Study finds high percentage of recalled dietary supplements still have banned ingredients

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About two-thirds of FDA recalled dietary supplements analyzed still contained banned drugs at least 6 months after being recalled, according to a study in the October 22/29 issue of *JAMA*.

The U.S. Food and Drug Administration (FDA) initiates class I drug recalls when products have the reasonable possibility of causing serious adverse health consequences or death. Recently, the FDA has used class I drug recalls in an effort to remove dietary supplements adulterated with pharmaceutical ingredients from U.S. markets. Prior research has found that even after FDA recalls, dietary supplements remain available on store shelves. However, it has not been known if the supplements on sale after FDA recalls are free of the adulterants, according to background information in the article.

Pieter A. Cohen, M.D., of Harvard Medical School, Boston, and colleagues conducted a study to determine if banned drugs were still present in dietary supplements purchased at least six months after a recall. The FDA recalled 274 dietary supplements between January 2009 and December 2012. Twenty-seven of the 274 recalled supplements (9.9 percent) met inclusion criteria for the study and were analyzed using the same methods at the FDA's laboratories (e.g., gas chromatography/mass spectrometry). Supplements were purchased an average of 34.3 months (range 8-52 months) after the FDA recall. Seventy-four percent of supplements (20/27) were produced by U.S. manufacturers.

The researchers found that one or more pharmaceutical adulterant was identified in 66.7 percent of recalled supplements still available for purchase (18/27). Supplements remained adulterated in 85 percent (11/13) of those for sports enhancement, 67 percent (6/9) for weight loss, and 20 percent (1/5) for sexual enhancement. Of the subset of supplements produced by U.S. manufacturers, 65 percent (13/20) remained adulterated with banned ingredients.

Sixty-three percent of analyzed supplements contained the same adulterant identified by the FDA. Six (22.2 percent) supplements contained 1 or more additional banned ingredients not identified by the FDA. Some supplements contained both the previously identified adulterant as well as additional pharmaceutical ingredients.

Banned substances identified in recalled supplements included sibutramine, sibutramine analogs, sildenafil, fluoxetine, phenolphthalein, aromatase inhibitor, and various anabolic steroids.

"To our knowledge, this is the first study to determine if adulterants remain in supplements sold after FDA recalls," the authors write.

"Action by the FDA has not been completely effective in eliminating all potentially dangerous adulterated supplements from the U.S. marketplace. More aggressive enforcement of the law, changes to the law to increase the FDA's enforcement powers, or both will be required if sales of these products are to be prevented in the future."

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