



Tufts Center for the Study of Drug Development

TUFTS UNIVERSITY

Impact REPORT

ANALYSIS AND INSIGHT INTO CRITICAL DRUG DEVELOPMENT ISSUES

ADF opioid development, uptake tied to efficacy, regulatory/payer policies

Lack of reimbursement is seen as the primary obstacle to ADF uptake

- Of the 10 opioid products with abuse-deterrent formulations (ADFs) that have received United States Food and Drug Administration (FDA) approval to date, four have been launched.
- More than two dozen applications for new drug ADF products are pending before the FDA.
- 96% of all opioid products prescribed in the U.S. in 2015 lacked abuse-deterrent properties.
- Whereas the FDA encourages development of ADF products, a lack of consistent regulatory policy may hinder innovation in this area.
- Lack of reimbursement by payers is the primary challenge limiting ADF uptake.