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Serving the DES-exposed community since 1978

Docket ID: FDA-2014-N-1413

Division of Dockets Management (HFA-305)
Food and Drug Administration
5630 Fishers Lane, Room 1061
Rockville, MD 20852

Dear FDA Reader:

Thank you for the opportunity to provide written comments for the October 27, 2014, Patient-Focused Drug Development meeting on Female Sexual Dysfunction.

DES Action USA advocates for individuals who were prenatally and generationally exposed to diethylstilbestrol (DES), an ineffective and harmful non-steroidal estrogen given to millions of pregnant women in the U.S. and around the world with the erroneous idea that it prevented miscarriage. Their prenatally DES-exposed daughters have much higher rates of reproductive tract problems, including ectopic pregnancies, miscarriages, infertility and cancer. And this drug disaster may continue to harm future generations.

Because several drugs have been approved for male sexual dysfunction, groups have asked whether the FDA is holding women's sexual satisfaction to a different standard. As a population already harmed by a FDA-approved drug, we wonder if political and media attention is the reason for considering and reconsidering drugs for any female health or disorder issue, rather than attention to safety and efficacy.

The gender equity argument ignores the real safety difference between any drug under consideration for female sexual disorder and the drugs approved for men. All but one of the drugs approved for men are taken on an as-needed basis, whereas a drug for women,

like flibanserin, is a central nervous system serotonergic agent with effects on adrenaline and dopamine in the brain and requires chronic -- daily, long-term -- administration. This raises toxicological concerns that make it appropriate for the FDA to subject this drug or any similar drug to elevated safety scrutiny. Adverse events reports and dropout rates in the trials rightly require serious consideration.

Hypoactive sexual desire disorder is no longer listed in the DSM-5 (5th edition approved by the American Psychiatric Association in May 2013). Rigorous DSM-5 processes were unable to support a distinction between sexual desire and arousal disorders for women; the new terminology, “female sexual interest/arousal disorder,” offers revised criteria for making a diagnosis.

DES Action’s online community of DES Daughters has shared information about non-drug hormone-free alternatives and natural remedies that effectively deal with vaginal dryness. And it has been the sharing of our on-going health and sexuality experiences that itself is a remedy. By learning what others are experiencing, we learn about ourselves, what is common, what is normal, and what we can do to relieve symptoms of vaginal dryness safely and inexpensively without pharmaceutical intervention.

No one, particularly the FDA, should be in a rush to “fix” women’s bodies via drugs. DES Daughters are living proof that good intentions and poor research lead to disaster, potentially for generations to come.

Sincerely,

Kari Christianson
Program Director
DES Action USA