Dietary supplements are widely used by Americans, who spend an estimated $36 billion on supplements annually with 76% of Americans in 2019 reporting having used a dietary supplement in the past year. But it is not clear how safe and effective these products are because the current regulatory framework does not require these products to undergo pre-market review or approval.

To identify and categorize current problems with dietary supplements related to their quality and safety by examining the FDA’s Recalls, Market Withdrawals & Safety Alerts database.

2. Categorized data based on reason for the recall.
3. In cases where the recall involved an active pharmaceutical ingredient (API), subgroups were created to find the prevalence of each type of API (Banned Substance, Drug on Market, Steroid) found.

The presence of drug ingredients was the most common reason for recall.

- Banned Substance
- Steroid/Steroid-like Substance
- Drug on Market
- Unspecified API
- Drug on Market and Banned

Figure 1: Reasons for Recall, 2015 to Present

Marketed and banned drug substances were frequently found in recalled products.

Recalls (2015-Jul. 2020) due to drug contaminants

- Microbial contamination
- Potential contamination of Stenotrophomonas maltophilia
- Undissolved citrus flavonoid

Recalls (2015-Jul. 2020) due to manufacturing issues

- Not manufactured in cGMP
- Misbranded dietary supplements
- Manufacturing/distributing unapproved new drugs

Recalls (2015-Jul. 2020) due to drug controls

- Allergen (Milk, Soy, Fish, Peanuts, Shellfish)
- Other

Figure 2: Type of Drug Found in Recalled Dietary Supplements

- Dietary supplements with quality and safety concerns may be prevalent in the U.S. marketplace.
- Approximately half of recalled dietary supplements contain drug contaminants (Fig. 1).
- The American public may unknowingly be taking dietary supplements that contain undeclared drugs.
- The current regulatory framework for dietary supplements may not be adequate in safeguarding public health.

The effectiveness of the current regulatory framework for dietary supplements will be studied further by examining the basis of health and therapeutic claims through a review of FDA Warning Letters and FTC actions.

The relationship between FDA Recalls, Market Withdrawals & Safety Alerts data, FDA Warning Letters data, and FTC actions will be compared and analyzed.
Kelsey Genda, BS ’21 MS ‘22, is a rising senior at USC hailing from Chappaqua, New York. She is majoring in Pharmacology & Drug Development with a minor in The Dynamics of Early Childhood. Recently, she has begun her progressive degree, working towards a Master of Science in Regulatory Science. Outside of school, she is involved in multiple organizations: Alpha Chi Omega, Teach for Los Angeles, USC Pre-Pharmacy Society. For Alpha Chi Omega, she served as the Social Chair for the 2019 calendar year as well as being chosen as a member for multiple committees in the house. As a member of Teach for Los Angeles, she volunteers as a math tutor. Currently, she is involved in a research project looking into the regulatory policies regarding dietary supplements. Specifically, Kelsey is researching adverse events related to dietary supplements to see if current regulation policies are adequate to protect the public’s health. In her free time she enjoys reading, listening to music and traveling. genda@usc.edu