



# Prescription Drug User Fee Act (PDUFA) Reauthorization

## FDA and Industry Finance Subgroup | Minutes

October 21, 2020 | 10:00am-12:00pm

Virtual Format (Zoom)

### PARTICIPANTS

#### FDA

Ozan Aygun	CDER
Josh Barton	CDER
Yanming Chae	CBER
Angela Granum	CBER
Bharat Khanna	CDER
Ted Liazos	OC
Alison Lyndaker	CDER
Robert Marcarelli	OO

#### Industry

E. Cartier Esham	BIO
Carl Garner	PhRMA (Eli Lilly)
Brad Glasscock	BIO (BioMarin)
Kelly Goldberg	PhRMA
Ann Kurowski	BIO (Alkermes)
Kristy Lupejkis	PhRMA
Mark Taisey	PhRMA (Amgen)
Lucy Vereshchagina	PhRMA

### MEETING SUMMARY

#### Inflation Adjustment

FDA presented its inflation adjustment proposal. The inflation adjustment is to account for annual changes in the personnel and operating costs for the PDUFA program. The personnel component of this adjustment currently accounts for the average cost of all FDA personnel, rather than the average cost of PDUFA program personnel. The PDUFA program has been experiencing higher increases in the average cost of personnel than FDA as a whole. The goal of this proposal is to more accurately reflect actual changes in personnel costs for the PDUFA program which will further FDA's ability to fully implement the pay flexibilities provided under the 21<sup>st</sup> Century Cures Act. This proposal will be discussed further at a subsequent meeting.

#### Resource Capacity Planning

FDA presented detailed information about how submission volumes are forecasted and how that data output is incorporated with time reporting data into a resource forecast expressed in full-time equivalents (FTEs). FDA addressed industry clarifying questions on this topic.

There were no other substantive proposals, significant controversies, or differences of opinion discussed at this meeting.