



August 25, 2021

National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK)
31 Center Drive
Bethesda, MD 20892

VIA Electronic Delivery

RE: National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Strategic Plan

Request for Information:

Dear Sir or Madam:

As advocacy organizations, and individual patient advocates committed to improving the lives of all people impacted by liver disease, we appreciate the opportunity to submit comments to the recently released National Institute of Diabetes and Digestive and Kidney Diseases (NIDDK) Strategic Plan Draft Document.

We welcome the agency’s interest in developing a broad vision for accelerating research into the causes, prevention, and treatment of diseases like liver disease. We thank the agency for its transparency and inclusion of many of our previously submitted recommendations to the 2020 draft. We also greatly appreciate the agency’s willingness to include the patient voice throughout the strategic planning process.

First, we applaud the consistent acknowledgment of the long-standing racial and ethnic health disparities that we expanded upon within our previous letter and have sought to eliminate for years. As an example, on page 12 of the 2021 NIDDK Strategic Plan Draft Document, the inclusion of noninvasive diagnostics to identify, adapt, scale up, and integrate evidence-based interventions in research along with diverse settings and populations will be critical.

Overall, by mentioning throughout the report that the NIDDK will prioritize diversity in the workforce, collaborating with diverse partners, diverse workforce expansion/support (page 19), and increasing diversity in clinical trials (page 18), the agency marks a critical first step towards institutional change. Even more importantly, by emphasizing the need to increase interdisciplinary research into how biological, behavioral, social, and environmental factors interact to affect human health (pages 10,11), the agency shows a willingness to positively move the needle towards dismantling systemic inequities and

increasing trust by disproportionately impacted communities in medical research (page 31).

Second, we appreciate the report's mention of the value of early intervention through nutrition (page 3), the role NIDDK can play in empowering a multidisciplinary research community (page 4), and the need to examine multiple outcomes at once, including the intrinsic link nonalcoholic steatohepatitis shares with obesity and diabetes (page 17). We also thank the agency for understanding that it must reevaluate its research dissemination and awareness strategies. This includes an expansion of its partnerships with disease-specific advocacy groups and developing new ways to address barriers to stakeholder engagement (pages 25, 27, 29, 32).

With all this said, we depend on the agency's leadership and partnership to move the field forward and shift the conversation on liver health. While the liver is mentioned throughout the strategic plan, to address the many hurdles that diverse patients with liver disease across our country face, it is vital for the NIDDK to more specifically elevate holistic liver health.

We stress for the NIDDK to acknowledge that liver conditions continue to be misunderstood, mischaracterized, and stigmatized, resulting in under-diagnosis, under-treatment, and unnecessarily poor outcomes, despite affecting more than half a billion people around the world. While the report acknowledges some of these points broadly, the NIDDK must think more precisely of liver health on the same level as some of the other therapeutic areas within the agency's portfolio. Liver health must be considered as an integral part of public health, from nutrition, physical activity, prevention, control and management of risk factors, to education, support, optimal clinical pathways, and policy for children, adults, and seniors.

To underline this point, in the United States, estimates show that:

- Cirrhosis impacts 633,000 people
- Liver cancer impacts 42,000
- Hepatitis B Virus (HBV) impacts 2.2 million
- Hepatitis C Virus impacts 3.5 million
- Nonalcoholic Fatty Liver Disease (NAFLD) impacts around 76 million
- Nonalcoholic steatohepatitis (NASH) impacts anywhere from 4.9 million to 19 million
- Alcohol-related liver disease (ALD) impacts 19 million people

The NIDDK must acknowledge that despite the development of vaccines and antiviral agents, the burden of liver disease is poised to grow further due to the confluence of several trends such as increasingly sedentary lifestyles and over-nutrition. This rise has only been amplified by the COVID-19 public health crisis and is in large part due to the harsh reality that the prevalence of metabolic liver diseases, including nonalcoholic fatty liver disease and alcohol-related liver disease, have increased, ultimately leading to more cases of end-stage liver diseases (liver failure, cirrhosis, and liver cancer).

In response, we urge the NIDDK to consider two vital recommendations:

- The NIDDK must elevate the Liver Disease Research Branch to the level of an Office or Division to better meet the cross-divisional, interconnected needs of a rapidly growing patient population and to better coordinate liver health-related research within NIDDK and NIH.
- The NIDDK must maintain a continuity of investment in ongoing important liver disease research programs while also consistently dedicating an appropriate percentage of new annual funds to transformative liver health research initiatives.

In conclusion, as a community for whom addressing liver disease is literally a life-and-death issue, we commend the NIDDK for including many of our previous recommendations within this draft report. We also welcome the opportunity to continue working collectively to ensure that future NIDDK efforts elevate liver health holistically. If you have any questions please don't hesitate to reach out to Global Liver Institute's Policy Director, Andrew Scott, at ascott@globabliver.org or 831-246-1586.

With appreciation and respect,

Global Liver Institute
Community Liver Alliance
NASH kNOWledge
Liver Wellness Foundation
Fatty Liver Foundation
Midsouth Liver Alliance
Texas Liver Foundation
Liver Coalition of San Diego