

NIH Centers for Dietary Supplements Research: Botanicals

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Herbs and Botanical Medicines

- **1.5 Billion Dollar Per Year Industry**
- **Covered by DSHEA Legislation of 1994**
- **Quality, Safety, and Efficacy Issues**
- **Licensing and Regulation**
- **Structure, Function and General Well-Being**
- **Research Agenda**

Office of Dietary Supplements Research (Dr. Paul Coates, Director)

- Established in cooperation with the National Center for Complementary/ Alternative Medicine at NIH to fund research on Dietary Supplements
- Strategic Plan calls for four centers
- Training Grant, Medical School Curriculum
- UCLA and UIC are the first two centers.

Goals of the UCLA CDSRB

- **Establish that multiple ingredients act differently than a single purified substance.**
- **Identify active constituents in botanicals and explore their mechanisms of action in well-defined biological systems;**
- **Conduct pre-clinical studies (cell culture and animals)**
- **Conduct phase I /II clinical evaluations of botanicals.**
- **Assess the bioavailability/bioactivity of botanical ingredients including phytochemical marker compounds and active ingredients**

Specific Projects in the Center

- **Chinese Red Yeast Rice**
- **Green Tea Extracts**
- **St. John's Wort**
- **Soy Isoflavones and Cancer Prevention**
- **Echinacea and Immune Function**
- **Flavonoid Bioavailability and Markers**
- **Phytoestrogen Screening by Bioassay**

Chinese Red Yeast Rice

- **Shown to Lower Cholesterol in Humans**
- **Are the other Monacolins Active ?**
- **What are the effects of the botanical preparation on plaque stabilization ?**
- **Develop preliminary human pharmacokinetic data for large multicenter trial of cardiovascular health.**

Green Tea Extract

- Catechins are very potent antioxidants in vitro and protect DNA from damage.
- Are the multiple catechins more active than EGCG in blocking oxidation and angiogenesis ?
- What is the bioavailability ?
- What are the effects on oxidation in man ?

St. John's Wort

- Found to be effective mood enhancer for mild dysthymia but mechanism not established.
- Does St. John's wort act as a serotonin reuptake inhibitor, a monoamine oxidase inhibitor or both ?
- Is hypericin or hyperforin the active ingredient or do both contribute ?

Soy Isoflavones and Cancer

- **What are the effects of soy isoflavones on prostate tumor growth by comparison to purified genistein ?**

Echinacea

- **What are the effective components in Echinacea and how do these affect immune function with regard to some specific markers of immune function relevant to the common cold ?**

Flavonoid Bioavailability

- **Flavonoids including quercetin and kaempferol are among the antioxidants taken in the greatest quantity in the diet and are derived from plants.**
- **What levels of flavonoids are indicative of getting a protective effect from fruits and vegetables in terms of antioxidation ?**

The Search for Phytoestrogens

- **Plants have developed chemicals with estrogenic potential that bind to two different classes of estrogen receptors.**
- **Can we develop a biological screening method for these ?**
- **This would help to develop female hormone replacement therapies.**

Core Laboratories

- **Analytical Phytochemistry Core at UCLA with collaboration at University of Kansas**
- **Agriculture/Botany Core: Cal State Poly Pomona School of Agriculture and the Plant Molecular Biology Group at the UCLA College of Letters and Sciences**
- **Biostatistics/Clinical Pharmacology Core to examine herb-drug interaction/metabolism**

A New Paradigm for Botanicals

- **Define the plant source genetically**
- **Grow under specified conditions**
- **Establish range for phytochemical contents**
- **Test in appropriate biological models**
- **Clinical testing in phase I, II trials**
- **Examine herb-drug interactions**
- **Build the science base for supplements**

Conclusion

- **Much more research is needed to fulfill the promise of botanical dietary supplements for public health through prevention.**
- **The NIH Centers for Dietary Supplement Research is a beginning in this process.**
- **Continued partnering of government, academia, industry and the public will advance the day when full benefits realized.**