



# pharmedix™

On Friday, September 16, 2011, Qualitest Pharmaceutical issued a “RETAIL LEVEL” recall of Oral Contraceptive products. Pharmedix ships both Previfem and TriPrevifem to our College and University health centers. The Qualitest recall was only to the RETAIL level, which effectively means they will take back and issue credit on cycles that have not been dispensed to patients. They do however recommend that patients who have received a Qualitest oral contraceptive be contacted and told to use an alternative method of birth control. Some of Pharmedix clients are recommending that women who have the affected product also get a pregnancy test. Since this is a retail level, and not a patient level recall, Qualitest will not reimburse for any dispensed product or the self elected pregnancy test.

This was clearly a packaging issue by Qualitest as reported in the press. It appears the schedule on which tablets are taken was reversed in the affected packs causing the patient to take the placebo during Week 1 instead of Week 4. Those stabilized on their O/C product would then be taking two straight weeks of placebo if they received an affected product. The product packaging is commonly referred to as a “blister pack” or “bingo card” where individual pills are pushed out the back of the package. The product places 4 rows of 7 tablets per row on the foil paper, which becomes the back of the card. A cardboard front is placed over it and the two are sealed together. On the cardboard front is printed Week 1 alongside the first row, Week 2 alongside the second row, etc. Qualitest may have loaded the cardboard cards upside down so that Week 4 (Placebo week) became Week 1. To compound the problem, the print on the cardboard covers up the lot number when reversed so you cannot read if you have an affected lot.

As a result of our paperwork and cross-referencing we are working to establish a return procedure as per manufacturer direction for any client that may have product in their inventory. This process will be completed and clients notified ASAP. Be aware that it is possible to identify whether your clinic or your patient has the affected product by visually inspecting the package. If there are no remaining tablets and you can clearly read the lot number and expiration date imprinted in the silver foil on the back of the pack the product is not affected. If there are remaining tablets, those with a greenish color are the placebo and should be the last row of 7 tablets alongside Week 4. If they are alongside Week 1, they are incorrectly packaged. The correct color order top to bottom for Previfem: blue, blue, blue, green. TriPrevifem: white, light blue, dark blue, green as illustrated below.

