Abuse-Deterrent Opioid Development and Uptake Are Tied to Efficacy and Regulatory/Payer Policies

BOSTON – July 13, 2017 – Although 10 new opioid products with abuse-deterrent formulations (ADF) have received regulatory approval in the United States, lack of willingness by insurers to reimburse patients for their use is seen as a primary challenge limiting ADF uptake, according to the Tufts Center for the Study of Drug Development.

According to Tufts CSDD, 96% of all opioid products prescribed in the U.S. in 2015 lacked abuse-deterrent properties, and only four of the 10 opioid products with abuse-deterrent properties thus far approved for sale by the Food and Drug Administration (FDA) have been launched.

"Developers are confronted with substantial payer reimbursement hurdles with respect to ADF products," said Joshua P. Cohen, associate professor at Tufts CSDD, who completed an analysis of the state of ADF opioid development and uptake by care providers. "In addition, lack of regulatory consistency regarding demonstrations needed to support labelling of abuse claims and lack of clarity regarding eligibility for three-year data exclusivity for ADF products is inhibiting their wider use."

Despite these obstacles, new ADF product development is moving ahead, as more than two dozen applications for new ADF drug products are pending before the FDA, Tufts CSDD said.

The findings were reported in the July/August Tufts CSDD Impact Report, released today, which also noted that:

- 36% of branded opioids prescribed in 2015 contained abuse-deterrent properties, but only 2% of generic opioids did.
- Medicare reimbursement of ADF products is often restricted, while coverage of non-ADF opioids is unrestricted.
- Drug developers face a special challenge in creating abuse deterrents for oral medications, as pills are the most common means by which pain medicine is administered.

"The U.S. opioid crisis is more pronounced than ever and, unfortunately, seems to be growing, increasing the urgency for ADF opioid products," said Cohen. "The FDA has adopted a flexible, adaptive approach to evaluating and labeling abuse-deterrent products, which will help. And the sooner developers can demonstrate ADF clinical effectiveness, the more likely payers will step up reimbursements for ADF products."
ABOUT THE TUFTS CENTER FOR THE STUDY OF DRUG DEVELOPMENT

The Tufts Center for the Study of Drug Development (http://csdd.tufts.edu) at Tufts University provides strategic information to help drug developers, regulators, and policy makers improve the quality and efficiency of pharmaceutical development, review, and utilization. Tufts CSDD, based in Boston, conducts a wide range of in-depth analyses on pharmaceutical issues and hosts symposia, workshops, and public forums, and publishes Tufts CSDD Impact Reports, a bi-monthly newsletter providing analysis and insight into critical drug development issues.

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