



Supplement makers should ensure safety

Last week, we described how U.S. Sen. Richard Durbin's (D-Ill.) proposed Dietary Supplement Safety Act would require supplement makers to report adverse effects experienced by consumers of their products to the U.S. Food and Drug Administration.

Those opposed to this bill want you to believe the legislation would give the big bad FDA inordinate amounts of power over the innocent little supplement industry. But let's get the facts straight.

Question: Who is David and who is Goliath?

Answer: A brief historical review may help determine the real giant. Many pharmaceutical drugs are derived from natural plant materials, but the raw herbal sources can vary considerably in concentration of active drug components. For this reason, it was difficult to obtain reliable doses from raw natural sources.

Chemists worked out ways to isolate the active chemicals from herbal sources, making it possible to make products with

reliable doses. Because most drugs (natural or synthetic) are powerful chemicals with potential benefits and risks, Congress passed the Food, Drug, and Cosmetics Act in 1938 to protect consumers.

In time, a large and powerful drug industry developed and it became necessary to require rigorous and very expensive evaluation of all new drug products, to ensure efficacy and safety.

Meanwhile, the small dietary supplement industry started selling pill forms of vitamins and minerals and other "safe" substances. These products did not fall under the same scrutiny as drugs and therefore required little regulation.

Q: If dietary supplements are safe, why do they now require more regulation than the Dietary Supplement Health and Education Act of 1994?

A: First, the industry is no longer small. In 2002, dietary supplement sales in the U.S. approached \$18 billion. Second, the fact that they do not have to conduct costly pre-market test-

ing has brought out the greedy side of too many businesses. And sadly, well-intentioned health-food stores and participants in supplement pyramid schemes are little more than pawns of this new Goliath industry.

Q: Will this act require supplements to be regulated like drugs?

A: No. Besides establishing a system to monitor problems related to supplement use, the act requires only supplements containing stimulants or steroid hormone precursors to obtain pre-market approval. And the manufacturer will not have to demonstrate effectiveness of the product -- it must prove only that the product is safe with normal use.

Because the supplement industry is able to multiply its voice through millions of small marketers and their customers, the Durbin bill is unlikely to pass even though it would bring a new level of legitimacy to the supplement industry and generate new consumer confidence in their products.

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