NEWS RELEASE

The FDA's Scheme to Reclassify Nutrients As Drugs

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The FDA and Senator Durbin's latest attack against the dietary supplement industry should leave consumers for natural health options at affordable prices up in arms. This attack will target some of the most popular and effective dietary supplements, removing them from the free market and placing them under control of large pharmaceutical companies. This move will drastically drive up the price of dietary supplements while severely limiting access to extremely safe and effective nutrients. For example, the GlaxoSmithKline prescription drug version of DHA fish oil (at a therapeutic dose) sells for $189 a month, whereas the equivalent, therapeutic amount of molecularly-distilled DHA sells for $35 a month in the dietary supplement marketplace. Proven to lower triglyceride levels at therapeutic amounts, it is not surprising that DHA is one of the first nutrients the FDA plans to go after. Other powerful nutrients, such as curcumin and resveratrol, are soon to follow.

This is the second article in what will be a series of articles on this critical topic. In my first article, "Senator Durbin & the FDA Viciously Attack Dietary Supplements," I outlined the scope and nature of the attack and called readers to take action. And it is still critically important that you do take action, so please visit the TAKE ACTION page immediately following reading this article.

The newly-proposed FDA regulations are complicated. We are just beginning to understand the full scope of their ploy. The FDA is hoping that the complexity of their regulations will confuse consumers so they do not understand the coming changes and resulting repercussions. It is my job to give you some concrete examples of how this will affect you.

It is not just DHA, curcumin and resveratrol that are slated for pharmaceutical industry takeover, hundreds of other nutrients and herbs are at risk. The unfortunate reality is if the FDA is allowed to carry out their illegal strategy then thousands of products currently on the market are likely to be deemed "misbranded drugs" and forced off the market under the FDA's criminal campaign to wipe out an industry, and ultimately gain even greater power and profit.

The Pharmaceutical Industry's Perfect Storm of Economic Collapse

Mapping the human genome was supposed to usher in the next generation of pharmaceutical "wonder" drugs. Scientists would identify a gene or set of genes causing each and every disease. New biotech drugs operating at the genetic level would fix the problems or compensate for them, ushering in "The Golden Age of Cures" and reaping huge 21st century profits for the pharmaceutical conglomerate.

This wishful thinking is not the case. Their first biotech drugs have caused more death and injury than benefit. At the same time, rapid advancements in tools to analyze gene function made it obvious that Mother Nature already provided a treasure trove of

potential golden cures—natural, safe and effective substances already widely utilized in the dietary supplement industry.

Multiple circumstances threaten hundreds of billions in drug company profits. Their pipeline of new drugs with widespread consumer application is scant, as they gamble their future on dangerous biotech drugs with limited use. Hundreds of their top-selling drugs are losing patent protection in the next few years, exposing them to generic competitors and massively driving down inflated profits. Widely-publicized adverse side effects and unnecessary deaths caused by many commonly-used pharmaceutical drugs have cast suspicion over their entire industry.

On the political front, Congress is looking for ways to control health care costs, even suggesting incentives for making people well—a far different tune than paying for lifetime drug prescriptions that seldom improve health. In fact, the gene science is actually proving that Western Medicine's drugs are damaging the human genome and are a significant cause in the onset of many of the diseases of aging—the very diseases they are pretending to treat.

Pharmaceutical companies define their primary assets as patent-protected drugs, giving the drug 15 to 20 years of product sales with no competition. It is vital for them to figure out a strategy to turn dietary supplement ingredients, especially those that could be used for type 2 diabetes, cardiovascular disease, obesity, depression, Alzheimer's, and cancer treatment into drug company "assets," eliminating from the free market many of the most helpful dietary supplement ingredients while drastically driving up prices for consumers.

The Poison-Dispensing Era of Western Medicine

Until the advent of the new gene-regulating drugs, virtually all medications worked on the principle of poisoning the function of a cell or enzyme system to hopefully produce a change that the doctor thinks "beneficial." If taking a drug results in a better-looking blood sugar, blood pressure, or cholesterol number, then doctors automatically assume the person is healthier. Rather, health has nothing to do with it. It is in the financial interests of drug companies to dispense more and more drugs, on an ongoing basis.

There is a night-and-day difference in quality of health between a person who has good numbers because they are healthy and a person who has reasonably-looking numbers because they are poisoned with drugs. Studies using high doses of metabolic and cardiovascular drugs to attempt to drive numbers down to the levels of healthy people invariably injure and even kill the participants—clearly failing to improve health quality and extend lifespan.

To make matters worse, the pharmaceutical industry fraudulently hides the actual risks of the drugs from both patients and doctors. This includes slanting, to blatantly falsifying, studies routinely published in medical journals and used for marketing, illegally promoting off-label use of drugs, using funding to bribe research universities to publish only favorable results and blacklisting researchers who refuse to accept, and paying influential doctors to present their data as independent research at medical meetings.

The scope and magnitude of the drug safety issue is a nightmare. In 2006 the Institute of Medicine (IOM) conducted interviews with FDA management and hundreds of FDA employees to ascertain issues leading to drug safety problems. Widespread

conflict of interest and many other issues led IOM investigators to label FDA management as dysfunctional. Little has changed.

The Gene-Experimentation Era of Western Medicine

The human body is no slouch when it comes to elaborate complexity. It is often the case that the same exact gene signal is "good" or "bad" depending on the context in which it is activated. In fact, the same genes often behave differently in different areas of the body. Unlike earlier toxic drugs that force cell and enzyme behavior at a rather crude level, biotech drugs turn gene signals "on" or "off" at a powerfully fundamental level of cell function. Unfortunately for consumers, our understanding of genes is in its infancy. There is daunting complexity in gene regulation, making use of any gene-regulating drug highly questionable.

One example of this problem involves diabetes drugs Avandia and Actos, which turn on the gene PPAR gamma. This gene signal helps to break down triglycerides. These drugs also stimulate the formation of new fat cells, which are more metabolically fit and therefore produce more adiponectin that stops insulin resistance. Thus, in theory, they are potentially great drugs for lowering triglycerides and benefiting people with type 2 diabetes. As these drugs became blockbusters it was soon observed that the patients taking them were experiencing devastating side effects. These drugs have no way to know the context in which they should be operating. They activate PPAR gamma in the wrong places, such as the heart, leading to a 40 percent increased risk for heart failure or heart attack. Additionally, inappropriate PPAR gamma activation in bones causes them to break more easily.

The FDA rushed these drugs to market despite the objections of its own safety supervisor who wanted employ a black box warning for heart failure. In other words, the FDA knew about the risks but prevented the public from understanding them, and still allowed the drugs to go to market. This was a major scandal at the FDA. The FDA has finally restricted Avandia, but Actos remains available in full swing. Actos has recently been highly restricted in Europe, but in America, the FDA continues to drag its feet. This is likely because the FDA has mud on its face for approving these biotech nightmares in the first place and would rather consumers suffer injury and even die than look bad. The mainstream media fails to aggressively report on or investigate this tragic issue as they are large recipients of drug company advertising dollars. Even when one of their own, Tim Russert, was likely killed by Avandia or Actos, they turned a blind eye.

DHA is a Superior and Intelligent Gene-Regulating Nutrient

The plot thickens. Nature's nutrient DHA, typically in fish oil, is a powerful activator of PPAR gamma, helping to break down triglycerides as well as make new metabolically-fit fat cells that boost adiponectin and help fight type 2 diabetes—the exact objectives of Big Pharma's Avandia and Actos. DHA is a near-miracle nutrient for the heart and overall cardiovascular health and also supports strong bones. It has all of the benefits of Avandia and Actos and none of the side effects.

And this is why Big Pharma is so interested in taking over many dietary supplement ingredients. The nutrients know how to work in harmony with gene function in the human body, since nutrition was a key part of human evolution. These nutrients appear to have inherent intelligence that no drug could possibly have. They understand the context of the gene signal and thus support the beneficial gene activity. They know

how to behave differently in different areas of the body to promote healthy function at every turn.

Under the FDA's new draft guidance that redefines the 1994 Dietary Supplement Health and Education Act (DSHEA), the FDA targets many nutrients for elimination from the market, and DHA is one of them. DHA is a component of fish oil, which is a pre-DSHEA nutrient. This means that it should be grandfathered in and not subjected to the newly-published New Dietary Ingredient (NDI) guidelines.

Various companies have been able to concentrate the DHA as well as remove toxins from the oil, enabling consumers to take higher amounts of the most important ingredient in fish oil. Consumers can now easily and safely reach doses of DHA that are consistent with studies showing extreme health benefit. Such doses of DHA are known to be safe, have been tested in clinical trials sponsored by the National Institutes of Health (NIH), and are consistent with the amounts consumed by people who regularly eat fish.

The FDA's point man on NDI guidance issues, Daniel Fabricant, has been telling the supplement industry what to expect. In a recent webinar he was asked, "Should it be necessary to submit an NDI notification over a small change in the ratios of the long chain omega-3 fatty acids EPA to DHA in one fish oil supplement versus another? Is this really a big safety issue?" Shockingly, Fabricant responded "If it is a different ingredient, a different chemical entity, then it should trigger an NDI notification."

Fabricant is saying that any modification of basic fish oil should trigger an NDI notification. This is utter nonsense, but it is exactly what the FDA is attempting to do. What Fabricant did not bother to say to the supplement industry webinar audience was that an NDI application for modified fish oil would be denied, since GlaxoSmithKline already has a fish oil prescription drug on the market called Lovaza. Again, shocking.

Yes, the new guidance document makes it clear that if an existing drug contains any form of the nutrient DHA, a NDI will not be allowed (section IV.C.8-11). In other words, if modified DHA did not require an NDI notification, it qualified as a grandfathered nutrient, an obvious part of fish oil. But if the FDA decides that the newly manufactured form of the nutrient, in this case DHA, is different than its typical concentration in food, it can require that nutrient to have an NDI notification. By retroactively applying this definition to nutrients that compete with drug applications, that nutrient will automatically be denied NDI status. As of now, this is the intended fate of DHA. It is gravely unfortunate, as DHA is one of the most beneficial and effective nutrients offered by the dietary supplement industry.

This is a blatant power play to hand the entire high-grade DHA market to GlaxoSmithKline, one of the largest drug companies in the world. Lovaza already costs five to seven times what a similar amount of high-grade DHA costs—imagine how high their price will go up when there is no competition.

The Rise of Epigenetics

The new frontier of science is the field of epigenetics. A true genetic change means there is a change in the DNA sequence. Epigenetics explains factors that are not such DNA changes. Rather, epigenetic changes relate to how genes are expressed. Some are set in response to early environmental influences such as prenatal malnutrition or nutrient deficiency. As cells split and divide, however, epigenetic factors play a large role in determining life-long human health and are strongly linked to poor

health and the onset of disease. Epigenetic weaknesses magnify during aging and are major factors in the cause of cancer, heart disease, neurological and cognitive disorders, obesity, diabetes, infertility and sexual dysfunction.

This new science is finding that when toxins interfere with the human genome, they can cause lasting damage in the form of adverse epigenetic changes which can occur at any point in one's life. This is not simply an issue of pollution. Researchers are now demonstrating that regular use of many drugs can cause adverse toxic epigenetic changes, a finding that has alarming implications today's medical practices. Up to this point in time, drug safety has not involved studying the impact of any drug on epigenetics. Science now has the ability to see what is going on in this realm. The pharmaceutical industry and the FDA, unsurprisingly, have no interest in understanding and considering this new, ground-breaking information as the public would significantly reduce their intake of drugs.

On the hand, research on dietary ingredients is showing them to be powerful regulators of epigenetics and some show extreme promise for helping to treat metabolic disease and even cancer. Nutrients are showing that they possess "intelligence" and are able to tell the difference between a stressed and struggling cell (one with epigenetic weaknesses) and a cell with cancer. In the case of the stressed cell, the nutrients can fix it. In the case of the cancerous cell, the exact same nutrient can actually help kill the cancer without any adverse side effects—even overcoming mechanisms that make cancer resistant to drug treatments. Two of the very best nutrients in this category are curcumin and resveratrol, making them potential prizes for the pharmaceutical industry.

As I reported in my recent article, "Curcumin Helps Change Gene Function to Combat Cancer," curcumin and resveratrol are under extensive genetic study at the MD Anderson Cancer Center. Regarding cancer, these researchers are at the forefront of all things drug and biotech. The last commissioner of the FDA, Andrew von Eschenbach, was in charge at the MD Anderson Cancer Center before joining the FDA. Researchers at the MD Anderson Cancer Center are practically drooling over the virtues of curcumin and resveratrol. Some quotes from their recent study include the following:

Recently, natural compounds, such as curcumin, epigallocatechin gallate (EGCG), and resveratrol, have been shown to alter epigenetic mechanisms, which may lead to increased sensitivity of cancer cells to conventional agents and thus inhibition of tumor growth. Curcumin (diferuloylmethane), a yellow spice and the active component of the perennial herb Curcuma longa, commonly known as turmeric, is one of the most powerful and promising chemo-preventive and anticancer agents, and epidemiological evidence demonstrates that people who incorporate high doses of this spice in their diets have a lower incidence of cancer. Furthermore, epidemiological evidence exists indicating that there is a correlation between increased dietary intake of antioxidants and a lower incidence of morbidity and mortality…. How curcumin exerts its powerful anticancer activities has been thoroughly investigated, and several mechanisms of action have been discovered…. curcumin exerts its biological activities through epigenetic modulation.

Extensive research over the past five decades has indicated that curcumin reduces blood cholesterol levels; prevents low-density lipoprotein oxidation; inhibits platelet aggregation; suppresses thrombosis and myocardial infarction; suppresses symptoms associated with type II diabetes, rheumatoid arthritis, multiple sclerosis, and Alzheimer disease; inhibits HIV replication; suppresses tumor formation; enhances

wound healing; protects against liver injury; increases bile secretion; protects against cataract formation; and protects against pulmonary toxicity and fibrosis. These divergent effects of curcumin seem to depend on its pleiotropic molecular effects, including the regulation of signal transduction pathways, and direct modulation of several enzymatic activities. Most of these signaling cascades lead to the activation of transcription factors.

Interest in the effects of dietary compounds such as resveratrol which activate class III HDACs (sirtuins) is growing rapidly because of their demonstrable role in extending lifespan and in reducing, or delaying, age-related diseases including cancers…. Resveratrol, a natural compound found in the skin of red grapes and a constituent of red wine, is believed to play a significant role in the reduction of cardiovascular events. Multiple studies have shown that resveratrol can activate sirtuin 1 (SIRT1), a histone deacetylase, and inhibit p300. Sirtuins, the class III HDACs, are widely distributed and have been shown to regulate a variety of physiopathologic processes, such as inflammation, cellular senescence and aging, cellular apoptosis and proliferation, differentiation, metabolism, stem cell pluri-potency, and cell cycle regulation.

Experimental evidence accumulated in the recent years clearly supports the idea that dietary nutraceuticals such as curcumin have great potential as epigenetic agents.

These researchers go on to cite all of the human safety and efficacy trials with curcumin, resveratrol and many other natural substances.

This is not dietary supplement companies extolling the virtues of these powerful nutrients. These are mainstream drug development researchers, stunned by the ability of nutrients to regulate epigenetics to support health and at the same time combat diseases that plague large numbers of people. The inherent capacity of these nutrients outshines that of any drug.

There should be no question in anyone's mind as to why the pharmaceutical industry wants to claim these powerful nutrients as patent-protected drug assets. The question is more about how they plan to pull off this major scheme, this heist, from the dietary supplement industry.

Curcumin (tumeric) has been around for thousands of years and is consumed in very large amounts in Eastern and Middle Eastern cultures. This means the basic spice is protected by DSHEA. Unfortunately, curcumin has relatively poor bioavailability and raw material companies have sought to produce purified extracts with advanced production technology and combine curcumin with other nutrients such as piperine, which can elevate the biological activity up to 2,000 percent. Researchers at MD Anderson Cancer Center have conducted cancer research specifically with one such curcumin product, made by Sabinsa, and found it very promising.

Under the proposed FDA guidelines for NDIs, such curcumin extracts would retroactively become NDIs as they were not available prior to 1994. The immediate impact would be the removal of curcumin from the dietary supplement market while submitting an NDI application. Sabinsa, however, has already been granted several investigational new drug applications for their curcumin complex as they work with researchers at MD Anderson Cancer Center. Under the new FDA guidelines the net result would be eliminating all high grade curcumin extracts from the dietary supplement market, as no NDI will be granted for any ingredient that is under investigation as a new drug. Sabinsa, a dietary supplement raw material supplier, will be able to sell its rights to

its curcumin compound to the highest pharmaceutical bidder while all other competing curcumin extracts, including Sabinsa's product, will be forced off the dietary supplement market.

It is a similar story for resveratrol, which is also under investigation as a new drug. In fact, numerous highly-effective and therapeutic extracts will be targeted in this way by the pharmaceutical industry. The FDA has a glaring conflict of interest and can easily approve investigational new drug applications for any nutrient of interest to the pharmaceutical cartel, automatically blocking them from entry or existence in a competitive dietary supplement marketplace. Dietary supplement companies could spend millions trying to get the FDA to pass a NDI application. The FDA just sits on the NDI application, to ultimately approve the nutrient as an investigational new drug and deny the dietary supplement company's NDI application.

Consumer options for therapeutic nutrition will rapidly dwindle. What is left on the market will be far more expensive and many nutrients will no longer be available without prescription. Once the pharmaceutical industry gains control of the nutrient, the new price will be ten to fifty times what consumers pay now.

A Call for Consumer Action

The most important force capable of preventing skyrocketing prices and the elimination of therapeutic nutrition from the dietary supplement marketplace is you, the consumer. If you wait to act until the products actually begin to disappear, it could be too late. Act now and help preserve your right to a wide range of these powerful and valuable dietary supplement ingredients and products at affordable prices. Say NO to the FDA's illegal strategy to help drug companies take over the dietary supplement industry. Let your voice be heard.

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Byron J. Richards, Board-Certified Clinical Nutritionist, nationally-renowned nutrition expert, and founder of Wellness Resourcesis a leader in advocating the value of dietary supplements as a vital tool to maintain health. He is an outspoken critic of government and Big Pharma efforts to deny access to natural health products and has written extensively on the life-shortening and health-damaging failures of the sickness industry.

His 25 years of clinical experience from the front lines of nutrition have made him a popular radio guest who callers find impossible to stump. He has personally developed 75 unique nutraceutical-grade nutritional supplement formulas with a focus on thyroid nutrition, healthy weight loss supplements, cardiovascular nutrition, and stress management.

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