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Dr. Robert Califf
C/O Dockets Management Staff (HFA-305)
Commissioner, Food and Drugs Administration
5620 Fishers Lane
Rockville, MD 20852

RE: GHLF Patient Group Comments on Laboratory Developed Tests (FDA-2023-N-2177)

Dear Dr. Califf,

Thank you for the opportunity to provide comments on the docket FDA-2023-N-2177: *Medical Devices; Laboratory Developed Tests*. The Global Healthy Living Foundation (GHLF) is pleased to offer insights into the patient's viewpoint concerning these tests and the potential repercussions of additional regulatory measures.

By way of background, the Global Healthy Living Foundation (GHLF) is a 501(c)(3) patient group that works to improve the quality of life for people with chronic disease, often focusing on those least able to advocate for themselves. Through our websites, social media channels, patient centered research registry and an omni disease platform, and conventional media, GHLF reaches more than 10 million chronically ill people monthly in the United States – in English and Spanish. Our patient community frequently faces the challenge of making decisions around multiple medications before ascertaining the one that may be most efficacious and also might work best for them keeping in mind patient preferences and values, tolerability and side effect concerns, insurance coverage and understanding of safety profiles. Diagnostic and other forms of laboratory testing is often done to guide our patient community as they navigate management of their disease and make informed and shared decisions around treatment options for optimal disease management to . To enable this, we remain committed to providing support to regulatory bodies like the FDA, so that tests remain safe and effective.

When it comes to healthcare medical testing, patients primarily care about three things: accessibility, affordability, and accuracy. When a patient walks into a lab for testing, it is not very common for them to ask questions about who manufactures a test or the regulations it has to go through to be utilized because the process of taking the test does not change significantly. This implies that they still need to go to a laboratory setting and have blood drawn and evaluated. Through structured and anecdotal conversations and other communication channels, we know that patients are concerned with information related to access, affordability, and accuracy. "Where is the most convenient place to take this test?" "Will this be covered by my insurance?" "How accurate is this test?" Because we know that these are issues that are highly important to patients, we must approach any potential regulations with an idea of how we will in fact answer

questions related to their access, affordability and accuracy if we want to maintain a patient centric approach While we have support and encourage innovation and fairness in price setting with an eye to affordability, ultimately tests do more harm than good if patients are unable to feel confident in the results.

When GHLF looked at the proposed rule changes for diagnostic and other laboratory tests and had the opportunity to meet with the FDA to discuss this topic further, we were encouraged to note that this rule change is an attempt to try and respond to the primary patient concerns which we identified earlier in our comments. As the FDA takes a closer look at regulating these tests, we are hopeful that gaining FDA approval will allow for greater access to more affordable forms of testing because insurance companies will be more agreeable to cover new forms of diagnostic testing as labs develop them. We know that insurance coverage is one of the key indicators in this country as to whether patients will utilize a product. The more tests that are covered, the more patients will be able to use them, and the more labs will be able to use their products enabling cost-effective utilization of healthcare services and products and thereby dealing with both the access and the affordability issues at once. Additionally, With FDA approval, there is also an expectation that these tests will fulfill specific accuracy requirements so patients will be more confident in the results of these tests. In light of this, GHLF supports this effort to increase regulations on laboratory developed tests because we believe that further scrutiny and oversight will benefit patients by ensuring their accuracy through appropriate oversight protocols and increasing the likelihood that they will be accessible and affordable.

On behalf of those in our community looking for answers that will increase their quality of life, we thank you for looking at ways to ensure safe and effective testing options. Should you need to hear from more patients directly, we are ready to help connect you with those who would benefit from these regulations.

Best Wishes,

Corey Greenblatt, MPH
Associate Director of Policy and Advocacy
Global Healthy Living Foundation