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### Liver let die – Challenges and opportunities in developing interventions for fatty liver disease (NAFLD/NASH)

**N**on-Alcoholic Fatty Liver Disease (NAFLD) is a chronic metabolic disorder marked by excessive fat accumulation in the liver that may affect as much as 30% of the population. It is not related to alcohol consumption or viral infection. NAFLD may progress to non-alcoholic steatohepatitis (NASH) and hepatocellular carcinoma (HCC). NASH was first named and described in a 1980 review of 20 Mayo Clinic patients. NASH is expected to overtake all other indications as the leading cause of liver transplantation in the next 10 to 20 years. Although this is a serious emerging health concern that has been described as the next global epidemic, there are currently no medications specifically approved for treating NAFLD/NASH. Until recently drug development in this space was stifled by the lack of a clear pathway to approval, necessitating outcomes trials. In 2015 the Food and Drug Administration (FDA) and the American Association for the Study of Liver Diseases (AASLD) published a manuscript of their joint workshop suggesting the acceptance of pragmatic surrogate biomarker endpoints such as the reversal of steatohepatitis with no evidence of progression to advanced fibrosis. Three years ago a Deutsche Bank report projected a peak NASH market opportunity of 35-40 billion dollars by 2025. Consequently, NAFLD/NASH interventions are becoming increasingly prevalent in drug development pipelines.

#### Biography

Clayton A Dehn is a Research Physiologist with expertise in Metabolic Disorders. He is the co-inventor of a process and substance for disturbing the inheritance pattern of ion-channelopathic disorders, and the sole author of the first publication cautioning against the risk of SGLT-inhibition inducing ketoacidosis in insulinopenic populations. He serves as the Editorial Board Member of four peer-reviewed journals, and has served gubernatorial appointment on the Arizona Biomedical Research Commission.

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