

Dear Physician,

Re: Hormone Replacement Drugs for the Treatment of Menopausal Symptoms
Premarin[®], Prempro[®] and DUAVEE[®]

Please refuse to prescribe the Premarin[®] family of drugs including DUAVEE[®].

Hormone Replacement Therapy drugs derived from the high concentration of estrogen (conjugated equine estrogens or CEEs) in pregnant mare's urine (PMU) such as Premarin[®] and Prempro[®] are listed as "known human carcinogens" by the National Toxicology Program as well as the World Health Organization (WHO).

It is widely believed that the risks of taking these medications far outweigh the benefits offered as has been proven time and again through several studies and surveys, particularly the alarming NHLBI / NIH's Women's Health Initiative (WHI).

The Women

Several nationwide studies, most notably the NHLBI / NIH's Women's Health Initiative, have unmistakably linked the use of HRT to cancer, heart disease, stroke and dementia even in reduced dosages.

Women who take these drugs face significantly increased risks of: invasive breast cancer (26%), heart disease (29%), strokes (41%), blood clots to the lungs and legs (50%), ovarian cancer (60%), impaired cognitive function, dementia and Alzheimer's, asthma, lung cancer, malignant melanoma, and reduced insulin resistance, among others. With each passing day new evidence is uncovered that supports the dire consequences associated with the use of these CEE-derived HRT therapies.

Despite these findings, particularly in the case of Prempro[®] which has been widely credited as the cause of increased breast cancer rates, Pfizer continues to sell these hormone replacement therapies with approval from the FDA and other regulating bodies around the globe. Even taking estrogen alone increases a women's risk of stroke as well as endometrial cancer and does not reduce their risk of coronary heart disease.

Yet more worrisome is the fact that these carcinogenic medications are available in the US and other countries without a prescription and therefore dangerously uncontrolled drugs.

In 2009, as part of an on-going lawsuit, a US District Court Judge granted a motion to publicize papers supporting the use of Prempro[®] and other derivatives of the Premarin[®] family of drugs written by non-accredited writers which were then "authored" by medical academics. Disturbingly these ghostwritten articles emphasized the benefits while diminishing the risks of using CEE hormone replacements.

Pfizer/Wyeth has lost the vast majority of Prempro® lawsuits it has faced since trials began in 2006 and has settled out of court on approximately 60% of the 10,000 claims filed.

As 2013 comes to a close, 95% of the lawsuits have been settled with expectations that Pfizer will have recompensed an estimated \$1.6 billion to resolve these claims when all is said and done. Yet Pfizer continues to market and sell these deadly drugs to millions of vulnerable women. The lawsuits have consistently and repeatedly shown that Wyeth (now a division of Pfizer) failed to adequately warn consumers about the risks of these drugs and purposely hid the risk of breast cancer and other diseases.

Most alarmingly, in January of 2012 Pfizer announced its intent to seek U.S. regulatory approval to sell the combination osteo-menopausal drug Aprela®. "Limited" studies on Aprela®, a combination of bazedoxifene (Viviant®) and CEEs in the same concentration as Premarin®, have shown to decrease some of the risks associated with the Premarin® derivatives.

In spite of the fact that bazedoxifene, a selective estrogen receptor modulator or SERM, has been unsuccessful in receiving approval from the FDA as a result of increased risks of stroke and thromboembolic events, in October 2013 the FDA granted approval for the sale of Aprela®, now re-labeled DUAVEE®. DUAVEE® is expected to reach the marketplace in February, 2014. Regardless of the claims that these two compounds have a synergistic outcome and mitigate the side effects of each other, this is nonetheless unsettling on both accounts given the history of CEE-based HRT and other SERMs, all of which have shown to give rise to life-threatening disorders.

The Horses

Life for the PMU mares is harsh.

The mares are repeatedly impregnated, on average of 12 years, and spend 6 months of their 11-month pregnancy confined to stalls so small they have difficulty turning around or lying down. Most of this time is spent standing up on cold concrete floors.

During this time they are permanently attached to cumbersome rubber urine collection bags hanging between their hind legs that chafe their flanks, cause infections and severely limit movement.

Water intake is routinely restricted to concentrate the amount of estrogen in their urine potentially causing life-threatening renal and liver disorders.

The fate of the foals – the "by-products" of the industry – and the mares who cannot conceive is bleak. Most are sold at auction to "kill buyers" and ultimately end up at the slaughterhouse where they will be improperly stunned, dismembered, butchered and their meat sold for human consumption in countries where there is an appetite for it.

Although Pfizer / Wyeth has significantly downsized the number of PMU farming operations in North America, Pfizer's projected annual sales for HRT therapies — Premarin® and DUAVEE® — are over one billion USD by 2015. In 2012 alone total sales of the available Premarin® family of drugs were in excess of \$1 billion USD with expected revenues of at least as much in 2013. What was once compelling evidence that they had moved these facilities to other parts of the world has since been confirmed — a thriving PMU industry has existed in China for close to ten years. There is also evidence to suggest that such farms are situated in other countries such as India, for example.

What was and is today a brutal industry in the abysmal treatment of the pregnant mares and their foals in North America will prove to be even more devastating for them in countries seemingly more accepting of animal abuse, horse slaughter and the consumption of the meat from these heinous practices.

Please Refuse to Prescribe Premarin®, Prempro® and DUAVEE® (available Feb. 2014)

Choosing plant-derived or synthetic estrogen or adopting dietary changes and exercise programs designed to alleviate menopausal symptoms can save the lives of both women and horses.

Just recently in June 2013, the FDA approved the first non-hormonal treatment for hot flashes — Brisdelle™, manufactured by Noven Pharmaceuticals, a low-dose version of paroxetine. While all drugs carry some risk, for women who don't want to take estrogens derived from CEEs, Brisdelle™, offers an alternative with a much more acceptable safety profile.

Please talk to your patients regarding alternatives to these CEE-based hormone replacement therapies. There are much safer and more humane treatment options available. The choice of a drug should no longer come down to which is most effective—but what is safest.

While women can choose whether or not to engage in a regimen of CEE-based therapy, unfortunately the mares and their foals have no voice and are at the mercy of the pharmaceutical industry. This is where you can make a difference. Thank you.

Sincerely,



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