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Health Options
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Don't dismiss your rights as a consumer

THOSE interested in dietary supplements should get ready for Round 2 of a fight between government and industry interests. Round 1 occurred 10 years ago when the supplement industry went up against the Food and Drug Administration. The result was the Dietary Supplement Health and Education Act of 1994. Industry won the ability to produce and sell dietary supplements with minimal FDA regulation.

Question: What does minimal regulation mean?

Answer: Under the supplement act, the FDA's enforcement role has been limited to ensuring that the manufacturing process is safe and that the statements on product labels are limited to "structure-function" claims related to promoting health rather than curing or preventing disease.

For example, a label can claim calcium builds strong bones but not that calcium prevents osteoporosis.

Also, no scientific testing to prove efficacy or safety is required prior to marketing. The FDA is only allowed to step in if a significant number of U.S. residents are clearly harmed by a product.

Q: How did the supplement industry beat FDA?

A: Health food stores nationwide collected signatures on petitions and U.S. legislators received more mail about this bill than they had received on any other issue.

Well, it's deja vu time. Petitions are showing up in health food stores in opposition to a bill for the Dietary Supplement Safety Act of 2003.

Q: What is the goal of this Act?

A: Illinois Sen. Richard Durbin's bill, introduced in March, would require dietary supplement makers to track all adverse-experience reports related to their products and promptly report any serious adverse experiences to the FDA.

Q: What is the difference between an "adverse experience" and a "serious adverse experience"?

A: An "adverse experience" is associated with the use of a supplement but is not known to be caused by the supplement. A "serious adverse dietary supplement experience" is one that causes problems related to pregnancy, premature or low birth weight, birth defects, significant or persistent incapacity, death, inpatient or prolonged hospitalization, a life-threatening condition or one needing medical/surgical intervention.

Q: How would consumers benefit from this act?

A: Companies will have to file an annual report with the FDA regarding adverse experiences. Serious adverse experiences would have to be reported within 15 days of the complaint. The FDA can then conduct a clinical evaluation, and if it decides a supplement is not safe, can halt further sales.

Because this bill could affect so many people's lives, we will focus next week on additional sections of the proposed act. Before you sign a petition on this issue, make sure you know what consumer rights you may be signing away.

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