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RESEARCH NOTES

Banned and discouraged-use ingredients found in weight loss supplements

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ABSTRACT

Objectives: To identify banned and discouraged-use ingredients, such as ephedra, 1,3-dimethylamylamine, and beta-methyl-phenylethylamine, in readily available weight loss dietary supplements within a 10-mile radius of Regis University.
Methods: A list of banned and discouraged-use ingredients was compiled with the use of the Food and Drug Administration (FDA) dietary supplement website which provides information on supplement ingredients that are no longer legal or are advised against owing to adverse event reporting. Investigators visited all retail outlet stores within a 10-mile radius of Regis University in Denver, Colorado. Retail chains were not duplicated and only one of each chain was evaluated.
Results: A total of 51 weight loss supplement products from retail stores were found with banned or discouraged-use substances listed on their labels. At least one banned ingredient was found to be listed on the product labels in 17 of the 51 studied supplements (33%). At least one discouraged-use ingredient was found in 46 of the 51 products (90%). Retail outlet stores dedicated to supplements and sports nutrition alone were found to have the greatest number of weight loss supplements that included banned and discouraged-use ingredients.
Conclusion: The FDA has taken action to remove some weight loss supplements from the market that contain banned ingredients. Unfortunately, based on the findings of this study, it is evident that products containing these ingredients remain on the market today.

Over the past 4 decades, the prevalence of obesity has doubled, resulting in more than two-thirds of Americans being overweight or obese.[1] Although health care providers agree that diet and exercise is the basis for a healthy lifestyle, many Americans are turning to weight loss dietary supplements to achieve weight loss goals.[2,3] Approximately 15% of American adults have reported the use of weight loss supplements at some point, with the majority of users being women between the ages of 18 and 34.[4]

Dietary supplements are regulated under the Dietary Supplement Health and Education Act of 1994 (DSHEA), which created the framework for controlling the safety and labeling of dietary supplements. The DSHEA mandates that manufacturers are required to ensure safety and validate all claims stated regarding their product. Although supplements do not require approval by the Food and Drug Administration (FDA), if a new dietary ingredient is brought to market after 1994, it is the manufacturer's responsibility to notify the FDA of its use and demonstrate why it is thought to be safe.[5] Since the implementation of DSHEA, 51,000 supplements have been brought to market, but only 170 notifications have been reported.[6] This low number of notifications, compared with the total number of new supplements brought to market, raises concerns regarding the safety of dietary supplements. Clearly, relying on manufacturers to self-report ingredients limits the FDA's ability to identify supplements that contain banned or discouraged-use ingredients. The lack of reporting has facilitated the availability of supplements with questionable safety. The fact that there is no mandate to ensure safety and efficacy before marketing dietary supplement products, in addition to poor manufacturer self-reporting, has led to the availability of dietary supplement products containing unsafe ingredients.

Banned ingredients, such as ephedra, sibutramine, 1,3-dimethylamylamine (DMAA), and beta-methyl-phenylethylamine (BMPEA), have been found in dietary supplements. In 2013,

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an increase in unexplained liver failure, identified by a transplant surgeon in Hawaii, resulted in an investigation by the Centers for Disease Control and Prevention (CDC). It was determined that the liver failure was a complication as a result of the use of OxyElite Pro, a weight loss supplement containing DMAA, manufactured by Hi-Tech Pharmaceuticals. Further investigation revealed nearly 100 patients suffering from hepatitis caused by that supplement. Unfortunately, liver disease is not the only concern. The FDA has received numerous reports regarding cardiovascular events, psychiatric disorders, and even death related to DMAA.[7]

Although these ingredients have been banned because of cardiovascular, nervous system, and psychiatric issues, many supplements containing these substances are still on the market today. Additionally, there are many other dangerous ingredients that are not banned yet are worthy of caution and education before consumption. Dangerous ingredients include those that are structurally similar to, and produce stimulant effects mimicking, illegal substances such as methamphetamine or highly controlled pharmaceutical amphetamines (Table 1). These effects, in combination with other stimulants commonly found in weight loss supplements, can act synergistically and amplify an already dangerous response. Additionally, the concern multiplies when combining comorbidities and prescription medications with weight loss dietary supplements.

A prime example is when picking up many prescription medications, patients are often counseled to avoid grapefruit juice owing to the inhibitory effects on the metabolism of medication. This interaction is common for drugs and ingredients metabolized by enzymes of the cytochrome P450 family, including amphetamines, cyclosporine, and some calcium channel blockers. This effect is caused by the natural component of grapefruit, 6,7-dihydroxybergamottin. This ingredient has been intentionally added to weight loss supplements to amplify the stimulant effect responsible for weight loss. When combined with prescription medications, 6,7-dihydroxybergamottin can result in dangerous side effects potentiated by toxic drug levels.[8] Owing to the accessibility of these supplements, it is crucial that consumers speak with health care providers to decrease the occurrence of unforeseen events.

Many ingredients have serious effects on the cardiovascular system, nervous system, liver, and other areas that are still unknown. Ephedra is a popular ingredient that was commonly used in these supplements in the 1990s and early 2000s owing to its ability to decrease weight and increase energy. However, ephedra was pulled from the market in 2004 after more than 18,000 adverse event reports were filed. Further research showed an association between ephedra and many side effects including hypertension, arrhythmias, heart attacks, seizures, stroke, and even sudden cardiac death.[9] Combining ephedra with other ingredients that may contribute to cardiovascular effects can greatly increase the risk of serious adverse events and mortality. These ingredients include synephrine, yohimbine, phenylethylamine (PEA), BMPEA, caffeine, guarana, and DMAA, all of which are readily found in weight loss dietary supplements. Case studies are available documenting healthy individuals experiencing cardiac events, strokes, and acute liver failure after the consumption of one or more of these ingredients.[10-13] An otherwise healthy 27-year-old woman in the Air Force experienced ventricular fibrillation after consuming Lipodrene, a product marketed by Hi-Tech Pharmaceuticals that was shown to contain synephrine among other stimulants.[14] Consumers need to be aware of the adverse events that can occur in otherwise healthy individuals and take this into consideration when consuming weight loss supplements.

Objectives

The primary purpose of this study was to identify banned and discouraged-use ingredients in readily available weight loss dietary supplements within a 10-mile radius of Regis University.

Methods

The investigation encompassed multiple retail settings, including pharmacies, grocery stores, vitamin outlets, etc. A list of banned and discouraged-use ingredients was compiled using the FDA dietary supplement website which provides information on supplement ingredients that are no longer legal or are advised against using owing to adverse event reporting.[5] This list provided investigators with the names that ingredients are most commonly known by and the numerous other names that manufacturers use to list these ingredients (Table 2). Investigators visited all retail outlet stores (Table 3) within a 10-mile radius of Regis University in Denver, Colorado. Retail chains were not duplicated and only 1 of each chain was evaluated. Products claiming to aid in weight loss were found in supplement aisles titled “weight loss, diet and/or fitness, digestion, energy, and lifestyle essentials.” The dietary supplements were evaluated for banned and discouraged-use ingredients (Table 2).

Results

A total of 51 weight loss supplement products from retail stores were found with banned or discouraged-use substances listed on their labels. At least 1 banned ingredient was found to be listed on the product labels in 17 (33%) of the 51 studied supplements (Table 3). The banned ingredients listed included ephedra, DMAA, BMPEA, and 4-amino-2-methylpentane citrate. At least 1 discouraged-use ingredient was found in 46 (90%) of the weight loss supplement products (Table 3). Retail outlet stores dedicated to supplements and sports nutrition alone were found to have the greatest number of weight loss supplements that included banned and discouraged-use ingredients.

Discussion

The results of this investigation are alarming. Even though there are ingredients defined as “banned” by the FDA, these products remain available to the unaware consumer. Although the primary objective of this study was to investigate the existence of banned materials in available supplements, other concerning observations were made. Many supplements contained a variety of ingredients that were used for the same purpose, especially stimulants. Commander, manufactured by 1st Phorm, included many ingredients that caused a stimulant effect, including caffeine, cocoa extract (theobromine), BMPEA,