Press Release

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SAFE Glen Cove Coalition: The FDA and the Opioid Crisis

In 2017, the Food and Drug Administration (FDA) announced their commitment to exploring the opioid crisis and collaborating on various approaches to address the opioid epidemic. An Opioid Policy Steering Committee (OPSC) was established to explore and develop additional approaches or strategies FDA can use to combat the opioid crisis. The Committee is comprised of senior FDA leaders as designated by the Commissioner and resides in the Office of Medical Products and Tobacco (OMPT) in the Office of the Commissioner.

The FDA's Opioid Action Plan has focused its efforts in the following four areas: Decreasing exposure and preventing new addiction; Supporting the treatment of those with Opioid Use Disorder; Fostering the development of novel pain treatment therapies; Improving enforcement and assessing benefit risk.

Dr. Scott Gottleib, Steering Committee member, discusses opioid misuse and abuse of "IR" immediate-release (IR) opioids. About 90 percent of all opioid pain medications prescribed – or 160 million prescriptions a year – are for IR formulations like hydrocodone and acetaminophen or oxycodone and acetaminophen combinations. Many people who are currently addicted to opioids became medically addicted. Their first exposure to opioids was from a legal prescription, and for many, that prescription was written for an IR formulation of these drugs. Many addicted patients may then move on to higher dose formulations or more accessible illegal street drugs.

The FDA feels that it is necessary to continue to take steps to address both ends of this continuum, the potential gateway to addiction that is often the IR formulations, and the higher dose, extended-release formulations, both of which carry a significant risk of overdose and mortality. They are taking action to address these challenges. For example, 74 manufacturers of IR opioid analgesics intended for use in the outpatient setting were informed that that their drugs will now be subject to a more stringent set of requirements under a Risk Evaluation and Mitigation Strategy (REMS). The REMS requires that training be made available to health care providers who prescribe IR opioids, including training on safe prescribing practices and consideration of non-opioid alternatives. The REMS requires that training be made available to health care providers who prescribe IR opioids, including training on safe prescribing practices and consideration of non-opioid alternatives.

Potential applicants who plan to develop, and submit to FDA, will be subjected to stringent application criteria when seeking approval of a generic version of abuse-deterrent formulations (ADFs) of opioid drugs. Most of the currently approved opioids with labeling describing abuse-deterrent properties are extended release/long-acting (ER/LA) formulations of opioids. These drugs are generally formulated to be more resistant to the sort of manipulation that would otherwise make them amenable to snorting and/or injecting. Addicted patients who start by using the IR drugs will sometimes migrate onto the ER/LA formulations, and then try to manipulate those higher-dose formulations in ways that can provide a more immediate “high” through injection or snorting. But there are currently only brand name ADF formulations. These steps that FDA is taking are aimed at addressing each end of the spectrum of abuse and addiction.

The SAFE Glen Cove Coalition is conducting an opioid prevention awareness campaign entitled "Keeping Glen Cove SAFE" to educate and update the community regarding opioid use and its consequences. For information about the Coalition visit us at: www.safeglencove.org, or follow us on: www.facebook.com/safeglencovecoalition.

To learn more about the FDA’s strategies to approach the opioid crisis, please visit go.usa.gov/xQxDU.