Congress Should Prioritize Dietary Supplement Reform as Part of Its Efforts to Strengthen Public Health

FDA needs a mandatory product listing requirement and clear recall authority to improve oversight

Four in 5 American adults report having used dietary supplements, including vitamins, minerals, herbs, and amino acids. The U.S. Food and Drug Administration regulates these products under the 1994 Dietary Supplement Health and Education Act, but the agency cannot effectively nor efficiently protect public health because of significant gaps in this outdated law. Two key issues that need to be addressed are FDA's inability to know what supplements are on the market and its inability to mandate the recall of supplement products containing drug ingredients.

Figure 1

Dietary Supplement Market Has Grown Exponentially Since Passage of Dietary Supplement Health and Education Act

Estimated 80,000 supplement products available to consumers as of 2016, roughly 20 times the amount in 1994

4,000
1994

80,000
2016

These shortcomings are particularly concerning because not all dietary supplements are safe. Between 2004 and 2013, FDA received more than 15,000 reports of health problems linked to supplements, including 339 deaths and nearly 4,000 hospitalizations. Additionally, in a recent survey of American adults by The Pew Charitable Trusts, 1 in 8 (12%) said they or an immediate family member had experienced a severe side effect, such as a heart, kidney, or liver problem, from a supplement. The survey also found that about half of adults overestimate FDA regulation of supplements, mistakenly thinking that the agency reviews or tests these products before they reach the market. When informed that this was not the case, 7 in 10 said that FDA cannot protect consumers from harmful supplements.

COVID-19 pandemic further highlights the need for reform

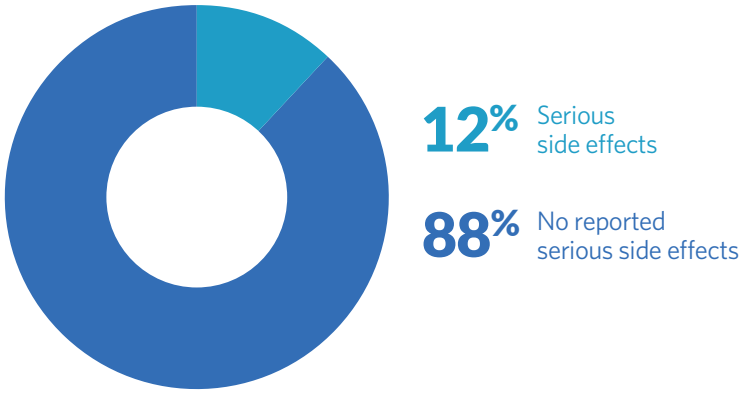
The COVID-19 pandemic has only exacerbated public health concerns within the supplement marketplace. Demand for supplements increased significantly in 2020 compared with the previous year, as consumers sought out products to support their health and wellness. This growing demand has allowed some businesses to exploit the pandemic by marketing products as dietary supplements that illegally claim to prevent, treat, or cure COVID-19.

Despite the limitations of current oversight, FDA has used its existing authority to hold some of these businesses accountable. Last year, FDA and the Federal Trade Commission (FTC)—which enforces antitrust and consumer protection laws—sent more than 100 joint warning letters to supplement producers for selling products with fraudulent claims of treating or preventing COVID-19. During the same period, FTC separately issued 62 warning letters and the Department of Justice obtained injunctions against three supplement producers for selling products that made druglike claims to treat serious diseases, including COVID-19. These actions against companies mark a significant increase in enforcement compared with the same period in 2019, when FDA issued just 13 warning letters to supplement producers for making druglike health claims. However, it is unlikely that the recent uptick in enforcement actions captures all, or even a majority, of the irresponsible actors in the market.

Figure 2

1 in 8 U.S. Adults Say They or an Immediate Family Member Experienced a Serious Side Effect After Taking a Dietary Supplement

Serious side effects include increased heart rate, high blood pressure, kidney problems, or liver damage



Part of the challenge is that FDA largely relies on postmarket approaches (after the product is available to the public) such as internet searches for illegal marketing claims, manufacturing facility inspections, and consumer or company reports to identify products that may be causing harm. But these tools provide limited insight into the up to 80,000 products on the supplement market. This lack of basic market insight makes the United States an outlier among higher-income countries; regulatory agencies in Canada, Australia, China, and Europe all have some form of registration or central listing requirement for dietary supplements. Though regulations and product definitions differ across jurisdictions, these regulatory agencies require manufacturers to provide, at a minimum, basic information about their products prior to marketing.

FDA needs modern authorities to keep consumers safe

Establish mandatory product listing

A mandatory product listing requirement is a low-cost, low-burden solution that would ensure FDA has the information it needs to provide adequate oversight of the supplement marketplace. A vast majority of American adults—95%—support this requirement, and the agency has asked for this authority in multiple budget requests.

Clarify FDA's recall authority

Although FDA can mandate the recall of dietary supplements, this authority does not extend to drugs, which must be recalled voluntarily by the manufacturer. In cases where a supplement is tainted with a drug ingredient, a loophole in the law makes the agency's recall authority unclear. These limitations raise serious questions about whether FDA can take effective action when problems with supplements arise, particularly if a company declines to recall its products voluntarily.

Figure 3

Strong Support for Mandatory Supplement Product Listing With FDA

Most support requiring manufacturers to provide FDA with a list of the products they make and their ingredients

FDA's limited authority is alarming given the scope of the problem. A study published in the *Journal of the American Medical Association* found that more than 700 dietary supplements sold from 2007 to 2016 included pharmaceutical ingredients—such as sildenafil (Viagra) and anabolic steroids—that had been the subject of FDA warnings. A separate study published in *JAMA Internal Medicine* found that several brands of supplements that contain at least one of four prohibited stimulants remain on the market, even though FDA had sent warning letters to their manufacturers and issued public notices about the ingredients.

Taken together, product listing and clear recall authority would greatly improve FDA's oversight of supplements by providing the agency with critical information about the products on the market and ensuring that it can act quickly when it becomes aware of a product that poses a risk to public health.

How Congress can act

Congress should pass legislation that provides FDA with the authority and the funding that it needs to implement these reforms. The following principles would help to ensure that this reform is meaningful and beneficial to public health:

Figure 4

Key Principles for Legislation to Reform Dietary Supplement Regulation

FDA should have authority to know what supplement products are on the market

- **All dietary supplement manufacturers must notify FDA when a product is introduced, modified, or discontinued. At a minimum, they should submit:**
  - ✓ Product names
  - ✓ Ingredients, including the composition of proprietary blends
  - ✓ A copy of the labels of the supplement product
  - ✓ Directions for use
  - ✓ Any relevant warnings or precautions
  - ✓ Allergen statements
  - ✓ Dosage amount
  - ✓ Serving size
  - ✓ Product claims
- **FDA should receive adequate funding to develop and administer a database to store this information.**
- **This information should be made publicly available except in cases where it is commercially confidential.**
- **Failure to list should be a prohibited act that may trigger enforcement action by FDA.**
- **If a product is marketed as a supplement, it should be subject to mandatory recall authority, regardless of whether it contains a drug ingredient.**

For further information, please visit:

pewtrusts.org/healthcareproducts

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