



May 18, 2015

TO: Bone, Reproductive and Urologic Drugs Advisory Committee  
Drug Safety and Risk Management Advisory Committee

On behalf of the 70,000 clinical nurse specialists in the country, the National Association of Clinical Nurse Specialists (NACNS) is pleased that the Food and Drug Administration's (FDA) Bone, Reproductive, and Urologic Drugs Advisory Committee and its Drug Safety and Risk Management Advisory Committee will be reviewing the application for a drug that is designed to treat hypoactive sexual desire disorder (HSDD).

Clinical Nurse Specialists (CNSs) are one of the four types of advanced practice registered nurses. They have the same education and training as other advanced practice nurses — nurse practitioners, certified nurse anesthetists and certified nurse midwives — in physiology, pharmacology and physical assessment, and they are educated and trained in their particular areas of specialty. CNSs have a unique and advanced skill set to improve quality and reduce healthcare costs. They are leaders of change in health organizations, developers of evidence-based programs to prevent avoidable complications and readmissions, coaches and direct care providers of those with chronic diseases, facilitators of teams in acute care and other facilities to improve the quality and safety of care. In addition, a growing numbers of CNSs are providing Medicare Part B services and have prescriptive privileges in most states.

As leaders in health care, the thousands of clinical nurse specialists NACNS represents are concerned about the lack of pharmacologic therapies to assist with the treatment of HSDD in women. This lack of treatment for women is problematic, but of greater concern is the apparent inequity in treatment between women and men. The FDA has approved 26 drugs for the treatment of male sexual dysfunction, and none for women.

This inequity must be rectified. HSDD is a life-changing disorder. In addition to coping with the psychological and/or physiologic processes that result from HSDD, women may experience significant changes in long-standing relationships.

NACNS understands that the FDA must approve pharmacologic therapies based on scientific evidence and an analysis of the benefits and risks for patients. In addition to these important criteria, NACNS asks the advisory committee to include quality of life and the need for access to pharmacologic treatments for women as part of your decision.

Treating sexual disorders in women needs to be as important as treating sexual disorders in men.

Sincerely yours,

Peggy Barksdale, MSN, RN, OCNS-C, CNS-BC  
President