Over-the-counter (OTC) products withdrawn from the United States due to the inclusion of undeclared prescription ingredients in the past 15 years

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This study was conducted to identify over-the-counter (OTC) medications and supplements that have been removed from the market due to the inclusion of undeclared prescription ingredients. Information was obtained from the FDA database of MedWatch Safety Alerts for Human Medical Products from January of 2001 through December of 2015. A list of products as well as the undeclared ingredients was included in these products. Selected manufactures or distributors of the products were contacted for sale availability. A total of 594 OTC products were found to have undeclared prescription ingredients. The majority of these supplements were sold for weight loss (41%), sexual enhancement (40%) and muscle building (16%). There were other various supplements marketed for general health, arthritis, hyperlipidemia, prostate health, diabetes, feminine health, hypertension and sleep. The most common undeclared ingredient in the weight loss supplements was sibutramine, while sildenafil analogs were the most common in sexual enhancement supplements. Steroids were the most common undeclared ingredient in the muscle building products. Several products were found to be available for purchase in some capacity on the internet by secondary distributors. FDA and regulatory actions may be necessary to avoid manufacturers as well as secondary distributors of these agents. Proper knowledge of patient use of OTC product and its ingredients should aid in prevention of adverse drug reactions and interactions.

Biography
Dr. Lavesh Patel is PhD student at South College School of Pharmacy, USA

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