

Adverse Event Reporting (AER) for Dietary Supplements

**Congress Passes
& President Signs
AER Legislation!**

Part III: Implementing the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006

Sponsored by:



**Thursday
January 11, 2007**

**Little America Hotel
Salt Lake City, UT**



SEMINAR PROGRAM

Congress has just passed the Dietary Supplement and Nonprescription Drug Consumer Protection Act of 2006. This legislation requires dietary supplement companies to report to FDA within 15 days serious adverse events for dietary supplements. Understanding details of this law and how to efficiently and effectively assure you are in compliance will become a top industry priority. This seminar is designed for executives responsible for operations, quality assurance, marketing, legal & regulatory and scientific affairs, all of whom will be involved in receiving, assessing and reporting SAERs.

8:00 – 8:30 am	Registration and Continental Breakfast	
8:30 – 8:45 am	Welcome and Review of the Day	Loren Israelsen Executive Director <i>United Natural Products Alliance (UNPA)</i>
8:45 – 10:15 am	AERs for Dietary Supplements: A Political and Consumer Mandate	Patricia Knight Chief of Staff Senator Orrin G. Hatch
	Critical Provision Analysis: Dietary Supplement and Nonprescription Drug Consumer Protection Act	Peter Reinecke Senior Advisor, <i>UNPA</i> President, <i>Reinecke Strategic Solutions</i> Former Chief of Staff Senator Tom Harkin
10:15 – 10:30 am	Break	
10:30 am – Noon	Creating, Managing or Outsourcing a Corporate AER Surveillance Program	Rick Kingston, PharmD President, Regulatory & Scientific Affairs <i>SafetyCall™ International</i>
Noon – 1:00 pm	Lunch: Little America Executive Buffet	
1:00 – 2:00 pm	Dealing with Health Professionals in Assessing AERs and Using Cautions and Warnings on Dietary Supplements	Don Brown, N.D. President, <i>Natural Product Research Consultants, Inc.</i> , Seattle, WA
2:00 – 3:00 pm	Herb/Drug Interactions: Characterizing Herbal and Dietary Interactions with Pharmaceuticals	Francis Brinker, N.D. Clinical Assistant Professor, Dept. of Medicine <i>University of Arizona</i>
3:00 – 3:15 pm	Break: Light Refreshments	
3:15 – 4:15 pm	Stimulant-Based Dietary Supplements: Will this be a Major Source of AERs?	Christine Haller, M.D. Assistant Professor of Medicine and Laboratory Medicine <i>University of California at San Francisco</i>
4:15 – 5:00 pm	Q&A: Speakers Panel / Other Invited Guest Presentations	
5:30 – 7:00 pm	Reception for All Attendees and Faculty	

P R E S E N T E R S

Patricia Knight

Patricia Knight is the Chief of Staff for Senator Orrin G. Hatch (R-Utah), where she is responsible for directing all aspects of the Senator's office, including policy, legislative development, staffing and administration. She is one of the Senate's longest serving chiefs of staff, having been appointed to that position in 1998. From 1993 to 1998, Ms. Knight served as health staff director to Senator Hatch, including four years of service on the Judiciary Committee and two on the Labor and Human Resources Committee (the predecessor to today's Health, Education, Labor and Pensions Committee).

Ms. Knight has had a long association with health care legislation, having served as Deputy Assistant Secretary for Legislation (Health) for four years in the Reagan Administration, and as the senior legislative assistant to Rep. James T. Broyhill, former Ranking Republican on the House Energy and Commerce Committee, for five years. She joined Senator Hatch's staff early in 1993 as Minority Staff Director of the Labor Subcommittee, having served the prior year in the Bush Administration where she was head of HHS' Office of Health Legislation.

During her work for Rep. Broyhill, Ms. Knight was involved in drafting a range of Public Health Service and health care financing legislation, an interest which carried over when she joined HHS in the fall of 1981 as Special Assistant to the Assistant Secretary of Legislation.

She has also been involved extensively in the appropriations process, first as Special Assistant to the Assistant Secretary for Legislation (Appropriations and Budget), HHS, and later as a professional staff member on the minority staff of the House Appropriations Committee (1990-1992). On the Appropriations Committee, Ms. Knight was responsible for annual development of three annual appropriations bill: Legislative Branch; Commerce, State Justice; and Foreign Operations. She developed expertise in these issues when she joined the Bush Administration in 1989 as Principal Deputy Assistant Secretary for Legislative and Intergovernmental Affairs at the Department of Commerce.

As health advisor to Senator Hatch, Miss Knight was involved in formulating public laws on a range of health-related issues, including children's health, regulation of foods, drugs and medical devices, and Medicare and Medicaid reimbursement. She was the lead staffer on several important laws Senator Hatch authored, including the Children's Health Insurance Program (CHIP) and the Dietary Supplement Health and Education Act (DSHEA).

Miss Knight is a resident of Arlington, Virginia and was graduated magna cum laude from Syracuse University with a degree in photojournalism and anthropology.



Peter Reinecke

Peter Reinecke is principal of Reinecke Strategic Solutions, Inc., providing strategic consulting and planning services with a focus on health policy. In 2005 he left public service after over 20 years working in various positions for the U.S. Congress in Washington, D.C. Most recently he served as Chief of Staff to Senator Tom Harkin (D-Iowa).

Mr. Reinecke has played an active role in the development of federal health care policy for over two decades. His experience includes major staff roles in the establishment of six Institutes and Centers at the National Institutes of Health, including the Office of Dietary Supplements, the Office of Alternative Medicine and the National Center for Complementary and Alternative Medicine. He also played a major role in the establishment of the White House Commission on Complementary and Alternative Medicine Policy and was Senator Harkin's principal advisor in the enactment and implementation of the Dietary Supplement Health and Education Act. Mr. Reinecke also worked on a range of legislation including Medicare reform, child nutrition, the Americans with Disabilities Act as well as measures to reorient the health care system towards prevention and wellness. He served on the White House Health Care Reform Task Force in 1994.

Prior to joining the Senate, Mr. Reinecke worked as Research Director for the U.S. House Subcommittee on Health and Long-Term Care. He also has worked for the Institute of Medicine, National Academy of Sciences and served as a Visiting Lecturer at Duke University.



Rick Kingston, PharmD

Dr. Kingston is President, Regulatory and Scientific Affairs for SafetyCall International, a multidisciplinary medical practice and poison center focused on postmarket surveillance and product safety for drugs, dietary supplements and consumer products. He is also a Clinical Professor, in the College of Pharmacy at the University of Minnesota where he serves as course director for "Therapeutics of Herbs and Other Natural Medicinals" and has previously served as a member of the University's "Center for Plants and Human Health" and NCCAM funded "Center for Spirituality and Healing". Dr. Kingston has 28 years professional experience in the areas of clinical toxicology and pharmacology, poison control, product post-market surveillance and, drug and dietary supplement safety. Previously, Dr. Kingston was co-founder and former Director of the Minnesota Regional Poison Center and its affiliated industry toxicology and product safety surveillance service programs at St. Paul Ramsey Medical Center, in St. Paul,

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Minnesota. He has 23 years critical care toxicology experience gained from practice in a University affiliated Level One Trauma Center. Dr. Kingston completed his Bachelor of Sciences in Pharmacy degree at the University of New Mexico, his Doctorate in Clinical Pharmacy at the University of Minnesota, and a Post-Doctoral Fellowship in clinical toxicology and pharmacokinetics at St. Paul-Ramsey Medical Center and the University of Minnesota. His research and practice interests coincide with SafetyCall™ International initiatives for corporate clients and include a focus on injury prevention, the epidemiology of toxicology related incident data, product safety and related regulatory affairs, and specific advances in the clinical management of patients being treated or evaluated for drug, toxin or consumer product exposures.



Donald J. Brown, N.D.

Dr. Donald Brown is a naturopathic physician and one of the leading authorities in the US on evidence-based herbal medicine and the safety and efficacy of nutritional supplements. A former assistant professor at the Bastyr University of

Natural Health Sciences in Seattle, he is the founder and director of Natural Product Research Consultants, Inc. and serves on the Advisory Board of the American Botanical Council. Dr. Brown has served as an advisor to the Office of Dietary Supplements at the National Institutes of Health.

Dr. Brown is a regular contributor and editor for the journal *HerbalGram* produced by the American Botanical Council. He is the author of *Herbal Prescriptions for Health and Healing* (Lotus Press, 2002) and contributor to *The Natural Pharmacy* (Prima Publishing, 2006), the *A-Z Guide to Drug-Herb-Vitamin Interactions* (Prima Publishing, 2006), and *The Textbook of Natural Medicine* (Churchill Livingstone, 2006). Dr. Brown also serves as the President of the Board of Directors for the Real Change Homeless Empowerment Project in Seattle, WA.



Francis Brinker, N.D.

Dr. Brinker holds undergraduate degrees in human biology from Kansas Newman College and in biology from the University of Kansas where he is a member of the Phi Beta Kappa honor society. He obtained his doctorate in 1981 at the

National College of Naturopathic Medicine in Portland, Oregon. Subsequently, Dr. Brinker completed a two-year postgraduate fellowship in botanical medicine there, after which he taught this subject at NCNM. He has functioned as consultant for Eclectic Institute, Inc., since 1986.

From 1993-1999 he served as a botanical medicine instructor at the Southwest College of Naturopathic

Medicine in Tempe, Arizona. For the past eight years Dr. Brinker has been involved as a preceptor and instructor in botanical medicine for the Program in Integrative Medicine at the University of Arizona. He is currently on the faculty as clinical assistant professor in the Department of Medicine, College of Medicine.

Based on his extensive literature research of historic, scientific and medical publications, Dr. Brinker has been editor of the *Eclectic Medical Journal Reprints*, regular reviewer for *American Herbal Pharmacopoeia* monographs, and author of many articles and books on botanical medicine. Two volumes of these writings have been compiled as the *Eclectic Dispensatory of Botanical Therapeutics* (1989, 1995). In addition, his books include *Formulas for Healthful Living* 2nd ed. (1998), *The Toxicology of Botanical Medicines* 3rd ed. (2000), *Herb Contraindications and Drug Interactions* 3rd ed. (2001), and *Complex Herbs – Complete Medicines* (2004).



Christine Haller, M.D.

Dr. Haller is an Assistant Professor of Medicine and Laboratory Medicine at the University of California, San Francisco. She serves as the Associate Chief of the Clinical Toxicology Laboratory at San Francisco General Hospital, and the

Assistant Medical Director of the California Poison Control System, San Francisco Division.

She is a past recipient of a K23 clinical research award from the National Center for Complementary and Alternative Medicine at the NIH to study the clinical pharmacology of ephedra and caffeine-containing dietary supplements that were previously used for weight loss and performance enhancement. She has conducted six clinical studies and published numerous papers on ephedra and and is well recognized for her expertise on botanical stimulants. She is also a principal investigator for studies examining the pharmacology of gamma hydroxybutyrate (GHB) in humans. Dr. Haller lectures frequently nationally and internationally on the toxicology and pharmacology of herbal medicines and dietary supplements.

Dr. Haller attended the University of Utah and received a Bachelor of Science degree in Chemical Engineering. She earned a Master of Science degree and an M.D. degree through the U.C. Berkeley/U.C. San Francisco Joint Medical Program. She completed a residency in Clinical Pathology at U.C. San Francisco in 1998, and a post-doctoral fellowship in clinical pharmacology and toxicology at the Veteran's Administration Medical Center in San Francisco in 2000, after which she joined the faculty at UCSF in the Division of Clinical Pharmacology and Experimental Therapeutics. She is board-certified in both Clinical Pathology and Medical Toxicology.

REGISTRATION

Adverse Event Reporting (AER) for Dietary Supplements Part III: Implementing the Dietary Supplement and Nonprescription Drug Consumer Protection Act

Registration Info:

Attn: Lindsay Wright, United Natural Products Alliance (UNPA)
1075 Hollywood Avenue, Salt Lake City, UT 84105
Tel: (801) 474-2572 / Fax: (801) 474-2571 / e-mail: lindsay@unpa.us

Registration Fees:

of Attendees

Fees

UNPA Members:

\$445 first person 1 x \$445 = _____

\$195 each additional from same company _____ x \$195 = _____

Non-Member Companies:

\$645 first person 1 x \$645 = _____

\$345 each additional from same company _____ x \$345 = _____

Early Registration 10% Discount
(Deduct 10% if registering by December 21, 2006) _____

Total Fees _____

**Thursday,
January 11, 2007**

**Little America Hotel
Salt Lake City, Utah**

500 S. Main, Salt Lake City, UT 84101
1-800-437-5288

Ask for the UNPA room block rate
of \$159 per night. Must reserve by
January 3, 2007 for hotel discount.

About the Sponsor:

UNITED NATURAL PRODUCTS

ALLIANCE (UNPA) is an international association representing leading dietary supplement companies in the state of Utah and throughout the world. Utah is a global manufacturing center for dietary supplements—with annual sales exceeding \$4.1 billion. World class production and quality control systems are a basic requirement of UNPA membership, as are rigorous raw materials specifications, in-process controls and analytical testing methods.

Registration Form: (No On-Site Registrations Accepted)

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Payment Method:

Check: Payable to UNPA. Please note "January 11th Seminar" on the check and send the to UNPA address listed above.

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