

The FDA Exposed

A Special Report by Mercola.com



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Take Control of Your Health

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In a sane, rational and reasonable world, the Food and Drug Administration (FDA) would be our premier consumer protection agency. They would make sure that your health maintained its position as the top priority for anyone putting food and medical products on the market. The world we live in, as it turns out, is neither sane, rational, nor reasonable.

Some of you may still hold on to the notion that “somebody out there” in your government has your back. That someone with your best interest at heart has taken the time to evaluate the safety of the products you put into your body, in an unbiased manner. You may still believe that science automatically equals safety.



Sadly, nothing could be further from the truth.

Millions of people have died as a result of flawed and/or fake science. The FDA may as well stand for Favors Dead Americans, as their enforcement of “safety rules” blatantly favors the illness industry and furthers corporate greed over the well-being of consumers.

Time and time again, the FDA has been proven to withhold information about the serious, and often deadly, health risks of numerous patent drugs, while at the same time engaging in an active war against natural medicine, including basic nutrition. The use of in-your-face terror-tactics and clever censoring of information is par for the course in this war against health.

In this report, you will get an overview of the rules, regulations and the newly stated missions of the

FDA that will shape the future of your health. Strap on your intellectual seat belt—it may be a mind-boggling ride.

DOES THE FDA FAVOR DEAD AMERICANS?

No, I don't believe so...

A more accurate and to-the-point statement would be that the FDA's clients—the multinational drug cartels—would love it if you were alive, but seriously ill.

The more people that can be considered “sick” and require expensive medications, the more money they can make. You can’t pay for their posh mansions, yacht vacations and global-domination plans if you’re six feet under.

Unfortunately, severely poisoned and ill people do have a nasty tendency to die. Drug prescription deaths have skyrocketed, nabbing the second place trophy for unintentional deaths in the United States, according to the federal Centers for Disease Control and Prevention.¹ Death resulting from prescription drugs rose from 4.4 to 7.1 per 100,000 in five years. These numbers represent a jump from 11,000 people to almost 20,000.

Psychotherapeutic drugs (anti-depressants and sedatives) nearly doubled, from 671 to 1,300 deaths. The statistics for the late Baby Boomer generation (ages 45–54) and those between the ages of 55 and 64 are no better. These two groups saw a **90 PERCENT JUMP IN PRESCRIPTION-INDUCED DEATHS BETWEEN 1999 AND 2004.**



According to Dr. David Graham—the now famous Vioxx whistleblower who actually works for the FDA—“death from adverse drug reactions is one of the leading causes of death in the United States, and **MOST OF THESE ADVERSE REACTIONS ARE ACTUALLY WHAT ARE EXPECTED, IN THE SENSE THAT THEY ARE AN EXTENSION OF THE DRUG’S ACTION**”.²

While one side of the FDA keeps a blind eye on what the pharmaceutical industry is putting out as “treatments and cures,” the other side is working their fingers to the bone to subdue the natural health movement.

One of the easiest, least “offensive” and most often used tactic is censorship. At first glance it may not look like censorship, but once you take in the whole picture, it becomes clear that the FDA rules on health claims are so contradictory to good health information, they equate to censorship.

THE UPSIDE-DOWN AND BACKWARDS MEANING OF HEALTH CLAIMS

The FDA regulates the labels and packaging of dietary supplements according to the law as stated in the Dietary Supplement Health and Education Act of 1994 (DSHEA).³ DSHEA was created to protect American’s rights to use supplements without prescription the last time the FDA tried to regulate them off the shelf as “untested drugs.”

In order to keep supplements on the market without being regulated into oblivion, the DSHEA rules spells out what health benefits can, and cannot, be legally claimed by supplements.

The type of claim that **CANNOT** be attached to a dietary supplement is the *health claim*. A health claim⁴ is a statement that shows the relationship between a substance and its effect on a disease or health-related condition. A health claim would alert you to the fact that a certain substance could either:

- a) reduce your risk of developing a certain disease
- b) treat or improve a disease or condition
- c) cure (eliminate the underlying cause of) a disease or condition

As it stands, only pharmaceutical drugs (aka patent drugs) are allowed to make this type of claim. So right from the get-go, the underlying message is that only drugs can treat your disease or cure you of your ills.

The DSHEA rules were also created to ensure you get valuable and accurate information about supplements, to protect you from false claims and bogus advertising by unscrupulous “snake-oil salesmen.” Unfortunately, that also provides the FDA with enough power to shut down **HONEST ATTEMPTS** at giving you the real scoop about real alternatives to allopathic (Western drug) medicine.

ARE YOU BEING PROTECTED FROM FALSE CLAIMS? OR DIVERTED FROM THE TRUTH?

In October 2005, the FDA decided to protect you from the evil-doings of one such group, who had the audacity to claim their product could actually relieve your pain—better, in fact, than aspirin and ibuprofen.

Cherry growers across Michigan were slapped with warning letters that they had better stop “making claims” about the benefits of cherries on their websites, or else.

There are two major problems here. Number one: the FDA should not have regulatory power over website content (as it is not part of the product’s label or package). And number two: the information used came from another government agency, the US Department of Agriculture (USDA), who funded the studies. This wasn’t some shady huckster making ridiculous claims. You’d think that the



USDA would—under reasonable circumstances—be considered a fairly reliable source of scientific data about a food product.

The FDA didn't care about the unreasonableness of either of these issues. When questioned about their authority to threaten farmers and dictate website content, their response was simply, "Websites are part of the legal definition of label," according to the author of *Why is the FDA Picking on Cherries*, published in Life Extension Magazine.⁵ However, after a quick read-through of the actual legal definition of a label, one serious question begs to be asked: "What?" — as there is absolutely no indication of web sites falling under this description.

The Legal Definition of Label⁶

The definition of label and labeling (21CFR1.3): (a) **Labeling** includes all written, printed, or graphic matter accompanying an article at any time while such article is in interstate commerce or held for sale after shipment or delivery in interstate commerce. (b) **Label** means any display of written, printed, or graphic matter on the immediate container of any article, or any such matter affixed to any consumer commodity or affixed to or appearing upon a package containing any consumer commodity.

Is the FDA really in the game to protect you from dangerous products and false claims? Or is their primary mission to choke off the stream of information about alternative health, which is the multinational drug cartel's major competition?

WHY SUPPLEMENTS' CLAIMS ARE LESS INFORMATIVE THAN DRUG CLAIMS



If dietary supplements and nutritional products can't make health claims, what kind of claims can they make?

Nutritional supplements are only allowed to use *structure and function claims*.

A structure/function claim describes **HOW** a nutrient affects the structure or function of the physical body. "Calcium builds strong bones," would be an example of a structure/function claim.

It can also describe how you may get some general well-being from taking the supplement, or describe a health benefit related to a **NUTRIENT-DEFICIENCY DISEASE**. An example of the latter would be, "Vitamin C treats scurvy."

Structure/function claims may, on the surface, appear rather similar to that of health claims, but there are some vital differences between the two. These differences are what place patent drugs in the driver's seat when it comes to "informing and educating" you about what you might need to get well.

- A health claim—which only drugs can make—openly tells you what disease (or diseases) these drugs treat.
- A structure/function claim for a supplement, however, cannot openly say—or imply—what disease would benefit from its use, since this type of claim cannot deal with disease risk reduction.⁷

A "disease" or "health related condition" means:

- Damage to an organ, part, structure or system of the body, such that it does not function properly (e.g. cardiovascular disease), or
- A state of health leading to such dysfunction (e.g. hypertension)

These are important distinctions that severely limit knowledge about the true health benefits of supplements.

Why?

Because although an ad is allowed to make a function claim that says "calcium builds strong bones," it must be clear that calcium is only good for building strong bones in an already **HEALTHY PERSON**. *Not* in someone with osteoporosis...

The powers that reign want you to believe that osteoporosis can only be treated or cured by pharmaceutical chemicals.

Likewise, a structure/function claim stating "fiber maintains bowel regularity," should be clearly conveyed as "maintains bowel regularity in people who are currently regular, and want to stay that way."

- This is why structure/function claims must show the double disclaimer, "This statement has not been evaluated by the FDA," and "This product is not intended to diagnose, treat, cure or prevent any disease."

You've probably seen this disclaimer a million times. Now you know why it's really there. It essentially says, "This supplement is only good for you if you are totally healthy. If you are sick, you need a pharmaceutical drug to make you well."



It doesn't mean supplements can't be a powerful tool in your health program. But **WERE THE FDA TO AGREE THAT A NATURAL SUBSTANCE MIGHT BE ALL YOU NEED TO LIMIT A DISEASE, IT WOULD AUTOMATICALLY BECOME A "DRUG," SINCE ONLY DRUGS CAN CLAIM TO HAVE AN IMPACT ON DISEASE. . .** Clear as mud, yes?

Since drugs are pumped out by pharmaceutical companies who cozy up with the FDA each night, "natural cures" is like the mistress no one wants to admit to or talk about, for fear it will end a highly profitable and mutually agreeable marriage.

THE PROBLEM WITH USING SCIENCE TO PROVE CLAIMS

Whereas the FDA regulates labels and packaging, the Federal Trade Commission (FTC) regulates advertising and marketing campaigns.⁸ Any product making statements about health benefits in their advertising or sales copy must substantiate that claim with scientific evidence.



This may include tests, analyses, research, studies or other evidence based on the expertise of professionals in the relevant area. Preferably, the evidence should be in the form of a well-designed clinical study that is independent, randomized, double blind and placebo controlled, and has published results in a peer-reviewed publication.

Unlike a drug (which can be advertised as having a health benefit because the drug is approved for the treatment of a particular disease by the FDA), a supplement must prove that a scientific study directly applies to their product. If it does not, they can't use the information in their marketing efforts.

For example, let's say a manufacturer makes 500mg vitamin C tablets, with a recommended daily dose of three tablets. A respected university has performed a study and their findings—published in a peer-reviewed medical journal—reveal a certain health benefit from taking 2,000 mg of vitamin C intravenously.

Can the manufacturer use this study to support a health statement in the sales copy for their product? The answer is no. Because in order for a supplement to use a scientific study as proof their product has health benefits, the study must have the identical ingredients in identical measures, as the product. In this case, they'd have to find a study showing the effect of 1,500 mg of oral vitamin C tablets.

Finding scientific proof that matches your product exactly, without actually paying for the study, is like finding a needle in a haystack. It rarely happens. This is why you don't see health products advertising all of their true potential benefits.

Perhaps the largest irony here is that the use of science is meant to ensure consumer confidence. Once something is “scientifically proven,” it's supposed to have a level of “certainty”, meaning that the findings are unlikely to be reversed by additional scientific information.⁹

All drugs are—supposedly—scientifically proven to be effective and safe, which is why they can claim to treat illness. Yet, additional scientific information has led to the recall of numerous drugs, which had by then killed tens of thousands of people in each instance...

ANOTHER PLACE TO FIND UNCENSORED INFORMATION

If you, like so many others, are still confused about where to find information about nutritional supplements, you have to look to a third kind of informational source—the independent writers.

This includes books, websites, newspapers and magazines that do not sell a product in conjunction with their writings. In order to not fall under the FDA/FTC stranglehold, the information must be non-commercial.

“Non-commercial” means it is put out by someone who does not make, sell, distribute or market supplements, and does not have a material connection to someone who does.

These writers are allowed to speak freely and can recommend product brands they believe are beneficial, whether it's based on science, folklore or just personal experience. It's up to you to decide whether you trust the source.



WHEN AND WHERE TO READ BETWEEN THE LINES

COMMERCIAL writing, on the other hand, is regulated by the FDA/FTC. An example of “commercial writing” would be what the FDA calls a “reading room”. Information distributed by someone with ties to the supplements they talk about must comply with the substantiation rules (statements backed up by scientific evidence) mentioned earlier, and cannot mention any particular brand or manufacturer. The information must also be distinctly separated from any products.

Getting your hands on a drug to treat your illness is easy. Getting the right nutritional information however, requires effort. It requires taking personal responsibility for educating yourself: evaluating the information you find, and then comparing products to see which product meets all the requirements that you’re looking for.

Being able to make a health claim (drugs) versus not being able to (natural remedies), is the difference between making it easy for you as the consumer, versus making it complex and frustrating.

This fact, combined with massive bribes to the medical community that dispenses the drugs, is what keeps the pharmaceutical industry alive and you less so.

A HISTORY OF VIOLENT RAIDS

Instead of raiding pharmaceutical companies and confiscating dangerous drugs after finding out they’re committing medical genocide, the FDA has a history of violence against alternative healers¹⁰ with no recorded consumer complaints or deaths.

The Life Extension Foundation is a non-profit organization that publishes information about natural health and the healing power of nutritional supplements.

On February 26, 1987, the FDA raided the Foundation’s Ft. Lauderdale offices with some two dozen armed agents. The founder, William Faloon, was detained at gunpoint. Employees were lined up and searched. More than 80 percent of everything seized over the next twelve hours turned out not to have been included in the search warrant.



The FDA filed 56 criminal charges against Foundation officers William Faloon and Saul Kent, who went on to defend their First Amendment rights in an unprecedented David vs. Goliath-like war against the FDA.

It took nine years—during which the FDA spent millions of your hard-earned tax dollars to prosecute LEF—but by February 1996, the Federal Court had dismissed every single charge. The FDA’s terror tactics and muzzling efforts failed, and LEF continues to inform the public about safe alternatives to deadly drugs.

If you’re still in the gray-zone about the lengths to which the FDA can, and will, go to “protect you” from healing without drugs, this next example might shed some light on the breadth of their reach.

Jimmy Keller had cured his own cancer with natural therapies, which spurred him into a career in natural medicine. Since treating cancer without patent drugs is illegal in the U.S., he opened up a practice in Mexico. Somehow, the success of his little Mexican clinic caught the eye of American health authorities who orchestrated a blatantly illegal “extradition.”

In March 1991, Mexican police officers kidnapped Keller at gunpoint—without a warrant—and delivered him to U.S. Justice Department bounty hunters, who drove him across the border and into the arms of the FBI. Keller was charged with wire fraud—as he’d held phone conversations with prospective U.S. clients—and received a two-year prison sentence.

These are just two examples out of many, where the FDA has used terror and physical force to squelch those who dare threaten pharmaceutical profits by offering alternative solutions.

Why would they keep quiet, allowing tens of thousands of people to die prematurely from patent drugs, and instead hunt down—at great expense—a little guy who runs a Mexican cancer clinic using natural remedies?

Because alternatives infringe on profits. If people know about safe alternatives to drugs that nearly kill you before they “cure” you, Big Pharma might lose a few bucks.



JUST SAY NO!—IT'S NOT JUST FOR STREET DRUGS ANYMORE

The FDA has a remarkable record of keeping dangerous drugs on the market rather than yanking them in the interest of public health and safety. There are many examples of this blatant disregard for life over profits; with Vioxx¹¹ probably topping the chart as far as public knowledge goes.

VIOXX® In November 2000, a large clinical trial study published results showing high-dose prescriptions of Vioxx increased the risk of heart attack by 500 percent. The FDA did not remove the drug from the market until late 2004. Between 1999 and 2004, Vioxx had caused approximately **160,000 HEART ATTACKS OR STROKES**, and about 100,000 unnecessary deaths.¹²

AVANDIA® Avandia—a 3 billion-a-year blockbuster diabetes drug—has taken an estimated 35,000 lives last year alone, based on GlaxoSmithKline's own research data. The FDA stands accused of knowing about the increased cardiovascular danger and death risk, and choosing to ignore it.¹³ In fact, the only reason the public became aware of the risks at all, is due to one independent researcher who pursued the issue and published his findings in *The New England Journal of Medicine*.

KETEK® In 2001 and again in 2003, the FDA refused approval for this now widely prescribed antibiotic, due to lack of safety information on the label. Its generic name is Telithromycin, and as of May 19, 2006, **TWELVE CASES OF LIVER FAILURE, INCLUDING FOUR DEATHS** had been attributed to the drug. In early 2007, the FDA mandated a boxed warning label for the drug, but did not remove it from the market.¹⁴

To put this into perspective, how many deaths did it take for the FDA to remove the herbal supplement ephedra, which was banned on April 12, 2004? None.

The FDA stated in their news release that they were taking this step “*after conducting an exhaustive and highly resource-intensive process required under... (DSHEA) of 1994 for banning a dietary supplement that presents a significant and unreasonable risk to human health... FDA gathered and thoroughly reviewed a prodigious amount of evidence about ephedra’s pharmacology; clinical studies of ephedra’s safety and effectiveness... The totality of the available data showed little evidence of ephedra’s effectiveness except for short-term weight loss, while confirming that the substance raises blood pressure and otherwise stresses the circulatory system...*”¹⁵

I’m not defending the use of ephedra. However, how is it that a supplement was removed from the market because it “raises blood pressure” and shows “little evidence of effectiveness,” whereas a widely prescribed antibiotic remains, after causing twelve liver failures and four deaths?

80% OF FDA MONEY GOES TO DRUG APPROVAL—NOT SAFETY

According to Dr. David Graham—a 20-plus-year veteran drug safety researcher with the FDA—the safety and efficacy standards of the FDA leave a lot to be desired.

When the FDA reviews efficacy (effectiveness), they assume the drug doesn’t work and the manufacturer has to prove it works. In order to prove it works, the drug is compared to a placebo (a sugar pill). All the drug company has to do in order to get the drug approved for efficacy, is show that the drug effect is different from the placebo. It doesn’t have to have a specific measure of effect, however. **IT JUST HAS TO BE BETTER THAN THE SUGAR PILL.**¹⁶ It also does not have to be better than anything else already on the market.

On the other hand, when reviewing safety, the tables turn and now the **FDA ASSUMES THE DRUG IS SAFE**—and the manufacturer is supposed to supply them with any data indicating the opposite!

An FDA staple response to deadly medicines is, “The benefits outweigh the risks.” But is that really so? Is it even an accurate statement to begin with?

What people don't know—because they don't tell you—is that the **FDA DOES NOT DO BENEFIT ASSESSMENTS**. They only approve drugs based on “efficacy.” Meaning: does the drug work, or does it not work? Does it lower your blood pressure or does it not?

Benefit assessment, on the other hand would include questions like: does the drug prolong your life? Does it prevent heart attacks? These questions are not part of the equation for drug approvals. **THE FDA HAS NO IDEA WHAT THE BENEFIT OF ANY DRUG REALLY IS, OR MIGHT BE.** But it sounds good, doesn't it?

Aside from the fact that they don't know what the benefits are, what benefit could possibly outweigh a statistically proven risk of “unintentional death” as an extension of the drug doing what it was designed to do?



THE DEADLY PATH OF THE CRITICAL PATH INITIATIVE

What's so critical about the Critical Path Initiative? This is the Real Focus of the FDA, and their brainstorm attempt at speeding up drug development to be able to kill more effectively for less money.

Launched in 2004, the purpose of the Critical Path Initiative is to modernize the development of new drugs by using cutting edge (read: unproven and risky) science combined with software technology related to genes, proteins and cells.¹⁷

The way this nightmare is supposed to work is by turning over the practice of medicine to FDA super-computers. Instead of using extensive human clinical trials, these computers will determine safety and efficacy, based on biomarkers. This is also called Risk Assessment, or Toxicology.

A biomarker is like a signpost, indicating a change in the protein at the cellular level. Some biomarkers indicate toxicity and others indicate a positive (or negative), change in a cell. The FDA is already developing its own software to analyze biomarkers, and creating the standards for drug development and treatment of disease accordingly.

THIS MEANS THAT THERE WILL BE NO MORE CLINICAL TRIALS TESTING THE SAFETY AND EFFECTIVENESS OF FUTURE DRUGS.

IT ALSO MEANS THAT NEW, POWERFUL DRUGS WILL ENTER THE MARKET MUCH FASTER, AND THE FDA WILL THEN MONITOR THE EFFECTS OF THESE DRUGS AS THEY'RE USED ON PATIENTS, TO MAKE THE FINAL DETERMINATION ABOUT THEIR SAFETY ON VARIOUS GROUPS OF PEOPLE (DEPENDING ON THEIR GENETIC MAKEUP).



On May 1, 2007, FDA Commissioner Andrew Von Eschenbach, is quoted as saying this new science will “explore the unique genetic and biologic features of individuals that will determine how he or she responds to treatment.”¹⁸ This would likely include profiling of your DNA, and entering it into the FDA super-computer before you can receive medical care.

IF NUTRIENTS ARE TOXIC, DO WE ALL EAT PROZAC FOR DINNER?

Language inserted into bill S.1082 also indicates that the FDA wants to expand the Critical Path Initiative to include using their biomarker Risk Assessment technology to test the safety of food and food ingredients. Under DSHEA, nutritional supplements are considered “food,” and as such, they cannot have regulated upper limits. Allowing the FDA to use Critical Path technology on foods will be like throwing the gates of hell wide open.

USING BIOMARKER RISK ASSESSMENT (TOXICOLOGY) TO ASSESS THE SAFETY AND NUTRITIONAL VALUE OF NUTRITIONAL SUPPLEMENTS AND FOODS IS SHEER MADNESS, AS FOOD DOES CHANGE PROTEINS AT THE CELLULAR LEVEL QUITE DRAMATICALLY—hence the health benefits!

Toxicology is the science of toxins. It is used to assess how much of a toxin it takes to produce a physical effect (change in the biomarker). As soon as there's a biological effect you've hit the upper, maximum limit for that substance.



This is, quite literally, diametrically opposed to nutritional science where you **WANT** to affect change at the cellular level in order to get either healthier cell activity, or decreased cellular activity, such as in a tumor.

In another damaging blow, the Supreme Court sided with the FDA on May 14, 2007, refusing to hear the case of *Nutraceutical Corp. v. FDA*.¹⁹ Nutraceutical Corp. had appealed a federal court ruling that permits the FDA to use risk assessment to determine the safety of the herb ephedra.²⁰

The refusal to hear the appeal, leaving the ban on herbal ephedra intact, is a slap in the face to the nutritional supplement industry, and another notch in the FDA's belt as they move closer to destroying the health industry.

The alternative/natural health industry is the only competition to Big Pharma. And, remember, the FDA is preparing to switch hats completely, becoming a drug developer itself, holding patents and licenses for everything they create (as opposed to “just” harboring massive conflicts of interest, like the methodical hiring of former industry lobbyists for top FDA positions, for example).

RUBBING SALT IN YOUR WOUNDS

To top off this entire debacle, and add serious insult to potentially deadly injury, the FDA has also put in place one of the most notorious protection schemes imaginable—a preemption policy that bans private lawsuits against drug companies in state courts, once a drug has achieved the FDA's stamp of approval.



This was a sneaky add-on to the preamble of their new rules for prescription labels, issued January 18, 2006.²¹ It reverses a long-standing policy, which permits State actions intended to protect consumers. On page 43 the FDA says, “*State law actions threaten FDA's statutorily prescribed role as the expert Federal agency responsible for evaluating and regulating drugs...*”

This preemption rule not only renders differing opinions of their “safety expertise” null-and-void, it also immunizes doctors from private lawsuits for failing to warn patients about risks associated with a drug—even when the drug is prescribed “off-label” (for treatment of ailments other than what the FDA approved the drug for).

It should not come as a surprise to find out that the vast majority of these changes to the way the FDA enforces “product safety” and “consumer protection,” is due to a long list of FDA officials being previous employees and lobbyists for the very industries they are now supposed to regulate: Big Pharma and Big Biotech.^{22, 23}

ONE FINAL THOUGHT

It should be abundantly clear to everyone, at this point, that the FDA is no longer in the business of protecting you. Neither from dangerous drugs, nor false health claims. The consumer protection agency is irrevocably broken.

It is time to create a new, truly independent agency with a structure that does not aid and abet conflicts of interest between the regulators and the industries being regulated. An agency that has but one employer: you, and but one purpose: ensuring your safety and maintaining your optimal health; protecting you against dangerous drugs with deadly side effects; and protecting your right to chose from any and all safe, alternative methods of natural preventive health and healing.

TAKE CONTROL OF YOUR HEALTH



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