

# OUR RESPONSE TO THE U.S. OPIOID EPIDEMIC

Over the course of Mylan's history, we have worked to help address some of the world's most pressing public health problems. The ongoing opioid crisis is no exception. Mylan fully recognizes the scope of this issue and is committed to doing our part to help in the fight against opioid addiction, abuse and misuse.

Regarding Mylan's presence in the U.S. opioid market, the company has a limited role. We supply approximately 1.1% of opioid-containing drug products sold, according to 2017 IMS data. Mylan's opioid portfolio consists of generic products and one branded product that is not part of the national discussion on opioids because it is an intravenous anesthesia medicine administered only by healthcare professionals in a surgery-center setting for which patients do not receive prescriptions. Mylan is not promoting or marketing any of its opioid products.

However, given our leadership position within the generic pharmaceutical industry in particular and our extensive scientific capabilities, we are committed to finding ways to be a part of the long-term solution to this challenge. In 2014, Mylan launched a generic, injectable, single-vial version of Naloxone, a product that is indicated for the complete or partial reversal of opioid depression induced by some natural and synthetic opioids, as well as for diagnosis of suspected or known acute opioid overdose. In the summer of 2016, Mylan launched a multiple-vial version of its generic Naloxone injectable, thereby increasing supply for customers, physicians and other providers seeking additional inventory of this important therapy. Mylan's injectable Naloxone products are primarily used by hospitals. Today, Mylan's Naloxone presentations are the lowest price options in the overall Naloxone market, which includes auto-injectors and prefilled syringes. Mylan stands ready to continue to provide reliable supply and access to this important product, including through a commitment to develop an auto-injector drug-device combination for Naloxone.

In April 2018, the company announced plans to leverage its world-class scientific platform to develop a novel delivery for Meloxicam, a non-opioid pain medication, and we remain committed to bringing this product to market. Promoting the development of non-opioid pain treatments is one of the many areas the FDA is focused on as part of its efforts to address this growing public health problem.

Mylan's portfolio includes the Fentanyl Transdermal System, which is a generic version of Johnson & Johnson's branded Fentanyl patch product, Duragesic™. Mylan's Fentanyl Transdermal System is indicated for the management of pain in opioid-tolerant patients, severe enough to require daily, around-the-clock, long-term opioid treatment and for which alternative options are inadequate. Mylan's generic patches utilize a matrix technology in which the Fentanyl is incorporated into the adhesive layer of the patch. Accordingly, Mylan's patches have no drug reservoir containing Fentanyl gel. Mylan's matrix patches are among the products containing the least amount of Fentanyl needed to deliver the labeled dose. At the time of its approval, Mylan's matrix technology design represented an important innovation for the product.

Mylan recognizes that Fentanyl is a big part of the national opioid crisis. Importantly, however, lawful Fentanyl products such as Mylan's Fentanyl Transdermal System have been broadly acknowledged by federal authorities as not being responsible for the current Fentanyl crisis. In its 2017 National Drug Threat Assessment Summary, the U.S. Drug Enforcement Administration concluded that "illicitly-produced Fentanyl is responsible for the current Fentanyl epidemic." Mylan further recognizes that there has been focus on payments made by drug manufacturers to third-party advocacy groups and professional societies. Former Senator McCaskill issued a report on February 15, 2018 on this topic that positively differentiated Mylan, finding that the company is "[a]t the other end of the spectrum" from the other companies whose payments were examined because Mylan made only de minimis payments, and to only one of the 14 third parties cited in the report. Moreover, Mylan continues to cooperate with separately disclosed government inquiries that it has received.

Mylan is also fighting the opioid epidemic by taking seriously the need to safeguard against diversion and abuse of opioids. We have internal practices designed to detect suspicious orders and prevent the sale of opioid-containing products where there may be a risk of diversion.

We remain dedicated to working with key stakeholders across the spectrum of opioid-related issues to continue to identify avenues to help bring an end to this public health challenge.