



Food and Drug Administration Advisory Committee Member Acknowledgment of Financial Interests

Name of Advisory Committee Member: Ira Dunkel, M.D.

Committee: Pediatric Oncology Subcommittee of the Oncologic Drugs Advisory Committee (PedsODAC)

Meeting Date: June 17-18, 2020

I acknowledge that contingent upon public disclosure of the following financial interests related to the agenda items:

On June 17, 2020, information will be presented regarding pediatric development plans for two products that are in development for an adult oncology indication. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of written requests for pediatric studies, if appropriate. The two products under consideration are: (1) SP 2577 application presentation by Salarius Pharmaceuticals, Inc. and (2) Marizomib, application presentation by Celgene International II Sàrl, a wholly owned subsidiary of Bristol-Myers Squibb; and on June 18, 2020, information will be presented regarding pediatric development plans for two products that are in development for an adult oncology indication. The subcommittee will consider and discuss issues relating to the development of each product for pediatric use and provide guidance to facilitate the formulation of written requests for pediatric studies, if appropriate. The two products under consideration are: (1) CD30.CAR-T, application presentation by Tessa Therapeutics and (2) SNDX-5613, application presentation by Syndax Pharmaceuticals, Inc., I may be considered for participation in the advisory committee meeting described above.

<u>Type of Interest</u>	<u>Nature</u>	<u>Magnitude</u>
I. Personal/Immediate Family		
consulting	(b) (4)	\$0 – \$5,000 per year
consulting	(b) (4), potentially competing firm	\$0 – \$5,000 per year
consulting	(b) (4)	\$0 – \$5,000 per year
consulting	(b) (4) potentially competing firm	\$10,001 – \$25,000 per year
II. Other Imputed Interests		
contract/grant	Bristol Myers-Squibb (BMS), party to the matter	(b) (4) per year to Memorial Sloan Kettering Cancer Center (MSKCC);

		\$10,001 - \$25,000 per year to Dr. Dunkel in salary support
contract/grant	Pediatric Brain Tumor Consortium (PBTC), unrelated entity and Apexigen, potentially competing firm	(b) (4) per year from Apexigen to PBTC; (b) (4) per year from PBTC to MSKCC
contract/grant	Pfizer, potentially competing firm	(b) (4) per year
contract/grant	Celgene, a subsidiary of BMS, party to the matter	(b) (4) per year
contract/grant	Novartis, competing firm Lyla Nsouli Foundation, unrelated entity	(b) (4) per year from each
contract/grant	Novocure, potentially competing firm	(b) (4) per year
contract/grant	Novartis, competing firm	(b) (4) per year
contract/grant	Pediatric Brain Tumor Consortium, unrelated entity	(b) (4) per year

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

5/29/20_____
Date