



**Food and Drug Administration Advisory Committee Member  
Acknowledgment of Financial Interests**

Name of Advisory Committee Member: **Benjamin Lebwohl, M.D., M.S.**

Committee: **Gastrointestinal Drugs Advisory Committee**

Meeting Date: **September 13, 2024**

I acknowledge that contingent upon public disclosure of the following financial interest related to the agenda item described below, I may be considered for participation in the advisory committee meeting.

On September 13, 2024, the Committee will discuss supplemental new drug application (sNDA) 207999 S-011, for Ocaliva (obeticholic acid) 5 mg titrated to 10 mg oral tablets, administered once a day, submitted by Intercept Pharmaceuticals, Inc to fulfill the accelerated approval postmarketing requirements specified in the Ocaliva approval letter dated May 27, 2016. The sNDA included data proposed to describe and verify clinical benefit for the indication for the treatment of adult patients with primary biliary cholangitis (PBC) without cirrhosis or with compensated cirrhosis who do not have evidence of portal hypertension, either in combination with ursodeoxycholic acid (UDCA) with an inadequate response to UDCA or as monotherapy in patients unable to tolerate UDCA.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
<b>I. Personal/Immediate Family</b>		
Stock/Investment	Healthcare sector mutual fund holding in [REDACTED] (b) (6)	\$300,000 to \$500,000
<b>II. Other Imputed Interests</b>		
None		

I hereby request that FDA make this information publicly available on my behalf if the agency grants a waiver allowing me to participate in the meeting described above. I understand that without public disclosure of these interests, I will not participate in the advisory committee meeting described above.

\_\_\_\_\_/s/\_\_\_\_\_  
Signature

\_\_\_\_\_/8/15/2024\_\_\_\_\_  
Date