Pharmacia and the U.S. Food and Drug Administration (FDA) have received reports from the spontaneous reporting system of myelosuppression in patients receiving ZYVOX.

To communicate this important safety information, the following has been added to the WARNINGS section of the labeling:

Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported in patients receiving linezolid. In cases where the outcome is known, when linezolid was discontinued, the affected hematologic parameters have risen toward pretreatment levels. Complete blood counts should be monitored weekly in patients who receive linezolid, particularly in those who receive linezolid for longer than two weeks, those with pre-existing myelosuppression, those receiving concomitant drugs that produce bone marrow suppression, or those with a chronic infection who have received previous or concomitant antibiotic therapy. Discontinuation of therapy with linezolid should be considered in patients who develop or have worsening myelosuppression.

Changes consistent with the added warning have been made to the ADVERSE REACTIONS section and are as follows:

Postmarketing Experience. Myelosuppression (including anemia, leukopenia, pancytopenia, and thrombocytopenia) has been reported during postmarketing use of ZYVOX (see WARNINGS). These events have been chosen for inclusion due to either their seriousness, frequency of reporting, possible causal connection to ZYVOX, or a combination of these factors. Because they are reported voluntarily from a population of unknown size, estimates of frequency cannot be made and a causal relationship cannot be precisely established.

Our primary concern is the safety and well-being of patients who receive ZYVOX. If you become aware of any case(s) of the events described above, in patients treated with ZYVOX, please report the event promptly.

You may contact Pharmacia at 1-800-253-8600 extension 38244, or the FDA MedWatch program, by phone at 1-800-FDA-1088…Sincerely…(219)

A medical journal characterized the collaboration between the FDA and the manufacturer in favorable terms (220). According to this journal, the manufacturer and the FDA worked together to change the labeling so that the warning of possible myelosuppression was added. The journal characterized the change as a success story, in that a product came on market with promise of significant efficacy, but rare adverse events materialized after marketing in the general population. The problem was found within the first year of marketing and the manufacturer was able to transmit the new safety information to the medical community.

b. *Dear Healthcare Professional* letter regarding birth control pills

The issue of *Dear Healthcare Professional* letters arises, on occasion, during litigation between patients and pharmaceutical companies (221). *Dear Healthcare Professional*

[219] Dear Health Care Professional letter (March 2001) Pharmacia Corp. Peapack, NJ.

[220] FDA MedWatch Program Update: Managing Risk of Use of Medical Products – the Zyvox example. Action Report Medical Board of California. 2002; vol. 80, page 11.

[221] Search on LEXIS NEXIS® conducted on March 23, 2011, using search terms "dear healthcare" and "dear health care," where the documents searched were all U.S. state and U.S. federal courts from the years 2000 to 2011. The result was about 40 relevant cases.