Foster the Development and Use of Abuse Deterrent Formulations of Opioids, Non-Opioid Analgesics as well as Medications to Treat Addiction and Overdose

The challenge of prescription drug abuse is multifaceted and requires a multi-pronged approach that ensures that patients with legitimate medical needs receive the treatments they need, offers a range of options for prescribers and patients to appropriately treat acute and chronic pain, and fosters the development of medications to treat addiction and address opioid overdose. Chronic pain is recognized as a major public health problem, producing a significant economic and socioeconomic burden derived not only from health care costs but also in terms of loss of productivity. Consistent with the recommendations of the President’s Commission Report on Combating Drug Addiction and the Opioid Crisis, we view better pain management, particularly for vulnerable populations such as pregnant women, as essential to preventing prescription opioid misuse, abuse, and diversion. We support a range of policies aimed at addressing research gaps to expand available treatment options to mitigate pain, treat addiction, and reverse overdose as well as policies to increase patient access to medical advances in these areas.

The National Institutes of Health (NIH) and National Institute on Drug abuse (NIDA) have reinforced the critical need to develop medicines in the following areas to address the opioid crisis:

- **Abuse deterrent formulations (ADFs).** ADFs help to prevent widespread abuse by impeding the delivery of their active ingredient or by making abuse of the drug more difficult or less rewarding. For example, an ADF may make it more difficult to crush a tablet to snort the contents, or more difficult to dissolve a capsule to inject its contents, or it may interfere with or defeat the euphoria associated with abuse upon manipulation. The FDA supports the development and use of ADFs as an important tool in addressing the opioid crisis and recently finalized guidance to support the development of generic ADFs.

- **Non-opioid analgesics.** These medicines offer a broad range of non-addictive pain management treatment options including, for example, non-steroidal anti-inflammatory drugs, novel treatments targeting pain signals in the brain, and more targeted approaches to numbing pain and preventing inflammatory processes. The development of safe and effective non-opioid alternatives will be critically important to addressing the opioid crisis in the long-term.

- **Medications to treat addiction.** These medicines used in combination with other forms of recovery and treatment services are an important part of a comprehensive treatment plan to help patients stay drug and alcohol free—particularly for opioid use disorder. There are currently 3 approved treatments for opioid use disorder (buprenorphine, methadone and naltrexone)
which serve as the current standard of care. However, about 60 percent of patients lack access due to stigma associated with these treatments according to NIDA. There also is an urgent need to develop improved formulations of these medications to help improve adherence and reduce relapse. There is also a need for new pharmacologic treatments for opioid use disorders, such as vaccines against opioid addiction and other novel approaches. The FDA has recently announced that it will issue guidance to help facilitate the development of new medications for the treatment of opioid use disorder and new formulations of the existing drugs that could have attributes that are better tailored to patient needs.iv

- **Medications to reverse overdose.** Naloxone is very effective in reversing an opioid overdose when delivered in a timely manner. However, there is a need for more lay friendly devices and approaches to delivering the medicine as well as more potent formulations to reverse overdoses caused by increased availability of very potent illicit fentanyl and fentanyl analogues which are currently fueling overdose mortality.

We support policies to foster the development and use of abuse-deterrent formulations, non-opioid analgesics, addiction treatments, and medications to reverse overdose, including the use of existing FDA authorities to:

- Expedite review authorities to encourage the development of medical advances to address the opioid crisis,
- Foster the development of novel biomarkers and surrogate endpoints to potentially serve as basis for accelerated approval;
- Support development and use of novel clinical trials designs through increased regulatory flexibility; and
- Ensure appropriate staff expertise in various FDA review divisions and offices in various aspects of acute and chronic pain management and as well as mental illness given co-occurring mental illness and substance use disorder is extremely common.

PhRMA also supports efforts to accelerate the development of medical advances to address the crisis through public-private partnerships. Biopharmaceutical manufacturers, NIH and NIDA are currently exploring how they can collaborate to accelerate the development of new technologies and treatments to help break the cycle of addiction. As innovators, the biopharmaceutical industry plays a unique role to play in combatting the opioid crisis and that is why the industry is committed to ensure these innovations reach patients as quickly and safely as possible.

PhRMA support policies aimed at addressing a range of coverage and access barriers including policies to:
- Support the practice of screening for substance abuse and other mental health issues and referral to appropriate treatment. There is also a need to expand training opportunities to address a lack of sufficiently trained treatment providers, which currently impedes access to various forms of
medication-assisted treatments for addiction as well as impedes access to a range of other treatment and recovery support services.

- **Increase treatment capacity.** According to the President’s Commission report, almost 40 percent of all U.S. counties did not have a treatment facility for substance use disorder with the percentage reaching 55 percent in rural counties.

- **Address coverage and access barriers imposed by insurers and pharmacy benefit managers to ensure they are not contributing to the opioid crisis by impeding access to ADF medicines that have demonstrated potential to deter and prevent abuse, non-opioid pain medications, as well as medications to treat addiction and overdose.**
  - Payers often provide preferred formulary placement for generic formulations that lack abuse deterrent characteristics, despite the usefulness of abuse-deterrent formulations in preventing abuse and reducing health care costs associated with abuse.
  - There are often substantial barriers to MAT among third party payers as well as in Medicaid, including in commercial plans fail-first protocols and onerous and frequent prior authorization requirements which can significantly delay access to treatment, and as of 2015, 48 Medicaid programs required prior authorization for at least one form of medication-assisted treatment, buprenorphine.

- **Enforce the patient protections enacted by the Mental Health Parity Act passed in 1996, which provided that large group health plans could not impose annual or lifetime dollar limits on mental health benefits that are less favorable than any such limits imposed on medical/surgical benefits. The Affordable Care Act extended the protections by requiring coverage of mental health and substance use disorder services as an essential health benefit in individual and small group plans. However, current enforcement efforts have been insufficient.**

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1 Available at: https://www.whitehouse.gov/sites/whitehouse.gov/files/images/Final_Report_Draft_11-1-2017.pdf
3 FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on steps to promote development of generic versions of opioids formulated to deter abuse. November 2017. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm586117.htm
4 FDA Statement, Statement from FDA Commissioner Scott Gottlieb, M.D., on the approval of a new formulation of buprenorphine and FDA’s efforts to promote more widespread innovation and access to opioid addiction treatments. November 2017. https://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm587315.htm