

PRACTITIONER CHAT



Dr. Judith A. Smith

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Q ■ Your research focuses on drug development for gynecologic cancers and women's health conditions with a specific focus on integration of nutritional supplements and herbs with traditional Western medicine. What role do supplements and herbs play in your research and potential treatments?

A ■ Nutritional and herbal supplements have many potential benefits for optimizing treatment outcomes and overall health. It is difficult to summarize in a few sentences especially since there are so many aspects to consider. Briefly, some nutritional supplements like omega-3s and l-glutamine may help in reducing potential for neuropathy or herbal supplements like curcumin may have a role in optimizing treatment of cancers. Over the past 10 years, we have been methodically evaluating many of the commonly used supplements for potential for drug-supplement interactions

Dr. Judith A. Smith is an associate professor in the Department of Obstetrics, Gynecology and Reproductive Sciences at University of Texas (UT) Health and Sciences Center Medical School at Houston, as well as an adjunct professor appointment in the Department of Clinical Sciences and Administration at the University of Houston College of Pharmacy, and is a Faculty Member at the University of Texas Health and Sciences Center Graduate School of Biomedical & Health Sciences – Houston. Dr. Smith actively participates in research and teaching activities within each of these institutions. The primary focus of Dr. Smith's position is research and she also supports clinical pharmacy activities for women's cancer at the UT Health Memorial Hermann Cancer Center. She is board certified in oncology pharmacy (BCOP) and certified provider of healthcare quality (CPHQ). Over the past 15 years, Dr. Smith has actively participated in the design and implementation of studies evaluating the safety, efficacy and integration of complimentary and alternative medications (CAMs) with commonly used medications, specifically chemotherapy. Dr. Smith was recognized nationally and internationally, respectively, by two leading pharmacy organizations, Fellow of American College of Clinical Pharmacy (FCCP) and Fellow of the International Society of Oncology Pharmacy Practitioners (FISOPP).

as well as potential benefits when given in combination with chemotherapy. In the next phase of our research we will be transitioning these studies to clinic to confirm our findings in human studies.

Q ■ Please discuss your work at the University of Texas Health Science Center. What is the primary focus?

A ■ My primary focus is on research in drug development in the women's health arena, specifically the integration of nutritional and herbal supplementation with traditional Western medicine. We are looking for interventions to decrease the risk of developing cancer such as this study for AHCC (active nexose correlated compound) supplementation to eradicate HPV (human papillomavirus) infections or a combination of interventions, including supplementation, to optimize weight management to reduce obesity and the risk of developing cancer such as endometrial cancer. We also have a number of studies evaluating the safety of medications and supplements during pregnancy.

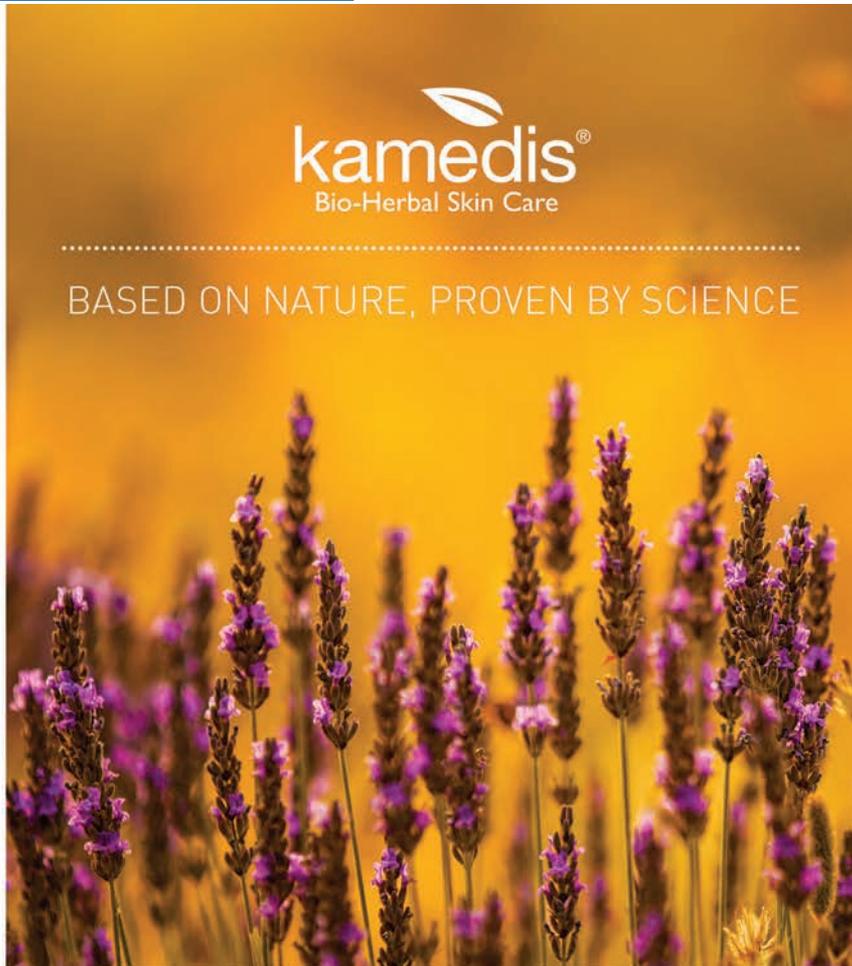
Q ■ You recently led a study in which an AHCC completely eradicated the

HPV in mice. Please discuss the study and what was discovered. What was the most surprising result and most encouraging outcome?

A ■ This study looked at the efficacy of a once daily supplementation of AHCC compared to vehicle (placebo) or no treatment for 90 days followed by 30 days of observation in two animal models, one HPV+ and one HPV- as control. I anticipated at least suppression of the HPV virus and I was encouraged to see that when treatment was stopped and when tested after 30 days of observation, HPV could not be detected, suggesting AHCC successfully eradicated the virus. This animal data is being confirmed in an ongoing study in humans.

Q ■ Can you further discuss your previous study evaluating AHCC with common chemotherapy agents used for the treatment of ovarian cancer to screen for potential drug interactions and improvement in activity?

A ■ We have been evaluating the role of AHCC with chemotherapy for over 10 years now. Initially evaluating the



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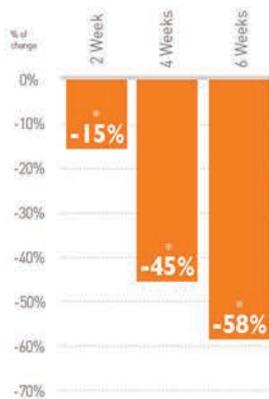
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potential for drug interactions via liver cytochrome P450 metabolism pathway, we then completed both *in vitro* and *in vivo* (mouse) studies to test the combination of AHCC with a panel of chemotherapy agents. To summarize, we observed an improvement in both paclitaxel and doxorubicin activity when administered in combination with AHCC compared to either chemotherapy agent alone. While AHCC does have potential for induction of the Phase I metabolism via Cytochrome P450 2D6 pathway, the commonly used chemotherapy agents are not substrate for this pathway. In general, the data suggested AHCC did not have any negative interaction with chemotherapy and if anything actually improved outcomes when given with paclitaxel or doxorubicin. These studies have not been confirmed in humans yet but clinical protocols are in development.

Q What do you see as future uses for AHCC? Are there other potential areas where it may have the same type of effect?

A I think that AHCC will continue to be used as a nutritional supplement to help maintain a strong immune system. While commonly used in Japan and other neighboring countries, I hope to see an integration of AHCC more commonly in Western countries. We have planned a follow-up Phase II clinical study to evaluate if AHCC is effective in eliminating HPV infections in women starting in the next few months once funding is secured. There are many other potential “difficult viruses” to treat that AHCC may also have potential benefits for. The important step is to do the research to support the use, which takes time and resources but in the long-term will provide a stronger foundation and rationale for the integration of supplements with traditional Western Medicine.

Q Is there any related research currently underway or planned for the near future?

A We currently are conducting a pilot study in HPV+ woman to confirm the preclinical study findings and determine the duration of supplementation required to eradicate HPV infection. This study is closed to accrual and we are currently seeking funding to move forward with the Phase II randomized, placebo controlled study to evaluate if AHCC supplementation will be an effective nutritional intervention option for the eradication of HPV infections.