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USP points to publicly available resources designed to address dietary supplement quality challenges in a special issue of "Drug Testing and Analysis" devoted to the topic

Rockville, MD June 16, 2016 - A special issue of the journal "Drug Testing and Analysis" devoted to "advancing supplement science: challenges and solutions" features a contribution by scientists from the United States Pharmacopeial Convention. Edited by Pieter A. Cohen, Bastiaan J. Venhuis and Simon D. Brandt, the March – April 2016 special issue includes articles on a wide range of topics such as: the history of dietary supplement regulation in the US; use of dietary supplements and its impact on specific populations – including the armed forces and young athletes; case reports on the health effects of illegal ingredients; analytic methods and tools; consumer perceptions of the dietary supplement health and education act (DSHEA) and proposals for improvements to dietary supplement regulation and research.In keeping with the focus of the special issue, USP's article identified two key challenges related to products marketed as dietary supplements – the prevalence of FDA warning letters issued to supplement manufacturers pointing to non-specific identity tests and the challenge of screening for unknown adulterants - and proposed quality analysis tools and solutions to address them.

In late 2015, these types of issues were among the underlying reasons behind multi-agency federal enforcement actions against over 100 makers and marketers of dietary supplements; in 18 states. As a solution to help address these concerns, USP advocates for widespread adoption of science - based public standards to serve regulators (e.g. the Food and Drug Administration - FDA), manufacturers and consumers by improving the consistency and quality of dietary supplements in the United States and globally.

Science-based public standards - that are arrived at through an open, transparent, process - offer validated, consistent, methods in support of public health.

The authors, Nandakumara Sarma, director of dietary supplements and herbal medicines; Gabriel Giancaspro, vice president – science, dietary supplements and herbal medicines; and Jaap Venema, chief science officer, proposed that wider use of public standards developed by USP in conjunction with GMP compliance, can help ensure the quality and consistency of dietary supplements. Public health protection could be enhanced by ensuring conformance with relevant USP standards, or in the absence of USP standards, other public compendial standards. To address challenges of intentional illegality and suspected adulteration, the authors pointed to two new tools USP is developing specifically targeting three categories of products recognized by the FDA as a major concern: sexual enhancement, weight loss and sports performance enhancement. USP

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General Chapter <2251> provides a logic to analytical testing for the detection of undeclared drugs and drug analogs. USP is concurrently developing The Adulterants Database, where it assembles information from peer-reviewed literature, notices issued by enforcement agencies worldwide, and chemical data characterizing the adulterants, all thoroughly cross-referenced with the FDA Substance Registration System. Like USP's Food Fraud Database, The Adulterants Database will collate data from numerous sources in a single searchable and publicly available resource.

Drug Testing and Analysis (DTA) is a bi-monthly peer-reviewed scientific journal published by John Wiley & Sons. It is devoted to the publication of papers dealing with the development and application of techniques for the determination of controlled or controversial substances.

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