

Are Over-the-Counter Diet Pills and Muscle-Building Dietary Supplements Safe? Research Studies Show the Answer Is *No*

- 1. Teens use dietary supplements for weight loss and muscle building--even though doctors say they shouldn't.** The American Academy of Pediatrics is strongly opposed to the use of supplements for weight loss and muscle building in adolescents. Yet a national survey found that 11% of teens had ever used a weight loss supplement. In the same survey, 5% of teens had used creatine, one of many dietary supplements sold for muscle building.
Wilson KM, Klein, JD, Sesselberg TS, et al. Use of Complementary Medicine and Dietary Supplements among U.S. Adolescents. *Journal of Adolescent Health*. 2006;38(4):385-394.
- 2. Unapproved drugs are often found in dietary supplements sold for weight loss, muscle building, and sexual function.** An analysis of the FDA's Tainted Supplements database showed that between 2007 and 2016, 776 supplements from 147 different manufacturers were tainted by unlisted and potentially dangerous drug ingredients. Most of these adulterated supplements were sold for weight loss, muscle building, or sexual function. **Tucker J, Fischer T, Upjohn L, Mazzera D, Kumar M. Unapproved pharmaceutical ingredients included in dietary supplements associated with US food and drug administration warnings. *JAMA Network*. 2018;1(6):e183337.**
- 3. Tainted supplements often remain on shelves and continue to be purchased for months and even years after an FDA voluntary recall.** The Drug and Food Administration does not have the authority to prescreen dietary supplements for safety or efficacy before they hit the market and can step in only after reports of injury or death. Unfortunately, voluntary recalls by the FDA are largely ineffective.
Cohen, P. The FDA and adulterated supplements – dereliction of duty. *JAMA Network*. 2018;1(6):e183329.
- 4. Recalls are not enough to protect people from supplements containing unlisted, unapproved ingredients.** In November 2009, the U.S. Food and Drug Administration banned Pai You Gou, a dietary supplement sold for weight loss, after detecting at least two banned pharmaceutical compounds, sibutramine and phenolphthalein, both of which have well-documented serious side effects, in this product. A year after the recall, nearly 1 in 4 Brazilian-Massachusetts women were still using this product.
Cohen P, Benner C, McCormick D. Use of a pharmaceutically adulterated dietary supplement, Pai You Guo, among Brazilian-born women in the United States. *Journal of General Internal Medicine*. 2012;27(1):51–56.
- 5. Dietary supplements marketed for weight loss and muscle building have dangerous side effects, including hepatitis and liver failure.** The U.S. Centers for Disease Control and Prevention documented a series of cases of severe acute hepatitis (liver injury) and liver failure of unknown cause. Of the 29 confirmed cases of acute hepatitis and liver failure, 24 patients reported using OxyELITE Pro, a dietary supplement sold for weight loss and muscle gain, within 60 days before illness onset.
Park S, Viray M, Johnston D, et al. Acute hepatitis and liver failure following the use of a dietary supplement intended for weight loss or muscle building – May-October 2013. *Morbidity and Mortality Weekly Report*. 2013;62(40):817-819.
- 6. Dangerous stimulants are often found in widely available supplements for weight loss and muscle building.** When one stimulant is banned, supplement makers often continue using the banned substances or replace them with a related, potentially dangerous chemical. Many of these chemicals have never been tested for safety in humans.

- a. Researchers found *N,α*-DEPEA, in a widely available muscle-building supplement. *N,α*-DEPEA is a banned and potentially dangerous designer stimulant closely related to methamphetamine.
Cohen P, Travis J, Venhuis B. A methamphetamine analog (*N,α*-diethyl-phenylethylamine) identified in a mainstream dietary supplement: *N,α*-diethyl-phenylethylamine identified in workout supplement. *Drug Testing and Analysis*. 2014;6(7-8):805–807.
 - b. Half of supplements marketed as containing the herbal ingredient *acacia rigidula* were found to contain β-methylphenylethylamine (BMPEA). BMPEA is a stimulant that has not been assessed for safety or efficacy in humans. It is closely related to the banned compound DMAA, which has been associated with several deaths.
Cohen P, Bloszies C, Yee C, Gerona R. An amphetamine isomer whose efficacy and safety in humans has never been studied, β-methylphenylethylamine (BMPEA), is found in multiple dietary supplements. *Drug Testing and Analysis*. 2015;8(3-4), 328-333.
 - c. Another DMAA substitute, 1,3-dimethylbutylamine (DMBA), has also been banned by the FDA. Despite the ban, researchers found at least a dozen supplements to contain DMBA in dosages ranging from 13 to 120 mg per serving.
Cohen P, Travis J, Venhuis B. A synthetic stimulant never tested in humans, 1,3-dimethylbutylamine (DMBA), is identified in multiple dietary supplements: 1,3-dimethylbutylamine (DMBA) in dietary supplements. *Drug Testing and Analysis*. 2015;7(1): 83–87.
7. **Muscle-building supplements may lead to increased risk of testicular germ cancer in men.** A study of nearly 1000 men found that men who developed testicular germ cancer had used more muscle-building supplements than similar men who did not develop testicular germ cancer. The association was particularly strong for use of two or more types of muscle-building supplements.
Li N, Hauser R, Holford T, et al. Muscle-building supplement use and increased risk of testicular germ cell cancer in men from CT and MA. *British Journal of Cancer*. 2015;112:1247-1250.
 8. **Many supplements with labels saying they contain “pro-hormones,” “natural steroids,” or “testosterone boosters” actually contain designer anabolic steroids—with dangerous consequences.** Use of these compounds through dietary supplements is widespread. In younger men, these supplements may be a common cause of liver injury, problems with bile secretion, testicular disorders, growth of breast tissue, and infertility.
Rahnema C, Crosnoe L, Kim E. Designer steroids - over-the-counter supplements and their androgenic component: Review of an increasing problem. *Andrology*. 2015;3(2):150-155.
 9. **Diet pills may block the function of other drugs, including cancer treatments. Diet pills may also be associated with organ toxicity.** Research suggests that the diet drug orlistat limits the function of a kind of protein, CES2, needed to activate a common cancer drug, PPD. Orlistat has also been associated with gastrointestinal issues, as well as liver toxicity.
Xiao D, Shi D, Yang D, Barthel B, Koch TH, Yan B. Carboxylesterase-2 is a highly sensitive target of the antiobesity agent orlistat with profound implications in the activation of anticancer prodrugs. *Biochemical Pharmacology*. 2013;85:439–447.
 10. **Diet pills could be abused by people with eating disorders.** In anticipation of the release of alli (the brand of orlistat now available over the counter), researchers expressed concerns regarding the potential for alli to be abused by people with eating disorders. Their concerns are based on documentation of adult and adolescent eating disorder patients frequently abusing supplements sold for weight loss, as well as the possibility that alli’s FDA approval would make it more appealing than other products sold for weight loss.
Cumella EJ, Hahn J, Woods BK. Weighing Alli’s Impact: Eating disorder patients might be tempted to abuse the first FDA-approved nonprescription diet pill. *Behavioral Healthcare*. 2007;27:32–34.