NATURAL PRODUCTS ASSOCIATION

440 1st St, N.W. , Ste. 520, Washington, D.C. 20001
(202) 223-0101, Fax (202) 223-0250
NPAinfo.org

NEWS RELEASE

For Immediate Release
July 26, 2017

Contact: Justin Bartolomeo
(202) 789-4365
jbartolomeo@hdmk.org

New Study Ignores Superior Safety Record of Dietary Supplements Compared to other FDA Regulated Products

Leading Association for Dietary Supplements Questions Methodology

WASHINGTON, D.C. – The Natural Products Association (NPA) today responded to the findings of a study in the Journal of Medical Toxicology. The Study, "An Increase in Dietary Supplement Exposures Reported to US Poison Control Centers" significantly exaggerates the safety risk of dietary supplements and ignores their superior safety record when compared to other Food and Drug Administration (FDA) regulated products.

"Adverse events from supplements are extremely low given their widespread usage, and most of these are the result of three factors: accidents, people not consulting with their doctor, or misuse of a product combined with other health factors. Supplements are safe, which is why millions of Americans use them every day," said Dan Fabricant, Ph.D., President and CEO of NPA. "The laws that regulate supplements require official reporting of adverse events so that the regulators, the health care community and others can review the data and make informed public policy decisions."

Specifically, NPA pointed out:

- Poison Center (PC) data does not automatically imply causality between ingestion of the ingredient in the product and appearance of symptom and clinical signs. According to the FDA's own CAERS database, which collects mandatory serious adverse events for dietary supplements, CAERS cases are not automatically considered causal. A temporal relationship between the product and event has to be established which it wasn't for any of the PC data.
- Regarding children-resistant packaging, currently, dietary supplements containing 250 mg or more of elemental iron in a concentration of 0.025 percent or more on a weight-to-volume basis for liquids and 0.05 percent on a weight-to-weight basis for non-liquids – must have child-resistant packaging due to the potential for child poisoning in those less than 6 years of age.

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- It's unclear how children under six gained access to products with child resistant packaging. While it's always concerning anytime a child appears ill, if packages aren't properly stored in their appropriate containers, that is the responsibility of the user of the product not the manufacturer.

According to the United States Food and Drug Administration's (FDA) website (http://www.fda.gov/Food/DietarySupplements/ReportAdverseEvent/) the Safety and Reporting Portal is a "convenient secure, and efficient method for letting FDA know when industry or consumers finds a problem with a dietary supplement."

Adverse Event Reporting is significantly higher for other FDA regulated products than it is for dietary supplements and natural products.

- Every 21 seconds someone calls Poison Control because of a medication error, according to a study published in *Clinical Toxicology* that analyzed calls to Poison Control Centers across the country over a 13-year period which resulted in serious medical outcomes.
- CDC estimates that each year roughly 1 in 6 Americans (or 48 million people) gets sick, 128,000 are hospitalized, and 3,000 die of foodborne diseases.

Natural Products Association

The **Natural Products Association (NPA)** is *the* trade association representing the entire natural products industry. We advocate for our members who supply, manufacture and sell natural ingredients or products for consumers. The Natural Products Association promotes good manufacturing practices as part of the growth and success of the industry. Founded in 1936, NPA represents over 1,400 members accounting for more than 10,000 locations of retailers, manufacturers, wholesalers and distributors of natural products, including foods, dietary supplements, and health/beauty aids. Visit www.NPAinfo.org. Follow NPA on social media:

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Natural Products Association: 440 1st Street, NW, Ste. 520, Washington, DC, 20001

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