

# Drugs aren't required to be tested in people who are obese. Here's why that's a problem

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Tablets of ibuprofen are arranged for a photograph in New York on Thursday, Nov. 2, 2017. In 2023, more than 40% of American adults are considered obese, but the medications many take are rarely tested in bigger bodies. That's because they are not required to be included in drug studies. Even a drug as common as ibuprofen, sold as Advil, may not relieve pain in people at higher weights when taken as directed, research shows. Credit: AP Photo/Patrick Sison, File

More than 40% of American adults are considered obese, yet the medications many take are rarely tested in bigger bodies.

That's because they are not required to be included in [drug](#) studies. And often, they're explicitly excluded.

"Clinical trials and dosing instructions don't always ensure that drugs will be safe and effective for people with obesity," said Christina Chow, a drug researcher who's reported on the challenges of considering obesity in [drug development](#). "There's no real emphasis for them to be studied at all."

Many widely prescribed drugs and over-the-counter medications work differently in people who are obese, but exactly how and at what dose often isn't clear. Research suggests that may include antibiotics and antifungal drugs used to treat serious infections, synthetic hormones used in Plan B emergency contraception and even ibuprofen, the common painkiller sold as Advil.

The U.S. Food and Drug Administration and the National Institutes of Health—agencies that regulate and fund [drug testing](#)—are putting new focus on the gaps in research. At a workshop last year, FDA Commissioner Dr. Robert Califf acknowledged a "deficit of evidence" about how medicines act in patients who are obese. The NIH now encourages researchers to consider the impact of excluding [obese people](#) in their studies, a spokesperson said.

At a recent medical conference, Chow presented a review of more than 200 studies for new drugs in the U.S. last year. Of those, nearly two-thirds failed to mention weight or body mass index—a common assessment of obesity—meaning they wouldn't ensure inclusion of people with obesity, she said.

The studies that did cite weight were most often used to exclude people with obesity from participating, said Chow, who works for Emerald Lake Safety, a California company that investigates severe drug reactions. People with a body mass index or BMI of 30 or higher are considered obese.

Historically, certain populations have been left out of testing for fear of harm, including pregnant people and children. Women, racial and ethnic minorities and the elderly, too, have been underrepresented before recent efforts to bolster diversity.

The reasons for excluding people with obesity are longstanding and varied, said Dr. Caroline Apovian, a researcher at Brigham and Women's Hospital in Boston and co-author of Chow's study.

Participants willing to sign up for studies are often leaner and don't reflect the general population, she noted. And researchers often worry that [health complications](#) that can come with obesity will cloud the results of their work.

"Sometimes patients with obesity have many more comorbidities than others. They'll have more diabetes, more heart disease, more strokes," she said.

But if drugs aren't studied in a condition that affects 42% of the U.S. population, the real-world consequences can be dire, experts said.

Some drugs can become concentrated in fat tissues and not in the bloodstream. That means there will be less medication in the blood, leading to undertreatment, Apovian said.

Other drugs remain in the body longer in the obese. That could result in harmful drug interactions if another medication is added too soon.

An antipsychotic drug called Rexulti is often prescribed for people suffering from schizophrenia or major depressive disorder, Chow noted. Research has shown that in obese patients it may take much longer to reach the concentration of Rexulti needed to be effective. As a result, many patients—and their doctors—may [stop treatment](#) too early or conclude that the drug doesn't work.

"Not treating or undertreating schizophrenia may be dangerous to themselves and the people around them," Chow said.

The emergency contraception drug Plan B One-Step is another example. Studies suggest that levonorgestrel, the active drug, may not work as well in people with obesity, possibly leading to drug failure and pregnancy, said Dr. Alison Edelman, an OB-GYN and researcher at Oregon Health & Science University, who studies contraception and obesity. But the FDA says the data are limited and conflicting, so there's not enough evidence to require a label warning.

Even a drug as common as ibuprofen, sold as Advil, may not relieve pain in people at higher weights when taken as directed, research shows.

But without adequate testing and clear instructions, doctors won't know how to adjust dosing for [obesity](#), said Dr. Colleen Tenan, a board member of the Association of Clinical Research Professionals.

"It's very hard to be a physician and say that I'm going to prescribe out of the normal range," she said.

Change is coming, but progress is slow, Edelman said. In 2019, the FDA issued [draft guidance](#) on hormonal contraception that asks study sponsors to lift restrictions on [body mass index](#) and include obese women. Even though the guidance isn't final, it already has changed how she and some other researchers structure their studies, she said.

"It's just something that we have to chip away at because it's so important," she said. "Because unless we see representation in our study population, we don't end up with treatments that work well for individuals."

In the meantime, Apovian said patients can ask their doctors about whether the standard dose of a medication is appropriate for their weight. The doctors may not know, but it could start an important conversation about effective treatment.

"This is a big issue," she said. "It can be important for patients to speak up."

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