

Supplements can contain far more melatonin than is safe, upping odds for illness

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When U.S. health officials reported a 500% spike in the number of

poison center calls involving kids eating melatonin gummies last year, Harvard researchers decided to take a closer look at the sleep supplements and discovered a disturbing fact: They contained up to 347% more melatonin than the label stated.

What's more, five of the products also contained CBD in higher amounts than the label indicated.

And the mislabeling was more common than one might think: The scientists found that across the 25 brands of melatonin gummies they tested, 22 were wrongly labeled. One product did not contain melatonin at all, but the much more common problem was excessive amounts.

It's not clear what, if any, [health consequences](#) that could have for people who use the gummies as directed.

But lead researcher [Dr. Pieter Cohen](#) pointed to the bigger picture: U.S. children and teenagers are more vulnerable to accidental ingestions and overdoses of the supplements than adults are.

Fortunately, last year's [study](#) from the U.S. Centers for Disease Control and Prevention found most kids suffered no serious problems. Still, nearly 4,100 had to be hospitalized, 287 required intensive care and two died, the CDC found.

"I was really surprised by that report," said Cohen, a physician with the Cambridge Health Alliance and an associate professor at Harvard Medical School in Boston. "There's always been a narrative out there that melatonin is completely safe."

No guarantees

Melatonin is a natural hormone that the brain produces in response to

darkness; it helps set the body's internal "clock" and promotes sleep. Melatonin gummies contain a synthetic version of the hormone.

But because they are marketed as dietary supplements, Cohen explained, they are not subject to the same regulations that medications are. That means there's no guarantee the ingredients match what's on the label.

After seeing the CDC report, Cohen said he wanted to find out what exactly is in the melatonin products Americans are buying.

So the researchers bought 25 brands of melatonin gummies, then quantified each product's amount of melatonin and CBD—the part of marijuana that does not produce a "high"—that is widely marketed for easing anxiety, among other benefits. They also looked for evidence of serotonin, a chemical that a previous study found as a contaminant in some melatonin supplements.

Overall, the study found, the actual amount of melatonin per gummy serving almost never matched the label information.

The products' actual per-serving melatonin dose ranged widely—from 1.3 to 13 milligrams (mg). And those amounts were anywhere from 74% to 347% of the label's stated amount, most often being higher.

Similar discrepancies were seen in the five products that listed CBD as an ingredient.

Caution advised

The findings, published April 25 in the *Journal of the American Medical Association*, came as no surprise to other experts: It's well known that [dietary supplements](#) may not contain what's on the label.

"Poison centers assume that the [quality control](#) may not be good," said [Dr. Kevin Osterhoudt](#), medical director of the Poison Control Center at Children's Hospital of Philadelphia.

In line with the national trend, Osterhoudt's center has seen a big increase in calls about melatonin gummy ingestions in the past several years. Most involved young children who'd accidentally gotten their hands on what, to them, looked like candy. There were, though, 195 incidents where teenagers intentionally overdosed.

Fortunately, only three kids had more serious symptoms—their parents had trouble waking them—and all cases ended well.

In the CDC report, most melatonin gummy ingestions nationally have involved young children, but teenagers who'd intentionally downed large doses accounted for most hospitalizations.

Osterhoudt said that while most of these incidents do not cause serious problems, it's always wise for parents to keep all medications and supplements "out of sight and out of reach of naturally curious children."

Then there's the question of whether children and teenagers with sleep difficulties should take melatonin at all.

Industry reaction

The Council for Responsible Nutrition, which represents supplement makers, took objection to the new study.

"This report does a complete disservice to a safe product when it is used according to manufacturer's instructions," [Steve Mister](#), president and CEO of the Council for Responsible Nutrition, said in a statement.

According to CRN, most of the 25 products examined in the study "contained adult servings and are expressly labeled for use in adults," but the researchers "conflate their findings with pediatric data."

CRN also noted that because of the long shelf life of many supplements, upping dosages ("ingredient overage") is routinely done by manufacturers to ensure that products maintain their potency mandated by the U.S. Food and Drug Administration over time.

"Supplement companies go to great lengths to ensure their products contain safe and consistent levels of dietary ingredients, as labeled," Mister said. "And while there may be some variability in overages as companies adhere to the FDA's requirements regarding shelf life and potency, it does not mean there is a risk in taking these products as intended. It's a misleading comparison to look at scenarios where kids, for example, got their hands on an entire bottle of adult gummies and became ill after eating multiple servings, versus having slightly more of an ingredient in a single serving that, if taken as directed, would pose no harm."

Do kids need melatonin?

However, for otherwise healthy kids with sleep problems, there's little evidence to support the use of melatonin at all, according to [Dr. Muhammad Adeel Rishi](#), vice chair of the American Academy of Sleep Medicine's Public Safety Committee.

The good news is that oftentimes, Rishi said, behavioral changes are all that is needed—such as establishing a consistent bedtime routine and limiting screen time (and exposure to artificial blue light) at night.

If melatonin is used for children, Rishi said, it should be only under a

doctor's guidance.

"It's important to realize that melatonin isn't really a supplement—it's a hormone," Rishi said. "You should talk to your provider before putting your child on any medication."

Of course, doctors also face the dilemma of not knowing what's in the melatonin gummies at your local health food store, both Cohen and Rishi said.

There are, however, a few [melatonin](#) products that carry a "USP verified" mark, the doctors noted. That does not mean they've been proven safe and effective, but it does offer more certainty that the product contains what is on the label.

More information: Pieter A. Cohen et al, Quantity of Melatonin and CBD in Melatonin Gummies Sold in the US, *JAMA* (2023). [DOI: 10.1001/jama.2023.2296](https://doi.org/10.1001/jama.2023.2296)

The American Academy of Sleep Medicine has advice on healthy [sleep habits](#).

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