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RECENT STUDY INDICATES USE OF OTC PROGESTERONE CREAM RESULTS IN THE SAME OVERALL DRUG EXPOSURE IN WOMEN AS PRESCRIBED ORAL PROGESTERONE PRODUCTS

Thousand Oaks, CA, USA (July 12, 2005) – There has been considerable concern about the risk that many over-the-counter (OTC) cosmetic preparations may pose to the public, since many of these are not regulated by the FDA and are commonly used without medical supervision. Progesterone, which is commonly prescribed in women, is often used in hormone replacement therapy in postmenopausal women, and for the treatment of amenorrhea, infertility and premature labor. Past studies revealing the health risks of FDA-approved hormone replacement therapy (including oral progestones and progestins) have contributed to dramatic declines in prescriptions for these products. However, unregulated natural progesterone continues to be sold over-the-counter in the form of herbal beauty creams, thus exempting them from regulatory scrutiny.

In a study recently published in *The Journal of Clinical Pharmacology*, (June 2005) researchers found substantial evidence that use of OTC topical progesterone results in similar drug exposure through skin absorption as that which results from taking a prescribed oral progesterone product.

The Bassett Healthcare supported study, led by Drs. Anne C. Hermann, Anne Nafziger and Joseph Bertino, consisted of twelve, healthy, post-menopausal women. Each subject was treated with topical OTC progesterone (Pro-gest cream) in one phase and prescribed oral progesterone (Prometrium) in the other phase of the study. According to the results, there was no difference between the two groups in the amount of progesterone exposure in the body. The women involved in this study also experienced similar rates of adverse effects while taking each type of progesterone. This study differed from previous studies because of its use of more precise and advanced drug analysis methods, giving results that are accurate compared to previous studies with topical progesterone products.

Given the risks associated with prolonged progesterone therapy, the researchers note with concern that women may be exposing themselves to similar risks without the counseling, screening and supervision that accompany the use of prescription products.

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The article "Over-the-Counter Progesterone Cream Produces Significant Drug Exposure Compared to a Food and Drug Administration-Approved Oral Progesterone Product" can be found on *The Journal of Clinical Pharmacology* web site at www.jclinpharm.org.

About The Journal of Clinical Pharmacology:

For over 45 years, clinical pharmacologists, clinical and pharmaceutical researchers, drug development specialists, physicians, nurses, and other medical professionals have relied on **The Journal of Clinical Pharmacology** for original research, special reviews, commentaries, and case reports on all phases of drug development. One of the most highly cited journals in the field, it features up to-the-minute and pertinent clinical information about the safety, tolerability, efficacy, therapeutic applications, toxicology, and total evaluation of new and established drugs for humans. JCP is the official journal for the American College of Clinical Pharmacology (<http://accp1.org>).

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