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CDC HEALTH ADVISORY

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Acute Hepatitis and Liver Failure Following the Use of a Dietary Supplement Intended for Weight Loss or Muscle Building

Summary: *Recently, a number of previously healthy individuals developed acute hepatitis and sudden liver failure of unknown cause after using a dietary supplement for weight loss or muscle building. CDC recommends increased vigilance by public health agencies, emergency departments, and healthcare providers for patients who develop acute hepatitis or liver failure following use of a weight loss or muscle building nutritional supplement. CDC requests that state health departments report such occurrences to the CDC. CDC also recommends that, as part of a comprehensive evaluation, clinicians evaluating patients with acute hepatitis should ask about consumption of dietary supplements.*

Background:

On September 9, 2013, the Hawaii Department of Health (DOH) was notified of seven patients with severe acute hepatitis and sudden liver failure of unknown cause. The patients were previously healthy and sought medical care from May through September 2013. Clinicians reported that the seven patients had all used OxyELITE Pro, a dietary supplement marketed for weight loss and muscle gain, prior to illness onset.

The investigation is ongoing and the data presented are preliminary. Thus far, clinicians have reported 45 patients to the Hawaii DOH in response to a public health alert. Of those, 29 patients, including the original seven, were confirmed to have acute hepatitis after using a nutritional supplement for weight loss or muscle building. The median age of the 29 patients is 33 years; 14 (48%) are male. The date of the first reported laboratory test was used as a proxy for illness onset and ranged from May 10 through October 3, 2013. The most commonly reported symptoms included loss of appetite, light-colored stools, dark urine, and jaundice. Median laboratory values reported at the peak of illness were the following:

- aspartate aminotransferase (AST) 1,128 IU/L;
- alanine transaminase (ALT) 1,793 IU/L;
- alkaline phosphatase 150 IU/L; and
- total bilirubin 12.6 mg/dL.

Ten patients had liver biopsy data available at the time of this report. Seven had histology consistent with hepatitis from drug/toxic injury, with findings including hepatocellular necrosis and cholestasis. Three patients had liver biopsy findings of acute hepatitis associated with other etiologies such as autoimmune hepatitis. Eleven (38%) patients were hospitalized, with a median duration of seven days. One patient died, and two patients received liver transplants. Two remain hospitalized, and all other hospitalized patients have been discharged.

Of the 29 identified patients, 24 (83%) reported using OxyELITE Pro during the 60 days prior to illness onset. There was no other dietary supplement or medication use reported in common by more than two patients.

National case finding efforts have identified several individuals from states outside Hawaii with reported OxyELITE Pro or other weight loss or muscle building dietary supplement use prior to the development of

acute hepatitis of unknown cause. CDC, in collaboration with state health departments, is collecting additional clinical and epidemiologic information from these individuals to determine if this outbreak is national in scope.

Case definition:

An individual with acute-onset hepatitis of unknown etiology that developed symptoms on or after April 1, 2013 following use of a non-prescription weight loss or muscle building dietary supplement during the 60 days prior to illness onset.

With acute-onset hepatitis of unknown etiology defined as having BOTH:

- ALT $\geq$ 4 times the upper limit of normal
- Total bilirubin $\geq$ 2 times the upper limit of normal

AND

-negative workup for infectious or other explicative etiologies for hepatitis. Workup for other potential etiologies should include:

- Hepatic imaging (i.e., ultrasound/doppler, CT scan, MRI) not consistent with alternative, explicative etiologies
- Negative viral hepatitis panel
- No pre-existing diagnosis of chronic liver disease (e.g., autoimmune hepatitis, primary biliary cirrhosis, primary sclerosing cholangitis, Wilson's disease, hemochromatosis)
- No recent hypotensive shock or septic episodes
- No history of alcoholism documented in medical records

Recommendations:

- Clinicians evaluating patients with acute hepatitis should ask about consumption of dietary supplements as part of a comprehensive evaluation.
- Clinicians should report patients meeting the case definition to the local or state health department, as well as the US Food and Drug Administration's MedWatch program online at <https://www.accessdata.fda.gov/scripts/medwatch/> or by phone at 1-888-INFO-FDA.
- People who use dietary supplements for weight loss or muscle gain should do so with caution and under a medical provider's close supervision.

For more information:

State public health agencies should contact CDC at (866) 933-5295 if they identify patients who meet the case definition.

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