Brief summaries of recent drug approvals, interactions, and adverse events

Dietary Supplement Causes Acute Hepatitis

When a patient has acute hepatitis, ask whether he or she is taking dietary supplements. In an ongoing investigation, the Centers for Disease Control and Prevention (CDC) have identified a growing group of patients who used a weight-loss or muscle-building dietary supplement prior to developing acute hepatitis.

In September 2013, the Hawaii Department of Health (HDOH) was notified of 7 patients with severe acute hepatitis and fulminant liver failure of unknown etiology. The patients were previously healthy. All 7 patients had used the same specific dietary supplement marketed for weight loss and muscle gain before the onset of the illness.

The CDC, U.S. Food and Drug Administration (FDA), and HDOH began a public health investigation and eventually gathered data on 45 possible cases in Hawaii, of which 29 were identified as cases. (Subsequently, data from poison centers and other sources revealed 4 more patients.) The patients in

Hawaii ranged in age from 16 to 66 years; 14 patients were men. The most common symptoms were loss of appetite, light-colored stool, dark urine, and jaundice.

The first reported laboratory tests were done between May 2013 and October 2013. Median laboratory values reported at the peak of illness revealed extremely high liver enzymes. Ten patients had liver biopsy data available at the time of the *Morbidity and Mortality Weekly Report (MMWR)*: 7 patients had histology consistent with hepatitis from drug/toxic injury, with findings including hepatocellular necrosis and cholestasis.

Eleven patients were hospitalized for a median of 7 days, although 2 patients were still being hospitalized at the time of the report. One patient died, 2 received liver transplants.

Of the 29 identified patients in Hawaii, 24 (83%) reported having used the aforementioned dietary supplement during the previous 60 days. Twelve patients (41%) were using only that supplement; 12 others (41%) reported using it in combination with at least 1 other dietary supplement. Although the FDA product testing

results are pending, so far the data suggest drug- or herb-induced hepatotoxicity, according to the MMWR, and on November 9, 2013, the company issued a recall of its dietary supplement. Attributing liver injury to a specific ingredient can be challenging, the MMWR notes, because of multiple ingredients, product variability, and lack of testing to confirm exposure to a product.

Clinicians should report patients meeting the case definition to local or state health departments, as well as the FDA's MedWatch program. To discuss patient management options with a medical or clinical toxicologist, call a local poison center at (800) 222-1222. The CDC says drug- and herb-induced hepatotoxicity often resolves when the patient stops taking the product.

Sources: Centers for Disease Control and Prevention (CDC). *MMWR Morb Mortal Wkly Rpt.* 2013;62(40):817-819.
U.S. Food and Drug Administration. FDA Investigates Acute Hepatitis Illnesses Potentially Linked to Products Labeled OxyElite Pro. U.S. Food and Drug Administration Website. http://www.fda.gov/food/recallsoutbreaksemergencies/outbreaks/ucm370849.htm. Updated November 20, 2013. Accessed December 20, 2013.