Quality, Safety and Efficacy Issues of Dietary Supplements
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BACKGROUND

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

The Dietary Supplement and Health Education Act of 1994 (DSHEA)
No premarket approval required, new dietary ingredient notification, dietary supplement manufacturers needed to use Good Manufacturing Practices

DSHEA is the regulatory framework for dietary supplements

- 76% of U.S. population consumes dietary supplements
- ~$36B American Annual Expenditure on Dietary Supplements

OBJECTIVE

To identify and categorize regulatory compliance problems with dietary supplements related to their quality, safety and efficacy by examining both the United States Food and Drug Administration (FDA) Recalls, Market Withdrawals & Safety Alerts and the FDA Warning Letters databases

METHODOLOGY

Identified: each recall/letter issued to a product either labeled or marketed as a dietary supplement
Compiled: date issued, manufacturer, product name, reason for the recall/letter being issued, issuing office
Categorized: based on reason for recall/letter (ex. drug claims, adulterated, misbranded, other)

RESULTS

Figure 1. Reasons for FDA Recall (Jan. 2015 - Jul. 2020)
Figure 2. Warning Letters for Dietary Supplements (Jan. 2015 - Dec. 2020)

CONCLUSIONS

From this examination of FDA Recalls, Market Withdrawals, & Safety Alerts and FDA Warning Letters databases (2015-2020) from FDA.gov:
- Many Americans consume dietary supplements that may contain undeclared drug substances
- 10% of these products should be classified as drugs, not dietary supplements
- Nearly 60% of warning letters dietary supplements receive are for, at least in part, making disease claims, demonstrating that these products can mislead the American public through their advertising
- Current regulations do not prevent these safety issues associated with dietary supplements from occurring nor the misinformation being perpetuated by them

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