

# THIS IS AN OFFICAL NH DHHS HEALTH ALERT

Distributed by the NH Health Alert Network  
[Health.Alert@nh.gov](mailto:Health.Alert@nh.gov)  
October 11, 2013, 1530 EDT (3:30 PM EDT)  
NH-HAN 20131011



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

### NH Division of Public Health Services (NH DPHS) recommends:

1. Review the attached CDCHAN-00356 for situation update.
2. Vigilance for patients presenting with acute hepatitis following the use of a weight loss or muscle building dietary supplement.
3. Prompt reporting of cases to NH DPHS at 603-271-4496 and to the FDA MedWatch program at 1-888-INFO-FDA.

### Epidemiology:

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.

This investigation is ongoing and the data 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.

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 without other obvious etiology. The most commonly reported symptoms included loss of appetite, light-colored stools, dark urine, and jaundice. This product has been distributed nationally. As CDC and NH DPHS learn more information, additional updates will be provided to clinicians.

- ▶ For more information and to report cases to the FDA's MedWatch program visit their website at <https://www.accessdata.fda.gov/scripts/medwatch/> or report by phone at 1-888-INFO-FDA.
- ▶ For any questions regarding the contents of this message, please contact NH DHHS, DPHS, Bureau of Infectious Disease Control at 603-271-4496 (after hours 1-800-852-3345 ext.5300).
- ▶ To change your contact information in the NH Health Alert Network, contact Denise Krol at 603-271-4596 or email [Denise.Krol@dhhs.state.nh.us](mailto:Denise.Krol@dhhs.state.nh.us)

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From: Elizabeth A. Talbot, MD – Deputy State Epidemiologist  
Originating Agency: NH Department of Health and Human Services, Division of Public Health Services

**Attachments:** CDCHAN-00356

**This is an official**  
**CDC HEALTH ADVISORY**

Distributed via the CDC Health Alert Network  
October 8, 2013, 2:30 ET (14:30 PM ET)  
CDCHAN-00356

## **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.

*The Centers for Disease Control and Prevention (CDC) protects people's health and safety by preventing and controlling diseases and injuries; enhances health decisions by providing credible information on critical health issues; and promotes healthy living through strong partnerships with local, national, and international organizations.*

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#### **Categories of Health Alert Network messages:**

**Health Alert** Requires immediate action or attention; highest level of importance

**Health Advisory** May not require immediate action; provides important information for a specific incident or situation

**Health Update** Unlikely to require immediate action; provides updated information regarding an incident or situation

**HAN Info Service** Does not require immediate action; provides general public health information

##This message was distributed to state and local health officers, state and local epidemiologists, state and local laboratory directors, public information officers, HAN coordinators, and clinician organizations##