

As a paediatrician who deals now only with mothers and babies who are having difficulty with breastfeeding, I am very concerned about the warning about domperidone which was issued by the Federal Drug Administration in the US on June 7, 2004. It warns *breastfeeding mothers* about getting domperidone to enhance milk supply because it conceivably can cause cardiac arrhythmias.

The FDA has basically come up with a political statement. They seem really bothered because people were going around using a drug which they have not approved. The deaths (and I believe there were two) occurred with *intravenous* domperidone, which is never used any more and has never been used for enhancing milk supply. Domperidone was given intravenously in huge doses to patients who were sick with other problems as well, notably cancer for which they were getting chemotherapy. Domperidone was being used to decrease nausea and vomiting. Some patients were getting 1000 mg of domperidone every 4 hours intravenously, compared to our usual dose of 30 mg 3 times a day, taken by mouth. It is also likely that some of the chemotherapy drugs the patients would have received have cardiac side effects (for example, doxorubicin) and it was the combination of the huge doses of domperidone intravenously plus other drugs that caused the problem. Furthermore, unlike what the FDA has led people to believe, perhaps unintentionally, these are not new cases, but 2 decades old.

Why didn't they mention metoclopramide in their warning, which is far more dangerous (it can cause severe depression in oral doses, which domperidone does not) and is also being used off label to increase milk supply in the US, but which, on the other hand, is available and approved for gastric motility problems in the US? Can it be that they are not concerned about the danger but rather the threat to their authority? Here is part of a letter I received about metoclopramide and domperidone as a result of this to do about domperidone. "...my mother...is on domperidone for gastroparesis. She's 5 feet tall, and lost over 20 lbs...down to 82 lbs. And why is she on domperidone? Because she had depression and SEVERE panic attacks with the Reglan (metoclopramide). She was in and out of the senior psych ward all last spring. So my folks get domperidone from outside the US."

Why didn't they mention the danger to diabetics, if they are so concerned, for whom some endocrinologists in the US are prescribing domperidone for gastric paresis? Why specifically for breastfeeding women? Why not specifically for diabetics who are at much greater risk of cardiac arrhythmias than women of reproductive age?

Why did this warning come out exactly on the day that the National Breastfeeding Campaign was to begin in the US?

I have used domperidone, in infants (for spitting up) but mostly to increase milk supply in women, in thousands of women, without any more than the occasional mother getting mild headaches or occasional menstrual irregularities or mild abdominal cramping as side effects. I cannot say the same for metoclopramide which I saw causing severe CNS side effects, aside from depression.

I have personally seen two children die of Stevens-Johnson Syndrome after taking Septra. If I have seen two, how many have actually occurred in the US and Canada? Why no such warnings on Septra? I have, as a medical resident, seen at least one person die and several get severely ill after taking ASA, from gastric bleeding. In overdose, many children have died and many have become seriously ill over the years because of ASA. Why no such warning on aspirin?

Many women have died and many more severely injured from taking the birth control pill. Why is it not banned?

The issue comes up about providing a drug for women in good health and that we should not be treating healthy women with a drug. I disagree. With all the talk about preventive medicine, when it actually comes down to trying to prevent illness, it is all lip service. The data are clear. Breastfeeding decreases the risk of breast cancer and type 2 diabetes in the mother. In the baby it decreases the risk of diabetes (type 1 and 2), obesity, hypertension, high LDL/HDL levels, otitis media, asthma, and allergies, gastroenteritis, and in premature babies, necrotizing enterocolitis. The first 4 of these are all risk factors for atherosclerosis, the most significant degenerative disease in affluent societies and the biggest killer. The data are clear that breastfeeding results in better cognitive development in children. The data are less clear, but suggestive, that breastfeeding decreases the risk of certain cancers in children (Hodgkin's and non Hodgkin's lymphoma, breast cancer in later life), multiple sclerosis and inflammatory bowel disease.

Thus, we should do all that is reasonable to maintain and increase the success of women who are breastfeeding. If this means that, in some cases, we use a drug that, in my experience of using it with thousands of women, is safe, with only minor side effects, we should have that option. Of course, there is no such thing as a drug which never causes side effects, and there are probably very few *approved* drugs (yes, even approved drugs) out there that haven't killed someone, but if one weighs the risk against the benefits, domperidone can do much good. I will continue to prescribe domperidone to women when I feel it will be useful. It's a shame, though, for women in the US to be deprived of this drug. The FDA says that it will monitor the border to make sure none gets through. Good for them. With heroine and cocaine getting through their borders as through a sieve, it's great that the US can now be sure that their borders are safe against an influx of the dreaded domperidone. What a waste of manpower! What a waste!

First written in June 2004 by Jack Newman, MD, FRCPC

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