

# Food: New Bill Repeals Key Sections of Dietary Supplement Health

Senator McCain Files New Bill

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McCain's bill is called The Dietary Supplement Safety Act (DSSA). It would repeal key sections of the Dietary Supplement Health and Education Act (DSHEA). DSHEA protects supplements if 1) they are food products that have been in the food supply and not chemically altered or 2) if they were sold as supplements prior to 1994, the year that DSHEA was passed. If a supplement fits one of these two descriptions, the Food and Drug Administration (FDA) cannot arbitrarily ban it or reclassify it as a drug.

These protections are far from perfect. They discourage companies from developing new forms of supplements. New supplements may be arbitrarily banned by the FDA or adopted by drug companies in a way that precludes their further sale as supplements.

McCain's bill would wipe out even the minimal protections contained in DSHEA. It would give the FDA full discretion and power to compile a discreet list of supplements allowed to remain on the market while banning all others.

Everyone knows that the FDA is friendly to drug companies (which pay its bills and provide good revolving door jobs) and hostile to supplement companies. Under this bill, this same Agency could quite arbitrarily ban any supplement it wished or turn it over to drug companies to be developed as a drug and sold for multiples of its price as a supplement.

We must prevent this bill from gaining traction! Protect your access to supplements by contacting your senators today and asking them NOT to co-sponsor the Dietary Supplement Safety Act but rather to oppose it.

#### **TAKE ACTION**

McCain's Dietary Supplement Safety Act (DSSA) appears to be supported by the US Anti-Doping Agency (USADA) which is funded by major league sports teams including baseball, football and others. The recent suspensions of NFL and other professional sports figures is much in the news, and the goal of the sports industry appears to be to shift the spotlight from their players to the supplements industry. In his comments, Senator McCain cited six NFL players recently suspended for testing positive for banned substances and purportedly exposed to these substances through dietary supplements.

The problem here of course is one of illegal sale and use of steroids. So why dismantle the supplement industry in order to control already illegal substances?

The FDA currently has complete and total authority to stop illegal steroids and, more broadly, to regulate dietary supplements. If the agency were doing its job, it could and would have prevented the sale of illegal steroids. The answer to this problem is not to give FDA more power. The Agency simply needs to do it's job.

#### **TAKE ACTION**

Why would a bill be offered to solve an illegal steroid problem that does not really address the steroid problem but instead gives the FDA complete and arbitrary control over all supplements? The answer is simple.

There are a lot of vested interests which are threatened by supplements. Drug companies do not like them because they represent a low cost, safer, and often more effective alternative to drugs. The FDA does not like them because supplements do not come through the FDA approval process and therefore do not support the FDA budget.

Why not simply require that supplements be brought through the FDA's drug approval process? Wouldn't that create a level playing field?

That is probably the argument that Senator McCain has been sold. But it is a completely false argument. The FDA drug approval process costs as much as a billion dollars. It is not economically feasible to spend such vast sums on substances that are not protected by patent, and natural substances cannot legally be patented.

This is the great "Catch 22" of American medicine. The FDA, which is supposed to guard and promote our health, is hostile to the kind of natural medicine—based on diet, supplements, and exercise—that represents the real future of healthcare. The Agency has either been captured by drug interests or is trapped in a catastrophically expensive, toxic, and ineffective patented-drug model.

Senator McCain has no doubt offered this bill in good faith. But he has been sold a bill of goods by special interests. And he has been naïve enough not to know that he is being used.

#### TAKE ACTION

This exceptionally bad bill also requires the reporting of all minor adverse events related to supplements. This is in addition to the already existing requirement to report adverse events. This will further stack the deck against small supplement companies by creating new, unnecessary, even more cumbersome, and of course very expensive administrative hurdles. The result: the consolidation of the supplement industry into a few big companies. If passed, this bill will likely result in the disappearance from store shelves of many supplements currently on the market. In addition to fewer supplements, there would likely be much lower doses available. Unbridled authority would be handed to the FDA, an agency that needs a top to bottom overhaul, not ever more power over our lives.

The FDA will like this because it believes that it can more easily control a few industry giants. But isn't it more likely that the industry giants will eventually gain control over the FDA?

The FDA is already misusing the adverse event reporting process that exists. Drugs rack up thousands of adverse event reports without any action. Just recently, the FDA yanked from

the market a supplement product based on just a couple of alleged adverse event reports without even allowing the company (an old and respected firm) to provide any counter-evidence or counter-argument.

The bill also allows the FDA to yank a product (at the company's expense) if there is a "reasonable probability" that it is "adulterated" or "misbranded". Let's remember that "adulterated" could mean there is a minor record keeping error on the producer's part and "misbranded" can mean that the producer simply tells the truth about the product. An "adulterated" and "misbranded" supplement in Orwellian FDA speak may actually be both completely safe and effective.

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If McCain's bill passes, we can look to Europe for a snapshot of what we may be in for: EFSA, the European Food Safety Authority, has sharply reduced the list of available supplements and is in process of reducing potencies to ridiculous levels, such as less beta carotene than can be found in half of a large carrot. Europeans already look to the US to obtain their dietary supplements. If this bill passes, where will we obtain ours?

Please take action immediately. <u>TAKE ACTION</u> Tell your senators NOT to co-sponsor this legislation and to do everything in their power to defeat it. Then forward this to your friends and family and ask then to do the same!

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