Press Release

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FOR IMMEDIATE RELEASE

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SAFE Glen Cove Coalition: FDA Requires Major Changes to Opioid Pain Medication Labeling to Emphasize Risks

The U.S. Food and Drug Administration (FDA) is requiring safety labeling changes to all opioid pain medications to better emphasize and explain the risks associated with their long-term use. These changes follow a public advisory committee meeting in May that reviewed data showing serious risks—such as misuse, addiction, and both fatal and non-fatal overdoses—for patients who use opioids over long periods. This labeling change will affect all opioid pain medications and support more informed decision-making FDA officials say the labeling change is long overdue and part of a larger process that also calls for modernizing their approval processes and post-market monitoring.

The updated labeling change reflects robust data from two large FDA-required observational studies, called postmarketing requirements (PMR) 3033-1 and 3033-2, which recently provided new data on how long-term opioid use can lead to serious side effects. After reviewing those results, public comments, medical research and recognizing the absence of adequate and well-controlled studies on long-term opioid effectiveness, the FDA decided to require safety labeling changes to help health care professionals and patients make evidence based treatment decisions. Unfortunately, the new drug application for OxyContin was initially approved without study data supporting its long term use to treat pain in many patient populations for which it has been prescribed.

The FDA has required an additional prospective, randomized, controlled clinical trial to directly examine the benefits and risks of long-term opioid use. The Agency will be closely monitoring the progress of this clinical trial to ensure its timely completion.

The labeling changes will include the following updates:

- Clearer Risk Information: A summary of study results showing the estimated risks of addiction, misuse, and overdose during long-term use.
- Dosing Warnings: Stronger warnings that higher doses come with greater risks, and that those risks remain overtime.

- Clarified Use Limits: Removing language which could be misinterpreted to support using opioid pain medications over indefinitely long duration
- Treatment Guidance: Labels will reinforce that long-acting or extended-release opioids should only be considered when other treatments, including shorter-acting opioids, are inadequate.
- Safe Discontinuation: A reminder not to stop opioids suddenly in patients who may be physically dependent, as it can cause serious harm.
- Overdose Reversal Agents: Additional information on medicines that can reverse an opioid overdose.
- Drug Interactions: Enhanced warning about combining opioids with other drugs that slow down the nervous system—now including gabapentinoids.
- More Risks with Overdose: New information about toxic leukoencephalopathy—a serious brain condition that may occur after an overdose.
- Digestive Health: Updates about opioid-related problems with the esophagus.

The FDA sent letters to the relevant applicants outlining the required changes. The companies will have 30 days to submit their labeling updates to the FDA for review.

More information is available in the FDA's Drug Safety Communication at https://www.fda.gov/drugs/drug-safety-and-availability

SAFE, Inc. is the only alcohol and substance abuse prevention, intervention and education agency in the City of Glen Cove. Its 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. To learn more about the SAFE Glen Cove Coalition please follow us on www.facebook.com/safeglencovecoalition or visit SAFE's website to learn more about the Opioid Epidemic at www.safeglencove.org.