And, as a further result of the reporting by MedWatch, the manufacture sent a *Dear Healthcare Professional* letter to the medical community, reproduced in part below. The *Dear Healthcare Professional* letter is a standard mechanism, used by the FDA, for warning physicians of AEs after marketing a new drug. Typically, these letters are sent within 1 year to up to 5 years after approval of any given drug (213). Drug withdrawals are extremely rare, compared to the frequency of *Dear Healthcare Professional* letters. Information on drug withdrawals, for safety reasons, can be found in the *Federal Register* and on the internet website of the FDA (214).

According to Giezen, et al. (215) most *Dear Healthcare Professional* letters concern safety issues regarding of hepatobiliary disorders, blood and lymphatic system disorders, cardiac disorders, and nervous system disorders. In a survey of about 2,000 pharmacists who had received the *Dear Healthcare Professional* letters, Lee et al. (216) discovered that about 40% always read the letter, that one third often read it, and that 6% rarely read it. *Dear Healthcare Professional* letters are generally sent at the request of the FDA, though the administrative law does not provide authority to require such communications (217). Shatin et al. (218) report that compliance with recommendations is low, as measured by the continued co-prescribing and co-dispensing of contraindicated drug combinations or completing recommended testing following label changes and mailed warnings.

The *Dear Healthcare Professional* letter reproduced below refers to the MedWatch reporting system. The letter provides a crystal-clear example of the responsible and ethical activities of the consumer, manufacturer, and the regulatory agency, in monitoring, reporting, and responding to adverse events of marketed drugs.

Dear Health Care Professional:

This letter is to advise you of important, new™ (linezolid injection, tablets and for oral suspension), a synthetic antibacterial agent of the oxazolidinone class. ZYVOX is indicated for the treatment of adult patients with the following infections caused by susceptible strains of designated microorganisms: vancomycin-resistant Enterococcus faecium*, including cases with concurrent bacteremia; nosocomial pneumonia; complicated and uncomplicated skin and skin structure infections; and community-acquired pneumonia, including cases with concurrent bacteremia.*

[213] Giezen TJ, Mantel-Teeuwisse AK, Straus SM, Schellekens H, Leufkens HG, Egberts AC. Safety-related regulatory actions for biologicals approved in the United States and the European Union. *J Am Med Assoc.* 2008;300:1887–1896.

[214] Lasser KE, Allen PD, Woolhandler SJ, Himmelstein DU, Wolfe SM, Bor DH. Timing of new black box warnings and withdrawals for prescription medications. *J Am Med Assoc.* 2002;287:2215–2220.

[215] Giezen TJ, Mantel-Teeuwisse AK, Straus SM, Schellekens H, Leufkens HG, Egberts AC. Safety-related regulatory actions for biologicals approved in the United States and the European Union. *J Am Med Assoc.* 2008;300:1887–1896.

[216] Lee LY, Kortepeter CM, Willy ME, Nourjah P. Drug-risk communication to pharmacists: assessing the impact of risk-minimization strategies on the practice of pharmacy. *J Am Pharm Assoc.* 2008;48:494–500.

[217] Shatin D, Gardner JS, Stergachis A, Blough D, Graham D. Impact of mailed warning to prescribers on the co-prescription of tramadol and antidepressants. *Pharmacoepidemiol Drug Saf.* 2005;14:149–154.

[218] Shatin D, Gardner JS, Stergachis A, Blough D, Graham D. Impact of mailed warning to prescribers on the co-prescription of tramadol and antidepressants. *Pharmacoepidemiol Drug Saf.* 2005;14:149–154.