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Are Botanicals Safer after Passage of Regulations for Mandatory Adverse Event Reporting in the US?

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Dietary Supplements containing botanical medicines remain one of the most abundant and available options for patients choosing self-care and wellness strategies to maintain and/or improve their health. Despite passage of mandatory adverse event reporting for serious adverse events (SAE's), questions regarding the safety of these products, or individual ingredients, continue to be raised in various regulatory, media and consumer safety venues. Has the new law enhanced consumer and regulator confidence in the safety of these products? Has the submitted data provided adequate information for regulators and others to determine if safety issues exist and have the requirements helped identify potentially unsafe products or ingredients? The SafetyCall International Poison Center (SCI), an academically affiliated, multidisciplinary, triple licensed medical practice composed of clinicians with specific expertise in clinical medicine and toxicology, natural product pharmacology and consumer product safety has managed thousands of supplement/botanical AE's, including SAE's, on behalf of hundreds of supplement manufactures and routinely identifies incidents meeting the SAE criteria and facilitates submission of appropriate reports to the FDA. This presentation provides a generic review of the SCI 3 yr supplement AE experience and presents strengths and weaknesses of the existing system from an inside view of an entity seeing all the events, both serious and non-serious. Additionally, an identity redacted example analysis of a manufacturer product safety assessment will be reviewed. In this review, both serious and non-serious events will be presented with data normalization utilizing denominator information to accurately track relative incident rates.