Attachment 6

Board of Pharmacy Inspections Involving Recalled Drugs Still in California Facilities

Recalled Drugs Found in California Pharmacies

Since the beginning of 2008, there have been five recalls of various heparin products and one recall of Digitek, a generic form of digitalis. In all these recalls, the manufacturers have specifically directed that the products not be provided to patients, and issued specific requirements to remove these products from the nation's drug supply. Regrettably, California regulators have found that these instructions have not been followed.

Specific heparin products were recalled following identification of an unapproved ingredient that has been linked to allergic reactions and more than 80 deaths in the US. Digitek's recall was due to oversized tablets containing more than the required active ingredient.

Inspections conducted late this spring by the Board of Pharmacy and the California Department of Public Health have identified numerous pharmacies and other health care facilities where these recalled products have been found in non-quarantined areas and in fact were still being dispensed or administered to patients.

During May 2008, the Board inspected 533 licensed hospital pharmacies in California. In 94 of these hospitals, the recalled heparin was found. And in 29 hospitals, the Board identified instances where the heparin was likely still being provided to patients. The Department of Public Health, working with the Board, declared multiple immediate jeopardy situations where they found heparin being provided to patients after the Board directed the quarantine of the recalled heparin. Both agencies continue to investigate these situations.

Of great concern is the fact that the recalled heparin was found well after the five separate recall notices were issued by the manufacturers. Three of the heparin recalls were the subject of a Board of Pharmacy Web site "subscriber alert," providing additional notice to pharmacies. Then, after discovering recalled heparin in several pharmacies in late April, the Board issued several subsequent subscriber alert notifications, again advising pharmacies the product had been recalled. The Department of Public Health also sent a specific mailing to all heath care facilities about the recalled heparin. The FDA released a nationwide alert of California's identification of recalled heparin in hospitals. However, the Board and the Department of Public Health continued to find recalled heparin in these facilities in late May.

The Class 1 recall of Digitek from patients has not been followed as well. In early May after finding recalled Digitek in pharmacies, the Board notified all 6,000 community pharmacies in a special mailing about the recalled Digitek. This mailing followed the manufacturer's recall notice and a separate Board subscriber alert issued at least a month earlier.

And yet in June, during routine inspections of community pharmacies, and in hospital pharmacies as well, the Board and the Department of Public Health continued to find recalled Digitek. The Board intends pursue administrative sanctions against those entities where recalled heparin and Digitek were found.

The Board strongly advises pharmacies and wholesalers to subscribe to the FDA's recall notices. The FDA's Web site is *www.FDA.gov*. The Board will continue to release recalled product alerts through its subscriber alert sytem (to sign up, go to the Board's Web site, *www.pharmacy.ca.gov*, and select "Join Our E-Mail List"). There have been two recalls in recent weeks as we go into publication of this newsletter.

The Board, the Department of Public Health and the FDA will work together to prevent consumer protection from being jeopardized by the presence of recalled drugs in the state's and nation's drug supply.