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Story at-a-glance

- Pro-pharmaceutical spokesmen have been repeatedly quoted as saying that dietary supplements are unregulated and need stricter oversight due to the hazards they pose to your health
- This is patently false, as the FDA regulates both finished dietary supplement products and dietary ingredients under the Dietary Supplement Health and Education Act of 1994 (DSHEA)
- Supplements that are deemed hazardous are typically “spiked” with some form of pharmaceutical drug or synthetic ingredient
- Suspect products are typically of the “diet” or “fat burner” variety, along with muscle-building and high-energy products
- Vitamin supplements have an enviably safety profile. Data from the European Union indicate that pharmaceutical drugs are 62,000 times as likely to kill you as dietary supplements

The Dr. Oz Show: Information I Couldn't Share

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By Dr. Mercola

Last week I went to New York to tape a segment with Dr. Oz on multivitamins. It's scheduled to air on Monday, February 10th. You can find the channel and time it airs in your area by going to a

[link on The Dr. Oz Show](#) and entering your zip code.

It was only a ten minute segment so there wasn't enough time to discuss the false and often repeated quote stating that dietary supplements are unregulated.

This is patently false, and you only have to look at the very first sentence on the Food and Drug Administration's (FDA) Website¹ to settle that dispute. There, it plainly states:

"FDA regulates both finished dietary supplement products and dietary ingredients. FDA regulates dietary supplements under a different set of regulations than those covering 'conventional' foods and drug products. Under the Dietary Supplement Health and Education Act of 1994 (DSHEA):

- *FDA is responsible for taking action against any unsafe dietary supplement product after it reaches the market."*

Should Supplements Be Regulated Like Drugs?

Dr. Paul Offit and others want supplements to be regulated *like drugs*, ostensibly to ensure their safety and effectiveness. But are drugs really safer? Prescription medications kill over 100,000 people each year when properly prescribed, while vitamins have not caused a single death in 27 years.

If the motive is safety, as they claim, wouldn't they start with the products that are the MOST dangerous and kill the most people? Zero deaths over 27 years is certainly not a good starting point! Painkillers alone kill 23,000 Americans each year. And Vioxx, created by Merck, was responsible for over 60,000 deaths before being pulled off the market. That was just ONE drug approved by the FDA as "safe."

As for counterfeit supplements, yes, some illegal products do enter the market, but so do counterfeit drugs. So does the existence of illegal or counterfeit drugs indicate a lack of drug regulation? See, there's a difference between regulation and *enforcement*.

We have all the regulations we need, and many we created for industry instead of consumer benefit. If anything is lacking, it's the enforcement of the regulations already in place, both for drugs, foods, and supplements. Although a case could be made that enforcement is perhaps greater when it comes to supplements than drugs.

Illegal products, whether drugs, counterfeit drugs, or a supplement spiked with drugs—they're all illegal by existing regulations. As far as enforcement goes, we really should start by the body count. There is no comparison in terms of safety, as supplements have one of *the* safest track records of *any* consumable product on the market.

FDA Takes Action Against Potentially Harmful Supplements

The FDA can, and has, shut down supplement makers that do not meet these regulations. For example, in November last year, federal agents seized more than \$2 million worth of supplements once it was discovered that the product contained methylhexanamine (DMAA).

DMAA is a vasoconstricting stimulant linked to potential cardiovascular health risks² The US Federal Trade Commission (FTC) is also quite active.³ Most recently, a number of weight loss companies were scrutinized by the FTC, and four were charged with false advertising. According to CNN:⁴

"The FTC has reached a settlement with Sensa, Inc. and a partial settlement with LeanSpa, LLC... The [press] release also announced the charges filed against L'Occitane and HCG Diet Direct."

So do we really have a problem with regulations or enforcement? These agencies have full rights under current regulations to pull any products that are either unsafe or improperly marketed. Not only have they exercised those rights in the past, they've also ramped up their efforts.

No Deaths from Supplements in 27 Years and Counting

Meanwhile, vitamin supplements have actually been proven *extremely safe*. In fact, they may be *the* safest consumable product category on the market. Three years ago, Orthomolecular.org issued a press release with the descriptive title: "No Deaths from Vitamins—None at All in 27 Years."⁵ According to this press release:

"Over a 27-year period, vitamin supplements have been alleged to have caused the deaths of a total of eleven people in the United States. A new analysis of US poison control center annual report data indicates that there have, in fact, been no deaths whatsoever from vitamins... none at all, in the 27 years that such reports have been available."

It goes on to explain how the American Association of Poison Control Centers (AAPCC) attributes cause of death. The AAPCC uses a four-point scale called Relative Contribution to Fatality (RCF), with each number on the scale having the following meaning:

- "Undoubtedly Responsible"
- "Probably Responsible"
- "Contributory"
- "Probably Not Responsible"

The investigation done by the *Orthomolecular Medicine News Service* Editorial Board revealed that the singular death from supplements listed for 2006 had an RCF rating of 4, meaning the supplement in question was in fact "*probably not responsible*" after all. The press release went on to say:

"In the other seven years reporting one or more of the remaining 10 alleged vitamin fatalities, studying the AAPCC reports reveals an absence of any RCF rating for vitamins in any of those years. If there is no Relative Contribution to Fatality at all, then the substance did not contribute to death at all.

Furthermore, in each of those remaining seven years, there is no substantiation provided to demonstrate that any vitamin was a cause of death. If there is insufficient information about the cause of death to make a clear-cut declaration of cause, then subsequent assertions that vitamins cause deaths are not evidence-based."

Other data further support the remarkable safety record of dietary supplements. For example, data from the European Union indicate that pharmaceutical drugs are 62,000 times as likely to kill you as [dietary supplements](#)! It should come as no surprise then that FDA-approved drugs are responsible for 80 percent of poison control fatalities each year.⁶

Hazardous Supplements Are Typically 'Spiked' with Pharmaceuticals

It's worth noting that supplements that are deemed hazardous are typically "spiked" with some form of pharmaceutical drug or synthetic ingredient. With very few exceptions, it's not the natural vitamin or herb in itself that is shown to be dangerous.

Suspect products almost always end up being of the "diet" or "fat burner" variety, along with muscle-building and high energy products.⁷ Lumping vitamins, minerals, and herbs with long historical use in with these highly adulterated types of supplements is unfair and inaccurate in the extreme, but most people don't make this separation when they read that "supplements are dangerous" in the news...

Are Supplements Just Useless?

Then there's the issue of efficacy. As recently as December 2013, the media was again rife with articles bashing supplements as being either dangerous or useless, or both.⁸ Mark Sisson⁹ published some insightful commentary on these attacks, including the following, which was in response to an editorial in the *Annals of Internal Medicine*, titled: "Enough is enough: stop wasting money on vitamin and mineral supplements."¹⁰

*"...The study the authors of the editorial chose to examine looked at the effect of multivitamins on cognitive decline and memory. Turns out multivitamin intake had no effect on cognitive decline or memory when compared to placebo. Of course, even if multivitamins have no effect on cognitive health it doesn't say anything about other health conditions. Just last year, a **study using the same PHSII data found a beneficial effect on cancer incidence from multivitamin use**, with daily multivitamin use predicted a moderate but significant reduction in overall cancer risk, particularly in men with a history of cancer."*

Dr. Alan R. Gaby, M.D., author of numerous publications and books, including the textbook *Nutritional Medicine*, also weighed in on the issue, stating that "the editorial appears to be biased and to lack scholarship, as it is based on selective reporting and a superficial analysis of the vast and complex body research on the health effects of nutritional supplements." He also noted that two recent double-blind trials in fact did find positive effects from multivitamins on cognitive decline—neither of which were mentioned in the derogatory editorial. He writes:

"In one of those studies,¹¹ daily supplementation with 400 mcg of folic acid and 100 mcg of [vitamin B12](#) significantly improved cognitive function in elderly men. The other study¹² showed that daily supplementation with 800 mcg of folic acid, 500 mcg of vitamin B12 and 20 mg of vitamin B6 slowed the rate of brain atrophy in elderly individuals suffering from mild cognitive impairment."

Appropriate Supplement Use Could Save Healthcare System BILLIONS Each Year

In 2002, the *Journal of the American Medical Association (JAMA)* reversed its long-standing anti-vitamin stance with the publication of two scientific reviews that were based on 30 year's worth of scientific papers looking at vitamins in relation to chronic diseases. *Both* of these reviews ended up recommending daily multivitamin supplementation for all adults,¹³ based on the accumulated evidence.

That was 12 years ago, and the evidence supporting the use of dietary supplements has actually gotten stronger since then. Perhaps most egregious of all, last year's supplement bashing was in stark contrast to one of the most news breaking studies published that year! The report, titled: "Smart Prevention—Health Care Cost Savings Resulting from the Targeted Use of Dietary Supplements"¹⁴ was published in September 2013. It concluded that appropriate use of just eight different dietary [supplements could save the US health care system BILLIONS](#) of dollars each year. As reported by Drugstore News:¹⁵

"[The report] examined four different chronic diseases and the potential for healthcare cost savings when US adults 55 years and older, diagnosed with these chronic diseases, used one of eight different dietary supplement regimens. It demonstrated that supplementation at preventive intake levels in high-risk populations can reduce the number of disease-associated medical events, representing the potential for hundreds of millions — and in some cases, billions — of dollars in savings."

I would add that this report actually failed to review several of the more well-known health benefits of [vitamin D](#), which is one of the least expensive supplements. For example, experts estimate it could cut the rate of cancer by half. So, were you to factor that into the calculations, the savings could likely go up by a factor of 1,000 or more, allowing for the potential of saving trillions of dollars instead of billions.

Why Not Enforce Stricter Regulations on the *Real* Health Hazards?

Meanwhile, in 2009 alone, there were nearly 4.6 million drug-related visits to American emergency rooms,¹⁶ with more than half due to adverse reactions to prescription medications – *most of which were being taken exactly as prescribed.*¹⁷ So where's the *real* danger to your health? Is it from vitamin supplements or pharmaceutical drugs?

A veritable mountain of data shows that [pharmaceuticals pose a significant threat to your health](#), and should be used with extreme caution. Drugs, not supplements, are the hazardous products Dr. Paul Offit, Congressman Henry Waxman, [Senator Durbin](#) and others really should spend some serious time investigating, if they want to protect public health.

The bottom line is, more regulations will eliminate competition and this is the end goal. Big Pharma is in perfect position to take over the industry, as they already own many of the largest supplement companies. Drugs are *62,000 times* more likely to kill you than your vitamins. Again, DSHEA and the [safety profile of supplements](#) in general render additional regulations of supplements completely unnecessary.

Why Are Children's Hospitals Promoting Junk Food to Sick Kids?

If Dr. Offit was worried about the safety of his patients, he might start looking into the food offered at children's hospitals, including the Children's Hospital of Philadelphia (CHOP), where he is Chief of Infectious Diseases. Even though many of these kids are critically ill, why are their vending machines loaded with typical junk foods that promote chronic poor health, and fast food eateries are oftentimes found right on the premises.

A 2012 report by Physicians Committee for Responsible Medicine¹⁸ revealed the worst of the worst of children's hospitals in all 50 states and the District of Columbia. One Gainesville, Florida hospital hosts at least *five* fast-food outlets on its premises!

CHOP's statements are quite contradictory when it comes to "choices." The way I see it, they seem to be "for" choice if it can do you harm and turn you into a patient, but "against" choice when it might end your reliance on their services. Judging from the comments¹⁹ made in defense of McDonald's at the Children's Hospital of Philadelphia (CHOP) in 2011.

CHOP had decided to close down the McDonald's franchise in its premises—not because the food is unhealthy, but because they needed the space. Chad Hough, the hospital's senior vice president for clinical support services told Philly.com: *"I think our job is not only to provide healthy foods. It's about variety and giving people choices and giving people information and educating them so they can make good choices."*

Conflicts of Interest Are the Name of the Game

Dr. Offit, as many of you probably know, received a reported \$350,000 grant from Merck to develop a rotavirus vaccine,²⁰ and has served on the scientific advisory board for Merck.²¹ He received another estimated \$6 million²² when CHOP sold the patent for the RotaTeq vaccine he developed. He was also on the CDC advisory board that approved the addition of a rotavirus vaccine to the US National Immunization Program (NIP) in 1998—a decision that appears to have paid off handsomely.

The original rotavirus vaccine added to the NIP, which was made by a competitor, was pulled from the market due to adverse effects. The RotaTeq vaccine replaced it, and he continued to receive royalty payments from the sale of RotaTeq to this day.²³ (According to *Wired Magazine*,²⁴ Merck's revenue from RotaTeq was \$665 million in 2008 alone, of which Offit and his RotaTeq co-creators are said to receive a percentage.)

In 2005, Merck, CHOP, and the University of Pennsylvania School of Medicine announced the creation of the Maurice R. Hilleman Chair in Vaccinology.²⁵ The chair, paid for by Merck, went to Dr. Offit,²⁶ who still holds it to this day.²⁷ In addition to his faculty salary at CHOP, he gets another \$90,000 a year from this Merck-endowed chair. Offit has been severely criticized for his blatant conflicts of interest in the past. A 2006 report by LawyersAndSettlements.com²⁸ discussed Indiana Congressman Dan Burton's investigation of the CDC advisory committee on which Offit sat. According to the article:

"Critics say the conflicts of interest of Dr Paul Offit while sitting on the advisory panel could not be more blatant. He was part of the team that mandated the use of the RotaVirus vaccine, even though he received a \$350,000 grant from Merck to develop the vaccine, shared the patent, and was paid to go around the country teaching doctors that vaccines were safe, according to the Wall Street Journal.

UPI discovered that Merck also had bought and distributed copies of a book written by Dr Offit titled, 'What Every Parent Should Know About Vaccines,' to physicians with a Dear Doctor letter that stated: 'Merck Vaccine Division is pleased to present you with a copy of the recent publication, 'What Every Parent Should Know About Vaccines.'"

Is Offit on a Vendetta Against Supplements for Big Pharma?

It turns out that in 2012—almost one year exactly before Offit's book, *Do You Believe in Magic? The Sense and Nonsense of Alternative Medicine*, came out—Merck was turned down²⁹ for the second time by the European Food Safety Authority (EFSA) on its request to be allowed to label its Seven Seas Glucosamine as good for joint health. Merck had done studies on the supplement, and submitted what the company thought was good information supporting glucosamine's effect on joint health, but the EFSA said that wasn't enough.³⁰

They want full-blown studies resembling drug trials. Also in 2012, Merck admitted to a miserable failure with its efforts to get its prescription-grade niacin approved. Merck wouldn't say what went wrong in the trials, but *Forbes*³¹ speculated it might be possible that "the flush-blocker Merck paired it with undermined its efficacy." ClinicalTrials.gov shows dozens and dozens of ongoing trials with vitamins and supplements, and results are beginning to come out supporting their use for a variety of health conditions.

How Do You Determine Whether or Not a Supplement Is a Good Choice?

What you may find most surprising, is that the group that most requires these vitamins are women of child bearing age. While it is important for women already pregnant to take a high quality vitamin, the latest studies show men's health at time of conception is critical to delivering a health child.

Fifty percent of pregnancies are not planned, so it is absolutely critical we educate our youth about the importance of multivitamins. This age group is typically not the most interested in obtaining proper nutrition, and I feel it is absolutely critical for the future generations that all young men and women consider a high quality multivitamin. Here are some general guidelines for selecting a high-quality dietary supplement:

- It is as close as possible to its natural (whole food) form.
- Follows industry standards for quality assurance including ISO 9001, ISO 17025, and Good Manufacturing Processes (GMP) certifications.
- Remember, if you are interested in optimizing your health, your BEST solution is to choose the highest quality foods possible, and eat a wide variety of whole organic foods. You can use my [free nutrition plan](#) and work your way up to the [advanced stage](#). Once you have addressed your diet and are looking for further improvement, odds are you might benefit from some supplements, such as animal-based omega-3 supplement and a probiotic, for example. There are many others you could then consider depending on your specific circumstances, including a high-quality multivitamin, additional antioxidant support, and others.