Dear Physician,

Re: Hormone Replacement Drugs for the Treatment of Menopausal Symptoms
Premarin®, Prempro® and DUAVEE® (approved Oct. 2013)

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 regulatory 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.

By the end of 2013, 95% of the lawsuits were settled where Pfizer is estimated to have recompensed an estimated $1.6 billion to resolve these claims when all was said and done.

More recently in Canada, a case filed with the Supreme Court of British Columbia approved a $13 million settlement for women who say hormone replacement drugs gave them breast cancer, ending Canada’s first class action lawsuit over the risks of a once ubiquitous treatment. Meanwhile, at least two other Canadian class action lawsuits over the same issue remain in the works. Wyeth Canada, in agreeing to the settlement, made no admission of fault. Yet, even now in 2015, 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.

While Premarin and Prempro (Premphase) have been the subject of much controversy, it did not stop Pfizer from its relentless pursuit of exploiting the PMU industry further. In January of 2012 Pfizer announced its intent to seek U.S. regulatory approval to sell the combination osteomenopausal 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® reached 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.

DUAVEE® reached the marketplace in North America in February, 2014 and has been making its debut in magazines and televised commercials with Pfizer’s menopause awareness campaign that focuses on “sex talk” for 50ish women, namely painful intercourse and vaginal atrophy. These are not terms tossed around at your average dinner party, and Pfizer’s campaign capitalizes on the uncomfortable.
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 limit movement.

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® – continue on the same trend of over one billion USD in 2015 as in previous years.

In 2014 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 2015.

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 at least 14 years. There is also ample evidence to suggest that such farms are situated in other countries such as India and Poland, for example.

What has always been and continues to be is 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®.

Choosing plant derived synthetic estrogens, which themselves have safety concerns, are nonetheless better options as is adopting dietary changes and exercise programs designed to alleviate menopausal symptoms can save the lives of both women and horses.

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.

Yours faithfully,

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