OXFORD
UNIVERSITY PRESS
ISSN 1096-6080
Volume 144, Issue 1
March 2015
www.toxsci.oxfordjournals.org

The Official Journal of
the Society of Toxicology
SOT | Society of Toxicology
Creating a Safer and Healthier World
by Advancing the Science of Toxicology
www.toxicology.org

PS

461 Assessing Potential Herb-Drug Interactions: Need for a Common Framework Approach

A. L. Roe[1], J. C. Griffiths[2], B. Gurley[3], R. Kingston[4], H. Oketch-R[5] and M. Paine[6]. *[1]The Procter & Gamble Company, Cincinnati, OH, [2]CRN, Washington, DC, [3]UAMS, Little Rock, AR, [4]SafetyCall International, Bloomington, MN, [5]USP, Rockville, MD and [6]Washington State Univ, Spokane, WA.*

Herbal product usage in the North American population continues to increase across all age groups. This population has ready access to conventional medications, with significant polypharmacy observed in older adults. Patients are reticent to disclose herbal product usage to their healthcare providers, and many providers still do not inquire about such usage. Dietary supplements, including herbal products, are not subject to the same regulatory guidelines for pre-market testing as drugs. Considerations such as history of safe use, literature data from toxicity studies, and constituent amounts in products may provide guidance on whether to assess herb-drug interactions (HDIs) experimentally. The literature is replete with reports of various herbal extracts and constituents as potent inhibitors of drug metabolizing enzymes, including the cytochromes P450, as well as transporters. However, without standard methods for herbal product characterization or *in vitro* testing, extrapolating these reports to clinically-relevant HDIs is difficult. This lack of a clear definition of risk prevents clinicians and consumers from making informed decisions about the safety of taking herbal products with conventional medications. A logical strategy is to borrow, as applicable, from the testing guidances for assessing drug-drug interactions established by regulatory agencies (e.g., FDA, EMA). For example, intestinal and hepatic *in vitro* systems can be used to assess potential HDIs. These data can be incorporated into PBPK models to help forecast clinical relevance. Lastly, a strategy for monitoring post-marketing signals related to potential HDIs is needed. In summary, a framework is needed that describes an integrated and sophisticated approach for assessing HDI potential of dietary supplement ingredients and products.