

EVIDENCE REVIEW 02 • CASE REVIEW

OxyELITE Pro and the 2013 liver-injury outbreak

A cluster of severe hepatitis was linked to one supplement. The epidemiology supported the association; the exact toxic ingredient was never confirmed.

REVIEWED 9 SEPT 2026 3 SOURCES SOURCE-CHECKED

BOTTOM LINE

Investigators linked a cluster of severe hepatitis and liver failure to OxyELITE Pro. The epidemiological association was strong, but the precise toxic ingredient and biological mechanism were never conclusively established — and public-health action did not wait for them.

KEY POINTS

- Of 76 reports in the Hawaii investigation, 44 met the case definition and 36 of those reported OxyELITE Pro use.
- Two exposed patients required liver transplants and one died.
- The implicated reformulation had replaced DMAA with aegeline, which the FDA had not accepted as a new dietary ingredient.
- Case counts from overlapping investigations describe some of the same patients and must not be added together.

In September 2013, clinicians at Hawaii's single liver transplant centre notified the state health department about seven previously healthy adults who had developed acute or fulminant hepatitis of unknown cause since May.

What followed is the clearest documented example of a supplement safety signal being found the only way it could be found: after the product was already in widespread use.

The signal appeared as a cluster

A joint investigation reviewed medical records, supplement exposures, product lots and laboratory testing. Physicians were asked to report anyone with acute hepatitis of unknown cause from 1 April 2013 onward who had used a weight-loss or muscle-building supplement in the preceding 60 days and lived in Hawaii during the exposure period.

Of 76 reports received, 44 — 58% — met that case definition. Of those 44, **36 (82%) reported using OxyELITE Pro** in the two months before becoming ill. Investigators found no other supplement exposure common to the group.

That pattern is what an outbreak looks like when the cause is a product rather than an infection: a cluster in time, a shared exposure, and no competing explanation.

The outcomes were serious

Within the exposed Hawaii group, two patients required liver transplantation and one died.

A separate Drug-Induced Liver Injury Network case series later described seven patients whose liver injury was attributed to the same product; six were hospitalised, three developed acute liver failure and two received transplants.

These figures overlap. The investigations shared patients, and the numbers must not be summed as though they described separate populations — an error that inflates the toll and is easy to make when the case series are read side by side.

The association was strong; the mechanism was not established

Several things pointed the same way: the timing, the clustering, the consistency of the exposure, and the decline in new cases after the implicated formulations left the market.

Suspicion centred on a reformulation in which aegeline had replaced DMAA — and the regulatory hook was precisely that, since the FDA had not recognised aegeline as a lawful new dietary ingredient. But product analyses did not isolate a single confirmed mechanism of toxicity.

This distinction is the review's main point. Public-health action can be justified by a strong epidemiological signal even when the chemistry has not identified the harmful agent. Waiting for a confirmed mechanism would have meant leaving the product on sale through the outbreak.

What the case teaches

Drug-induced liver injury can look like viral or autoimmune hepatitis. Diagnosis depends on someone asking for a complete list of what a patient has been taking — vitamins, herbs, powders, performance products — and supplements are routinely omitted from that list unless asked for directly.

Voluntary reporting is imperfect and cannot calculate how often injury occurs. It can still reveal hazards that premarket review never had the chance to catch, because for most supplements there is no premarket review to catch them: see [how supplements are regulated differently from medicines](#) (/evidence/supplement-regulation-vs-medicines/).

Symptoms that warrant urgent attention include yellowing of the skin or eyes, dark urine, severe fatigue, persistent nausea and pain in the upper-right abdomen. Anyone experiencing these while taking a supplement should stop it and seek medical care.

In New Zealand, suspected adverse reactions — including to supplements — can be reported to the Centre for Adverse Reactions Monitoring, which feeds Medsafe's post-market surveillance. The reporting system carries the same strength and the same blind spot as the American one: it detects signals well, and cannot measure incidence at all.

SOURCES

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<https://pmc.ncbi.nlm.nih.gov/articles/PMC4529836/>

Medical note. General information only. Not personalised nutrition or medical advice. This review explains published research and cannot diagnose or treat a condition. Ask a qualified clinician or pharmacist about your own health, medicines and supplement use.

Source of record. The current version of this review, with working links, is at

<https://www.proteinnotes.com/evidence/oxyelite-pro-liver-injury-2013/>