



July 26, 2021

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Global Liver Institute
4323 Westover Place, NW
Washington, DC 20016

Email: Info@GlobalLiver.org
Website: www.GlobalLiver.org
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Dr. Janet Woodcock
Acting Commissioner
Food and Drug Administration
10903 New Hampshire Ave
Silver Spring, MD 20993-0002

RE: Booster Vaccine Approval For Transplant Recipients

Dear Dr. Woodcock,

As the leader of a patient advocacy organization committed to improving the lives of all transplant recipients, and a 26-year transplant recipient myself, I read with interest about the preliminary support for COVID-19 booster vaccine shots for immunocompromised people by the Advisory Committee on Immunization Practices advising the U.S. Centers for Disease Control and Prevention ("[U.S. Vaccine Panel Signals Preliminary Support for Covid-19 Booster Shots.](#)" The Wall Street Journal, July 22, 2021).

The support is welcome but the committee has reached the limits of its authority in advancing such a booster vaccine. The article makes clear that the next step is regulatory action. On behalf of all transplant recipients, I urge the Food and Drug Administration to do everything in its power to authorize and recommend a booster vaccine for the immunocompromised and immunosuppressed population as soon as possible.

Now, in the absence of expert government guidance, and an anemic response from the leading organ transplant medical societies, immunocompromised people are "left to their own devices" on whether, when, and how to get a booster vaccine

([phrase](#) from Dr. Robert Montgomery, director of the transplant institute at New York University Langone Health and a transplant recipient himself).

News reports and anecdotal information indicate that doctors are quietly administering booster shots to patients who are in the know to ask for them. This scattershot approach leaves scores of immunocompromised individuals behind. Every patient who could benefit from a booster shot

should have one. Regulators must analyze the growing safety and effectiveness data and issue clear, practical guidance on which patients should receive booster shots and which of the vaccines are most effective. Rather than murmured conversations in select doctors' offices, researched-backed guidance on booster shots should derive from the government's leading authorities on vaccine safety and indications.

Millions of Americans are immunocompromised. First, we waited for the vaccines. Then, we waited for our fellow Americans to get vaccinated. While our peers with healthy immune systems tired of isolating during the pandemic, we were forced to isolate even longer. Some of us must still isolate, even as society re-opens. Now we watch with renewed worry as the Delta variant spreads, a sizable portion of the eligible population refuses to get vaccinated, and U.S. regulators have yet to act on booster shots for the immunocompromised.

Dr. Woodcock, we can wait no longer. As the article on the advisory committee notes, there exists "sufficient [data](#) to suggest an additional dose would be helpful, once the regulatory clearance is given." As the article further notes, our population wants to be vaccinated. We desperately want to protect our weakened immune systems from a deadly virus and its pernicious variant. We are navigating living, working, and caring for our families, like everyone else. We, too, want to attend cook-outs and baseball games this summer.

Please use your regulatory authority to help cancer, transplant, and other immunocompromised Americans safely rejoin society. If you have any questions, please don't hesitate to reach out to Global Liver Institute's Policy Director, Andrew Scott, at ascott@globalliver.org or 831-246-1586.

Thank you for your attention and consideration.

Sincerely,

A handwritten signature in black ink that reads "Donna R. Cryer". The signature is written in a cursive, flowing style.

Donna R. Cryer, JD
Chief Executive Officer
Global Liver Institute

CC: Dr. Rochelle Walensky
Director, Centers for Disease Control and Prevention

Dr. José R. Romero
Chair, Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention

Dr. Beth Bell
Chair, COVID-19 Vaccines Working Group

Advisory Committee on Immunization Practices
Centers for Disease Control and Prevention

About Global Liver Institute

Global Liver Institute (GLI) was built to solve the problems that matter to liver patients, equipping advocates to improve the lives of individuals and families impacted by liver disease. GLI promotes innovation, encourages collaboration, and supports the scaling of optimal approaches to help eradicate liver diseases. GLI believes liver health must take its place on the global public health agenda commensurate with the prevalence and impact of liver illness. GLI is the only patient-created, patient-driven nonprofit organization tackling liver health and all liver disease holistically, operating globally. Follow GLI on [Twitter](#), [Facebook](#), [Instagram](#), [LinkedIn](#), and [YouTube](#).