

April 19, 2000

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Dear Food and Drug Administration,

I had been sent the "Guidance For Industry, Labeling Guidance for Estrogen Drug Products...Prescribing Information for Healthcare Providers and Patient Labeling". Draft Guidance.

It says that, "This guidance document is being distributed for comment purposes only. This guidance document represents the Agency's current thinking on estrogen class labeling" As a very concerned consumer, I have some important concerns and comments. I ask the following questions as to the confusion caused in the enclosed proposed estrogen drug labeling guide. I hope you will please reply, and consider changing the labeling for the sake of consumer clarity. This labeling as you sent is very confusing, and more often misleading.

UNDER,

INDICATIONS and Usage- #4. What does this mean that estrogens are used for the treatment of breast cancer (for palliation) in appropriately selected women and men with metastatic disease? Are you talking about the estrogens Premarin, Prempro or Premphase for this treatment? Or are you talking about the estrogen Tamoxifen? Can you be more specific please? For women with cancer, what classifies a woman as "appropriately selected?"

6. Under the same heading of, INDICATIONS and Usage.....Prevention and management of postmenopausal osteoporosis. Can estrogen alone prevent osteoporosis? If a woman sitting in a chair, or bedridden, and she takes ERT, without eating, without vitamin or calcium supplements....Can estrogen alone prevent osteoporosis? What clinical studies have proven that ERT or HRT prevents or even manages osteoporosis for all women, or even some of the women who are prescribed it? Being long-term use, what is the "safety" evidence of clinical studies conclude with the increasing risk of cancers?

Under CONTRADICTIONS,

#2. "Known or suspected cancer of the breast, (except for appropriately selected patients being treated for metastatic disease). Are you talking about the very same estrogen for both sides of your statement? ERT promotes metastasis, so do you mean, don't take it if you think you have cancer, but then it is confusing because you say "yes do take estrogen for metastatic disease. Please clarify if you are talking about the same ERT estrogen in the statement or ERT in the beginning, and change to Tamoxifen in the second part, to treat metastatic cancer. What does this mean.... please clarify. For what purpose would ERT which causes cancer metastasis, be prescribed to treat metastasis?"

#3. Known or suspected estrogen-dependent neoplasia. Why not call neoplasia, "cancer" for the layperson. What is the purpose of the above statement? Why are the areas of estrogen-caused cancer metastasis not listed, i.e., liver, lungs, bone and brain, and wherever else estrogens cause metastasis. How sure can a person be that she does not

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have “known or suspected estrogen-dependent neoplasia”? What tests can a woman take which are 100% sure she does not fit into this category? And what about the year she is taking ERT prior to her doctor visits, what if she contacts cancer and doesn’t know it, what will likely happen to her, taking ERT on top of undiagnosed cancer?

Under WARNINGS,

1. Induction of malignant neoplasms,

B. Breast Cancer, It begins by stating “The majority of studies do not show an increased risk of breast cancer in women,” is a statement completely PRO- Drug Industry, and not for the women prescribed ERT.. According to the Freedom of Information Staff the best studies and most qualifying studies as “clinical studies” DO show a higher risk of breast cancer with the use of prescribed estrogens.

It is WELL recognized that endogenous estrogens are carcinogenic as Breast Cancer risk in women (and men), and it is stated that prescribed estrogens as ERT are “natural” estrogens most like a woman’s. When is it time to recognize the ERT risk of breast cancer as it is well known for a woman’s own “natural” estrogen?

The American Cancer Society recognizes the risk of ERT and a definite link to breast cancers as studies have constantly proven, by stating this fact in the ACS, “Cancer Facts and Figures”. ALSO, Dr. Raphael a spokesperson for Wyeth Ayerst makers of Premarin and the like, stated as fact that prescribed estrogens DO “cause” breast cancer. He also stated the fact right on the slide as presented to the audience. The National Cancer Institute ALSO told me in a letter that prescribed estrogens cause 3 cases of breast cancer out of 100. It is ONLY the FDA who is not recognizing the ERT connection to breast cancer. Why?

With millions of women taking prescribed estrogens it is certainly time to recognize and state the truth that it is well documented that Yes, prescribed estrogens cause cancer.

Even the fine print on the Prempro, and Premphase ads state, “However some studies have reported that breast cancer developed more, up to twice the usual rate in women who used estrogens.”

Do these statements mean ERT does NOT cause breast cancer? Why is the FDA hiding the breast cancer link to prescribed estrogens?

WHY are you, the FDA still protecting the drug industry first, by allowing the statement, “While the majority of studies have not shown an increased risk of breast cancer”? Even if there was controversial studies, why should controversy of such a frightful and fatal disease continue to be construed as a major benefit for a multi-billion dollar drug industry, instead as the benefit for the human life? Please tell me why?

“Especially in excess of 10 years” is a stretch of the truth. The studies proving the estrogens connection with the causing of breast cancer in as few as one year, three years, and five years. Why again does the FDA offer the risk of cancer as a benefit to the drug industry and not human life?

Under PRECAUTIONS

A. General

(b) impairment of glucose tolerance. Does this, can this impairment cause or contribute to diabetes?

E. CARCINOGENESES, mutagenesis, and impairment of fertility. “Long term continuous administration of natural and synthetic estrogens in certain animal species increases the frequency of carcinomas of the breast, uterus, cervix, vagina, testis, and liver.” Why does the FDA not convey these animal studies as probabilities in humans? Why has the FDA not calculated these same carcinogenic risks, or have you calculated the cancer results from human examples as women have been prescribed ERT for over 58 years? There is certainly an extreme increase with all these cancers. Where can I find the FDA’s follow-up data on these cancers in human beings who have been prescribed ERT or HRT?

ADVERSE REACTIONS,

1. Genito-urinary system. I have read in the Freedom of Information records that ERT causes incontinence, yet it is not mentioned. Why?
2. Breasts- “Tenderness, enlargement” Why is cancer left out, when there are important studies by Hoover, Herbst, Colditz, and a host of others proving the greater risk of breast cancer and users of ERT and HRT?
4. Skin- “Chloasma, melasma, erythema multiforme, erythma nodosum, hemorrhagic eruption, hirsutism. This is not language women can understand. Why doesn’t the FDA enforce these words to be defined to be better understood?
6. Miscellaneous, again the language of porphyria, edema, anaphylactoid, are not words the layperson can understand. Why doesn’t the FDA enforce these words to be defined to be better understood?

DOSAGE AND ADMINISTRATION,

1. For treatment of moderate to severe vasomotor symptoms..... Is this treatment or is the use of ERT for this indication a “delay” of vasomotor symptoms? Why is it FDA approved for women with “moderate” symptoms which pass naturally in time, indicated for the use of a carcinogenic drug? What had been stated for several decades has disappeared!.....”and such long term treatment carries important risks”. Why has this statement disappeared?
6. For prevention and management of osteoporosis. Can ERT or HRT “alone” prevent osteoporosis? As with treatment for vasomotor symptoms, and vulvar atrophy, why isn’t “should be discontinued as promptly as possible” indicated for osteoporosis? Why does the FDA approve a carcinogenic drug for long term treatment????? The risk is cancer!

III PATIENT LABELING

INTRODUCTION

“Estrogens have important benefits but also some risks. Why has the FDA decided not to allow the correction, “Estrogens have important risks but also some benefits?”

Estrogens are used:

* “To reduce moderate to severe menopausal symptoms.” The statement, “Between the ages of 45, and 55, the ovaries normally ‘stop’ making estrogens.” This is NOT true. It is medically documented that the ovaries and other areas of the body, adrenal glands, always produce estrogen. Fat and muscle also store and produce estrogen. Why does the FDA allow a false statement as this?

I will like to know of the documentation which proves that it is actually estrogen which causes the “change of life”. Why does the FDA label menopause as, “the change of life”?

* “To treat certain cancers in special situations, in men and women.” I will like to know which cancers ERT or HRT are prescribed as a ...cancer treatment?

* “If you have had cancer- Estrogens may increase the risk of certain types of cancer.” The word “types” is plural, what “types” of cancer is this referring to?

“Using progestin therapy together with estrogen therapy may reduce the higher risk of uterine cancer related to estrogen use.” The fact that progestin drugs are documented as a carcinogen is withheld from the people. Why? The fact that progestin drugs are NOT FDA approved for all the reasons that estrogen drugs are prescribed is also withheld information from women. Why?

Why are estrogens and progestins, as documented carcinogens, labeled as a “therapy”?
What is the definition of the word “therapy” in medical terms?

*Cancer of the Breast- Most studies have NOT shown a higher risk of breast cancer.....the word NOT is highlighted in darker ink. This statement is a cover-up for all the best studies which have proved the fact of estrogens, with and without progestins to cause breast cancer. Why is this permissible by the FDA?

“However, some studies suggest there may be a higher risk of breast cancer in women who use estrogens for a long period of time, especially 10 years or more.” This is a misleading statement. Most all the studies proving estrogens cause breast cancer are for 3 to 5 years. Why is the FDA protecting the estrogen drug industry rather than human life?

Why isn't the fact as Wyeth Ayerst states, “Small doses of estrogen postmenopausal estrogens can stimulate cancer,” Morton Lipshutz, March 31, 1989, EVER allowed as public information, as a dangerously fatal side effect of prescribed estrogen hormone drugs????

REDUCING THE RISKS OF ESTROGEN USE-

“If you use estrogens, you can reduce your risks by doing these things:”

“See your doctor regularly.”

“Reassess your need for estrogens”.

“Be alert for signs of trouble”

Please tell me.....HOW is it that any of the above will prevent estrogen-caused cancers, cancer metastasis, fatal blood clots, gall bladder disease, and a host of other side effects?

I will appreciate and look forward to a reply to clarify the issues brought forth in this letter.

Thank you,

A handwritten signature in black ink, appearing to read "Gail Elbek", with a stylized flourish at the end.

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