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## AS WE SEE IT

### What Do “Regulated” Supplements Cost?

Some curious events are occurring in Washington, DC. Despite record-breaking numbers of adverse reactions to prescription drugs, the federal government is calling for tougher regulation of dietary supplements.<sup>1,2</sup>

As was the case when the FDA pretended that imported prescription drugs are “dangerous,” the government is issuing deceptive reports questioning the safety and reliability of supplements.<sup>3</sup> No new findings of health problems are cited; instead, the government has compiled data collected over several decades. Based on isolated events such as the problem with contaminated tryptophan in 1989, some in the federal government now proclaim that dietary supplements should be regulated in a manner similar to prescription drugs.



by William Faloon

As Life Extension members are well aware, the FDA has egregiously failed to protect Americans from lethal prescription drugs. Yet that simple fact does not deter bureaucrats from attributing imaginary risks to supplements, thereby creating a fictitious basis for enacting new regulations.



As I pointed out four months ago in an article titled “Death by Regulation” (*Life Extension*, March 2005), the FDA’s umbrella of consumer protection is a charade.<sup>4</sup> The fact is that more than 100,000 Americans die each year by taking prescription drugs that the FDA has declared “safe.”<sup>5-7</sup> In most years, no deaths or even serious injuries are reported because of someone taking a dietary supplement.<sup>8</sup> Yet some politicians and bureaucrats are determined to make dietary supplements conform to the same standards as prescription drugs.

More regulations mean higher supplement costs, less innovation, and certainly no more consumer protection, since there is no safety problem to begin with.

### COST OF SUPPLEMENTS IN EUROPE

Rather than speculate on what would happen if new laws were enacted in the United States, one has only to look at what supplements cost in Europe to understand the risks posed by regulations.

Many of the supplements that Americans freely access here are banned outright in Europe. Potencies of European supplements are often very low. What stands out most, however, are the high costs that Europeans pay for their regulated supplements.

Earlier this year, Life Extension asked its European correspondent to conduct a meticulous review of dietary supplement prices in Europe, based on national pharmaceutical databases. It turns out that while supplement prices differ greatly between different European countries, our correspondent felt that German prices represent somewhat of a European average. On the following page is a table showing German and Swiss supplement prices that illustrates how much more Europeans pay for their “regulated” supplements than Americans do in our deregulated marketplace. It is important to note that most of the supplements listed on this table are considered pharmaceuticals in Europe.

#### PRICES IN SWITZERLAND COMPARED TO THE UNITED STATES

PRODUCT / STRENGTH	COUNT	SWISS/GERMAN EQUIVALENT PRICE	US PRICE*	% SAVED BY AMERICANS
Swiss Price: Acetyl-L-Carnitine, 1000 mg	30	\$175		<b>76%</b>
US Price*: Acetyl-L-Carnitine, 500 mg	100		\$42	
Swiss Price: Boswella, 400 mg	100	\$45.75		<b>38%</b>
US Price*: Boswella, 300 mg	100		\$28.50	

Swiss Price: CLA, 750 mg	120	\$39.33		<b>60%</b>
US Price*: CLA, 500 mg	120		\$15.75	
Swiss Price: Creatine Powder	500 grams	\$37.50		<b>42%</b>
US Price*: Creatine Powder	500 grams		\$21.75	
Swiss Price: Ginkgo, 120 mg	50	\$104		<b>79%</b>
US Price*: Ginkgo, 120 mg	100		\$21.75	
Swiss Price: Methylcobalamin, 1 mg	100	\$23.40		<b>68%</b>
US Price*: Methylcobalamin, 1 mg	60		\$7.46	
Swiss Price: Methylcobalamin, 5 mg	60	\$66.30		<b>64%</b>
US Price*: Methylcobalamin, 5 mg	60		\$24	
Swiss Price: Saw Palmetto, 160 mg	60	\$65		<b>68%</b>
US Price*: Saw Palmetto, 160 mg	60		\$21	
Swiss Price: Vinpocetine, 30 mg	20	\$22.50		<b>40%</b>
US Price*: Vinpocetine, 5 mg	100		\$13.50	

### PRICES IN GERMANY COMPARED TO THE UNITED STATES

German Price: Acetyl-L-Carnitine, 500 mg	100	\$78		<b>46%</b>
US Price*: Acetyl-L-Carnitine, 500 mg	100		\$42	
German Price: Lipoic Acid, 200 mg	100	\$37.50		<b>26%</b>
US Price*: Lipoic Acid, 250 mg	60		\$27.75	
German Price: Boswella, 400 mg	100	\$58.50		<b>51%</b>
US Price*: Boswella, 300 mg	100		\$28.50	
German Price: CLA, 1000 mg	90	\$19.00		<b>17%</b>
US Price*: CLA, 500 mg	120		\$15.75	
German Price: Creatine Powder	500 grams	\$26.50		<b>18%</b>
US Price*: Creatine Powder	500 grams		\$21.75	
German Price: Ginkgo, 120 mg	120	\$90.83		<b>76%</b>
US Price*: Ginkgo, 120 mg	100		\$21.75	
German Price: Methylcobalamin, 1 mg	100	\$23.40		<b>68%</b>
US Price*: Methylcobalamin, 1 mg	60		\$7.46	
German Price: Methylcobalamin, 5 mg	60	\$66.30		<b>64%</b>
US Price*: Methylcobalamin, 5 mg	60		\$24	
German Price: PectaSol® (Citrus Pectin Powder)	500 grams	\$146.19		<b>49%</b>
US Price*: PectaSol® (Citrus Pectin Powder)	454 grams		\$74.25	
German Price: NADH, 5 mg	30	\$30		<b>10%</b>
US Price*: NADH, 5 mg	30		\$26.96	
German Price: SAME, 200 mg	30	\$118.33		<b>71%</b>
US Price*: SAME, 200 mg	50		\$33.75	
German Price: Tocotrienols, 50 mg	60	\$58.50		<b>30%</b>
US Price*: Tocotrienols, 50 mg	90		\$37.43	

#### Example of calculations:

#### Acetyl-L-Carnitine

#### POTENCY COUNT PRICE

1000 mg 30 \$105 European retail price

500 mg 100 \$42 equivalent US price

500 mg 30 \$52.50 corrected European price

500 mg 100 \$175 corrected European price



500 mg 100

\$42 LE price

**\$42/\$175.00 = 76% savings.**

\* Life Extension member price.

## AS WE SEE IT

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#### THE NEW GERMAN DIRECTIVE

Earlier this year, a German regulatory body issued a 341-page report (the German Food Supplements Directive) assessing the risks of dietary supplements.<sup>9</sup> The report recommends maximum potency levels that are well below those commonly found in supplements sold in the US. Because of this report, some people might assume that commonly available dietary supplements in the US are unsafe.<sup>10</sup>

A look at the actual findings in this German report reveals a startling level of ignorance about nutritional science. For example, the report recommends a maximum vitamin C level of only 225 mg. Life Extension members have been consuming 2000-20,000 mg of vitamin C daily for more than 25 years, with no reports of serious consequences. To restrict vitamin C potency to 225 mg per capsule is absurd and would deny consumers the benefits of higher doses of vitamin C that published studies indicate are needed to provide benefits.

The German report sets the maximum recommended dose for vitamin B6 at 5.4 mg. As Life Extension members know, it can sometimes take as much as 1000 mg of B6 to reduce artery-clogging homocysteine levels to safe ranges. In fact, a recent study showed that even 25 mg of vitamin B6 in the presence of high-dose folic acid and vitamin B12 did not adequately reduce homocysteine or reduce the risk of secondary stroke.<sup>11</sup> Life Extension learned long ago that the B6 dose needed to lower homocysteine varies widely among individuals. Some people need only 100 mg of B6 a day, while others require 250-1000 mg a day. The ridiculously low “maximum” dose of 5.4 mg of B6 would provide virtually no benefit.

For vitamin B12, the German report recommends an astonishing low maximum amount of 9 mcg per tablet. As was discovered in a recent study, when aging adults are restricted to this kind of low dose, many develop anemia and require additional B12 to regain their health.<sup>12</sup> Educated American vitamin consumers consume from 300 to more than 1000 mcg of B12 each day because of studies showing that higher levels of B12 can prevent and even reverse cognitive decline.<sup>13</sup>



by William Faloon

#### THE 341-PAGE GERMAN ANTI-SUPPLEMENT REPORT

The German government published a 341-page report with its recommendations as to what should constitute the “upper safe levels” of dietary supplements. The table below compares supplement dosages typically taken by Life Extension members to the proposed Codex upper limits.

Vitamin/Mineral	Life Extension's Basic Recommendations	Maximum Permitted Levels Based on German Report
Vitamin C	2000-20,000 mg	225 mg
Vitamin D	800 IU	5 IU
Vitamin E	400 IU	15 IU
Vitamin K	10,000 mcg	80 mcg
Vitamin B1	125 mg	1.3 mg
Vitamin B2	50 mg	4.5 mg
Niacin (B3)	75-1000 mg	17 mg
Vitamin B6	100-1000 mg	5.4 mg
Folic acid	800-5000 mcg	400 mcg
Vitamin B12	600-5000 mcg	9 mcg
Pantothenic acid	600-1500 mg	18 mg
Biotin	3000 mcg	80 mcg
Zinc	50 mg	10 mg
Selenium	200-400 mcg	70 mcg
Chromium	500 mcg	100 mcg

## WHY AMERICANS SHOULD BE CONCERNED

The maximum levels for vitamins and minerals proposed by the German government are in many cases far lower than those required for optimal health. The Germans have produced data that are meaningless for the majority of the population, especially aging adults who are in need of higher-potency supplements.



The problem is that the *European Food Safety Authority* will view this report seriously. This bureaucracy is developing maximum potency levels for Europe and for the Codex Alimentarius Nutrition Committee, which is setting global guidelines for vitamins and minerals. In the worst-case scenario, these potency recommendations could be adopted in Europe, which could be catastrophic for vitamin consumers throughout the world.

In response to the seriously flawed German report, the Life Extension Foundation and others contributed to a lawsuit in Europe seeking to block implementation of potency restrictions sought by the Germans.<sup>14</sup> The importance of this lawsuit cannot be overstated. If the European Food Safety Authority's recommendations were to be enacted, 75% of the vitamin and mineral supplements now sold in England would be banned!

If the United States adopted Codex standards, a far greater percentage of the supplements that Americans use safely every day would disappear. For consumers, the health consequences of such a prohibition would be catastrophic. For the pharmaceutical industry, however, this would represent a financial windfall, as demand for drugs to treat the consequences of inadequate nutrition would skyrocket.



## COULD THIS HAPPEN IN AMERICA?

Such a ban probably could not happen in the US, but there are reasons for concern. For instance, the FDA could use Codex as a basis for lobbying Congress to amend the Dietary Supplement Health and Education Act (DSHEA). Lawmakers could use the "Codex Guidelines for Vitamin and Mineral Food Supplements"<sup>15,16</sup> as a basis for enacting new laws that could restrict Americans' free access to supplements.

While the Codex guidelines are considered "optional," the World Trade Organization could use them in trade disputes, which theoretically could compel the United States to adopt draconian Codex standards.

Disagreement remains about how serious the Codex threat really is. The frightening thing about Codex is that it all comes down to a matter of "trust." Can Americans trust their government to protect them against the strict standards being adopted by the Europeans?

If history is any guide, health-conscious citizens are going to have to fight hard to protect their free access to low-cost, high-potency supplements.

## WE WIN PARTIAL ANTI-CODEX VICTORY!

As noted earlier, Life Extension and others contributed to a lawsuit, filed in the European Courts of Justice, challenging the German Food Supplements Directive.<sup>17</sup> This directive would have effectively proposed banning 75% of the vitamin and mineral forms now used in Europe.

On April 5, 2005, supplement users in Europe awoke to tremendous news: the Advocate General of the European court rendered an opinion that was highly favorable to supplement users, opposing the draconian Codex proposals contained in the German Food Supplements Directive.

The chances of consumers being able to continue using natural food supplements are now greatly increased. In this legal case challenging the European Union's proposed supplements ban, few thought we had a chance to win. Against tremendous odds, the consumer may come out on top in what is a remarkable, modern-day example of a David versus Goliath victory.



In a statement released in Luxembourg on April 5, 2005,<sup>18</sup> the Advocate General concluded that:

- The Food Supplements Directive infringes the principle of proportionality because basic principles of Community law, such as the requirements of legal protection, legal certainty, and sound administration, have not properly been taken into account.
- It is therefore invalid under European Union law.

It should be stressed that the Advocate General's pronouncement is not a ruling. That will come from the European Court of Justice judges later. Typically, however, in the vast majority of cases, the court's judgment follows the Advocate General's recommendations.

If the Advocate General's recommendations are adopted, the proposed ban on vitamin and mineral forms due to take effect on August 1, 2005, will be, in effect, declared illegal.



### THE LARGER THREAT REMAINS

On any given day, any of our 535 US representatives and senators can introduce a bill that interferes with our health freedoms. For example, some frightening legislation introduced two years ago died only when the 108th Congress concluded its session in December 2004. One of the bills would have granted the FDA authority to regulate supplements in the same way that it regulates over-the-counter drugs.

The fact is that we as citizens are at the mercy of the lawmakers we elect. The good news is that these lawmakers do pay attention if enough Americans contact them about a particular

issue.

I encourage Life Extension members to write their representative and two senators to express concerns about any proposed legislation that would grant the FDA greater authority over the regulation of dietary supplements. Feel free to photocopy the price-comparison charts to show law-makers how much more expensive "regulated" dietary supplements are in Europe than in the US.

To make it easier to contact Congress, we have a new program on our website ([www.lef.org/lac](http://www.lef.org/lac)) that makes it very easy to locate and email your representative and two senators. Those who do not have access to or use a computer can obtain your Congressional representatives' names and addresses by calling the Capitol switchboard at 1-202-225-3121.

★ take action now

For longer life,

William Faloon

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