Safety Assessment of Over-The-Counter Botanicals and Nutraceuticals: Update and Challenges

April 19, 2017
Lister Hill Center Auditorium
NIH Campus, Bethesda, MD

Please visit NCAC-SOT at https://www.toxicology.org/groups/rc/ncac/
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<td>8:30-9:00 AM</td>
<td>Registration opens</td>
<td></td>
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<tr>
<td>9:00-9:05 AM</td>
<td>Introductory welcome comments, logistics</td>
<td><strong>Tracy Chen</strong>, Symposium Chair (NCAC-SOT President)</td>
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<tr>
<td>9:05-9:45 AM</td>
<td>Botanical identity, uses, and safety translated to new dietary ingredient notification (NDIN) information</td>
<td><strong>Steven J. Casper</strong>, Center for Food Safety and Applied Nutrition (CFSAN), U.S. Food and Drug Administration (FDA)</td>
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<td>9:45-10:30 AM</td>
<td>Toxicology Studies and Previous Human Experience to Support Botanical Drug Development</td>
<td><strong>Jinhui Dou</strong>, Center for Drug Evaluation and Research (CDER), U.S. Food and Drug Administration (FDA)</td>
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<td>10:30-10:45 AM</td>
<td>Break</td>
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<td>10:45-11:30 AM</td>
<td>USP botanical quality standards: contributions in quality control &amp; safe use of botanicals</td>
<td><strong>Hellen A. Oketch-Rabah</strong>, United States Pharmacopeia (USP)</td>
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<td>11:30 AM -1:30 PM</td>
<td>Lunch: Cafeteria is on the floor below LHC auditorium. Mentoring Luncheon: 11:30 AM-12:30 PM Poster Session: 12:30-1:30 PM</td>
<td>General audience: Lunch on your own. Participants in the mentoring luncheon will meet at the lobby area to receive boxed lunches and to join the activity. Please contact Dr. Nancy Beck for details.</td>
</tr>
<tr>
<td>1:30-2:10 PM</td>
<td>Advising cancer patients regarding risks and benefits of botanicals and nutraceuticals</td>
<td><strong>Jeffrey D. White</strong>, National Cancer Institute (NCI)</td>
</tr>
<tr>
<td>2:10-2:50 PM</td>
<td>Analytical developments for identification and authentication of botanicals</td>
<td><strong>James Harnly</strong>, United States Department of Agriculture (USDA)</td>
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<td>2:50-3:30 PM</td>
<td>National Institutes of Health support of dietary supplement research</td>
<td><strong>Barbara C. Sorkin</strong>, <strong>Adam J. Kuszak</strong>, Office of Dietary Supplements (ODS), National Institutes of Health (NIH)</td>
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<td>3:30-4:00 PM</td>
<td>Panel discussions</td>
<td>Moderator: <strong>Jinhui Dou</strong></td>
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<tr>
<td>4:00-4:10 PM</td>
<td>Wrap-up</td>
<td><strong>Tracy Chen</strong> (NCAC-SOT President)</td>
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Logistics

Lister Hill Center Auditorium (LHC)
- Attendees are prohibited from bringing food and drink, including all water bottles, into the auditorium.
- A conference microphone is located at each table position in the lower section and can be activated by pressing the “MIC” button. A red ring will light up when the microphone is active. Only 6 microphones can be active at one time. Press the “MIC” button again to turn the microphone off when finished speaking.

Security
All NIH visitors must go through a security clearance at the new NIH Gateway Center to receive a visitor’s badge. Visitors may be required to pass through a metal detector and have bags/purses inspected or x-rayed. All visitors must present a government-issued photo ID to enter the campus.

Public Transportation
The Washington D.C. Metrorail system has a station on the NIH campus called "Medical Center." Upon exiting the station, it is a short walk to the NIH campus shuttle, which will take you to NIH buildings on the main campus and in Rockville.

Metrorail service is available from Ronald Reagan Washington National Airport and from Union Station (railway). Take Metro’s Red Line to the Medical Center Station.

For more information, visit Washington Metropolitan Area Transit Authority and NIH Campus Shuttle Schedules.

Directions
The Lister Hill Center Auditorium (LHC, Building 38A) is located on the NIH main campus. Visitor parking is limited, so take public transportation if possible. The campus is located on the Red Line at the Medical Center Metro stop. Proceed to the new NIH Gateway Center for security clearance. The LHC is located a short distance behind the Gateway Center.

See http://www.nih.gov/about/visitor/ for more information.

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Visitors should arrive by Metro or plan to park in the MLP11 parking lot and enter through the Gateway Center. (There is NO CAMPUS PARKING available for this meeting.) Please plan for at least 30 minutes at the Gateway Center in case of possible delays. Additional security information, including identification requirements and restricted items, is available on the NIH Visitor Website at: https://www.nih.gov/about-nih/visitor-information

Campus shuttle service is available from the Gateway Center to the Lister Hill Center Auditorium (LHC, Building 38A). The NIH Campus (Red Line) shuttle departs from the Gateway Center/Metro entrance about every 15 minutes. Transit time to the LHC is approximately 21 minutes. For additional information, consult the NIH shuttle website at: https://www.ors.od.nih.gov/pes/dats/nihshuttleservices/Pages/shuttle.aspx
Map of Lister Hill Center Auditorium (back to Table of Contents)
Presentation Abstract

Botanical identity, uses, and safety translated to new dietary ingredient notification (NDIN) information

by

Steven J. Casper, Ph. D.

As with all subjects, difficulties arise between groups of people who understand the subject from different perspectives. The subject of botanicals is so vast and varied that, while it can be known from one perspective such as in an herbalist’s office, the view of the exact same subject matter can be quite different from another perspective, say a regulatory perspective. How does one use botanical knowledge in a regulatory setting? A close view of the NDIN review process can clarify how botanical identity, use, and safety information can be adapted to satisfy regulatory requirements.

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Toxicology Studies and Previous Human Experience to Support Botanical Drug Development

by

Jinhui Dou, Ph.D.

FDA CDER established the Botanical Review Team in 2003 and finalized the first Guidance for Industry: Botanical Drug Products in 2004. The Guidance outlined that sponsors may reference prior human experience of botanical products (e.g., as dietary supplements and herbal medicines) to support early phase clinical trials under Investigational New Drug (IND) applications. Therefore, to support initial clinical trials for botanicals, the nonclinical pharmacology and toxicology information that must be provided under 21 CFR 312.22(b) may be markedly reduced compared to that expected for new molecular entities without prior human experience. This approach is still acceptable in the revised final Guidance for Industry: Botanical Drug Development (published in 2016). CDER has received over 450 botanical INDs submitted for clinical investigation as treatments for various diseases (e.g., cancer, infectious diseases, and arthritis). Approximately 15% of the INDs were found to have one or more clinical hold issues, such as lack of the supporting quality or safety information, or unresolvable serious protocol deficiencies.

When sponsors plan to advance their clinical development into late phases (e.g., phase 3 trials/NDA), standard toxicology studies, as outlined in M3(R2) will be required. There are two market approvals of New Drug Applications (NDAs): Veregen, a topical drug for the treatment of genital and perianal warts, and Fulyzaq (now called Mytesi), an oral drug for the treatment of HIV/AIDS related diarrhea. In the case of Veregen, toxicological studies of the drug product were carried out for up to 3 months in rats and dogs and for up to 9 months in mini-pigs with minimal to severe local reactions. Oral carcinogenicity study of the drug substance in transgenic mice was also conducted with negative findings. For Fulyzaq, the nonclinical reviewers recommended approval based on the NOAEL in dogs that provides a sufficient margin of safety for the recommended clinical dose.

The multiple disciplinary review experience of botanical drugs in the past decade is the foundation of the revised final Guidance, which included recommendations on late phase drug development and NDA submissions. The revised Guidance described a “totality-of-evidence” approach to apply conventional CMC data and additional information, including raw material control, clinically relevant bioassay(s), and other data generated based on a multiple-batch and multiple-dose clinical trial of the botanical product, to ensure therapeutic consistency.
References:

4. Lee, SL; Dou J; Agarwal, R; Temple, R; Beitz, J, Wu, C; Mulberg, A; Yu, LX; Woodcock, J. Evolution of traditional medicines to botanical drugs, Science (Suppl), S32-34, January 2015.
7. King ST, FDA CDER NDA 202292 Review (accessed online at https://www.accessdata.fda.gov/drugsatfda_docs/nda/2012/202292Orig1s000PharmR.pdf, on March 27, 2017)

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USP botanical quality standards: contributions in quality control & safe use of botanicals

by

Hellen A. Oketch-Rabah, Ph.D.

USP botanical quality standards are essentially a collection of specifications (in a USP monograph) as well as additional requirements which together make the quality standards. They include USP monographs and General Chapters as well as Reference materials. Botanical monographs in the USP-NF contain information that addresses identity, purity, strength and composition as well as limits of contaminants. The USP general chapter on Identification of Articles of Botanical Origin <563> describes different approaches that can be applied to define the identity of complex articles containing multiple components such as botanical materials or botanical extracts. The botanical monographs have a section designated as “Identity”, that provides identity tests, their procedures and acceptance criteria that should enable identification of an article. The provided identity tests are usually two or more orthogonal tests and in most cases include pattern recognition of typical fingerprints obtained using chromatographic techniques such as HPTLC, HPLC or LC versus microscopic techniques versus spectroscopic techniques. Where the constituents of the botanical are well known, the presence and relative content of its constituents may offer a consistent pattern useful in determining the identity. However identification section of a monograph is just the starting point of determining identity and most often other tests are needed to identify the material as defined. Thus to claim that an article is identical to USP article requires complying with all sections of the monograph.

An important aspect of USP quality monograph development is a process referred to as “USP Dietary Supplements (DS) Admission Evaluation” which precedes all DS USP quality monograph developments. The process includes an evidence-based safety evaluation of an article to determine whether or not it is qualified for admittance to the USP monograph development process. Using an example of a USP botanical monograph this talk will illustrate how the USP admission evaluation and quality monograph together can serve in ensuring the quality and safety of over the counter botanicals.

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Advising cancer patients regarding risks and benefits of botanicals and nutraceuticals

by

Jeffrey D. White, M.D.

Cancer patients frequently decide to use various dietary supplements after varying degrees of research and with varying degrees of expectations of outcomes. Patients also frequently don’t have thorough discussions with their healthcare providers about the risk:benefit ratio associated with taking dietary supplements during cancer treatment and there is relatively little information about the potential interactions between these products and standard cancer therapies. This talk will provide an overview of some statistics about the use of dietary supplements by cancer patients, reports of adverse effects and interactions and some of the research results indicating potential benefits of certain dietary supplements used by cancer patients.

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Analytical developments for identification and authentication of botanicals

by

James Harnly, Ph.D.

Authentication of natural products is essential for safety. While most adulteration is aimed at economic gain, adding or substituting any unknown material is unacceptable. Authentication of the raw botanical ingredients (e.g., leaves, stems, rhyzomes, and roots) is usually approached by collecting authentic materials, selecting a comprehensive chemical fingerprinting method, developing a multivariate model, setting statistical limits, and then determining if an unknown material fits the model (authentic) or doesn’t (not authentic). The most difficult aspect of this approach is usually collection of the authentic materials. Today, there are new analytical fingerprinting and modeling methods that provide speed and specificity to the authentication process. In recent years, MS, NMR, NIR, and even UV spectrometry have proven to be valuable tools for comprehensive chemical fingerprinting. Modeling based on chemometric methods, can be very straightforward, doesn’t require extensive expertise, and can be obtained from numerous commercial packages. Application of this approach to finished commercial supplements is more difficult as the production process frequently results in a loss and/or gain of compounds. Consequently, models based on raw materials are not appropriate for validating their presence in a commercial supplement. In this case, marker compounds are necessary to confirm the presence of extracted ingredient compounds, e.g., one expects to find flavonol glycosides and triterpene lactones in Ginkgo biloba supplements and ginsenosides in American or Asian Ginseng supplements. A simpler approach, based on MS fingerprinting, is spectral correlation, a point-by-point multiplication of the spectra. Principal component analysis of the correlation spectra can then be used to determine if the specified ingredient is present.

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National Institutes of Health support of dietary supplement research

by

Barbara C. Sorkin, Ph.D. & Adam J. Kuszak, Ph.D.

The U.S. National Institutes of Health (NIH) supports mechanistic, toxicological, clinical, and epidemiological research relevant to dietary supplements (DS), including botanical natural products. The NIH’s Office of Dietary Supplements (ODS) and National Center for Complementary and Integrative Health and other NIH Institutes fund investigator-initiated research on DS mechanisms of action, biological effects and health outcomes, as well as on DS-drug interactions. Additionally, ODS supports the development and dissemination of validated analytical approaches to determine DS identity, purity, and composition through grants as well as through partnerships with other federal agencies. Finally, botanical DS safety is the subject of evaluation projects in the National Toxicology Program at the National Institute of Environmental Health Sciences. This presentation will provide a broad overview of these and other NIH efforts to increase research capacity and expand scientific understanding of the chemistry and health effects of botanical DS.

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Speaker Biographies
(Alphabetical Order by Last Name)

Steven J. Casper, Ph. D.

Dr. Casper is a member of the Evaluation and Research Staff in the Office of Dietary Supplement Programs. He reviews new dietary ingredient notifications for identity and safety. He is a subject matter expert in botany for the center and is consulted on botanical issues by many stakeholders. Dr. Casper is an Ethnobotanist who received his doctorate degree at Washington University in St. Louis studying antimalarial plants of the Peruvian Amazon. Before that, he was a plant molecular biologist at Scripps Research Institute in La Jolla, California and at the Plant Gene Expression Center in Albany, California.

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Jinhui Dou, Ph.D.

Pharmacologist and Pharmacognosist
Botanical Review Team
Office of Pharmaceutical Science
Center for Drug Evaluation and Research (CDER)
U.S. Food and Drug Administration

Dr. Dou received his Ph.D. degree in Pharmacognosy from the Pharmacy School of University of Mississippi. After obtaining his doctoral degree, he conducted his post-doctoral research at the University of Kansas on immuno-modulating medicinal plants. He also holds a bachelor's degree in Pharmacy and master's in Pharmacognosy from Beijing University of Chinese Medicine.

Dr. Dou joined the Botanical Review Team (BRT) in CDER in 2002, and is currently the Team Lead and expert reviewer on botanical drugs. He provided pharmacognosy reviews in supporting the approvals of two botanical New Drug Applications (NDAs), Veregen and Fulyzaq (now called Mytesi) and clinical trials of hundreds investigational new drug (IND) applications. He has also reviewed numerous INDs and NDAs of small molecule as a pharmacology reviewer. His contribution in developing guidance and policies had won him numerous CDER, FDA, and HHS awards.

Prior to joining the FDA, Dr. Dou worked as a lead natural products scientist for a biopharmaceutical company on anticancer drug discovery and development from medicinal plants.

Dr. Dou is a member of American Society of Pharmacognosy (ASP).

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Dr. Harnly serves as the Research Leader for Food Composition and Methods Laboratory (FCMDL), part of the Beltsville Human Nutrition Research Center of the US Department of Agriculture. His lab is tasked with the development of new analytical methods for nutrients and bioactive compounds in foods, dietary supplements, and botanical materials in support of nutrition research at USDA. Current projects in the lab include development of new methods for vitamins, metabolomics, and chemical fingerprinting of foods and botanical supplements. His personal research interest is the development of chemometric methods for the identification and authentication of botanical materials. Dr. Harnly received his BA from the University of Colorado and his PhD from the University of Maryland. He joined USDA as a research scientist in 1979 and became the Research Leader in 1997. He has served on the Board of Directors for Association of Official Agricultural Chemists (AOAC) International, the Advisory Board of the American Botanical Council, and numerous Expert Committees for US Pharmacopeia and AOAC. He served for 22 years as the US Editor for the Journal of Atomic Spectrometry for the Royal Society of Chemistry and is currently the Editor in Chief for the Journal of Food Composition and Analysis.

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Adam J. Kuszak, Ph.D.

Adam J. Kuszak earned his B.S. in the Pharmacology-Toxicology Program at the University of Wisconsin – Madison, and his Ph.D. from the Department of Pharmacology at the University of Michigan Medical School.

Dr. Kuszak first joined the Office of Dietary Supplements (ODS) at the National Institutes of Health (NIH) as an American Association for the Advancement of Science (AAAS) Science & Technology Policy Fellow in 2014, and currently serves as a Health Science Administrator and Policy Analyst. Prior to joining ODS, Dr. Kuszak completed his postdoctoral training at the National Institute of Diabetes and Digestive and Kidney Diseases.

Dr. Kuszak primarily supports the administration and implementation of the ODS Analytical Materials and Reference Materials Program. In addition, he works with most of the ODS staff on several initiatives, including the Nutritional and Dietary Supplement Interventions for Inborn Errors of Metabolism Program, the Dietary Supplement Label Database, and the development of ODS dietary supplement Fact Sheets. Dr. Kuszak's primary research interests are in the chemical and biological characterization of complex natural products and understanding their effects on cellular signaling networks.

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Dr. Oketch-Rabah is a Pharmacognosist. She is currently a Senior Scientific Liaison at the United States Pharmacopoeia in the Department of Dietary supplement and Herbal Medicine where she leads the effort in critically evaluating literature information pertaining to the Safety and Benefits of Dietary Supplements for purposes of determining admission of articles to be USP monograph development process. She is also an invited Expert Committee member of the 2017-2021 Joint (FAO/WHO) Expert Committee on Food Additives.

Previously Dr. Oketch-Rabah was the Principal Scientist at Herb Pharm Inc. a dietary supplement manufacturing facility in Oregon, where she managed the Analytical and R & D laboratory and new product development.

As a private citizen, Dr. Oketch-Rabah leads a non-profit organization (ElimulSfoundation.org) that supports girls and boys in STEM education. Dr. Oketch-Rabah received her Ph.D. in Pharmacognosy from the Royal Danish School of Pharmacy in Denmark. B.Ed (Sc) and MSc from Kenya University in Nairobi in Kenya. She has presented at many scientific conferences, published numerous peer-reviewed articles, written book chapters, and was an interviewee in the scientific documentary on herbal medicines titled “Numen the Nature of Plants”. Dr. Oketch-Rabah is an active member of the Society of Toxicology (SOT), American Society of Pharmacognosy (ASP) and Sigma Xi.
Barbara C. Sorkin, Ph.D.

Barbara C. Sorkin, received her B.S. and M.S. from the Department of Molecular Biophysics and Biochemistry at Yale University, and her Ph.D. from the Laboratory of Developmental and Molecular Biology at the Rockefeller University, where she was appointed Assistant Professor prior to moving to the Scripps Research Institute. Dr. Sorkin was also on faculty at the Forsyth Institute in Boston, Massachusetts, where she obtained her first NIH award. Her research focused on the molecular structures, biological functions, and molecular biology of cell-cell adhesion molecules belonging to the immunoglobulin superfamily and the cadherin family.

Dr. Sorkin joined the NIH Office of Dietary Supplements (ODS) as the Director of the Botanical Research Centers Program in October 2011. Before moving to ODS, Dr. Sorkin was responsible for administering extramural research in the areas of antioxidants, healthy aging, cancer and sleep at NIH’s National Center for Complementary and Alternative Medicine (NCCAM), where she had worked since 2003. She also coordinated NCCAM’s Natural Product Integrity, Developmental Centers for Research on CAM, Partnerships for CAM Clinical and Translational Research, and Centers of Excellence for Research on CAM Programs.

Dr. Sorkin has been an author of research reviews and original research papers in many areas ranging from cell adhesion molecule structure through health effects of dietary supplements to enhancing rigor and reproducibility in research on botanical and other natural products.

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Jeffrey D. White, M.D.

Dr. White joined the Metabolism Branch of the National Cancer Institute (NCI) in 1990 as a Medical Staff Fellow where he performed laboratory research in immunology and molecular biology. While in the Metabolism Branch, he served in various positions culminating as director of the Clinical Trials and Clinical Care Program. In that capacity, he coordinated the development and administration of phase I and II clinical trials using unmodified and radiolabeled monoclonal antibody constructs. Dr. White has been principal investigator for and has reported the results from trials of various experimental treatments for patients with adult T-cell leukemia/lymphoma (ATL) and cutaneous T-cell lymphoma (CTCL).

From 1995 to 1998, Dr. White also served as an oncology consultant to the director of the NIH’s Office of Alternative Medicine. In October 1998, the Deputy Director of Extramural Science of NCI, Dr. Robert Wittes, chose him to serve as director of a new office in the NCI titled the Office of Cancer Complementary and Alternative Medicine (OCCAM). The office was created to augment the activities of the different divisions at NCI that were already supporting complementary and alternative medicine (CAM) research. OCCAM continues to promote and support research and generation of good quality information on the various disciplines and modalities associated with the field of CAM as they relate to the diagnosis, prevention and treatment of cancer.

Dr. White graduated from Cornell University with a B.S. in Applied and Engineering Physics in 1979 and received an M.D. from Howard University in 1984. He completed a residency in internal medicine in 1987 and fellowships in oncology and hematology in 1990 at The Washington Hospital Center in Washington, D.C. Dr. White is board certified in internal medicine and medical oncology.

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