3600 American Boulevard W.
Suite 725
Bloomington, MN 55431

p: 952.852.4600
f: 952.852.4601

www.safetycall.com

Botanical Risk Assessment for Quality and Safety: Are corporations doing what they should, regulators getting what they need, and supplements as safe as they should be?

Abstract for 2012 Annual Oxford International Conference on the Science of Botanicals in conjunction with the Food and Drug Administration.

Rick Kingston PharmD
SafetyCall International
May 2012

Despite the inherently wide margin of safety for botanical ingredients typically found in dietary supplements, manufacturing, quality and other safety issues can arise. Proactive quality control measures can prevent many safety issues but other unexpected toxicity concerns can emerge. The list of potential health risks is long and includes interactions and previously unrecognized side effects with the listed ingredients as well as unknown risks associated with undeclared contaminants and adulterated solvents. For those safety issues that escape detection and mitigation in the premarket process of quality assurance for manufacturing and distribution of a finished product, post-market surveillance is the last and only safety net that can identify potential toxicity concerns. Companies can and should put robust and sensitive post-market surveillance systems in place to monitor the quality and safety of their products, but the data that is generated can sometimes be misinterpreted by various stakeholders and further confuse the issue. Current regulatory requirements for mandatory reporting of serious adverse events were designed to establish a safety net to help regulators identify the most egregious of safety issues. But, review of the relatively few reported events may not signal emerging safety threats, accurately distinguish between real and perceived issues, or predict the future safety of a given company's products. Ultimately, the question that remains is whether or not the existing regulations are meeting the needs of regulators and other stakeholders alike and would more regulation make any difference? This presentation focuses on barriers that exist on both sides of the fence as regards establishment of a safety surveillance "system" that works for both regulators and the regulated community. Lastly, independent of whether or not the system works for regulators or the regulated, does it work for other new or existing stakeholders. The list of stakeholders includes; academics researching new uses for properly sourced and manufactured ingredients, insurers assessing the insurability of new or existing manufacturers, health professionals desiring to recommend quality products for their patients, and consumers looking for quality products that contain what's listed on the label to help them attain their health and wellness goals. Examining the experience to date helps inform and shape the future of botanical safety. This presentation explores and identifies the role that academics and other professionals can play in helping to identify "best practice" companies and products that deserve the recommendation of experts in the field.