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## **FDA Approved Evamist: Harmful to Pets and Children? Dr. Randolph Sets the Record Straight**

**JACKSONVILLE BEACH, Fla. (August 18, 2010)** – A late-July news release from the U.S. Food and Drug Administration stated “women using the product Evamist® may harm children and pets who have skin contact with the drug.” Evamist was FDA approved in 2007. From July 2007 to June 2010, FDA received eight post-marketing cases of unintended exposure to Evamist in children ages 3 years to 5 years. Adverse events reported in unintentionally exposed children include premature puberty, nipple swelling and breast development in females, and breast enlargement in males. Since 2007, two reports of secondary exposure to Evamist in dogs also have been received by FDA’s Center for Veterinary Medicine. Pets exposed to Evamist may exhibit signs such as mammary/nipple enlargement and vulvar swelling. Not surprisingly, this breaking news has erupted a cauldron of concern for women currently using the product and, also, for their physicians prescribing it. Now nationally-recognized hormone health expert C.W. Randolph, Jr., M.D., R.Ph., sets the record straight:

“Evamist is a pharmaceutically-manufactured bioidentical estrogen product, specifically a bioidentical estradiol topical spray, often prescribed for the treatment of moderate to severe hot flashes associated with the onset of menopause. This is a safe and effective product to prescribe for women who are estrogen deficient if a bioidentical progesterone product is also prescribed and used in tandem. The issue is this: when too much estrogen circulates in the human system, it can stimulate cell proliferation or growth. If unchecked, this cell growth can be a precursor to certain types of cancer including breast and endometrial. Progesterone keeps the cell growth in check.”

Randolph continues, “When it comes to the safety of children and pets, the issue with Evamist is the risk of inadvertent exposure. Because this bioidentical estrogen product is absorbed transdermally, e.g. through the skin, it is possible for children and pets to rub against a woman who has recently applied the product and get some of the extra estrogen into their system. In addition to stimulating cell growth, estrogen is the hormone most responsible for the development of female sex organs and secondary sex characteristics such as breasts and pubic hair.”

While patients of Dr. Randolph’s Ageless and Wellness Center are most often prescribed individualized prescriptions of compounded bioidentical estrogen and progesterone, Dr. Randolph and his team of medical professionals do have patients for which they prescribe Evamist.

Randolph states, “Evamist is traditionally indicated for the inner surface of the forearm. Although the application of Evamist to other skin surfaces is not detailed in the product literature, I recommend that my patients apply the mist to their inner thigh. This minimizes risk of inadvertent exposure for children, pets, spouses or anyone else frequently rubbed up against. I also emphasize the importance of holding the applicator upright and resting the plastic cone flat against the skin with no gaps between the cone and your skin and allowing no contact with the area for at least 30 minutes after application.”

### **Bioidentical Hormone Replacement Therapy (BHRT) vs. Synthetic Hormone Replacement Therapy (HRT)**

BHRT is a protocol that uses plant-based bioidentical hormones to treat women and men for hormone depletion or imbalance – usually as a result of the aging process, extreme stress or exposure to environmental toxins. BHRT is safe and effective, but it is less well known than its alternative protocol, HRT, that uses synthetic

hormones. Unlike bioidenticals, their chemical structure has been altered in the lab to produce new molecules that can be patented - bioidenticals derived from natural substances cannot be patented. Synthetic hormones have a lower-than-optimal RBA (relative binding affinity), so fit improperly in the cells of the body and cause dangerous side effects. In recent years, medical research has linked the use of synthetic hormones, such as the Premarin® and Prempro® family of products, to increased risks for cancer, cardiovascular disease, strokes and blood clots, osteoporosis and Alzheimer's disease.

### **Resources**

FDA. (2010). FDA Advisory: Avoid Unintentional Exposure of Children and Pets to Evamist.

Randolph CW, James G. From Hormone Hell to Hormone Well. Deerfield Beach: Health Communications Inc., 2009.

### **About Randolph Medical Enterprises**

Randolph Medical Enterprises is a healthcare company defined by both an unrelenting attention to clinical excellence in the field of gynecology medicine and unparalleled passion and commitment to inform and empower not only our patients, but also women, men and medical professionals across America – about the safety and medically proven health benefits of bioidentical hormone replacement therapies (BHRT), vitamins and other nutritional supplements. Their mission is fulfilled through the company's four business entities; Dr. Randolph's Ageless and Wellness Medical Center, in-house compounding dispensary, Natural Medicine Store and Natural Hormone Institute.

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