't or can’t the owners be boisterously proud of what they do and what they stand for? The only thing I can think of is they are hiding from one or several elements that if known, would derail the success of the overall venture.

## “Proprietary”: The Word to Run Away From

Another aspect behind the need for more transparency is the industry overuse of the phrase *proprietary*. Using the word proprietary on a label allows manufacturers not to have to reveal the exact amounts they are using. In other words, they are hiding behind the fact that since they are the creators or owners of whatever they are selling, they feel they have the right to keep certain elements hidden from view. They keep that in their bag of tricks under the guise of it being based on an “old family recipe” or secret that is only for their knowledge. Proprietary is a codeword for “I’m simply not going to tell you the truth about this product.”

When someone says or uses the word proprietary, they are skating just inside the *letter of the law* as it pertains to the FDAs label requirements. The FDA label requirements are different per product to make things even more confusing. They're different per size bottle , and different per industry. This hiding behind unclear labels and the heightened privacy behind proprietary, has to come to a screeching stop.

I view it much like the days your child comes home from school with that super-duper report card for the first time with nothing but straight A's. Being proud, you probably call grandma and grandpa, take a picture with your child, and post it on social media. You probably put it on the refrigerator's door; you did everything so everybody could see it. That is the same with having all the pertinent information about you and your company so anyone who wants to see it, can.

What happens if that same child comes home with a C, a D, or an F? You probably will not call grandma and grandpa and will not be as supportive and celebrative as in the first scenario. You will certainly not take pictures and post them on social media, either.

So now we understand why those companies did not put anything up about themselves or their companies because they had brought home a bad 'report card.' They are not celebrating that because they have something to hide. They are ashamed and even embarrassed. It is the same with many of the other owners and CEOs of Kratom companies. They hide behind a corporate veil that does not have a social media presence or does not want to share what they are up to. It only lets me see that they are not proud of what they're doing. They are not proud of the grades that they are getting.

Regardless, there needs to be complete transparency from start to finish regarding what is in the product being sold. You can still choose to consume something that has half as much active ingredients as needed to achieve any sort of stated benefit or effect. That becomes your choice, which ultimately is the difference between a label and its bioavailability.

Let us take a moment to look at that word, “bioavailability”. It’s used by the Science Community that is *supposed* to help the general public understand basic information that could affect their usage of supplements. Bioavailability refers to how much of a drug or supplement actually gets absorbed into your bloodstream after you take it[[3]](#footnote-2). When a medication is given directly into a vein, its bioavailability is 100%. But when it's taken in other ways, like swallowing a pill, some of it may not be absorbed as well due to how the body processes it in the gut and liver. This can affect how effective the medication is. Bioavailability is an average measure, and variations among people are considered when determining the right dosage to ensure it works as intended.

 In other words, simply put, it’s how much of what you are taking is actually used by the body. Protein powders are a great example of this. You pick up a protein powder to supplement your diet and you see a serving has 35 grams. And if you take a sample of the powder and send it out to a lab, they would say, “Oh yeah, there's 35 grams of protein per serving.”

And that is accurate because the lab only looks at the level of amino acids, which are the building blocks of protein. However, when you break down the *types* of protein, you will discover that a majority of the protein is in the form of *gelatin*. And while gelatin is legally a protein, it’s a protein that is not easily used by your body. It is literally just waste. Yet, you as the consumer, continue to take this product thinking you’re being healthy and taking plenty of protein.

This is referred to as *protein spiking,* and it went on inside the Protein Powder Industry for the better part of seven years. The reason a manufacturer would spike their protein with fillers is, of course, profits. Fillers are extremely cheap. Therefore, they could significantly boost their cost of goods for every serving. And again… *legally* they were compliant. However, they were advertising something they knew your body could not easily digest. They were violating the spirit of the law and label transparency.

Eventually, other companies making legitimate products became suspicious that certain companies were selling their protein for such low prices when the price of raw protein was going up for everyone in the industry. The honorable manufacturers of protein powder got together when they discovered what was happening and decided the industry needed a new standard so that the customer-base could know who they are and exactly what the bad actors were doing wrong.

With enough marketing share and power, these honorable manufacturers created a scenario where the entire industry was forced to self-regulate. They believed the customer deserved to know exactly how their products worked so they could make an educated decision. If you still wanted to buy cheap protein entirely because of price, at least you weren’t being misled.

This brings up the obvious question: Why doesn't the FDA regulate this? Doesn’t the FDA have the burden of protecting consumers from shady practices like this? Frankly, the FDA simply can’t police every product. There are just too many of them. Unless, or until, there's a series of adverse effects that is significant enough to catch the awareness of the FDA, there's a good chance that most products will skate under the radar. Knowing this, would it surprise you if you knew that the number of products that skate under the radar of the FDA is well over 93% of products manufactured?[[4]](#footnote-3) 93% of things you consume have never been tested, there is no certificate of analysis, there is no chain of custody as to the process of what you’re putting in your mouth went through. That should give you at least some level and reason to pause before you put something in your mouth that you believe is safe.

Understand, it’s not the FDA’s fault. The FDA only has so much “capability” to do anything within their mission statement. They function from our Tax Dollars and of course, we don’t want to pay more taxes than we already are. So how effective can the FDA really be with a limited budget versus the unlimited amount of work facing them?

Another aspect the FDA is faced with when trying to regulate the health supplement industry is the lack of any standardized serving sizes. With drugs, every drug has a mandatory dose size. Not so with supplements. Let’s just take something as innocuous as Vitamin C to prove the point. There are over 2,000 individual Vitamin D products listed on Amazon. And every single one of them has a different serving size. As little as 25 mcg all the way to 250 mcg… a serving size difference of over 1,000%! Can you take too much Vitamin D? Absolutely. Can overdosing on Vitamin D kill? Yes. And yet, is that listed on any of the labels of those 2000 products? Not at all. And that is just ONE product out of thousands and thousands.

Is there a solution? Yes. *Industries need to start regulating themselves, erring toward consumer health and marketing integrity.* Much like how the protein industry banded together to force change and eliminate product spiking, other A-player in other industries could do the same. If this were to happen, it would allow the FDA to become simply a backstop or a secondary investigation arm for consumables. Which would allow them to focus their efforts almost entirely on Drugs. The key benefit to industries self-regulating would be that the FDA could stop being the first-line of defense.

As CEO of MIT45, it makes sense to me that a supplement manufacturer would do research and development on their products. They would send results of those efforts out for third party testing. There would be focus groups and sample sizes to understand what might happen to the population at large if their products were used by the public.

Doing all those things, with backup documentation of all the validated research results, would create peace of mind as you take it to market. You do it not only because you want to make it available to your customers, you do it because it would be a truly unique value-selling proposition *because no one else is doing it.*

## Marketing Mayhem: Overpromising and Under Delivering

The hang-up, then, is that in a competitive landscape, where time is of the essence, that becomes incredibly challenging. Any moment of any day, a new company pops up with more aggressive marketing tactics, bigger label claims, stronger formulations, and larger serving sizes. And that creates an arms race where larger products with bigger outputs and bigger effects become the norm.

As a result, some companies are almost in a catch-22 situation: If they don’t launch their product because they’re waiting for market test results to come back, they could miss out on a sizable piece of the market share. I’ve even witnessed some companies worry so much about the heat of competition, that they’ve launched their product before having any tests. They’re essentially launching a product and hoping for the best, all in a desperate bid to gain market share. They do this despite knowing that this is not in the consumer’s interest, only what is best for their profit margins.

This is why one of the things we're pushing for with MIT 45 and the *Kratom*  space is to work on standardized servings inside of our industry. But this standard should be inside of every industry. That's an industry wide stance, not a federal government stance.

The safest way to do this is to standardize the serving size to the lowest common denominator: The novice user that's never been exposed to the product before.

I’m talking about the curious consumer whose decision is swayed more by clever branding and marketing vs. the expert user who has researched a product and is taking it with the expectation of a certain result. This is the middle-aged woman walking around Whole Foods, pushing her cart, talking to her husband or friend on the phone, mostly paying attention to what is going on around her and not what she intends to purchase. That is, not until she sees a bottle of any number of Kratom products on the shelf and grabs one because she likes the colors on the label.

Using Kratom as the example, MIT45 has determined that a 25 milligram serving of active alkaloid will deliver a pleasant experience for this particular consumer demographic, specifically middle-aged women. This serving size is not an “industry standard” by any means. It’s an internal *‘self-regulation’* that we settled on. And, until we have studies and science to confirm our decision, hopefully, it will be better than no regulation at all. In the meantime, I’ve been reaching out to every Kratom manufacturer I can get hold of to get them to settle on this serving size at all. Mostly, all I’ve gotten is pushback. We will discuss more about Kratom in the next chapter, but for now, understand that most Kratom manufacturers want to put as high a dose of active ingredient as they can because they mistakenly believe that will provide the best experience for the consumer.

### The Dangers of Exaggerated Claims

Having no standard dosing size is reckless at a minimum and dangerous at a maximum. In this way, there is a high chance of creating a bad experience for a consumer . This will create and force safety hazards on us.At which point, every company will be required to follow new information and new data and adjust accordingly.

Instead, the current trend in most consumable markets is companies are focused instead on quick, easy wins by creating stronger products. Products are spiked with adulterate claims that exaggerate outputs or results. Make no mistake about it, these are nothing more than *sales* claims and based on facts or detailed testing actions. This needs to stop.

For most consumers, the entire reason they decide to pick up a product is based on the claims on the label. A prime example is, “*If you take this product, you'll lose five to seven pounds in the next 14 days.”*

So you pick up that product without knowing what truly goes into it and frankly, you probably don’t even care what goes into it. All you want is the result. You want it because it will increase your focus and help make you more alert. It will make you prettier with thicker hair. It will help you have better eyesight. It will help you reduce wrinkles and have softer skin. And yes, that it will in fact help you lose five to seven pounds in the next 14 days.

The bottom line is you don't know what the *downside effects* of consuming that product are. Is it wearing on or taxing your body in some unknown way? Can it lead to poor sleep habits? (Thus making you even *more* tired and needing to take even more of the product to stay alert.) Without you knowing that poor sleep habits also lead to a shortened life expectancy. And you don’t know the downside effects because virtually no manufacturers are telling you on the label what those are!Makes you think a bit more before you grab that bottle of an unknown product off the shelf, doesn’t it?

Now certainly the argument could be made that it is *‘Buyer Beware.’* That fact cannot be understated. There is, after all, a sense of ownership and responsibility that *YOU* as a consumer must take as well. The argument can also be made that it is *‘Shame on You’* for the manufacturers who are transparent about what's in the product. Or What may or may not happen by consuming it.

I also realize, as the CEO of a successful supplement company, that I can't possibly put every contradiction, every warning, or even every stated potential possible benefit on a product. There is simply not enough space on the label. There's not enough time or resources available.

But what we can do is not over market the product. What we can do is educate our customers on how to make our product a part of a healthy lifestyle that includes proper hydration, eating a nutrient rich diet and creating quality sleeping habits. At which point our product can *supplement* their weight loss efforts. That would be a heck of a lot better than simply saying “This will help you lose five to seven to pounds. That's a different way to sell, I will admit. But that's a way to get around the misleading and sketchy advertising that goes on inside the industry today.

That brings us to the next area in the consumer supplement space that needs addressing: advertising, especially online advertising. Nearly every person who looks something up online will do so through Google. And no matter what you search for, Google will start serving ads so specific to your needs that you may feel like your phone is listening to you.

Those ads are challenging because in that landscape supplement companies are paying to put that information in front of someone. As a manufacturer, you are bidding for the same amount of eyeballs and attention as your competitors. The ads only work if they convert a looker into a buyer. One way to make an ad perform better is to exaggerate your claims. You’re already familiar with this version with online articles and their outrageous headlines, also known as “Click Bait.” And to some degree, this works. The more people click on your ad, the more sales you can make. The more sales you make, the more you can spend, the more traffic you can get, and the more money you can make.

As you're doing all of that, your competitors are trying to figure out what you're doing. They will study your ads and figure out every way they can to beat them and make their ads stand out more. I call this ‘panic-mode’ marketing because they make stronger, more exaggerated, untested claims. And the circle never ends. Because the system is built *not* to end. After all, the more clicks there are, the more money Google makes. And the marketers are selling you products by trying to get an angle that will successfully entice you to buy so they can make money on the products you say you already want.

### Case Study: The Ozempic Weight Loss Phenomenon

An example of this type of misleading and sketchy advertising is the drug Ozempic. Ozempic was designed to help diabetics keep their blood sugar in check. It’s a diabetic drug. Yet, if you enter a search for Ozempic online, you will be flooded with ads, articles and videos telling you that Ozempic is primarily used to help people lose weight. Which it was not designed to do. Like all drugs, there are serious side effects that are not mentioned on the packaging.

Saying that it's going to help you lose copious amounts of weight in short amounts of time without any clear and transparent contraindications feels foolish. Yet such statements are almost the norm for both drugs and supplements.

Green tea extract pills or goji berries are mostly marketed online as weight loss products. And you can find advertising saying that Dr. Oz endorsed these types of products for that purpose. And since Dr. Oz is a trustworthy person, the average consumer may believe these outrageous claims[[5]](#footnote-4). What you don’t know is that Dr. Oz never endorsed the product. Someone stole his name, image and likeness, and they sell products with applied facts or benefits that didn't exist. They even go further and show *Before and After* pictures that were altered with Photoshop.

Simply put, they are lying to consumers by making untrue claims. This is all in an effort to get more clicks on their ads, which will lead to purchases you would normally never consider because you want the result they are selling.

How big of a problem is this? Let’s assume that the average order value of vitamins and other supplements is around $200. Seeing as the supplement industry is a $50 billion industry, as I write this, that means $50,000,000,000 / $200 = 250,000,000 million individual purchases. And again, many of those purchases are based on misleading and deceptive marketing. Obviously, we do not know what the actual average spent per consumer is, but this is just to understand that it is a big deal. There's an entire multi-billion dollar industry based around false claims, implied benefits, deceptive marketing, and very angled or skewed information that only shows the results you want, versus what is actually realistic.

## Standardization: A Missing Piece of the Puzzle

It is important to understand that what is real is the fact that there is no *quick fix.* There is no one-size-fits-all all. There is no *guaranteed solution* to any of the problems that you believe a nutritional supplement or consumer-packaged good will solve for you. That’s because your entire body is an ecosystem. To make lasting and impactful changes to your ecosystem, it takes more than introducing one new variable. It's typically part of a more significant lifestyle change.

Yet, from a marketing standpoint, there are no profits in a lifestyle change. Lifestyle changes are complicated and difficult to manage. Not to mention that Lifestyle changes are slow, and results take many months to see. It’s much easier to tell you to take a pill and that you will feel better in the morning. Then. back that up with loads of “before and after” stories, pictures, and scientific-sounding jargon. So you figure, “it can’t hurt” and you buy that particular pill. Unfortunately, the truth appears over time, and you realize that it really isn’t working as you had convinced yourself it would. And thus the cycle begins again where you see new ads for new products with even better marketing… and this will continue non stop.

the majority of supplements people consume would be better taken as part of a *holistic, education-based platform.* That would allow some type of monitory process along the way so that adjustments can be applied based on *individual results.*

I have no doubt that there are tens of millions of people in the US that suffer from anxiety. It's a real thing. Yet, in order to solve anxiety, you probably want to see where it actually started from. Because knowing the origin of something can help you determine a better path for long term resolutions and solutions.

As a nutritional supplement company owner, I do believe that appropriate supplementation is part of a well-rounded approach to solving most any problem. The key phrase is a well-rounded approach. Wild and incorrect claims that have zero third party validation should not be part of any well-rounded approach to solving your health issues.

Now, as if the unregulated marketing landscape wasn’t enough to frighten you as a consumer, consider this: *Anyone* can start a supplement company. And you can run it right out of your apartment if you choose. Yes, even you. There are any number of websites where you can buy raw materials and have them shipped directly to your home. You can then weigh that raw material using nothing more than a food scale in your kitchen, put it in plastic jars using induction sealers to seal the top screw on a lid. Then heat-shrink a plastic seal around the top, create a shiny label and put a webpage up where people can order and voila! You’re a supplement manufacturer.

You can even model the bigger companies and make the same outrageous claims on your website stating your miracle pill will solve almost anything under the sun. And while you might eventually be told to take it down, there is no level of compliance required to start. Not only that, but there is nothing that forces you to have third-party testing or validation for any of the claims you make. Think about that the next time you go to put something in your mouth that you got online from a random seller.

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