

# GLOBAL LIVER INSTITUTE LEADING IN LIVER HEALTH POLICY

## OPTN Reforms

GLI Founder and CEO Donna R. Cryer joined President Joe Biden in the **Oval Office** signing ceremony of the Securing the U.S. Organ Procurement and Transplantation Network Act. The legislation followed hearings in which Ms. Cryer and GLI advocate LaQuayia Goldring testified, both at the House Oversight Committee on May 4, 2021 and again for the Senate Finance Committee on July 20, 2023. GLI will continue to lead as HRSA advances the OPTN Modernization Initiative.



## ADVANCED ADVOCACY ACADEMY



GLI held its Advanced Advocacy Academy September 29-October 2, 2023. In the midst of a possible government shutdown, around **50 advocates** met with nearly **60 Congressional offices** on October 2, 2023, generating new cosponsors for the Treat and Reduce Obesity Act, the Liver Donor Protection Act, and the Medicare Multi-Cancer Early Detection Screening Coverage Act. Soon after, the Saving Access to Laboratory Services Act finally achieved a hearing in the House Energy and Commerce Committee on October 19, 2023.

## THORN RUN PARTNERS

In February, 2023, GLI hired Thorn Run Partners to serve as its policy and government affairs team. Thorn Run's team of policy experts are known to provide a unique end-to-end package of tools and services that have achieved considerable success for their client partners.

## FDA APPROVAL PROCESS

On February 4, 2022 GLI led an *Externally-Led Patient-Focused Drug Development Meeting (EL-PFDD)* on **Primary Biliary Cholangitis** (PBC). On May 19, 2023, GLI's trained advocates participated in the FDA's Gastrointestinal Drugs Advisory Committee (GIDAC) meeting related to Intercept Pharmaceutical's application for obeticholic acid (OCA) as a treatment for NASH. Since the **meeting**, GLI has called on FDA not to undermine its process by allowing advisory committees to change the endpoint. GLI continues to push FDA to meaningfully consider outcomes that matter to patients in its approval process for drugs and devices, providing comments to FDA as it considers policies such as the use of **patient preference information**.

## CONGRESSIONAL APPROPRIATIONS

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GLI founder and CEO Donna R. Cryer, JD provided **public witness testimony** to the House Appropriations Committee on March 23, 2023. She called on appropriators to invest in the tools to reduce liver disease and liver cancer, including for the 10 percent of children with Nonalcoholic Steatohepatitis (NASH), for the non-Hispanic blacks for whom liver disease is the ninth leading cause of death, and for the African American/Black men who are 60 percent more likely to have — and to die from — liver and Intrahepatic Bile Duct (IBD) cancer. GLI is at the forefront of efforts to support the health programs as funded by the Senate appropriations packages that were developed with bipartisan cooperation and support in committee.

## SUPPORT FOR AGENCY LEADERSHIP

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GLI strongly supported the nomination of Dr. Monica Bertagnoli as the new NIH Director, a move recognized and appreciated by the **White House**. She was recently confirmed by the Senate. GLI also nominated Julius M. Wilder MD, PhD to be a member of the NIDDK's National Diabetes and Digestive and Kidney Diseases Advisory Council (NDDKAC). Not only is Dr. Wilder an accomplished gastroenterologist, transplant hepatologist, and medical sociologist with a national reputation in health equity, he would bring much-needed diversity to the NIH NIDDK Council. The nomination is supported by GLI, Color of Crohns & Chronic Illness (COCCI), the Digestive Disease National Coalition (DDNC), and the Association of Black Gastroenterologists and Hepatologists (ABGH).

## NASH NOMENCLATURE IMPACT

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Following the official publication of changes to NASH nomenclature, GLI continues to advocate for an impact analysis to mitigate confusion among patients and clinicians and understand the associated costs and necessary next steps to ensure access to high quality care.

## COLLABORATION WITH POLICYMAKERS - ICER

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In 2023, GLI provided public comment on the Institute for Clinical and Economic Review's (ICER) Resmetirum and Obeticholic Acid for NASH draft evidence report. In response to GLI's comments, ICER invited patient advocates to speak at their NASH public meeting to provide their thoughts on the drugs under review and reactions to the ICER report findings, and to discuss the impact of NASH on patients' lives. Ms. Cryer has long been a leading voice on how to improve value assessment methods, participating in efforts with the Partnership to Improve Patient Care (PIPC), the Innovation and Value Initiative and the Patient-Centered Outcomes Research Institute to better account for outcomes that matter to patients in determinations about health care effectiveness and value. GLI continues to advise policymakers and work for a consistent policy banning use of discriminatory and flawed value assessment measures across federal programs, such as included in the proposed rule related to Section 504.

## STRONG PARTNER ADOULATE ON OTHER KEY ISSUES

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GLI is proud to collaborate, knowing that a united voice is stronger than operating in silos. Our team has met with high-level HHS officials related to the need for obesity treatment coverage and was at the forefront of efforts to identify the connection between eliminating hepatitis C and achieving the Cancer Moonshot. We continue to work with partners such as *Prevent Cancer Foundation*, *Obesity Action Coalition*, *Obesity Care Action Network*, *Deadliest Cancers Coalition*, *Hepatitis Appropriations Partnership* and *Digestive Disease National Coalition* to advance our shared policy goals.