People are receiving unapproved extra COVID-19 vaccine doses. Is it a problem?

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For many immunocompromised people, the COVID-19 pandemic has been a living nightmare—and the omicron variant may make life even

more unsettling.

Authorities and drug manufacturers alike have warned that the protection conferred from being fully vaccinated may not be sufficient to ward off the omicron variant in certain immunocompromised groups, deepening fears of what infections might look like for the more than 7 million Americans with weakened immune systems. Being fully vaccinated means you've either had two doses of the Pfizer-BioNTech/Moderna vaccines plus a booster, or one dose of the Johnson & Johnson vaccine plus a booster.

With cases surging again, some people with weakened immune systems have been skirting guidelines in order to receive unapproved vaccine doses, an effort to bolster immunity and avoid infection, the *New York Times* reports. So-called off-label dosing has been going on for some time, with the Centers for Disease Control and Prevention reporting over the summer that as many as 1.1 million people in the U.S. received unauthorized extra doses of the vaccine.

The break with CDC guidelines doesn't present a huge ethical concern in situations where immunocompromised patients are, in consultation with their physicians, receiving additional shots, particularly if they haven't been able to generate antibodies from the earlier doses, says Brandon Dionne, associate clinical professor of pharmacy and health systems sciences at Northeastern.

"If patients have an immunocompromising condition and haven't had an adequate response to the three doses, then I don't necessarily have an ethical concern with them trying a fourth or a fifth dose," Dionne says.

And it's considerably less sticky, ethically speaking, with a drug that's received full federal approval, such as the Pfizer vaccine, Dionne adds. But the fact that the Moderna vaccine is still under emergency-use

authorization opens the door to potential legal problems.

The CDC updated its guidelines in October to recommend a fourth shot for certain immunocompromised groups. These are patients who may have had organ transplants, be on immunosuppressant medication, or have certain chronic conditions. But given the recommended intervals between doses that are part of the guidelines, that additional booster for most would be administered in late February or early March 2022—six months after the third shot.

Over the summer, federal officials warned that circumventing vaccine guidelines could get providers into legal trouble. That was before the CDC and the Food and Drug Administration ultimately OK'd the booster.

Still, pharmacists and providers administering the vaccine must sign an agreement with the CDC that states if they break the rules, they could get kicked out of the federal vaccination program. Moreover, if patients have an adverse reaction, providers may not be shielded from litigation if they deviate from the guidelines, federal officials said.

But it shouldn't come as a surprise that those who are more vulnerable to COVID-19 would try to take matters into their own hands, says Wendy Parmet, a leading public health law expert and director of Northeastern's Center for Health Policy and Law. After all, the ethos of modern medicine empowers patients to make their own decisions about matters affecting their health.

"For decades now we've told people that they are supposed to make their own decisions about their healthcare," says Parmet, who is Matthews Distinguished Professor of Law. "We say, you know, "Do your research." So I don't blame them. People are going to do what they think is right for them."

Parmet says the federal agreements with providers should allow for physicians to prescribe vaccine doses, giving providers and their patients more agency in pursuing options for protection. For immunocompromised people, that extra early shot might yield some promising results, as preliminary research in Israel involving people ages 60 and older suggests.

As it stands, it's unlikely pharmacists administering the unapproved doses nor the patients themselves will face any legal consequences, especially given that many of the vaccines are being thrown out anyway, Parmet says. The U.S. has had an oversupply of the COVID-19 vaccine for some time because the demand for the shots has fallen off significantly since they became available more than a year ago.

But Parmet also warns that the flaunting of federal health guidelines points to a "breakdown of public trust" that can lead to "rampant individualism."

"We're essentially coming into a do-it-yourself pandemic," she says.

Provided by Northeastern University

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