



AACU Policy Stance on Low Dose Vaginal Estrogen (Outdated Black Box Warnings)

The American Association of Clinical Urologists, Inc. (AACU) would like to weigh in on a vital issue of importance for women's health in urology. This policy stance concerns how the urology community needs to rally behind getting rid of outdated black box warnings for vaginal estrogen for improved patient outcomes.

Founded in 1968 by urologists concerned by the government's increasing role in the practice of medicine, the AACU is a professional organization representing the interests of more than 3,700+ member urologists, and urologic societies engaged as advocacy affiliates across the United States. We are dedicated to developing and advancing health policy education as it affects urologic practice in order to preserve and promote the professional autonomy of our members and support the highest quality of care for patients.

The FDA's mandate to include a black box warning on all estrogen products is hindering patient access to the safe and effective treatment of low-dose vaginal estrogen. The current warning, which states that these products may cause stroke, blood clots, cancer, and possibly dementia, is misleading and outdated.

Unlike oral systemic synthetic hormone products, low-dose vaginal estrogen is not systemically absorbed into the bloodstream and is therefore safe for women of all ages. The inaccurate labeling exacerbates fears regarding the safety of menopausal hormone therapy and has resulted in the underutilization of this treatment option.

The FDA needs to update prescription labels for topical vaginal hormone treatment and remove the black box warning for low-dose vaginal estrogen. This simple change will increase access and improve women's lives.

Join us in spreading the word to Congress, the FDA and the medical community on how this needs to change so that patients can get the help they need.