Regulatory and Compliance Challenges of Dietary Supplements in the Areas of Quality and Therapeutic Claims
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**Background**

American Annual Expenditure on Dietary Supplements
~$36B

Approx. 3/4 of the U.S. population consumes dietary supplements

Authorized “health claims” for dietary supplements if they complied with FDA regulations

The Dietary Supplement and Health Education Act of 1994 (DSHEA)
Created the current regulatory framework for dietary supplements requiring manufacturers to use Good Manufacturing Practices (cGMPs), and submit new dietary ingredient notifications but does not require premarket approval or review.

**Objective**

Identify and categorize frequently observed regulatory challenges and draw attention to public health concerns regarding dietary supplements by examining both the United States Food and Drug Administration (FDA) Recalls, Market Withdrawals & Safety Alerts and FDA Warning Letters databases

**Methodology**


2) Identified each recall and letter issued to products either labeled or marketed as a dietary supplement

3) Compiled data on the letter/recall was issued, manufacturer, product name, reason for the recall/letter

4) Categorized data based on reason for the recall/letter (ex. drug claims, adulterated, misbranded, other)

**Results**

- Since March 2020, the FDA found 56 dietary supplements made claims they either treated, prevented, cured, or diagnosed COVID-19
- Drug contaminants found were primarily prescription drugs (ex. sildenafil, tadalafil) followed by banned drugs (ex. sibutramine)

**Results (cont.)**

- Disease claims are prevalent, potentially misleading consumers to believe dietary supplements can treat, cure, prevent or diagnose a disease.
- The results of this study indicate the current regulatory framework for dietary supplements may not be adequate in protecting the safety of the U.S. public from adulterated or misbranded dietary supplements entering the marketplace.

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**References**
