



For Immediate Release

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***HOUSE FOLLOWS SENATE, APPROVES S. 3546,
TO IMPROVE DIETARY SUPPLEMENT,
OVER-THE-COUNTER DRUG REPORTING, ENZI SAYS***

Washington, DC – U.S. Senator Mike Enzi (R-WY), Chairman of the Senate Health, Education, Labor and Pensions Committee (HELP Committee), today said the House of Representatives has approved S. 3546, the “Dietary Supplement and Nonprescription Drug Consumer Protection Act,” a bill to help the Food and Drug Administration (FDA) better understand the adverse affects of dietary supplements and non-prescription drugs, by requiring manufacturers of dietary supplements and over the counter (OTC) drugs to report all serious adverse events associated with use of their products to the FDA.

The bill now goes to the President to be signed into law.

Enzi hailed final passage of the bill, saying, “Most OTC drugs and dietary supplements are safe. But by requiring manufacturers and distributors to report serious adverse events, the FDA will have good information to decide when to act and what to do if serious problems arise. This bill will not only ensure that the FDA is properly informed, but will also preserve access to dietary supplements that are safe and properly labeled.”

The bill, S. 3546, represents months of work across party lines on the parts of Senator Orrin Hatch (R-UT), Senator Tom Harkin (D-IA), Senator Richard Durbin (D-IL), as well as Chairman Enzi, and the Committee’s Ranking Member, Senator Edward Kennedy (D-MA). It contains the following major provisions:

- **Adverse Event Reporting:** The bill would require manufacturers and distributors of supplements and OTC drugs to report all serious adverse events, such as death, life-threatening conditions, hospitalization, a persistent or significant disability or incapacity, or a congenital anomaly or birth defect, to the FDA. This reporting is an entirely new requirement for dietary supplements. Some OTC drug manufacturers are already required to report serious adverse events.

- **Recordkeeping:** The bill requires manufacturers to keep all adverse event records for six years, and allows the FDA to inspect these records. It also sets a 15-day time limit for manufacturers to give the FDA the reports of serious adverse events they receive. Records of less serious adverse events would have to be maintained, but not submitted to FDA.
- **State Responsibilities:** States will continue to work with the FDA on safety concerns. The new, mandatory, Federal reporting requirement would replace a potential patchwork of state requirements.
- **False Reports:** The bill prohibits making a deliberately false adverse event report to a manufacturer or to the FDA.

“Passing this bill is an important step to ensure that the millions of Americans who use non-prescription drugs and dietary supplements have confidence that government officials are aware of any serious problems with these products,” Enzi said.

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