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| Erin Allmann Updyke | "What is this mysterious force that gives beauty to women and power to men? Since science wrested from nature those mysterious life-giving health-building elements, the vitamins, thousands upon thousands can enthusiastically tell you of the amazing and almost magic-like results from their use. Vitamins, as mysterious as electric current yet as definite in results, are of three classes, all equally important. Eminent authorities declare that all three of the vitamins are necessary to health, energy, beauty, and proper physical development. Yeast is rich in one class of vitamins, water soluble B, raw unpasteurized milk is rich in another one of the vitamins, fat soluble A, certain fruits and vegetables are rich in another one of the vitamins, water soluble C. |
| | But with the discovery of a special process for successfully concentrating and combining all three of the vitamins as in Mastin's Vitamon Tablets, millions of men and women everywhere have turned to this new and better way. Sufferers from constipation, indigestion, lowered vitality, skin troubles, underdevelopment, weakened nerve force, and lack of energy. Folks who have been ailing for years, the victims of undernourishment brought on by a lack of sufficient vitamins find in Mastin's Vitamon Tablets just what they had always hoped and longed for but never expected to find. So no matter what your age nor how scrawny, haggard, careworn, and run down you may be; no matter what tonics or preparations you may have tried in the past or how hopeless you are of ever becoming alert, healthy, properly developed, and physically fit with strong nerves, a keen active mind, a clear skin, and generally improved appearance, you will find it well worth your while to make this simple test. If it isn't Mastin's, it isn't Vitamon." |
| TPWKY | (This Podcast Will Kill You intro theme) |
| Erin Welsh | Vitamon. |
| Erin Allmann Updyke | VITAMON. It's always in all caps so it's important that you say it that way. |
| Erin Welsh | That is exactly how I transcribed it from the newspaper ad in the Washington Times from January 8th, 1922. |
| Erin Allmann Updyke | I love it. I love it so much. |
| Erin Welsh | I do too. I do too. And I found a bunch of different ads too but that one just really, it really struck a chord. |
| Erin Allmann Updyke | It said it all. |
| Erin Welsh | I don't know what kind of chord but... Disharmonious. Wonderful. |
| Erin Allmann Updyke | A little bit of both. |
| Erin Welsh | Yep, yep. Hi, I'm Erin Welsh. |
| Erin Allmann Updyke | And I'm Erin Allmann Updyke. |
| Erin Welsh | And this is This Podcast Will Kill You. |
| Erin Allmann Updyke | We're going to have fun today. |
| Erin Welsh | I really think that we are. |

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| Erin Allmann Updyke | Yeah. |
| Erin Welsh | I'm thrilled. This was such a fun... I mean fun may not be the right adjective to describe it. But this was a really eye opening and fascinating subject to research. |
| Erin Allmann Updyke | Yeah, yeah. |
| Erin Welsh | I had to stop myself from going down 1000 different rabbit holes and just be like no, we're sticking to this. This is what we're doing. |
| Erin Allmann Updyke | Same, same. I was like keep it tight, Erin. |
| Erin Welsh | Keep it tight. Keep it understandable. Keep it to the point. |
| Erin Allmann Updyke | Yeah, yeah. |
| Erin Welsh | But yeah. Yeah, today we're talking about supplements. |
| Erin Allmann Updyke | Supplements. |
| Erin Welsh | And so there are a lot of different areas that we could explore with this and we did toy with the idea of being like should this be like a four parter? But I think what we wanted to do is that so in the past we have explored different vitamins or like vitamin deficiency diseases in our episodes and we're going to keep doing that in the future. And so the purpose of this episode is not to go into each supplement that's on the market and talk about whether it's effective or does what it says it promises to, all that kind of thing. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | What we want to talk about is just sort of like what is a supplement? |
| Erin Allmann Updyke | Right. |
| Erin Welsh | What constitutes a supplement? What does not? And then how are they regulated? |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Which of course we want to explore how they used to be regulated and how that compares with today's regulation. And then kind of go into also like what that regulation means, what someone can say on a label vs what they can't say on a label or in a commercial. And also wrap it up with like what is the supplement industry look like by the numbers. |
| Erin Allmann Updyke | Right. Yeah. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | And we're painting with very broad brushes here, like Erin said. |
| Erin Welsh | Definitely. |

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| Erin Allmann Updyke | We're talking about a very broad categorization, defining supplements. And so please everyone keep in mind a couple of things as we do this. We're not coming after your favorite supplement individually at all. And it's important I think to know too, like we said, we've covered a lot of vitamin deficiency diseases. There are times and places and situations where supplements like vitamins or minerals are really important for particular people for particular situations. And as we'll see the marketing of these things is phenomenal so all of us end up buying supplements that probably in fact don't do anything for us at the same time. So me too. |
| Erin Welsh | Yeah. Well and I think a big part of it is just sort of in not knowing. Like I learned so very much about- |
| Erin Allmann Updyke | Same. |
| Erin Welsh | What supplements, like what they're allowed to say these days. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | And so I think that that's a big part of it is that like you- |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | There's very careful wording that is designed to make you want to buy things. |
| Erin Allmann Updyke | Yes. And that's what we're focusing on kind of the supplement industry as a whole. |
| Erin Welsh | Yes. Yep. |
| Erin Allmann Updyke | And the ways that the FDA and the FTC even has kind of dealt with regulations surrounding these supplements. Which also means that this is a pretty US centric story but I have at least some data on things in other countries as well too. And we have sources. So if you live somewhere else and you're interested in what's it like in Australia vs South Korea vs the US, we've got some info on that too. |
| Erin Welsh | Right, right. |
| Erin Allmann Updyke | All of that is jumping ahead because first it's quarantini time. |
| Erin Welsh | It is. What are we drinking this week? |
| Erin Allmann Updyke | Nothing other than Snake Oil. |
| Erin Welsh | Yeah. I mean- |
| Erin Allmann Updyke | Had to be. |
| Erin Welsh | Had to be. The Snake Oil elixir nostrum whatever. |
| Erin Allmann Updyke | Nostrum? |

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| Erin Welsh | All of the different things. And in Snake oil it's actually quite delicious. |
| Erin Allmann Updyke | It's fantastic. |
| Erin Welsh | It has bourbon, it has blueberries, it has lemon juice, it has simple syrup and a little bit of mint. We may have made something like this before. |
| Erin Allmann Updyke | 150 episodes in or whatever. |
| Erin Welsh | Yeah. I think it's okay. |
| Erin Allmann Updyke | But we'll post the full recipe for that quarantini as well as our nonalcoholic placeborita on our website thispodcastwillkillyou.com and all of our social media channels. |
| Erin Welsh | And on our website thispodcastwillkillyou.com you can find all sorts of cool things including but not limited to transcripts, you can find links to bookshop.org and our Goodreads list, you can find the sources for each and every one of our episodes, you can find links to merch, you can find links to Patreon. You can find a firsthand account form and this is not really related to our website but please rate, review, subscribe. Couldn't think of a good transition there. |
| Erin Allmann Updyke | It worked. It totally worked. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | It really does help us get new listeners and be able to keep making the podcast. So thank you for your support. |
| Erin Welsh | Yes, thank you. Let's get started. Okay? |
| Erin Allmann Updyke | Yeah. I'm excited. |
| Erin Welsh | Okay, good. |
| Erin Allmann Updyke | Okay. So we're starting out defining what the heck a supplement actually is. Easy, easy, logical place to start. And this definition comes straight from Congress really in an Act that I think, Erin, you're going to end up talking a little bit about and that is the Dietary Supplement Health and Education Act or the DSHEA. |
| Erin Welsh | I've also seen D-shay. |
| Erin Allmann Updyke | D-shay? Can I say that? Okay. |
| Erin Welsh | That's how I saw it in one news article. It was like pronounced D-shay and I was like okay. |
| Erin Allmann Updyke | Oh I love that they say we can pronounce it that way. |
| Erin Welsh | I know, I know, I know. |

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| Erin Allmann Updyke | So the DSHEA which was passed in 1994. So according to this definition and according to the FDA website, a dietary supplement is a product that you ingest, it must be ingested, which contains a quote "dietary ingredient" intended to quote "supplement your diet". They literally just use the term to define the term. That's what they do. |
| Erin Welsh | That means nothing. Right? |
| Erin Allmann Updyke | I know. |
| Erin Welsh | Like is that really it, Erin? |
| Erin Allmann Updyke | That is the definition. So let us actually dig down into breaking down what that really means, shall we? |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | Because they don't, that is the actual definition listed. What this means regulatory-wise is it's anything that you can purchase, that you're buying, to ingest, specifically it must be ingested. So this means you're eating it, you're drinking it, you're chewing it. Specifically you're not rubbing it on, so it's nothing topical, it's nothing meant to be injected. And in fact previously it wasn't even anything that was like just dissolving in your mouth like sublingual, although there's gray area around that. The point is it's supposed to be something that you ingest and it goes into your stomach. |
| Erin Welsh | Okay. |
| Erin Allmann Updyke | That isn't directly a food product, meaning it's not meant to serve as food, it's not meant to be a meal or a snack or anything like that. And is also not a medication, meaning it's not something that's prescribed and it's not an over the counter drug either. These are supplements. So what are the kind of categories of this? These are all of our vitamins, meaning multivitamins and single vitamins. It's also minerals, it's prebiotics, probiotics. It's things like liquid IV supplements, fiber supplements, collagen supplements, herbs, botanicals, amino acids, protein powders, enzymes, extracts. It's a very long list of things. |
| | And they can come in a lot of different forms. It can be pills, capsules, gummies, but also concentrates powders, teas, even bars as long as they are not marketed to be a meal replacement bar but if they're marketed as a supplement bar then they are a supplement. It's an incredibly broad categorization of items. And part of the definition of a supplement is that the product itself is intended to do something more than what food does. It is not intended to be a part of your diet. The intention behind it is to supplement, to add or augment our diet. And we are going to get deep in this episode into how these things are labeled and regulated and how they are "intended to be used" quote unquote vs how they are actually used. |
| Erin Welsh | Interesting. |
| Erin Allmann Updyke | And I'm going to stop really soon because I want to just get straight into the history of these supplements. But I think that that part of it, this definition of supplements,that they are intended in a specific way is an important part of their definition because specifically supplements cannot claim to and can't be intended to treat, cure, or prevent or even really alleviate the symptoms of any specific disease or condition or groups of diseases. Their function is really supposed to be to augment the nutrients in our diet and provide us a potential benefit to our nutritional status and therefore our health and wellbeing beyond the things that we eat. That's it. That's what a supplement is in the US. |

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| Erin Welsh | Okay. I mean I feel like a lot of the questions that I have are probably going to be answered later once we get more into the nitty gritty of DSHEA and like all of that- |
| Erin Allmann Updyke | Yes. |
| Erin Welsh | What you can put on a label, what you can claim and how much you can claim as long as you have that. The FDA has not... What is it? |
| Erin Allmann Updyke | Evaluated. |
| Erin Welsh | I have it in here. Evaluated these claims and this is not intended to cure, treat, or prevent any disease. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | It is very interesting. Okay. But I feel like this is a really good starting point. |
| Erin Allmann Updyke | Yeah. Just like we know kind of what a supplement is. So like Erin, and I will say briefly in Canada, the definitions are slightly different in different countries. So in Canada herbals and vitamins and things like that are pretty similar what we call dietary supplements but the regulations are different. In the EU vitamins and minerals are regulated one way and then herbal remedies are regulated as something different. And so each different country does have a different system. So this is the definition of dietary supplement as defined by the US and that's kind of what we're focusing on. So Erin. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | How did we get here to this definition? Tell me about it. |
| Erin Welsh | Oh it's a journey. |
| Erin Allmann Updyke | I love it. |
| Erin Welsh | It's a journey. |
| Erin Allmann Updyke | I can't wait to go no. |
| Erin Welsh | I think we can take a very quick break again and then get into it. |
| Erin Allmann Updyke | Yeah. |
| TPWKY | (transition theme) |
| Erin Welsh | The history of the dietary supplement industry in the US really begins with the passage of the 1906 Federal Food and Drugs Act. |
| Erin Allmann Updyke | Okay. |

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| Erin Welsh | Aka Wiley's Law. And you could also say that it begins with the discovery of vitamins because vitamins have historically made up the bulk of the supplement industry here in the US. Other types of supplements like herbal or botanical supplements, they date back themselves like thousands of years in their use by humans. But in this history I'm not as focused on how people have used supplements over time as much as I am on how they've sold them. And when their production began to be regulated. |
| Erin Allmann Updyke | Yes. |
| Erin Welsh | So it's really just this is the history of the regulation of the supplement industry in the US. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Which sounds like very specific but let me tell you, this is a very broad topic. |
| Erin Allmann Updyke | Well and it sounds like you would think like oh the regulatory history of supplements, like that sounds boring. It's not going to be boring. |
| Erin Welsh | Oh no, anything but boring. It is like twists and turns, shocks, surprises. I gasped out loud at least once or twice doing this research. |
| Erin Allmann Updyke | The amount of text messages with like question mark, exclamation mark, question mark, exclamation mark. |
| Erin Welsh | I was like can you believe this? This is outrageous! It's not how I speak. |
| Erin Allmann Updyke | But it's how you text. |
| Erin Welsh | That's how my text voice. Yeah, it is. But this then brings us past the snake oils and tonics and elixirs of the 1800s that sold a promise of health and vitality without any evidence or sometimes evidence to the contrary. And it brings us to 1906 when those elixirs and tonics and snake oils were still sold still with this false promise of health and vitality but with like the tiniest sprinkle of regulation. So long story short, really truly long story short, a growing awareness of the problem with mislabeled or tainted food and and also drugs, then some food poisoning scandals, a few exposes on the food industry, especially 'The Jungle' by Upton Sinclair, and the work of food safety warrior Harvey Wiley, all of these things led to the passage of this Act, the 1906 Federal Food and Drugs Act. And this Act was largely intended to protect consumers by requiring that producers had to accurately label what they were selling. Like you couldn't put on a bag 'brown sugar' when really what was in there was ground up lice, which is what had been the case. |
| Erin Allmann Updyke | Oh wow. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | Or like this is ground cinnamon, actually it's brick dust. |
| Erin Allmann Updyke | Right. |

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| Erin Welsh | These things happened. And if you listen to our Book Club episode last year on Deborah Blum and 'The Poison Squad', some of this stuff is like you're like oh yeah, Wiley, Wiley's Law, brick dust, pond water in milk. Like all that is very familiar. That is such a great book that it explores this particular Act and some of the events leading up to it in much more detail. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | Highly recommend. Anyway this Act required producers to accurately label what they were selling. It required them to list certain ingredients, things like alcohol, morphine, opium, cocaine, cannabis, etc. There was like a list of a certain number of ingredients that had to be included on your label. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | And that drugs, quote "substances used to cure, mitigate, or prevent disease" end quote, had to quote "abide by the standards of strength, quality, and purity in either the US Pharmacopeia or the National Formulary." End quote. Essentially this 1906 law was intended to give consumers more information on what they were consuming so that they could decide whether or not they wanted to consume it. Buyer beware. And because it was mostly about the content of the items that were being sold, drugs were still able largely to advertise as essential to health and preventative for all disease, whether that was true or false or somewhere inbetween. And perhaps the biggest growing segment of this newly regulated drug industry was vitamins. In the last few decades of the 1800s and into the 1900s, scientists had discovered vitamins. They had done a huge amount of research on like actually finding that there was more to food than just protein, carbohydrates, fats. And they were also making the links between vitamins and deficiency diseases. Vitamin C and scurvy, thiamine and beriberi, vitamin D and rickets, and so on. And this was a huge breakthrough, this discovery of vitamins, as was the isolation and production of these vitamins which by the 1920s had become widely available and widely advertised. As we heard in the firsthand account, there were ads for vitamins everywhere and a lot of these vitamin ads also tended to target parents for their kids. |
| Erin Allmann Updyke | Yes. |
| Erin Welsh | So you could find ads for vitamins in Good Housekeeping, Parents Magazine, sort of warning parents, warning readers that if your kid doesn't have this particular proprietary concoction of vitamins, their teeth and bones may never develop and they'll be sick all the time. |
| Erin Allmann Updyke | Wow. |
| Erin Welsh | And they could say that, like these ads could say that. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | And so it's certainly the case, like as we've established on this podcast through some of the episodes that we've covered, there are deficiency diseases that if you are deficient in certain vitamins, you can have very substantial health impacts. But what was much less clear today but also especially back in the 1920s, 1930s was whether an excess of vitamins, whether there was a point at which Moore is not going to do anything or could potentially be toxic, right. |
| Erin Allmann Updyke | Yeah. |

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| Erin Welsh | So was an excess of vitamins helpful or not? A lot of researchers working on the subject were suspicious that no, it actually did nothing at all and we need to do something about this. And so in the 1930s the FDA which became official around 1930 as the first consumer protection agency- |
| Erin Allmann Updyke | Wow. |
| Erin Welsh | They established a lab specifically to study these vitamins, like the health claims made about them, whether their labels were accurate, and especially whether they contained the amount that they were supposed to. And that was sort of under regulation, right. It was... What did I say here? It was strength, quality, and purity. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | And guess what they found? |
| Erin Allmann Updyke | That things were a total mess I'm guessing. |
| Erin Welsh | 100%. Multivitamins that had no vitamins at all. Garlic pills that didn't prevent diphtheria as advertised, shockingly. |
| Erin Allmann Updyke | Shock. Shock. |
| Erin Welsh | Shock. Cod liver oil with just pitiful amounts of vitamin D and so, so many other things. So there's no surprise there. But the key thing is that these evaluations were made on drugs, on vitamins that were already on the market. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Yeah. And it wasn't before they made it to the market, this wasn't like the final step in their production and mass advertising to consumers, it was once they were already on the market. Under the 1906 Act, there was no real procedure for ensuring the safety and quality of drugs before they made it to the market. Enforcement of the law itself was difficult due to a lack of organization and funding for enforcement, like no one knew how to go about this in any sort of straightforward way. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | And drug companies could take a lot of shortcuts to start selling their product as soon as possible. I can see you nodding your head like yes, things haven't changed at all, have they? |
| Erin Allmann Updyke | Are you talking about 1930s or are you talking about 2020s? |
| Erin Welsh | Yep, yep, yep. Oh gosh. |
| Erin Allmann Updyke | Wow, okay. I can't wait for the ups and downs and how we- |
| Erin Welsh | I'll tell you what, it's made me feel a little despair. |
| Erin Allmann Updyke | It's okay. |

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| Erin Welsh | But anyway, we'll just leave the despair in the future. Going back now to the 1930s. And so yeah, this is sort of the way things stood with this 1906 Act. Just really no great regulatory control before these products went to market. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | And in 1937 this oversight would have very tragic consequences when a chemist at a Tennessee pharmaceutical company, if you're interested it's SE Massengill Company, I may have talked about this on the podcast before. This chemist put together, made a concoction of sulfanilamide which was an early antibiotic, combined it with raspberry extract and diethylene glycol to add some sweetness. Diethylene glycol has a sweet taste, it's cheap, colorless, odorless, and it's essentially commercial antifreeze. No studies, I think there had been like two toxicology studies done on DEG before this concoction was made. But I don't know if this chemist had access to them, I doubt it. And no studies were done, animal studies, human studies, anything on this elixir sulfanilamide before it was produced and released and sold to multiple different states. Within a few months, reports of illness and death began to trickle in. And when the dust finally settled, at least 365 people were sickened, including many small children and 105 people died from taking this. |
| Erin Allmann Updyke | Wow. |
| Erin Welsh | Yes. Bad. And the owner of the pharmaceutical company pled guilty to adulteration and misbranding because DEG was not on the label and he was slapped with a hefty fine. But that's it. There was nothing else that the government could be like oh you violated this Act. Those were the ways that he violated this Act, that the company violated this Act. |
| Erin Allmann Updyke | By not putting it on the label. |
| Erin Welsh | There was no requirements for safety testing. |
| Erin Allmann Updyke | Right, yeah. |
| Erin Welsh | And so nothing... And there was like an evaluation by a task force and what they came to the conclusion of was that there was nothing in the 1906 Act that could have prevented this from happening. It reminds me a little bit in some ways of the Tylenol poisonings, things didn't have to be sealed. There were no protective labels in that way. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | So it's really interesting to think about proactive vs reactive regulation. |
| Erin Allmann Updyke | 100%. |
| Erin Welsh | But anyway, it was clearly time for a new Act. In 1938 the Food, Drug and Cosmetic Act was passed which among other things required that pharmaceutical companies show that their products were safe before selling them. And this Act defined a drug as quote "articles other than food intended to affect the structure or any function of the body of man or other animals." |
| Erin Allmann Updyke | Fascinating, Erin. |

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| Erin Welsh | Isn't that so interesting? |
| Erin Allmann Updyke | Wow. Okay, okay, okay. |
| Erin Welsh | Yeah. And this Act also required that vitamins and other products sold for quote unquote "special dietary needs", that they had to label their contents clearly, show also the proportion of minimum daily requirements that it met for vitamins and minerals, and include instructions for use. So it was a step forward. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | In the 1940s and the 1950s, the FDA came down hard on many companies selling vitamins and mineral supplements for their false health claims. And one case in particular against a company called Nutrilite led to a decree that set out clearer limits on what supplement companies could claim on their label and in advertisements. And so what this decree stated was that a company could say if a symptom is caused by a vitamin deficiency, then in that case the product could help if it contained that vitamin, assuming the link between vitamin deficiency and symptom had already been established scientifically. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | But they could not make additional claims like such and such vitamin could relieve symptoms of arthritis, diabetes, cancer, impotence, etc. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | It had to be this can treat this if this is a deficiency, if you have a deficiency in this. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | But you can't make claims beyond that. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | Beyond what was scientifically known. |
| Erin Allmann Updyke | So if your gums are bleeding from scurvy, then vitamin C in this supplement can treat you. |
| Erin Welsh | That is my understanding. Yeah. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | It's all very hard honestly to interpret the nitty, like these wordings of things. |
| Erin Welsh | I know, I feel like I need a degree in policy or law or something to... |
| Erin Allmann Updyke | Something, yeah. |

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| Erin Welsh | To something, yeah. |
| TPWKY | (transition theme) |
| Erin Welsh | Yeah. So they could say this supplement fortifies your diet. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | But they could not say that it cured or treated any disease. |
| Erin Allmann Updyke | Okay, okay. |
| Erin Welsh | Yeah. And over the rest of the 1950s and into the 1960s, more amendments were passed that increased FDA oversight of the supplement industry. If you claimed your product cured or treated an illness, you had to prove it before it went to market. That phrase 'minimum daily requirements' was replaced with 'daily requirements' because minimum implied that more could be beneficial when that had never been shown to be the case. |
| Erin Allmann Updyke | Okay, cool. Okay, interesting. |
| Erin Welsh | Yeah, yeah. Minimum and maximum daily amounts were set out for these vitamins and minerals, kind of putting an upper limit on yes, there could be a toxicity that people could develop if they have too much of this. And all supplements had to put this statement on their label. So think about this in contrast with the whole 'the FDA has not evaluated this' etc, not intended to treat and cure whatever. Quote: "Vitamins and minerals are supplied in abundant amounts by the foods we eat. The Food and Nutrition Board of the National Research Council recommends that dietary needs be satisfied by foods. Except for persons with special medical needs, there is no scientific basis for recommending routine use of dietary supplements." End quote. |
| Erin Allmann Updyke | That used to be on every single supplement? |
| Erin Welsh | That used to be the requirement. |
| Erin Allmann Updyke | Wow. |
| Erin Welsh | Yes. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | And So this is, I don't remember exactly what year that was, whether it was the 60s or 70s, which decade. But I think what's really interesting is that you start to see this shift in sentiment surrounding these supplements. So the 1938 Act seemed really welcomed by the public as necessary for protecting consumers because probably the sulfanilamide poisonings were so horrifying. But these new regulations, these new amendments in the 60s and 70s, people began to push back really hard against them and there would continue to be pushback from the public and also from the industry. |
| Erin Allmann Updyke | The industry. |
| Erin Welsh | And the senators and congress people who were receiving money, campaign funds. |

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| Erin Allmann Updyke | Being paid money by the industry. |
| Erin Welsh | By the industry. And so there was just like an increasing amount of pushback. And I think it is really worth contemplating why. Even if we don't have that answer, I think it's really important to try to understand what are the drivers of this. And I think there's first that the supplement industry had grown so much and saw the potential for growth over subsequent decades. And it also put this extra resources into lobbying against any regulations or additional regulations that would force them to be transparent or be held accountable for the health claims that they made. Right? So it was like the best way that we're going to make more money is going to prevent any additional laws from being passed. |
| Erin Allmann Updyke | Right. I mean duh. |
| Erin Welsh | Duh. |
| Erin Allmann Updyke | But like sorry, what? |
| Erin Welsh | Yeah, I know. Yeah. And then I think the other big piece of this puzzle is that it seems like throughout this time period, just on a big picture scale in the US, there seems to be this trend towards mistrust of government and changes in health decision making. Technology had shown its dark side in atomic weapons, Bhopal gas tragedy, Chernobyl, DDT. Like all of these things where it was like look how far technology has come and now it will destroy the planet and kill everyone. |
| Erin Allmann Updyke | Right, yeah. |
| Erin Welsh | And then also there were things like the Dalkon Shield IUD which injured many people who used it. There was thalidomide, even though that did not happen in the US because of the FDA and the steps that we took to prevent something like that from happening. But there was also like the estrogen DES which led to many awful outcomes including infertility, miscarriages, cancers, etc. All of these things eroded public confidence in the ability of government institutions to protect them. So it was sort of like how are you going to say that you're going to add these extra regulations when you have failed to protect us in the past with these regulations? I don't know. |
| Erin Allmann Updyke | Yeah. It's so interesting though to think of it that way because in the 1930s when they realized hey, this regulation that we thought was decent actually isn't protecting us so we need to do better. So if you're feeling like you're not being protected by the regulations from your government, how do you get to the answer of well let's strip away these regulations because they're not doing their job, rather than like let's come up with regulations that are actually going to protect us? I don't know, it's hard to get into that mindset I feel like. |

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| Erin Welsh | It is. And I think it also represents this shift in the 1960s and 70s that was sort of as a reaction to the darker side of technology where it was like let's go back to natural remedies, natural alternative medicine, we have left something behind by just casting all of that away. And I think that there's really interesting... I came across some interesting psychological research about the word 'natural' and how even though the word natural has kind of lost meaning in a regulatory sense but how the word alone inspires more trust. Ingesting something seems more natural and safer than being injected with something. And that interpretation, that perception remains even when someone is presented with scientifically proven data about the health benefits of vaccines compared to the lack of effects of some naturopathic remedies. Because it's like well but what's the harm also? And I think too that some of this is just an overall rejection of the paternalistic approaches of medicine and the government's role in medicine. Sterilizing people without their consent, informing a husband about his wife's cancer but not the wife so that the husband could decide whether or not to tell her. That happened all the time. |
| Erin Allmann Updyke | Oh yeah. |
| Erin Welsh | The government's complete apathy during the AIDS pandemic, dismissal over things like myalgic encephalomyelitis that we just talked about, endometriosis. I think people felt like increasingly they had to take their own health decisions into their hands. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | It was 'I know that this supplement works for me' even if that is not scientifically proven, even if it's a placebo effect. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | Even if it's just because you firmly believe what the supplement is telling you. I also don't know. This is not something, I do have some papers about this but I feel like this is something that I've tried to synthesize or think about- |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Where it is just an overall rejection of 'keep your hands off of my health' decisions. |
| Erin Allmann Updyke | Okay. Yeah. |
| Erin Welsh | I don't know. |
| Erin Allmann Updyke | Interesting. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | It's very interesting. It's also like the parallels or comparing that to where we exist today in 2024- |
| Erin Welsh | Yes. |
| Erin Allmann Updyke | And like the things that governments are trying to do with regards to our health. Yeah, okay. It makes sense. But it's like this... Yeah. Oh gosh, how interesting, Erin. |

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| Erin Welsh | I know. There are so many factors. And I feel like we often tend to lay the blame entirely at the feet of the supplement industry or like these people who are lobbying for regulation to allow them to do whatever they want. Or we lay the blame at a few individuals who are spreading all of this misinformation and disinformation. And I think that we fail to recognize or acknowledge the role that the government or science or medicine has played in further eroding this trust or in breaking it to begin with. |
| Erin Allmann Updyke | Yeah, yeah. |
| Erin Welsh | Anyway, food for thought. Supplements for thought. So anyway. And so throughout the 1970s, the FDA attempted to redraw regulations to gain firmer control over the sale and promotion of supplements. But lobbying from the supplement industry knocked down proposed legislation as well as popular opposition to this legislation. And one of these examples is that there was a proposed legislation that required high dose supplements to be labeled as drugs and then thus require like a prescription to get and then that was completely knocked down. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | As the 1980s came to a close, another Act was making its way through Congress, the Nutritional Labeling and Education Act which would require foods to have labels containing information on serving sizes, calorie, fat, vitamin and mineral content. It would have to define things like light, free, low, reduced, less, high. And in the supplement realm, quote: "A claim made with respect to a dietary supplement of vitamins, minerals, herbs, or other similar nutritional substances shall be subject to a procedure in standard, respecting the validity of such claim established by the regulation of the secretary." End quote. So it was like if you're going to make any claim about this supplement improving the health in any way, you have to prove it. You can imagine the supplement industry's feeling about this. Not happy. So as this fight went on, a public health crisis emerged that called into question the whole like if these vitamins don't do anything, what's the worst that could happen? I think that was a big part of it too where it was like you're telling me that these things don't do anything, so then what's the harm? Why do you care if I take them or not? Well in 1989 the answer to that was because bad things can happen. |
| | So that year reports of eosinophilia myalgia syndrome linked to ingestion of L-tryptophan began, which is an amino acid, began to pop up. And ultimately there were 37 deaths and 1500 cases of EMS that were linked to or caused by this amino acid supplement. The FDA issued recalls, banned foreign imports of the supplement and formed a task force to prevent something like this from happening again. And what's so fascinating to me is that we saw what happened in 1937 with the sulfanilamide tragedy leading to the passage of the 1938 Act that led to much better standards for protection of consumers. What happened in 1989, there was no public outrage that seemed to accompany this that would have pushed the legislation, this new regulatory legislation through. So under pressure from the public and especially lobbyists for the supplement industry, Congress passed another Act after this one from 1990, the Nutritional Labeling and Education Act. So after that was passed there was another act that Congress passed in 1992 and it suspended that 1990 Act for a year from being put into effect. |

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| | And even though it then would take effect, that extra oversight granted to the FDA to protect consumers would be very short lived because enter then the 1994 Dietary Supplement Health and Education Act. This was the brainchild of Republican Senator Orrin Hatch from Utah and to a lesser extent Democratic New Mexico Representative Bill Richardson. This Act, the 1994 DSHEA, reframed supplements as an economic issue, not a health one. And it was one that was already according to this Act facing too much restrictive legislation as it was. Orrin Hatch claimed that this bill would cut down medical costs across the country by increasing consumer access to preventative measures in the form of untested and unregulated supplements. His claim really was, like he said we can help cut down the cost of medicine for Americans and for the American government if we allow more supplements to make it to the market because then they can help with preventative medicine. |
| Erin Allmann Updyke | Then the public will be healthier. |
| Erin Welsh | Yes. |
| Erin Allmann Updyke | As a result of these supplements. |
| Erin Welsh | That was his reasoning. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | And I should note that at the time Utah, the state that Hatch represented, was and actually is still one of the largest producers of dietary supplements. Huge, huge market. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | This bill undid the work of decades of progress that was intended to protect the consumer and essentially completely change the regulatory landscape of supplements. With the passage of DSHEA in 1994, it was no longer the consumers that were protected but the manufacturers. Manufacturers didn't have to provide proof of efficacy or proof of safety before herbs or other dietary supplements made it to the market. All the companies had to do was just put that, I mean I'm sure that there's more that you'll talk about, Erin, but the number one thing that they really had to do is just put that fine print that we all know so well on the label. 'This statement has not been evaluated by the FDA. This product is not intended to diagnose, treat, cure, or prevent any disease.' The ramifications this had and continues to have on the supplement industry and the wellness industry overall are huge because the regulations today are largely unchanged from this 1994 Act. 30 years ago. 30 years ago. |
| Erin Allmann Updyke | Happy anniversary. 30 years ago this year. |
| Erin Welsh | Happy anniversary! It's so lovely. And so to tell us more about these regulations and what supplement manufacturers can and cannot do, over to you, Erin. |
| Erin Allmann Updyke | I will take it away. Ooh, I'm so excited to right after a quick break. |
| TPWKY | (transition theme) |

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| Erin Allmann Updyke | So under DSHEA, the regulation of supplements falls under the category of food. FDA is Food and Drug Administration. But the regulation of supplements falls under the larger umbrella of food rather than drugs and is importantly entirely separate from foodstuffs or conventional foods. And of course it is separate from drugs. So drugs, pharmaceuticals, things that are in fact brought to market with the intention to cure, treat, or prevent diseases undergo pretty intense scrutiny. And we've talked a little bit about this process on the podcast before. Drug manufacturers have to show satisfactory evidence of safety and efficacy before new drugs or pharmaceuticals can be brought to market. This involves clinical trials, multiple phases, years and years of work and lots of data before new drugs are approved by the FDA and usually only for very certain indications. |
| | Food and food ingredients in conventional foods are regulated as well but in a very different way, food additives either have to be in a category that's called generally recognized as safe or GRAS which means that there's enough data on them or like they've been used for a long enough time and in a long enough situation that there's kind of a consensus that they're safe to consume, even if we don't have very specific studies on those ingredients. Or they have to in fact be approved for use with safety data that has to go into it and be presented to the FDA if you're going to use a new ingredient or a new food additive. |
| | With the creation of this new category of dietary supplements, there came a new term: dietary ingredient. A dietary ingredient does not fall within this food additive category and therefore also does not have to fall into the generally recognized as safe category. In short FDA has no oversight whatsoever of these products, that is dietary supplements, prior to the time that they come to market. Let me say that again. The FDA does not have any authority to approve or deny any dietary supplements or their ingredients prior to manufacturers selling them to the public. The one exception of this is that if products are using a new dietary ingredient, which is anything that wasn't marketed prior to DSHEA in 1994, they have to notify the FDA 75 days prior to going live. |
| Erin Welsh | Just notify. |
| Erin Allmann Updyke | Just notify them. So like there's some red flags in terms of safety regulation right there. It's just that there is no regulation whatsoever about what comes to market and it is only in the post market phase that FDA can kind of do any sort of regulation and even then only if adverse events are reported. The reporting of adverse events, the responsibility for the reporting of adverse events falls entirely on the manufacturers and only the manufacturers. |
| Erin Welsh | Which initially they weren't even required to report. |
| Erin Allmann Updyke | I believe yes, I believe at some point they weren't required. It seems like from reading the FDA website it is required that manufacturers report and there is a safety reporting portal that anyone can report concerns- |
| Erin Welsh | Right. |
| Erin Allmann Updyke | With regards to supplements and pharmaceuticals as well. But the only people who are technically held to supposed to be reporting are the manufacturers of the supplements themselves. A little bit, a small amount of a conflict of interest there. |
| Erin Welsh | Yeah. I think that's only as of 2006 is what I remember that there was actually mandatory reporting. |

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| Erin Allmann Updyke | Yeah. Because a lot of the papers I read from earlier than that were like you don't even have to report any adverse events. |
| Erin Welsh | They don't have to report. Yeah. It's so fascinating to me. |
| Erin Allmann Updyke | I know. |
| Erin Welsh | That this is happening all of the time. |
| Erin Allmann Updyke | That's the thing, it is happening all of the time. Thousands and thousands of new products are coming to market all of the time. |
| Erin Welsh | Oh yeah. |
| Erin Allmann Updyke | The FDA has said outright they have no list, like running list of all of the things that are currently on the market being sold as dietary supplements. Like they could not possibly, they do not have the staff, they do not have the resources to keep up with every single new thing that comes to market. There is a repository of dietary supplement labels which is really interesting. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | But I mean they're constantly updating it but it's constantly out of date because of how many supplements are on the market. But that's not even all, Erin. It's like the one small part, right. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | That's like okay, so there's a safety potential red flag that you're not getting things approved before they come to market. |
| Erin Welsh | Well hold on. Before we go on to the next portion, whichever that is, I don't know what it is but I know it's gonna be bad. But there have been a lot of safety issues with people getting really sick or dying from these supplements. And are the supplements still on the market? Like why don't we hear about that? It's just so interesting. |
| Erin Allmann Updyke | Absolutely there has been. I think... So from one of the papers that I read which I think was from 2018, the FDA estimated at least 50,000 adverse events annually which is likely a drastic underestimate because it's estimated that only about 1% are actually reported. Some of these adverse events that are attributable to dietary supplements are likely very trivial but some are potentially life threatening. The biggest ones that we see not uncommonly are things like liver failure or renal failure. And this can happen from either toxicity from overdose, especially of things like for example vitamin A or things that are lipophilic and your body is not excreting. So if you're taking them in high, high quantities, it can cause toxicity.<br><br>But the other thing is that there are a lot of interactions that can happen between supplements and supplements or supplements and other medications, especially because a lot of pharmaceuticals and supplements both rely on our CYP450 system and our liver for metabolism. So if you're taking a lot of different of these supplements and medicines that each of them are affecting the metabolism of the other, you can cause really serious damage because you're affecting the blood levels of these medicines and supplements. And many people don't report their supplement use to physicians or physicians fail to ask people about what supplements they're taking, so this can easily get missed. |

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| Erin Welsh | Or they don't go to the doctor because they don't have health insurance. |
| Erin Allmann Updyke | Exactly. |
| Erin Welsh | Yeah. I'm sorry but just 1%, this is an estimated 1% and it's 50,000 per year and that is 1%. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Is there some Erin math that we can do? |
| Erin Allmann Updyke | Well so I didn't do Erin math because what it sounded like is that the FDA estimated 50,000 but they also estimate that only 1% are reported. |
| Erin Welsh | Oh as in- |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | It's unclear what... Okay, okay, okay. |
| Erin Allmann Updyke | Right. So how did you get to that number? |
| Erin Welsh | Still a staggering number. |
| Erin Allmann Updyke | A staggering number. |
| Erin Welsh | A staggering amount of problems. And I think there was one paper, the title, who had something like Pandora's box in the title and I was like oh yes. |
| Erin Allmann Updyke | Yes. |
| Erin Welsh | Because now that this is out there, now that the supplement industry has grown so, so, so much, is there anything that ever is going to increase regulation? |
| Erin Allmann Updyke | Right. How do we rein it back in? And it's not just the toxicities from overdose or things like that, there's also safety issues that again because these things can come to market without any pre market review or testing, manufacturers are still supposed to adhere to good manufacturing practices the same way that any food manufacturer is supposed to, right. |
| Erin Welsh | Right. |
| Erin Allmann Updyke | They're regulated in the same way as food. But reports back in the early 2010s and things like that revealed things like for some examples, 93% of supplements in some studies had various amounts of heavy metals in them. In some studies, up to 59% of botanical supplements had plant species that weren't listed on the label whatsoever. And then 83% of this time in some studies active ingredients were substituted for each other. So like what it said was in there, it's literally the 1930s in the 2010s. There also have been a lot of cases of adulteration of quote unquote "dietary supplements" with actual pharmaceuticals. Think fen-phen. |
| Erin Welsh | Oh yes. |

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| Erin Allmann Updyke | Right? |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | So fen-phen, in fact half of all drug recalls since 2004, like drug recalls, have actually been from supplements because they were supplements that were adulterated with actual pharmaceuticals. And in many cases, these still sit around on shelves for months even after they are banned. |
| Erin Welsh | Right. Also how much is... Like I remember reading something too about again going back to what's accurate on the label and the problems that could have is some herbal or botanical supplements that have nothing of what they... Like ginseng. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | It was like there is zero ginseng in these 100,000 bottles of ginseng. Or because when you have, and I think we've talked about this several times on the podcast before, but when you are using something that's derived from a plant- |
| Erin Allmann Updyke | Oh yes, we've talked about this. |
| Erin Welsh | There's not... Different plants, different individuals of the same species, different parts of the plant can contain drastically different concentrations of whatever compound it is that you're interested in. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | And that can lead to huge problems if we don't standardize how much you're getting because then that affects use, that affects like the amount, like maybe there's a certain amount that doesn't interact with the other medications that you're taking. But how do you know how much that amount is? Yeah. |
| Erin Allmann Updyke | 100%, Erin. 100%. |
| Erin Welsh | It's just everything. |
| Erin Allmann Updyke | But this is just one half of the problem with the lack of regulation, right. Because that is the safety half, right? |
| Erin Welsh | Right. |
| Erin Allmann Updyke | The safety half of regulation is an issue because there is no oversight before things come to market. So it's all post market that safety issues have to be identified and then dealt with. And the FDA does not have the capacity to look at and analyze all of the things that are coming to market and check them to make sure that they are what they're supposed to be, etc. There's just too many. But the other thing that DSHEA did in the creation of this new category of supplements is that it allowed for supplements to make a lot of claims about what it is they are intended to do. And the vast majority of these claims are entirely unregulated by the FDA which is very troublesome and confusing for consumers. So let's go over these types of claims. |

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| | There's three main categories of claims and some of them are regulated by the FDA and some of them are not. So health claims, which are things like adequate calcium can reduce your risk of osteoporosis or like if you look on your Cheerios box, this is not an ad for Cheerios, but Cheerios can quote "help lower your cholesterol and reduce the risk of heart disease", right. These types of claims that link a substance, a vitamin, a whatever to a disease or a specific condition are called health claims and these are in fact regulated by the FDA. They have to be based on evidence, they are reviewed by the FDA, and they have to be approved prior to marketing. There are both foods and supplements that can make these types of claims. Although apparently in 2009 the FDA sent a big warning letter to Cheerios that said that the way that they were marketing them would make them an unapproved drug. |
| Erin Welsh | What? |
| Erin Allmann Updyke | Because it's like so intense. But I'm pretty sure it still says that on the Cheerios box. Anyways. |
| Erin Welsh | I feel like it does, yeah. |
| Erin Allmann Updyke | Yeah. Anyways. But so those are health claims, right. If it's something about a substance doing something in relation to a specific disease, then it's a health claim. And that is at least to some degree regulated, right, that has been reviewed by the FDA. |
| Erin Welsh | I want to know more about that. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Like in the context what does that mean that it's been regulated by the FDA? |
| Erin Allmann Updyke | Yeah. It means that the links exist enough that scientific data showing links for example of calcium helping to reduce the risk of osteoporosis, right. We know that there are links, there is enough data to show that calcium can reduce the risk of osteoporosis although even that now is a little bit in question. But so to be able to say that, that statement has been kind of approved by the FDA. So if your supplement provides calcium, then you could say something like calcium can reduce your risk of osteoporosis and this product has calcium in it, therefore this product can help reduce your risk of osteoporosis. |
| Erin Welsh | Okay. |
| Erin Allmann Updyke | That's how Cheerios does it. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | Because we know that eating soluble fiber can lower your cholesterol which can reduce your risk of heart disease. And Cheerios contain soluble fiber. |
| Erin Welsh | Okay. |
| Erin Allmann Updyke | That makes sense? |
| Erin Welsh | Yes. But it's saying like we as a product can do this because... Without saying it's not just all soluble fiber, it's like but we are special. |

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| Erin Allmann Updyke | Yes. |
| Erin Welsh | Okay. |
| Erin Allmann Updyke | That's where it is very confusing and murky, right? |
| Erin Welsh | Yeah, yeah. |
| Erin Allmann Updyke | And like can it do it as well as a statin? No, definitely not. But anyways. Then there are nutrient content claims and these are pretty basic. This is just things like this product is high in fiber or low in sugar. |
| Erin Welsh | Okay. |
| Erin Allmann Updyke | And this comes from that Act that you mentioned, Erin, the nutrient education nutrition something. |
| Erin Welsh | 1990, yeah. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | NLEA or something like that. Yeah. |
| Erin Allmann Updyke | So these are also kind of a standard set of definitions that are regulated by the FDA. You have to have this much amount of sugar or this much amount of sodium to be low in sodium or low in sugar or whatever the claims are. So if you are claiming things that don't match up with your label, then you can be fined or reprimanded by the FDA. Those claims are regulated. |
| Erin Welsh | Okay. |
| Erin Allmann Updyke | But supplements can and do make another type of claim which is called a structure function claim. And these are the ones that get really, really tricky. And it was interesting, Erin, because you said in the 1938 one it was like anything saying that they have an effect on the structure or function of your body needs to... Yeah. |
| Erin Welsh | Yep. |
| Erin Allmann Updyke | So structure function claims are any type of claim that describes, and I will quote here, quote, "the role of a nutrient or dietary ingredient intended to affect the normal structure or function of the human body." What? That is the most ambiguous term. So what it ends up meaning in practice is statements like quote "calcium builds strong bones" or quote "fiber helps your bowels be regular". Right? These types of things are structure function claims, they're not directly saying a disease. |
| Erin Welsh | Right. |
| Erin Allmann Updyke | Right? They're not directly relating to the treatment or cure of a condition. They're things like boosts metabolism, improves focus, strengthens hair and nails, glowing skin. |
| Erin Welsh | Yes. |

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| Erin Allmann Updyke | Right? None of these are regulated in any way by the FDA. They do not have to be preapproved and this is where it's even like another layer of tricky, marketing and advertising is not controlled by the FDA, that's controlled by the FTC. So it's like a whole another regulatory agency. |
| Erin Welsh | So I don't have cable TV anymore, I just have streaming services. And I was in a hotel yesterday and the day before and of course I always put on the TV. The amount of commercials for supplements... And I mean every single commercial that I watched was a supplement or a drug. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | It was... It's been such a long time, it was so appalling. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | That it was just like one after the other and then always that fine print, always that fine print. |
| Erin Allmann Updyke | Yes. Yeah. |
| Erin Welsh | That's just like we can say whatever we want. And I know that that's not, as you're describing, it's not quite the case. But so what does then, like how does that regulation differ? |
| Erin Allmann Updyke | Yeah. So manufacturers that make these products are supposed to have evidence that their claims are truthful and not misleading. But they do not have to provide any of this proof to the FDA. And again, the FDA has no oversight of these claims prior to supplements coming to market. And that is why any supplements that are making a structure function claim have to have that disclaimer on the label that states 'these claims have not been evaluated by the FDA'. Because the FDA is not looking at these claims, it is only the manufacturer who supposedly has evidence that these claims are not misleading. Now let's break that down a little bit more because it could be that as an example a particular dietary ingredient in mice at some unknown or specific quantity or concentration did in fact improve a mouse's concentration on a particular task, right. That is evidence that this ingredient improves concentration. Or it could be that in cell culture a particular ingredient at some quantities, some concentration, improved mitochondrial function. And then you could make that claim without being misleading. |
| Erin Welsh | But these are studies done by the supplement companies. |
| Erin Allmann Updyke | Potentially. Or it could be studies done by anyone, right. |
| Erin Welsh | Sure. |
| Erin Allmann Updyke | The supplement company just has to have... There has to be evidence that they have in existence that the claims that they are making are not misleading. |
| Erin Welsh | Okay. But digging into this evidence a little bit more. Does that have to show up in peer reviewed journals? Can it show up in a pay to publish journal? Can it show up anywhere? Can it be one? Can it be a super subjective measure where it's one mouse who looks like maybe they're concentrating a bit more? |

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| Erin Allmann Updyke | Erin, you are asking exactly the right question. Because the truth is that without anyone overviewing this evidence other than the manufacturer, we as consumers have no way of knowing what this evidence is, what populations the studies were done in. Was it a dish? Was it a single mouse? Was it dogs? Was it humans? Was it peer reviewed? Was it done by the manufacturer? Also what were the concentrations of this ingredient or this molecule that were being used? What form was it being given in? Was it an eye dropper on a petri dish or was it thousands of milligrams of something but the supplement contains 4 mg of whatever this thing is and you're going to ingest it? We don't know and neither does the FDA. That's the point. |
| Erin Welsh | This is appalling. I don't know why I'm surprised. I guess I shouldn't be surprised. |
| Erin Allmann Updyke | Yeah. And so like in theory if things are marketed in a way that is misleading, then the FDA could investigate and say hey, this doesn't match up with what you're saying. But how often can that happen? |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | Because the industry is so saturated, right. |
| Erin Welsh | Right. And if there is a complaint that is made, who makes that complaint? Who follows through that complaint? |
| Erin Allmann Updyke | Right. |
| Erin Welsh | Can it be like can we just get a team of citizen scientists working together? Like just grassroots effort to be like hey, this label says X, Y, and Z, I looked into the literature and found that there are no links. I'm making a complaint. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | Like how does that process work? |
| Erin Allmann Updyke | Right. |
| Erin Welsh | Or does it have to be... |
| Erin Allmann Updyke | These are the questions, Erin, and I don't know the answers to them. There's also another just kind of little under layer of confusing this. It's very confusing. |
| Erin Welsh | Yeah, intentionally so. |
| Erin Allmann Updyke | Yes, it really is. Because supplements also have to have that asterisk that you mentioned, Erin, that it does have to state that this supplement is not intended to diagnose, treat, cure, or prevent any disease because that is part of the definition of a drug and therefore not a supplement. So there's this statement on the FDA's website that if a supplement is marketed with one of those intentions or used with one of those intentions, then they are subject to regulation as a drug, as a pharmaceutical rather than a supplement. But I still don't understand how that actually happens. What I will say is that if you go on the FDA's general page about supplements, it is just a long list of links of warning letters and things that they've identified. Like don't take this honey supplement that claims to do X, Y, and Z because it's actually full of sildenafil. |

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| Erin Welsh | Yes. Yes. |
| Erin Allmann Updyke | It's Viagra in a honey supplement. And so it's not that they're not doing their job, it's just that all of their job is in post market review and there's way too many supplements on the market and that is way too difficult and it means that consumers are getting their hands on things that are not regulated, entirely by design. |
| Erin Welsh | By design. |
| Erin Allmann Updyke | By design. And like we already mentioned, there are plenty of instances, and we'll link to a lot more for everyone, of times when this has failed consumers drastically. |
| Erin Welsh | It's so interesting the amount of anger, vitriol, attacks on things like vaccines. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Which are subject to a degree of oversight and regulation that is something that the supplement industry has never ever seen. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | The scrutiny is there to protect consumers. That those are the target of so much disinformation and like undermining of... |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Yeah. Whereas this entire industry... And it's also kind of I think it relates to this weird paradox of the wellness industry. What is wellness? This is like a whole other thing. But I mean I think that it relates to supplements in that when you're talking about that there is the structure and function to improve the normal. Then first of all what is the normal? What does that mean? |
| Erin Allmann Updyke | Right. |
| Erin Welsh | That phrase is meaningless. |
| Erin Allmann Updyke | It is. |
| Erin Welsh | How often is normal re-evaluated? And that also I think relates to stuff that we've talked about when it comes to like vitamin D and what is the daily requirement? |
| Erin Allmann Updyke | Right. |
| Erin Welsh | And maybe we do need to increase that. But I think it's like this wellness industry saying on the one hand you're healthy and you're great but you could be healthier. |
| Erin Allmann Updyke | You could be better. |

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| Erin Welsh | You could be better. But you're not, but there isn't a disease that we're treating. So it's like I think that it doesn't make any sense because if you're saying you could be better but you're already healthy and regulated right now but your bowels could be better- |
| Erin Allmann Updyke | Right. |
| Erin Welsh | Then doesn't that suggest or imply a state of disease? |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | I don't know. |
| Erin Allmann Updyke | I don't either, Erin. |
| Erin Welsh | Yikes. |
| Erin Allmann Updyke | Yikes is right. I have honestly more that I could get into but I'm kind of just curious. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | Curious about the financial state of the... |
| Erin Allmann Updyke | The financials of things. Yeah. |
| Erin Welsh | Okay. |
| Erin Allmann Updyke | It's just such... Tell us how big of an industry it really is, Erin. |
| Erin Welsh | Okay. Let's take a quick break. I think we need a break. |
| Erin Allmann Updyke | (transition theme) |
| Erin Welsh | Okay. So these are primarily US numbers but I will throw in a few global ones that I came across. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | In 1994 when Orrin Hatch's DSHEA was passed, around 40% of the global population in the US reported regular use of dietary supplements. And the US dietary supplement industry came in at around an estimated $3.5-4 billion. |
| Erin Allmann Updyke | I already know some numbers from today so I'm like oh my god. |
| Erin Welsh | Oh my god is right. Around that time, an estimated 600 US supplement manufacturers produced around 4000 products. |
| Erin Allmann Updyke | Oh my god, Erin. |

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| Erin Welsh | Okay. 25 years later in 2019, we laugh because otherwise we'd cry, that number of products in 2019 had shot up to nearly 90,000 from 4000 25 years earlier. And the dietary supplement market was an estimated $40 billion, 10 times more, with around 60% of us adults reporting regular use. And things probably would have continued to steadily rise as they had before. But then a little something called COVID-19 came onto the scene. |
| Erin Allmann Updyke | Oh no. |
| Erin Welsh | Before COVID vaccines were released, were widely available, before antivirals for COVID were developed, people increasingly turned towards dietary supplements that promised to boost or enhance their immune system. The most recent numbers that I found for the US are that in 2022 the dietary supplement market was valued at $50.91 billion. So nearly $51 billion. So that's three years prior it was 40 billion. |
| Erin Allmann Updyke | Wow. |
| Erin Welsh | And that's the US alone. By 2030 it's projected to reach $78.94 billion. It's staggering. So you mentioned the National Institute of Health's dietary supplement label database. And so this keeps a record of as many dietary supplements as they can, current and historical. And so I went to there and I filtered to look at just those currently on the market and it came to 111,336 labels. |
| Erin Allmann Updyke | Wow. |
| Erin Welsh | Those are just the ones in this database. |
| Erin Allmann Updyke | No the market. Yeah, in the database. On the market. |
| Erin Welsh | Yeah. On the market, in the database. Yep. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | That's up from 4000 in 1994. Comparing just 2019 and 2020, herbal supplement sales in the US rose to $11.26 billion in 2020, up 17.3% from 2019. So they shot up nearly 20% in one year, sales for herbal supplements. These trends are also happening on a global scale. During COVID there was a global increase in overall supplement use of 23%, a 40% increase in intake of vitamin C, and an 82% increase in multivitamin consumption globally. |
| Erin Allmann Updyke | Why are people so obsessed with vitamin C? I'm sorry. |
| Erin Welsh | I know. Good marketing. |
| Erin Allmann Updyke | Yeah, I guess. |
| Erin Welsh | It's literally just marketing. The global dietary supplements market was estimated to be $177.5 billion in US dollars in 2023. That's projected. So from $177.5 billion, 2023, projected to reach $327.4 billion in US dollars by 2030. So in seven years it's going to nearly double. And that's the global market. |
| Erin Allmann Updyke | Wow. |

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| Erin Welsh | Yeah. Clearly the dietary supplement industry is booming and it's going to continue to boom unless something is done regulation-wise, which it probably won't be. And I think it's completely understandable why people take supplements. We've talked about that there are supplements that are important to take and there are certain people that should be taking certain dietary supplements as discussed with their physician to make sure that there are no interactions, that they're getting exactly what they need in the amounts that they need it, all those things. |
| Erin Allmann Updyke | Yeah. And like if we take a step back and think about the idea of supplementation on a large level globally- |
| Erin Welsh | Yes. |
| Erin Allmann Updyke | Globally over 800 million people worldwide are chronically undernourished and 2 billion people are affected by micronutrient malnutrition. Children are often the most affected by these, like 45% of deaths among infants under age five are attributable to undernutrition. So the idea of supplementation makes a lot of sense in a lot of scenarios and especially in a lot of countries that are low income countries or where food is difficult to come by. And so undernutrition is an issue. But the truth is that most of the parts of the world that are economically advantaged are able to meet their nutrient needs with foods without supplementation of vitamins and minerals except in certain scenarios that we have data for, like folate in pregnancy or like vitamin D in rickets, right. |
| Erin Welsh | Right. |
| Erin Allmann Updyke | Just the idea of supplements is not necessarily the issue. It's the rest of it. |
| Erin Welsh | Well and that market share is not in these areas that need it. |
| Erin Allmann Updyke | No. |
| Erin Welsh | The market share is in the areas that already can, where the vast majority of people get all of their needs met with the food that they eat. |
| Erin Allmann Updyke | Right. |
| Erin Welsh | I think that we want to make clear that there is a very strong need for dietary supplementation in certain contexts. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | And what we're talking about is not necessarily that really. |
| Erin Allmann Updyke | Yep. Not. |
| Erin Welsh | We're talking about the other sphere of things that is the more revenue generating sphere. |
| Erin Allmann Updyke | Yeah. Right. |

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| Erin Welsh | And I also think that going back to what we've already talked about, in places where people can meet most of their dietary needs through the foods that they eat, they're also seeing on TV or anywhere else convincing ads. They're always carefully worded but they're very powerful in their persuasive ability to be like you could use this. And even if you don't need it, it could enhance. |
| Erin Allmann Updyke | Enhance. |
| Erin Welsh | Enhance. |
| Erin Allmann Updyke | What a word. |
| Erin Welsh | Our healthcare system, like we talked about, makes these supplements appealing. No one wants to go to the doctor, especially here in the US where like okay it's going to take you three months to see you're primary care physician. And then you go and you're like a copay or you want me to make another appointment because I forgot to list that I want you to look at a mole in making an appointment so now I have to make another appointment. |
| Erin Allmann Updyke | Yeah. Well because you only had 15 or 20 minutes at that appointment anyways. |
| Erin Welsh | Yes. |
| Erin Allmann Updyke | Because the primary care doctor has to see 40 patients in a day. |
| Erin Welsh | And they're scribbling notes and you're like are you even listening to anything that I'm saying? Yeah. And so I think that these supplements can provide this false promise that if you take them, it counts as preventative medicine and you won't have to go to the doctor. Or maybe you do go to the doctor and like we talked about only 15 minutes, they're not listening to you, they dismiss your concerns, they can't provide answers. And a lot of the times those supplements will promise answers, even if they can't provide proof because they're not regulated, they're not required to follow through on those promises. |
| | There is this dark side to the supplement industry and I think it became especially prominent during COVID. The early days of the COVID pandemic were like I've already mentioned a boon to the supplement industry. Without curative medicine or medicine that treated without vaccines, people turned to supplements to protect themselves against this new respiratory virus. And that's evident in the growth of the industry. And then when the vaccine was ready for deployment, it shook the supplement industry up a bit. There would be sort of releases from CEOs being like don't worry everyone, like calm down, we're going to weather the storm of the vaccine being available. |
| Erin Allmann Updyke | Wow. |
| Erin Welsh | People will still want to take supplements. We just might need to change our strategy. Sometimes that pivot meant that supplement brands would advertise their supplements as boosting your immune response to the vaccine itself, promising a more robust response to the vaccine. No proof, no proof. And other supplement companies or people who represented supplement companies would attack the vaccines themselves. A study from 2023 found that one in three of the anti COVID vaccine major actors that they, and I don't mean actress as in like acting business- |
| Erin Allmann Updyke | Not like Hollywood you're saying. |

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| Erin Welsh | Like the main people. One in three of the main anti COVID vaccine people that they studied in this study sold health supplements or merch or advertised for supplements. One in three of the major anti anti COVID vaxxers. And so they gave as an example in this paper the website stopmandatoryvaccination.com which sold a product called Pure Body Strength, which was advertised for children who had gotten vaccinated. |
| Erin Allmann Updyke | Okay. |
| Erin Welsh | Other websites like healthytraditions.com or vaccineimpact.com advertised for or sold supplements directly. And of course this is not new to COVID. Just remember Alex Jones and InfoWars which made $165 million between 2015 and 2018 selling supplements and merch and is famously anti-vaxx as well as pushing other incredibly harmful, horrible conspiracy theories. But many supplement companies or people who represented supplement companies or were paid by them as spokespeople I guess took advantage of the fear and health anxiety during the pandemic and they leveraged that to make money. These companies or influencers paid by these companies would tell you don't get vaccinated, take these supplements instead, you don't need a vaccine, you don't need to inject those harmful things into your body, those chemicals. You should ingest these natural supplements. Are supplement companies alone responsible for the rise in anti-science and anti-vaccine rhetoric during the pandemic? No, of course not. |
| Erin Allmann Updyke | Yeah. |
| Erin Welsh | There are many factors at play. So there's some great research done by the Center for Countering Digital Hate and I'll include a paper, a report by them in the notes for this episode because there are so many different sources of misinformation and disinformation. But only some of the misinformation is coming from people trying to sell supplements and only some supplement companies are peddling vaccine misinformation. But I think that this reveals a larger issue with the way that companies are permitted to profit off of misinformation directly or indirectly, right. If you're promising to boost immune health, even if you're not directly saying vaccines are bad, it's still saying something that is unlikely to be supported by scientific data in a way that is meaningful. |
| | I don't have a solution for how to better regulate but I feel like testing the supplements for safety and efficacy before they reach the market seems like a good place to start. And I don't think that's, I mean maybe this is very pessimistic of me but I feel like that's not about to happen. I really do hope that something changes though and it's not a reactive change to some horrible thing that happens because of this unregulated or lack of regulation surrounding supplements. And maybe the smallest step forward is just people growing more aware of the lack of hurdles that supplement brands face before getting something to the market and the vast profits that they enjoy. And so with that, you can find all of this information, more information about the lack of regulation- |
| Erin Allmann Updyke | So much more. |
| Erin Welsh | And all the profits and etc in our sources. |
| Erin Allmann Updyke | Let us tell you where we got this information from. |

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| Erin Welsh | Yes. One of the main papers that I used for the history part was by Swann from 2015 called 'The History of Efforts to Regulate Dietary Supplements in the USA'. And then there are several papers about the industry. I'll link to all of them but there's like one great paper by Arora from 2023 called 'Global dietary and herbal supplement use during COVID'. I do really want to shout out a paper by Moran et al from 2024 called 'Vaccine misinformation for profit: conspiratorial wellness influencers and the monetization of alternative health'. Fascinating. |
| Erin Allmann Updyke | Love it. |
| Erin Welsh | Yes. |
| Erin Allmann Updyke | I want to read that one. |
| Erin Welsh | Yeah. |
| Erin Allmann Updyke | I got most of my information directly from the FDA website. How handy is that? |
| Erin Welsh | Heck yeah. |
| Erin Allmann Updyke | But also a few papers that kind of went over and have highlighted some of the issues that have arisen as a result of this regulation. And then a couple others on the global landscape because sorry that this was a very US centric episode but that's what we talked about today. We'll post the links though, we'll post all of our sources from this episode and every one of our episodes on our website thispodcastwillkillyou.com under the EPISODES tab. |
| Erin Welsh | We certainly will. A big thank you to Bloodmobile for providing the music for this episode and all of our episodes. |
| Erin Allmann Updyke | Thank you to Tom and Lianna for the wonderful audio mixing. Couldn't do it without you. |
| Erin Welsh | Thank you to Exactly Right. |
| Erin Allmann Updyke | Thank you to the dog that won't stop barking. And thank you to you, listeners. We really liked putting together this episode. |
| Erin Welsh | Yes. |
| Erin Allmann Updyke | So please tell us if you loved it, if you hated it, if you want more. Obviously we're going to do more deficiencies, we end up talking about supplementation there. But do you want more on the more controversial supplements or the supplements that you take? What do you take? Do you want us to do an episode about it? |
| Erin Welsh | Turmeric? |
| Erin Allmann Updyke | What's the deal on this one vs that one? |
| Erin Welsh | Collagen? CoQ10? |
| Erin Allmann Updyke | CoQ10? |

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| Erin Welsh | All of them. |
| Erin Allmann Updyke | I've got collagen in my cupboard. I know it doesn't do anything. |
| Erin Welsh | And yet. |
| Erin Allmann Updyke | And yet. |
| Erin Welsh | See? |
| Erin Allmann Updyke | Marketing. |
| Erin Welsh | Yeah, happens at Costco. Costco is, yeah. Anyway. |
| Erin Allmann Updyke | Anyway. |
| Erin Welsh | Thank you especially to our wonderful, generous patrons. We really appreciate your support so, so very much. |
| Erin Allmann Updyke | We really do. Thank you. |
| Erin Welsh | Until next time, wash your hands. |
| Erin Allmann Updyke | You filthy animals. |