

DRUG LAW AND POLICY

Fall 2019

Debate I: Prescription Drug User Fees as a Stream of FDA Funding

Under the Prescription Drug User Fee Act (PDUFA), pharmaceutical companies are charged fees that are used to help fund the FDA's drug approval process. Since PDUFA was first passed in 1992, it has become a major revenue stream for the FDA's drug review operations, with user fees funding upwards of 65% of the agency's expenses on that labor-intensive process. Over the same period, the number of overdue applications pending with the FDA has fallen precipitously, as has the average application turnaround period.

Position 1: Drug user fee system is in the best interest of consumers.

Position 2: Drug user fee system is not in the best interest of consumers.