We also found a number of recalled products to be manufactured outside of the United States, where manufacturing practices may not be subject to the same oversight and regulation required of domestic companies. However, most recalled products were manufactured in the United States. Indeed, the FDA has found violations of good manufacturing practices to be rampant in nearly half of the domestic dietary supplement firms it has inspected.

Our study has some limitations. First, our focus on only class I recalls may have led us to underestimate the magnitude of recalls of dietary supplements given their mass availability and the lack of regulation of these products. Second, we were unable to associate the use of many of adulterated supplements with adverse events. However, the FDA is not required to specify whether a recall occurs owing to an adverse event in Enforcement Reports. Finally, it is unclear whether the increase in recalls of dietary supplements is due to improvement in detection by the FDA, improved enforcement by the FDA, or an increase in the number of adulterated supplements that are being marketed.

Recalls of dietary supplements containing unapproved pharmaceutical ingredients are increasing. With over 150 million US residents consuming these products, the challenges posed by this growing and unregulated industry are enormous. To protect the health and safety of the public, increased efforts are needed to regulate this industry through more stringent enforcement and a standard of regulation similar to that for pharmaceuticals. Keeping the status quo may taint the dietary supplement industry as a whole.

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How Can We Know if Supplements Are Safe if We Do Not Know What Is in Them?

A mericans spend over $20 billion annually on dietary supplements. Although supplements are regulated by the US Food and Drug Administration (FDA) under the Dietary Supplement Health and Education Act, there is no requirement for supplement manufacturers to demonstrate efficacy or safety of their products prior to marketing them. However, companies may not include unapproved ingredients. It turns out that even this minimal requirement is not fulfilled. Harel et al identified 237 dietary supplements that were recalled by the FDA owing to inclusion of unapproved drug ingredients. Given the limited regulation of these products, it is likely that the number of recalls grossly underestimates the number of products on sale with unapproved ingredients. Dietary supplements should be treated with the same rigor as pharmaceutical drugs and with the same goal: to protect consumer health.

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