

Legislative Emergency!

It is very important for you to make phone calls to the following key Congressmen right away between Thursday, December 7 and Friday, December 8. What's happening is that the Dietary Supplement and Non-Prescription Drug Consumer Protection Act (the AER bill), which threatens your access to dietary supplements, was passed in the U.S. Senate at 9 pm Wednesday, December 6. Now we must take immediate action to stop the companion bill (HR 6168) in the U.S. House of Representatives.

So, please call: **202-225-3121** (U.S. Capital Switchboard, which is always open) and ask for:

1. Dennis Hastert
2. John Boehner- (tell him not to allow it to be put on the calendar- he opposes the bill, but now there's going to be huge pressure on him to let it be voted on.)
3. Joe Barton

What to Say to These Three Members of the House

"Please do not vote to pass HR 6168. A large sector of the Dietary Supplement Industry including Solgar, Nutraceutical Corp, Nature's Plus, Life Extension Foundation, Wellness Resources and many other companies oppose HR6168, The Dietary Supplement and Nonprescription Drug Consumer Protection Act. This legislation has nothing in it to determine the cause of an adverse event. Safe dietary supplements would be wrongly blamed for problems actually caused by pharmaceutical drugs taken concurrently with one or more dietary supplements, and there would be no medical or scientific review required by the FDA before they could release the flawed "data" obtained if this bill passes. This is not good government and it would do nothing to protect the public health.

"There must be hearings on this legislation, and there must be changes made to its language before it would actually serve its intended purpose. Do not ram it through on us during this lame duck session of Congress. If you do, you will enrage the millions of Americans who take dietary supplements, who flooded Congress in the 1990s, with more mail during the campaign to pass DSHEA (the Dietary Supplement and Health Education Act) than Congress ever received in its history on any issue."

We can kill this bill, but only if you make these calls and urge your friends and family to also take action. If we can kill the AER bill in the House during this lame duck session which ends Friday, December 8, the bill would have to be reintroduced in the next Congress under new bill numbers. In short, they'll have to try again, and we will have time to push very hard for a hearing on the bill in order to get the changes made to it that we need.

AER DIETARY SUPPLEMENT LEGISLATION

First, we believe that this bill is a step towards treating dietary supplements more like pharmaceuticals and not like food. (The Dietary Supplement Health and Education Act put the burden of proof for safety of supplements where it belongs: on the FDA, but this bill flips things back around and puts the burden of proof on manufacturers which is wrong given that supplements are far safer than food in common form.) Second, we believe that this bill will ultimately have a negative impact on the dietary supplement industry and the consumer. (Large companies could more easily absorb the red tape expenses, while many very good small companies- often those manufacturing the industries best and most innovative products could easily be driven out of business- while the costs of compliance would be passed on to consumers.) Third and most importantly, a person experiencing an adverse event (especially one that is serious) from a drug (prescription or OTC), food, or supplement, should work with their healthcare professional to determine the cause, this burden shouldn't be put on a supplement company especially when the bill does not require the full disclosure necessary to determine causality.

What's At Stake?

Technical Analysis

Adverse Event Reporting (AER) would be created only for serious adverse events which is defined as an experience that resulted in

- (A) Death
- (B) A life-threatening condition

- (C) An inpatient hospitalization or prolongation of hospitalization
- (D) A persistent or significant disability or incapacity
- (E) A congenital anomaly, birth defect, or other effect on pregnancy, including premature labor or low birth weight; or
- (F) Based on reasonable medical judgment, required medical or surgical intervention to prevent one of these outcomes.

Reporting And Manufacturer Compliance

A manufacturer, distributor, or retailer of a dietary supplement would be required to file an AER incorporated into the existing FDA Med Watch form within 15 days of receiving a consumer notice. Under S 3546, retailers can be exempted, and distributors can be exempted, if there is agreement among the parties as to which party's address and 800 phone number is printed on the product label.

Upon receipt of a serious adverse experience from a person having purchased a product, the "responsible person"/company is required to file with the FDA within 15 calendar days after initial receipt of an AER.

Having your name on a product label, qualifies as a responsible party, but distributors and retailers must also have written "exemption" agreements to establish this exclusion, or something to this effect.

The responsible "person" must also develop and comply with written procedures for receipt, evaluation, and transmittal of AER information to the FDA. S 3546 requires that the FDA issue an industry GUIDANCE* document within one year. This Guidance is to explain the minimum data elements that are to be included, via a revised Med Watch form, in a submitted serious adverse event report.

Depending upon which entity - manufacturer, distributor, retailer - is listed on a dietary supplement product label as the "responsible person", there is a refined requirement to submit any new "medical information" associated with a submitted adverse event report, within one year of the initial report. This must also be done within 15 days of the receipt of any new medical information. It is unclear as to what would be included. Does this cover patient medical records and/or published research studies? This would have to be clarified in the Guidance document.

*Guidance document is not administrative law, nor is it enacted law. In its literal sense, it is a statement of what the FDA expects, and will be guided by. By the same token, it also opens up the FDA a more rigorous explanation of its interpretation of the law, good, bad, or indifferent. In short, drug companies have been doing a lot of things over the years, based on the argument that an FDA industry Guidance was not clear, for example.

On the process side, if enacted, there is the matter of integrating the currently voluntary reporting system into the FDA's Med Watch reporting system and having this effectively transferred into enforcement actions.

What is clear is that if this Senate bill is approved and enacted into law, there will certainly be more regulatory confusion and cost associated with supplements. The cost consideration does not take into account the prospect, if enacted, of future dietary supplement User Fees being imposed on the industry and, indirectly, upon dietary supplement consumers.

All Contents Copyright © 1995-2009 Life Extension Foundation All rights reserved.

LifeExtension[®]

These statements have not been evaluated by the FDA. These products are not intended to diagnose, treat, cure or prevent any disease. The information provided on this site is for informational purposes only and is not intended as a substitute for advice from your physician or other health care professional or any information contained on or in any product label or packaging. You should not use the information on this site for diagnosis or treatment of any health problem or for prescription of any medication or other treatment. You should consult with a healthcare professional before starting any diet, exercise or supplementation program, before taking any medication, or if you have or suspect you might have a health problem. You should not stop taking any medication without first consulting your physician.