THE MODEL HEALTH SHOW

EPISODE 512

The Truth About The FDA

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SHAWN STEVENSON: Welcome to the Model Health Show. This is fitness and nutrition expert, Shawn Stevenson, and I'm so grateful for you tuning in with me today. Following a landmark decision by the FDA to approve a new series of medications, there's a lot of questions that are now swirling around in the air. I thought it would be a good opportunity for us to really dig in and to investigate the efficacy of the organization that is responsible for determining efficacy of drugs and of food that is on our store shelves and also reaches our bodies, and to see where this entity began, and where is it at today? How good is the FDA at doing their job? And so this is going to be an incredible adventure and a lot of things to take notes on, so focus in, and let's dive into this adventure exploring the Food and Drug Administration.

The modern era of the FDA dates back to 1906, with the passage of the Federal Food and Drugs Act. What later became known as the FDA, the Food and Drug Administration, was then known as the Bureau of Chemistry. The FDA was established to enforce measures to ensure food safety, during a time when poor conditions and lack of quality standards led to high rates of food-borne illnesses. This was a time when it was a regular occurrence for you maybe go grab you a couple of slices of baloney and find yourself with your head in the toilet, alright? The regulation around meat and around food stuffs overall, and companies finding little unique ways to distribute food that is well past its expiration date, for example, by maybe adding some kind of chemicals, adding some fragrance, so that you don't really notice that the stuff has gone bad. So, all of these things brought about a lot of public demand for greater government regulation for food safety, so that was a big driving force for the FDA in the beginning.

Now, they did a lot of interesting things that would seem obvious today as well. Like getting Coca-Cola to stop putting cocaine in Coca-Cola, which is a real thing. And ensuring that children's cough syrup didn't have this interesting combination of opium and alcohol, which again, was a real thing. The FDA brought about conformity to approved medical devices, cosmetics, food additives, and more. And in 1938, the Food, Drug and Cosmetic Act established new drug regulations, including pre-market approval of all new drugs, meaning that drug companies had to prove that their drug was safe before it could be sold to the public. Prior to this, people was just putting stuff out on the streets, putting stuff on store shelves without a lot of regulation, and so this really brought it to bear. And again, this wasn't that long ago, it's 1938 when this transformation took place.

Now the FDA grew in power immensely in the proceeding years through legislation and through government influence. And in 1960, for example, drug makers tried to get the sedative, Thalidomide approved in the US as it had been approved already in several other countries. But the FDA blocked it, calling for further safety studies to be done on its use. And

as it turned out, Thalidomide actually caused thousands of birth defects, and the FDA's decision to play it safe and to call for further testing, saved lives and helped to solidify the FDA as a leading regulatory agency.

Now, all of these things sound pretty great, but things have changed dramatically in recent years. The FDA was once an organization that was exclusively funded by taxpayers and thus working for our citizens. Today, however, the FDA is substantially funded by pharmaceutical companies themselves, to the tune of billions of dollars each year.

Now, to find out how we got from there to here and what the results have been because of it, we must take a deep dive into the world of this regulatory agency. The FDA, the Food and Drug Administration. Now, you might think that a drug receiving approval from the FDA has been carefully vetted, it offers a higher degree of safety and efficacy. Well, a 10-year analysis, published in the Journal of the American Medical Association, tracked the negative safety events from FDA-approved drugs. The researchers found that nearly one-third of all drugs approved by the FDA had some kind of a safety event after reaching the market. Nearly one-third.

Now, what's most alarming about all of this is the timeline of the safety events being noticed and being acknowledged. The average time from approval of the drug, getting to market, and the first post-market safety event, was 4.2 years later. 4.2 years after the drug is deemed to be safe and allowed to be marketed to our citizens. Now in this analysis, again, published by the Journal of the American Medical Association, the FDA was right about drug safety about 69% of the time.

If we were to use the analogy of our education system, for example, the FDA would be a D student. Now, that's okay, if millions of lives weren't routinely destroyed because of the D student level success rate. That would be okay if they didn't receive billions of dollars in funding each year to ensure that they were above a D level student, to ensure that they are actually doing things with high efficacy, but they're receiving this funding under the guise that having this supreme influence and supreme control is needed in order for them to be the best of the best in the world, but if you actually look at the success rate its far from what people are led to believe.

Again, the median time, the average time from the drug being approved as safe then allowed to be marketed and consumed by the public, the average time from it getting released, and being approved to the first acknowledged safety event is an average of 4.2 years later. Years later. Now, with this being the case, unfortunately, there have been very well-educated and well-intentioned people who've naively believed that the recent drugs that have been approved by the FDA, that if there was a big problem, that it would be seen within the first few

weeks or the first few months, when in reality, most of the safety events are seen years later and it's just as if this is lost in this conversation and overlooking how biology really works, we don't know all the ramifications of a new drug intervention that quickly. That's just not how biology works.

Now, in an attempt to excuse the poor performance seen in this FDA analysis, David Gortler, a former FDA official stated, "There is nothing to be alarmed about with this," noting that drugs will clearly work differently in a person who weighs 200 pounds for example, versus someone who is 125 pounds. Race, gender, ethnicity and other health problems, underlying things, all can affect how a drug works. "We may all be human beings, but drugs react differently in all of us, so you are going to see these issues, this is to be expected." We are so radically different, so why then are we participating in a one-size-fits-all drug campaign? Why is this happening? When the what about-ism, when the perspective shift to, "Of course, these drug incidents are normal because we're all so different," why are we not doing things differently for different people? So I just want you to take that, put that in your back pocket, stick that in your superhero utility belt and let that be something that we continue to mull over and to ruminate on and to really think about and contemplate, because at the end of the day, we have to realize how unique we are and how unique our needs are and how unique our biochemistry is. Our metabolism is unlike anybody on planet Earth.

We are similar, of course we're in the same species, but the make-up of things and how our body is organized, our hormone cascade, neurotransmitters, neuropeptides, our immune system, so many variables make us so incredibly dynamic and unique, it's really hard to track any of this stuff. So, erring on the side of safety, and long-term safety should be the priority. Now, another big, big understanding for us to take away is that the FDA doesn't actually test any of the drugs that it approves. They leave it up to the honesty of the pharmaceutical company to test and then to report their conclusions to the FDA. It's sort of like grade your own homework, it's sort of like that opportunity when you're in school, like, "Of course I'm going to get 100%, you kidding me? I get to grade this myself. I get to do all this stuff behind the scenes, grade my own paper and then turn it into you to give me a stamp of approval," or not, which we're going to see as we evolve here in this conversation, what does that approval rate look like with pharmaceutical companies having a major influence now by being a major funder of the FDA itself?

So, with this being the case, and the FDA having a D level of success in determining safety of drugs, what are the real-world implications? What does this look like for us as citizens in our society? Well, a report from the International Journal of Health Services found that in a recent 17-year span, an analysis of 17 years here in the US, unsafe drugs were prescribed more than 100 million times before being recalled. Approximately 4,500 drugs and devices are recalled every single year. These are the same products that were given FDA approval, and in many

cases, were widely ingested or injected before being recalled. Now, to be clear, all recalls are not for safety events but a scary amount of them are and I believe that you have the right to know about it. Thousands of individuals here in our society die each and every year from these drugs, millions more injured, and they just get recalled and then they get replaced with different ones.

It's starting to look like a revolving door of cash grabbing and a lack of integrity and efficacy with the way that this system is running, but again, when I say some of these numbers, I want to get more specific. The EJS Center for Ethics at Harvard University states that properly prescribed drugs, properly prescribed drugs cause about 1.9 million hospitalizations each and every year, nearly two million a year. Another 840,000 hospitalized patients are given inappropriate medications that cause serious adverse reactions for a total of 2.74 million serious adverse drug reactions. The Harvard researchers reported that nearly 130,000 people are killed each and every year in the United States from taking pharmaceutical drugs as prescribed, and another 70,000 people are killed each year from prescription drug overdoses. This totals about 200,000 deaths each year at the hands of pharmaceutical companies in their analysis.

The Center for Ethics at Harvard states, "The FDA does not acknowledge these facts and instead gathers a small fraction of the cases." Millions of people have died from prescription drugs. Yet, most people never hear a peep about it. A big reason for this is the negligence in reporting by the FDA and other regulatory agencies. It's a complicit system. It's not just the pharmaceutical industry, it's also the regulatory agencies that allow these things to go unchecked and continue to happen each and every year. And again, most people never hear a peep about it. Do you think that's an accident? Prescription drugs actually kill far more people than illegal drugs do, far more people, yet, where is the war on drugs when it comes to pharmaceutical companies and negligence? Where is the war on drugs when it comes to oversight by the FDA?

Again, working in tandem to put drugs on the market that repeatedly demonstrate unsafe outcomes, and again, we're operating in a medium right now, we're a very drug-heavy, drug-dominant culture. In the United States were the most drugged, pharmaceutical drugged, to be clear, culture in the world. About 70% of our citizens are on pharmaceutical medications. That's right, the majority of our citizens are on prescription medications, and most of them are taken habitually to treat our epidemics of chronic diseases, and it's important for us to take an honest assessment, has our drug-heavy, drug-dominant medical system, system of healthcare, has it actually brought about beneficial results? Are we seeing the rates of heart disease decline, the rates of cancer, the rates of Alzheimer's, the rates of liver disease, kidney disease, obesity...?

The list goes on and on, stroke, heart attacks, and if we're taking an honest assessment, something's not working here because things continuously get worse and worse and worse. And we do know that pharmaceutical medication has its place for sure, it definitely has its place, but in particular, they're best suited for acute instances, so acute situations. But if we're talking about a reliance on medication to mask a symptom of abnormal blood sugar, for example, we'll say... We'll take the example of metformin, and somebody is experiencing insulin resistance and abnormal blood sugar, metformin can be helpful in helping to keep the person alive, but the question is what's causing the insulin resistance? Is there some kind of disruption with the person's alpha cells and beta cells and their pancreas? Is there something going on with their body fat ratio and the insulin sensitivity of their muscle cells versus their fat cells? Is there something going on with their liver that has a major role in managing glucose and blood sugar as well?

There's so many different factors here that people aren't getting educated on, but instead of analyzing those things and figuring out where is the actual cause of this disease coming from, we put a drug on top of it to treat a symptom rather than addressing the underlying cause of the abnormal blood sugar. So what does that do? When we're not treating the underlying cause of the insulin resistance, for example, which might be the rampant ingestion of highly refined sugar, which is causing this cascade of metabolic dysfunction, what that's doing is sort of like turning on the faucet in a sink that's clogged, and the water is now starting to overflow and flood the room causing damage, aka disease. And throwing drugs at the issue is sort of like running in with buckets and towels to try and slow the progress of the disease. When in actuality, the solution is to remove the clog or to just turn off the damn water. Either one is going to help to remedy the situation, but we're treating symptoms. Again, we're coming in with buckets and towels. When in actuality, the water that's overflowing in our metabolic sink is the toxic food and beverages that have become normalized in our culture, and the clogged sink is akin to the gross lack of movement in our society today.

We are also the most sedentary population in the history of the world. This is not okay. And instead of addressing these issues and making movement accessible and a part of our lives and our livelihood, we are inundated with conditions that lead us to be more and more sedentary instead of ensuring that people have access to healthy food and to real nutrition that our genes literally expect us to have versus the brand-new invented chemical-laden food, it's not even food, I struggle to even call it food, that we are consuming today. Instead of getting access to real food and providing that, we have a four trillion-dollar healthcare system. If just a fraction of that was used to ensure that our citizens were getting access to high quality food our epidemic rates of disease would be plummeting because these are the very things that we're making our tissues out of.

All that cellular communication, it's all based on food. Your cells are literally made from the food that you eat. Your hormones are literally made from the food that you eat. Your immune cells are literally made from the food that you eat. How much attention are these things getting? Instead, we're treating symptoms, and we're even having this conversation about the safety of drugs, which taking a deeper analysis of the whole process is bringing up some huge concerns because in the average year, according to Johns Hopkins University researchers, pharmaceutical drugs are the third or fourth leading cause of death in our society. It's funny you don't hear more about that. And it has a lot to do again with who's tracking things behind the scenes and propping that up. When you go and check out, what are the top 10 causes of death? You're not going to see that unless you know where to look, because it's true, it's absolutely true, pharmaceutical drugs kill hundreds of thousands of Americans every year, and you have the right to know about it.

Now, you would think that the all-powerful FDA would crack down on pharmaceutical companies, crack down on all of these deadly incidents to protect US citizens, but then you'd be failing to realize that, today, pharmaceutical companies provide the FDA with nearly half of their overall budget, and upwards of 75% of its scientific review budget of the FDA itself is coming from those same pharmaceutical companies that it's supposed to be regulating. In fact, pharmaceutical companies provide billions of dollars in funding to the FDA every year, the very organization responsible for regulating drug companies is massively funded by those same drug companies. The question is, how is this happening? Well, it began with the advent of something called user fees. Under the guise of providing the FDA with more resources to approve drugs and get them to the market for patients who may need them faster, legislation was passed, put in place to allow drug companies to begin paying the FDA directly hefty user fees with a guaranteed date of review to be completed for them, so they're going to pay these massive fees to the FDA for fast review and a guaranteed date on when they're going to get to their approval.

Again, these user fees are the magnitude of billions of dollars collectively from pharmaceutical companies' pockets to the FDA's coffers. An analysis that was published in the Journal of Law, Medicine and Ethics, titled Institutional Corruption of Pharmaceuticals and the Myth of Safe and Effective Drugs states, "The authorization of user fees in 1992 has turned drug companies into the FDA's prime clients, deepening the regulatory and cultural capture of the agency. Industry has demanded shorter average review times and with less time to thoroughly review evidence, increased hospitalizations and deaths have resulted. Meeting the needs of the drug companies has taken priority over meeting the needs of patients. Unless this corruption of regulatory intent is reversed, the situation will continue to deteriorate."

The report also states, "The pharmaceutical industry has corrupted the practice of medicine through its influence over what drugs are developed, how they're tested, and how medical

knowledge is created, and heavy commercial influence has compromised Congressional legislation to protect the public from unsafe drugs." Having a system here in the United States that allows the FDA to be funded by the very same entities to the tune of billions of dollars each year by the same industry that is supposed to be policing, creates an obvious conflict of interest that has been repeatedly reported in some major published analysis, peer-reviewed journals, the list goes on and on, but what's being done about it? And even more importantly for this context right now, what are the results?

What's happened since the advent of user fees? Well, the FDA's rejection of new drugs has plummeted. Didn't see that coming. In 2017, the FDA only denied 19.7% of all applications for new drugs, biologics and efficacy supplements, compared to denying a high of nearly 60% of applications in 2010. Big difference, dead giveaway. Since the FDA began receiving funding from pharmaceutical companies, we've also seen the approval of some of the most addictive and deadly opioids that have destroyed millions of lives and devastated countless families. Again, these drugs, here in the United States it's well noted now that about half a million people have died directly from pharmaceutical companies pressing and allowing addictive opioid onto the market. Those are just the deaths, which is... We can't even understand that.

Half a million people, 500,000 lives, lost? That's not to mention the millions upon millions, upon millions of other lives that were destroyed, people that were injured, families destroyed due to this, and the FDA signed off on these drugs, giving them the stamp of approval that they're safe. How do we not have a major problem with that, and look for accountability? And now the craziest part, and why this is getting done right now, this masterclass on the FDA, we're looking to these same entities to determine what we're putting in our bodies right now. What's wrong with us? How can we allow this to happen?

We're acting as if these organizations are operating from a place of efficacy. We're acting like they don't grade their own homework. We're acting like they don't control the media and the reports that you get. Who is controlling the information that you receive, and what is their track record? Because it's not hard to find. Pharmaceutical companies are a major contributor to our major media networks, our major news outlets, again, to the tune of billions of dollars each year. Do you think you're going to hear the reports about pharmaceutical drugs killing people on a regular basis, because it's happening on a regular basis to the tune of thousands of people each day? Absolutely not. They're not going to do that and then cut right to a commercial break where they're having their advertisement for a drug, a new drug. That's just not going to happen. But what are you plugged into?

Now, digging in deeper here, with all of the rapidly approved drugs, again, the rate of drug denials for approval plummeted, alright? Now again, with all of the rapidly approved new drugs, this is where we're at today, there is now a 20% chance, a one in five chance that

trusting citizens will experience an adverse event when taking a prescription drug, a one-in five chance. You got better odds with Russian roulette, it's six, one in six at least. And some of these instances are literally deadly. Literally killing our citizens. And I want to reiterate this point as well, you have to keep in mind just how difficult it is to actually prove that the drug company is at fault when somebody is injured or lose their lives, only a small fraction of those cases are acknowledged. These pharmaceutical companies have the most powerful legal team on planet Earth. Their job is to make sure that it's not their fault, it is your fault or it's the fault of something else.

So, as we're seeing these numbers, keep that in mind, keep that in mind, because it's a much bigger problem than even what we're highlighting here. Now, the same companies that our citizens blindly put their trust in are routinely, these pharmaceutical companies, routinely charged with felonies, bribery, fraud, falsifying data, and again, they've killed millions of our citizens. For example, we talked about this multiple times, but I'm just going to hit a couple here. Pfizer had to pay out $1.2 billion, over a billion dollars, to settle lawsuits stemming from side effects from Prempro, again, approved by the FDA, that ended up causing women to develop breast cancer. We didn't know at first, but later on, cancer.

And this is just, again, one of the many instances where this takes place, but also on the back side with these pharmaceutical companies consistently engaging in criminal activity. Pfizer also had to pay the largest healthcare fraud settlement in the history of the Department of Justice, $2.3 billion for committing felony charges, fraudulent marketing, lying, but we act like they're telling the truth now. And then if we look at another power player in this current campaign, Johnson and Johnson, for their role in the opioid epidemic, their massive role being the major supplier of narcotics used to make opioids, they're El Chapo. Johnson and Johnson has the friendly baby commercial with the suds and the bubbles, they're El Chapo, alright? They're supplying other drug companies with the product, getting it cut up, sent to you.

For their role in the opioid epidemic, Johnson and Johnson is now part of a massive $26 billion settlement for their crimes, $26 billion, that's a lot of money. It's a lot of money, but not to them, not really. They're still business as usual, especially with the gold rush they're experiencing right now. Not to mention Johnson and Johnson was also caught illegally promoting anti-psychotic drugs, illegally, knowing that this isn't for them, children, seniors and people with developmental disabilities. The justice department notes that their criminal and civil fines because of their, again, criminal activity, their fines were $2.2 billion. It was that bad. But if you do hear about it, it's here today, gone today. If you hear about it.

But what's often overlooked in this is that the pharmaceutical companies aren't putting dangerous drugs on the market on their own, they're doing it in tandem with the FDA. The advent of user fees was to accelerate the entry of more drugs to the market in response to our

skyrocketing rates of chronic diseases. Again, drugs have their place, especially in the treatment of acute conditions, but our system of health care has become so drug-dominant that it has completely moved away from actually teaching people how to be healthy, it's called Health Care, using drugs to treat the symptoms of disease that are caused by diet and lifestyle behaviors, doing this that... What we've been doing is aimless. It's idiocy.

We're doing the same thing over and over again, expecting a different result, the definition of insanity. This isn't a good insanity; this isn't like Shaun T insanity. This is like, something is wrong with us. We're still using drugs to treat conditions caused by poor diet and lifestyle choices. The Journal of the American Medical Association 2018 meta-analysis published a report affirming that poor diet is the leading cause of our most pressing deadly chronic diseases: Heart disease, diabetes, obesity. They're just publishing data to affirm what we know already, but the question is, what are we doing about it? "More drugs. Drugs for the win, Kobe! Drugs for the win." It's not working. But again, our pharmaceutical interventions have their place, but clearly something is wrong here, the system is not just broken, it's designed to operate this way, and there are people profiting mightily off the farming of sick people, off of the farming of our citizens.

Now this brings us back to the FDA, because another layer of concern here is the revolving door of employees working at the FDA and then working at pharmaceutical companies or vice versa, there's a revolving door, they're just sharing people. There's no conflict of interest here. Not only do pharmaceutical companies provide the FDA with massive amounts of funding that will clearly be a conflict of interest, the FDA and pharmaceutical companies also engage in a revolving door of sharing employees. For example, the former FDA Commissioner, Scott Gottlieb left the FDA and joined Pfizer as a member of its board of directors just prior to the beginning of the pandemic in 2019. Now, listen to this, even prior to his appointment as the FDA Commissioner, Scott Gottlieb actually served on the board of directors for multiple pharmaceutical companies. He also served on the Investment Board of GlaxoSmithKline, currently the fourth largest vaccine maker in the world.

And Scott Gottlieb has continuously been a strong proponent of mandatory vaccination, whatever entities he's been a part of. This is just one example where someone in a position of power at the FDA has also profited mightily from the drugs the pharmaceutical companies sell by literally working at those same pharmaceutical companies. This instance isn't rare, this scenario is not rare in the slightest, because nearly 30% of FDA employees leave the FDA and get high-paying jobs at pharmaceutical companies. This would logically make you question what FDA employees may be doing to get in the good graces of the pharmaceutical company for their future cushy job with them. And the reverse happens as well, where pharmaceutical company agents, employees join the FDA with their insider information.

One of our US senators stated, "This kind of revolving door, influence peddling, smacks of corruption and makes the American people rightfully cynical and distrustful." Rightfully cynical and distrustful. We need to have a healthy level of skepticism right now, more so than ever. We need to be more cautious about what we're putting in our bodies, not less, we need to be more cautious about the people who are telling us what we need to do to care for our own bodies and our families more than ever, not less, where we're being pressed and influenced to abandon our reason, to abandon our skepticism in the face of this overarching, magnificent, all powerful regulatory agency that supposedly has your best interest at heart, but if you check the track record, it's very different than what people are led to believe.

Now, there's actually another step in this process. There is an approval board of physicians working with the FDA who are actually responsible for reviewing the pharmaceutical company's data for their drugs and clearing the drugs for approval if they choose. So again, there's an approval board of physicians working with the FDA who are responsible for reviewing pharmaceutical drug companies' data, they're not actually testing the drugs, reviewing their data for the new drugs and clearing the drugs for approval if they choose. Now, is there any influence happening with these physicians who are on this board of approval? Well, an analysis published in the Journal Science found that nearly 40% of physician advisors on the FDA approval boards received payments from pharmaceutical companies at some point after they approved a drug. It might be three months later, six months later, doesn't matter. When they track this down, which is again, not difficult to find, it's not going to get reported with the FDA, but they found that somehow money from pharmaceutical companies' land in the pockets of the physicians in the form of cash payments, grants or other means.

Money was found also changing hands when certain drugs were not approved. The report also tracked payments received from the competitors of drug companies who were seeking approval. That's interesting as well. I know you got an approval coming up with company X, company B's like, "I don't want their stuff to get approved." Or they might feel that company X, and you got company Z making a payment, they're like, "We want company X's product to get approved because it's going to help to increase our market share as well and increase our exposure. So, this is all happening, this is called post hoc contribution, so this is after the fact. So, it's not like they're giving them money right then and there to make the approval, they're just like, "You know what, we'll wait a little while. You go ahead approve this, we'll wait a little bit, nobody will notice. We'll give you a little something later. Let's make this happen."

Could be to the tune of tens of thousands, hundreds of thousands, there were even some instances where these physicians received over a million dollars. It's available, these things sounds... It sounds like a movie of corruption and deceit, but it's real. So, think about the drugs that are getting put onto the market, the drugs that are getting mandated for people to take, where is the efficacy really at? Are we doing stuff the right way, because in reality, we're seeing

that when a drug is approved and it's marketed to the public and used by the public, it's over four years later when that first safety event is being acknowledged? We don't know what's going to happen. And I encourage you, I implore you to take more precaution and to be more patient with this than ever before, regardless of the pressure, regardless of what the media or the pharmaceutical companies or well-meaning physicians and advocates, who truly do want to do the right thing, where do you think they're getting their information from? They're getting educated by the same entities that are ripe with corruption and manipulation, consistently criminal organizations...

Now, this brings us to the point of the FDA, with these well-noted, well-documented... Again, this is published in the Journal of Science, 40% of physician advisors on the FDA approval boards receiving payments from pharmaceutical companies at some point after they approved a drug. This is called bribery. This is illegal. But who's going to prosecute the FDA? Who's going to hold the FDA accountable when the FDA is given these God-like powers to hold everyone else accountable? We have to truly, more than ever, take control of our minds and be able to look at all sides of these things because it's a very dynamic complex situation that we're facing, these pay-later conflicts of interest, which have gone largely unnoticed, and entirely un-policed.

Now, finally, one more dynamic with the FDA, and there's many more. There's many more, but one more we're going to cover right now, and it's in its name, Food and Drug Administration, food. They're also responsible for regulating... They're supposed to be the regulatory agency looking out for us and what's coming through the system of food. Now, here's a recent summary of the FDA's involvement in food safety. Companies have added thousands of ingredients to foods with little to no government oversight. That's thanks to a loophole in a decades-old law that allows them to deem an additive to be generally recognized as safe, or GRAS, without the FDA lifting a finger to make sure that it's actually safe. The loophole, born in 1958, was originally intended to allow manufacturers of common ingredients like vinegar, and salt, when added to process foods, to bypass the FDA's safety review process.

So, this is where it started. Vinegar, salt, cool. We know about salt, we know about vinegar, cool. But over time, companies have found that it's far more effective to take advantage of the exemption with GRAS, Generally Recognized as Safe, to get their products on store shelves quickly. Some of these products contain additives that even the FDA has found to pose dangers to human health, but have done little about it. The GRAS process permits companies, rather than the FDA, to determine whether a substance meets the definition of GRAS or not, alright? It allows the company to determine, but the definition of GRAS is supposed to be under the guise of peer-reviewed evidence on the safety of the food additive, alright? So, it's generally recognized as safe, and it's supposed to be some expertise behind it. But the question is, who are the experts saying that it's safe for human consumption? What is actually known about it,

and especially, what's known long-term as far as its safety? And what are the intended uses? All of these things come into factor here, but they're not acknowledged.

The FDA has not clarified most of these questions, and thus companies have, to a significant degree, discretion over which ingredients they add without approval, because companies make their own GRAS determinations. In the past 50-60 years since GRAS hitting the scene and being this little bit of a loophole for the FDA to not be involved, to be hands-off, the number of food additives has skyrocketed from about 800 to well over 10,000 different food additives, including a myriad of synthetic chemicals. They're added to everything, from baked goods, to our beverages, to cereals, to... You name it. I mean, you already know. You know the processed food nation that we are existing in. And many of the ingredients aren't even analyzed by the FDA at all.

So again, when you think that this entity is looking out for you, we've got a system where our food is the number one causative agent, documented by the Journal of the American Medical Association, our food is the number one causative agent for our epidemics of chronic disease. The food, and then the drugs, or what you take to help to reduce the symptoms, or to manage the symptoms, or suppress the symptoms of the food making you sick in the first place. And there's one entity responsible for keeping their eye on it all. And this is why we also need to be even more adamant about the companies that we do choose to get our food from, that we choose to get our supplements from, and to acknowledge that this process of regulation and what's being introduced to our bodies and to our families, it's not very well policed. It's just not. And so, this is why I'm such a huge fan, and I advocate for these entities, these organizations that are going above and beyond and they're showing you their track record, they're showing you their commitment to real health.

And for example, when it comes to simple things like my nootropic, or the honey that I use, or the immune system kind of modulatory propolis that I use, I'm seeking... I'm not just getting any brand, or any product from company whatever, who isn't going above and beyond. I'm checking for, and bringing for everyone companies that are doing stuff the right way. And the company that I use uses third-party testing for over 70+ pesticide residues that are common in bee products. They're also looking at pervasive offenders, including DDT, making sure that that's not there. They're testing for a wide spectrum of other toxins that come along in our products, like heavy metals, like arsenic, cadmium, lead, and mercury, and also nefarious bacteria like E. Coli, Salmonella. This is what should be the standard. And what we're giving our children as well, if you look at the common conventional cough medicines, for example, containing FD&C Blue No. 1, again, the FDA allows it.

Red #40. What is that? High-fructose corn syrup, propylene glycol, these are common ingredients in one of the most popular cough medicines. Well, here's what we can do to do

better. A randomized double-blind placebo-controlled study revealed that honey was able to outperform a placebo and significantly reduce cough frequency and severity at night and improve sleep quality, add to that the power of elderberry, a double-blind placebo-controlled study published in the peer-reviewed journal, Advances in Traditional Medicine, found that after 48 hours of treatment with elderberry, coughing was relieved in 31% of patients versus the placebo. The study also noted significantly reduced fever, headache, muscle aches, nasal congestion than 24 hours of treatment with elderberry.

These are combined together. High quality organic honey, elderberry, chaga mushroom, propolis, in the B.Better Cough Syrup from Beekeepers Naturals. Go to B-E-E-K-E-E-P-E-R-Snaturals.com/model, you're going to get 15% off, you need to have the B.Better Cough Syrup in your medicine cabinet for what's coming up here with cold and flu season, and also their incredible propolis spray is just one of the most remarkable things. There are over 300 active compounds in propolis, the majority of these compounds are forms of antioxidants, specifically, polyphenols, that are well documented to reduce inflammation and fight disease. Even more specifically, polyphenols have been proven to inhibit the activity of Coronavirus, according to recent data published in the peer-reviewed journal, Archives of Virology. So definitely get the propolis spray as well. So, these are just some of the amazing things that they have. Going above and beyond, we've got to invest, we've got to demand that companies are stepping up to do the right thing, because the majority of companies are not. And the regulatory agency over all of this stuff, we've already detailed how the bribery, the manipulation of science and the corruption is rampant in this organization, but I believe that we can do better, I believe that we can create a system of efficacy, of sustainability, of honesty, but we have to stand for it.

We have to stop allowing for these entities to take advantage of us and to manipulate us and detracting us from their actual track record of results. Here in the United States right now, we have 70% of our citizens are already on pharmaceutical drugs, yet we're getting sicker and sicker as a society. These treatments are not working very well, they have their place and they work well for some things for sure, but if we're just continuously masking symptoms... We have a system of health care that is not about health, that is not about getting citizens healthier, but instead treating symptoms of disease with very expensive medications that make billions for pharmaceutical companies and for the FDA. We have a serious problem, but there cannot be a problem without a solution, and you are part of that solution.

I appreciate you so much for tuning into the show today. If you got a lot of value out of this, please share this out with your friends and family, and of course, you can tag me, I'm @shawnmodel on Instagram and Twitter, and I'm @themodelhealthshow on Facebook. And I want you to stay up-to date with me because a lot of the information, even especially if you're watching this on YouTube, we are not able to put some of the things that we're publishing out

on this particular channel on YouTube, so I want you to go to themodelhealthshow.com/connect to make sure that you stay connected with me and get up-to-date information about many of the things that are transpiring with our health and wellness, so especially the folks watching on YouTube, so you can make sure that you get access to all the videos because we're not publishing every video here on this platform. But generally, for everybody listening, let's get connected, let's get together, we need to get the Avengers united because we've got quite a challenge here ahead of us, but we are well equipped to do it. Go to themodelhealthshow.com/connect. I appreciate you so very much for tuning into the show today. Take care. Have an amazing day, and I'll talk with you soon.

And for more after the show, make sure to head over to themodelhealthshow.com. That's where you can find all of the show notes, you could find transcriptions, videos for each episode, and if you got a comment, you can leave me a comment there as well. And please make sure to head over to iTunes and leave us a rating to let everybody know that the show is awesome, and I appreciate that so much. And take care, I promise to keep giving you more powerful, empowering, great content to help you transform your life. Thanks for tuning in.