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www.reachmd.com info@reachmd.com (866) 423-7849

The Sense and Nonsense of Alternative Medicine

#### Dr. Brian McDonough:

Do You Believe in Magic? That's the title of a book by Dr. Paul Offit and it takes a look at the alternative medicine industry, talking about how some popular therapies can be helpful and how some popular therapies can be harmful.

Hi, I'm Dr. Brian McDonough and welcome to Primary Care Today on ReachMD. My guest today is Dr. Paul Offit. Dr. Offit is internationally known. He has a tremendous background in his work as the Chief of the Division of Infectious Diseases and Director of the Vaccine Education Center at the Children's Hospital of Philadelphia.

You're world famous for a lot of the work you've done with vaccines and development of these things, but right now, your topic is a very interesting one, a book that you've just written, which takes a real serious look at alternative medicine. Perhaps, as you say, the sense and nonsense.

So, Dr. Offit, first, welcome to the program.

Dr. Paul Offit: Thank you Brian.

#### Dr. Brian McDonough:

My first question for you is, I mean, certainly you've gotten a great deal of attention and we have a physician audience. Tell me a little bit about your sense of the overall alternative medicine world. Is this something that's harming our patients? Can it help them? Where do we stand right now?

#### Dr. Paul Offit:

I guess my principal objection is to the word or to the phrase alternative medicine. I think there's no such thing. I think if an alternative medicine works then it's not an alternative, it's just medicine. And if it doesn't work then it's not an alternative. So I guess the terms like integrative, holistic, complimentary and alternative, I just see as a lot of sort of hand waving. If something works, great, and if it doesn't work, then we shouldn't use it.

# Dr. Brian McDonough:

A lot of the problems I see as a family doctor is I often ask my patients, I do med reconciliation, I'm basically really obsessivecompulsive when they come to the hospital what they come in with and what they leave with, but I often don't know the first thing to ask about some of these alternative therapies. Is that an issue?

#### Dr. Paul Offit:

Well, certainly in our hospital it is. I mean, when patients come in to our hospital and they use some of these dietary supplements it's important for us to know that they're using them. One, because they can interact with the drugs that we're giving, and we've had this notion of patients taking St. Johns Wort. I mean St. Johns Wort is metabolized through the liver. It can interfere with immunosuppressive therapy. It's certainly well documented that patients reject their transplants or have rejected their transplants because unknown to the physician at the time, that patient was taking St. Johns Wort. So this is just one of many things that I think you need to be aware of. When we ask patients whether they're taking any other medicines they often don't say dietary supplements because they don't consider them to be medicines.

#### Dr. Brian McDonough:

When you talk to people about that concern, about they don't believe its medicines and the alternative route, a lot of it has to do with

regulation, a law. I guess it goes back to 1994 or so about the regulation of these substances.

# Dr. Paul Offit:

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That's exactly right. I think people don't realize this but when they look on the label of these products of which there are about 54 thousand on the market, they assume that what's on the label is what's in the bottle. That's not necessarily true. The Food and Drug Administration doesn't regulate this industry. If you look at the fine print on the bottle it'll say that, you know, the FDA does not recognize this product for either diagnosis or testing or treatment or prevention of any disease. In our hospital we were trying to find some of these products, quality products, for some things that people do want to use in the hospital. We had a hard time getting companies to send us something called a Certificate of Analysis, which is just simply a sheet that says that a third party has looked at this product and that what's on the label is in fact is what's in the bottle. It's a little scary. You know, I would say every week or every two weeks the FDA is pulling some of these products off the market only after they've been found to cause harm because they were inadvertently contaminated with other things. It's a problem industry.

#### Dr. Brian McDonough:

Dr. Paul Offit is our guest on Primary Care Today. Dr. Offit has received numerous awards including the Bill and Melinda Gates Award during the launch of their foundation's Living Proof Project for Global Health. In 2012 he received the distinguished Medical Achievement Award from the College of Physicians of Philadelphia, numerous awards, and to take this on it had to be something very important to you because I'm sure you're probably getting a lot of pushback from many of these companies that produce these products.

#### Dr. Paul Offit:

Yeah. I definitely have and from the consumer. The consumer sort of puts this industry under an untouchable halo. It's all natural. It's all good. You know, it's made by elves on flowering meadows. Then, on the other hand, there's big bad pharma. Certainly it's true that pharmaceutical products can do harm and in fact can do harm that can cause death. That's absolutely true. Chemotherapeutic products can critically suppress the immune system. I mean, there are allergic reactions to antibiotics. That's certainly all true but the good news is that you know about it. I mean at least you can look on a package insert and see what the benefits are, see what the risks are because these products have to be tested for safety and efficacy before they're put on the market. That's not true with this other industry, with the dietary supplement industry, so you often don't know whether there's any safety profile because often there isn't. You often don't have studies that prove efficacy, and frankly, when people have looked hard at some of these products, they find that their claims are fanciful. So it's much more of a black box and I think that makes it much more difficult for the physician who comes in contact with patients who want to use these products.

#### Dr. Brian McDonough:

Well with so much money on the line and so many people potentially being harmed or potentially helped, why isn't there more regulation? What has the barrier been there? Why hasn't that happened?

#### Dr. Paul Offit:

Money. It's at least a 28 billion dollar a year industry. It's probably bigger than that and so they have money and therefore they have influence, and they bought that influence at the congressional level to create in 1994, as you mentioned earlier, the Dietary Supplement Health and Education Act, which essentially prohibited the FDA from in any way effectively regulating this market. I mean, in the world of pharmaceutical products, you at least have to prove that your drugs are safe and effective, at least in some group of people, before it's licensed, usually thousands of people before its licensed. That's not true with this industry. Even though the FDA in the early 1990s wanted to regulate it, what you see in 1994 is this so-called Dietary Supplement Health and Education Act was response by the industry using their influence in congress to basically tell the FDA to keep their hands off.

#### Dr. Brian McDonough:

Do you think it's going to change? I mean, would a book like this and the discussion, certainly New York Times, Op-Ed pieces, you're on this program. I mean, you're all over the country talking about this. Do you think it's going to raise enough attention?

#### Dr. Paul Offit:

I think there's only two ways to change this. The first is if the consumer stands up and says, "Look, I think it's only fair that I know about products that I'm putting into my body. Dietary supplements can have a physiological effect therefore they are drugs and they should be regulated as drugs." I don't see that happening. I think the industry is very good at marketing itself as all natural, all good, can't possibly hurt you, and we're susceptible to that, and people are much more likely to watch commercials on television than they are to read articles in the Annals of Internal Medicine.

I think the only way it really would effectively change, frankly, is through litigation. If you look, for example, at vitamin A, I think it is absolutely clear that if you take mega doses of vitamin A, meaning doses in excess of the recommended daily allowance which is readily available in these stores, you clearly increase your risk of prostate cancer. I don't think the data could be clearer. I think it would be

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interesting if a group of ten men or whatever got together and said, "I took large doses of vitamin A. We all have prostate cancer. I want to sue the company because where on the label did it say that there was a risk of prostate cancer and they failed to warn me about that risk." That, I think, would get the attention of the American public.

# Dr. Brian McDonough:

One of the options, or I guess one of the things I get to do in my role for working and with radio stations around the country for news organizations is they'll say to me, "Dr. McDonough, here's a product. This advertiser wants to come to our station. What do you think? What do you think about their claims?" It's often a natural so-called substance and there are all sorts of claims and I come back and say, "Well you know, you can't really refute the claims because each and every part of this product at some point could say it will help with erectile dysfunction or building muscles or headache, you name it, because there is something in the natural substance that does it, but they basically throw everything, in many cases, but the kitchen sink in there and say it does all those things," and then they want to run the ad and I'll usually say, "You know, I'd hold off. You should be careful about the audience," but so many stations run these ads and the word gets out. It really doesn't seem like there's any barriers out there.

# Dr. Paul Offit:

You're right. Usually, they don't make specific medical claims. It's much more of a wink and nod claim. So you know, supports joint health, supports prostate health, supports heart health. They won't say this product will shrink your prostate. That is a specific medical claim, and if you're going to make a specific medical claim, then the FDA will regulate you, so they don't do that. It's much more of a wink and nod thing, and I think that's the danger in all this, and frankly, I don't even know what the word natural means anymore. I understand that it has come to be a good thing, but you know, I mean Ebola virus is natural, so is polio, so are lice. I don't see how the word natural...in my world, in the infectious disease world, natural infections are a bad thing, so it's lost it's meaning to me.

# Dr. Brian McDonough:

If you're just tuning in, you're listening to Primary Care Today on ReachMD. I'm your host, Dr. Brian McDonough. My guest is Dr. Paul Offit. Dr. Offit is the author of the book Do You Believe in Magic – The Sense and Nonsense of Alternative Medicine.

While we have a group of physicians listening, what are the concerning so-called natural alternative substances that are out there that you feel as physicians we should know that our patients could be potentially harming themselves with? Is it something you could summarize?

# Dr. Paul Offit:

I think physicians should know that this industry is essentially not regulated. For example, we have patients who will come into our hospital who will bring a bottle of selenium with them, and they'll want us to give their child selenium while that child's in the hospital. The label may say 200 mcg of selenium. That bottle could contain 40,000 mcg of selenium per dose. You don't know, and in fact, that's been true with two recent products. I mean, there's a company in Farmingdale New York recently, the so-called Purity First Product Company, that made a vitamin C preparation as well as they make multi-mineral preparations and a B complex preparation that was contaminated with two powerful anabolic steroids. Now we could have had that on our formulary. It was perfectly possible. When that was announced, we went to look to see whether or not that was a vitamin C preparation that we had on our formulary that we could have given to a vulnerable population of hospitalized children. That's why at Children's Hospital of Philadelphia we don't do this anymore. We will not let anyone take a product in our hospital unless it is clear that it is made under good manufacturing practices and that there's a Certificate of Analysis that guarantees what's on the label is what's in the product. Otherwise, we have the patient sign a waiver that says that basically they are taking responsibility for this because we can't and it gives us the chance to educate the parents and the patient about the weaknesses of this industry.

# Dr. Brian McDonough:

I know there is concerns about garlic and Coumadin interactions, all sorts of things. Any big ones out there that you're concerned about?

# Dr. Paul Offit:

Yeah. Garlic's a big one because concentrated garlic is a common cause of bleeding. You saw probably recently in the New York Times that concentrated green tea extracts is a cause of hepatitis. You know some of these products can cause arrhythmias, they can cause seizures. I mean there are side effects to these products because, as everyone should know, anything that has a positive effect can have a negative effect, and these products are no different but somehow the industry's been able to market it as its all good, all-natural, can't hurt you and that's never true.

# Dr. Brian McDonough:

A few more questions while we have you with us. What have some of the major arguments against your book been? Have there been any ones that you look at and go,

"They made a good point," or has it really just been pretty aggressive?

# Dr. Paul Offit:

I think the major arguments are, you know, that pharmaceutical products also cause harm, but of course that's true. You know, when someone comes into our hospital, for example, with cancer, I mean we certainly could treat them with emu oil and crystals. I think that would certainly be a lot safer. It just wouldn't work. You know, serious diseases require serious medicine. So pharmaceutical products, certainly because of the benefits are greater because they're clearer, also can have harms. Of course, that's true. I think that's sort of comparing apples to oranges. When I criticize the dietary supplement industry I'm not saying that the pharmaceutical industry should get a free pass. The other criticism is that I think people think that on one hand there's big pharma and then on the other hand there's this industry. I think what people don't realize is that this industry, this dietary supplement industry is big pharma. I mean Pfizer's a major player in this game and so is Hoffmann- La Roche, so I give credit to the industry for being able to paint themselves as something different than what they are.

I think the pushback has come from some chiropractors to some extent who when I criticized that group at least for their genesis being that all diseases are related to misaligned spines, that's obviously not true. So there's been some pushback but I would say that nine out of ten of the emails that I get are generally positive and say thanks for standing up for the science.

# Dr. Brian McDonough:

A few more quick questions and one would be, when you talk about pharmaceuticals and you talk about the different types of alternative medicines and things, what about teenagers and the whole body building supplement industry right now? That's a concern. I remember doing a television story years ago about Mark McGwire and androstenedione and people were saying, "Oh, that's just something over the counter. That's not a steroid," and nobody understood the concept of precursors and metabolism and things leading to other problems.

# Dr. Paul Offit:

Yeah and actually the good news is I think this has gotten so out of hand that the FDA actually is starting to crack down on this to some extent to the degree that they can. I mean I walked into my son who's a junior in college, I walked into his dorm room, and his roommate had just shelves of this. It was like looking at, you know, this pre-renal disease shelf was the way I felt. You know, just there were all these high-energy protein products, and some of these products have been shown, as you say, to be contaminated with anabolic steroids, with testosterone, and certainly when you protein load, you always run the risk of causing renal disease, so you're right. I think there in danger lies. You have to be careful with this. I mean, if you really want to do something natural, eat lots of fruits and vegetables and exercise. That's probably the most natural thing you can do. The minute you start taking these products that are in concentrated pill form, that's not a natural thing to do. It bypasses the stomach satiety level. People think, "I'll just pop 1000 mg of vitamin C." You would have to eat eight cantaloupes to achieve that and maybe you're not supposed to eat eight cantaloupes at once.

# Dr. Brian McDonough:

I want to tell one funny story before we head off. Dr. Offit, if you don't know, he's published more than 140 papers. He's developed all sorts of things, and in fact, he's the co-inventor of the rotavirus vaccine, RotaTeq, and I remember years ago, you saved me on this one because I read it and about an hour before the official press release went out, I was telling everyone be careful and learn all about Rotate Q I believe, and you got the word out to me, "No, no, no, no. It's RotaTeq before you were humiliated nationally," and I do appreciate that.

Dr. Paul Offit:

# My pleasure.

# Dr. Brian McDonough:

Dr. Offit, I really want to thank you for joining us, and I appreciate the book you wrote. I think it leads to a lot of great discussions and the physicians who are listening just to make them aware be careful and understand this. I think that's an important message you got out.

Dr. Paul Offit: Thank you.

#### Dr. Brian McDonough:

This is Dr. Brian McDonough. If you missed any of this discussion, please visit ReachMD.com/primarycaretoday to download the podcast and learn more on this series. Thanks again to Dr. Paul Offit, author of Do You Believe in Magic – The Sense and Nonsense of Alternative Medicine, for taking the time to join us. Until next time, thanks for listening.