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.

Developers, regulators, and payers hold the keys to improving access to ADF products.

While prescription opioid products have become an important component of modern pain management, abuse and misuse of these products have created a serious and growing public health problem. In 2016, more than 33,000 opioid-related deaths were recorded in the U.S., with the aggregate medical and productivity loss costs associated with prescription overdose, abuse, and dependence estimated to be $78.5 billion annually. In response, the pharmaceutical industry has shown strong interest in developing opioid analgesics with abuse-deterrent formulations, the goal of which is to maintain effective pain relief while reducing the potential for abuse.

Building on the FDA’s view that development of ADF drugs should be a high public health priority, Tufts CSDD convened a roundtable of pharmaceutical company experts to assess the clinical development, regulatory, and reimbursement challenges confronting ADF product development. Highlights of that discussion, supplemented by Tufts CSDD research, are summarized in this report.