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MANCHIN STATEMENT ON WALMART'S NEW OPIOID PRESCRIBING GUIDELINES

Washington, D.C. – U.S. Senator Joe Manchin (D-WV) applauded Walmart's announcement to limit the number of opioid pills prescribed for an initial opioid prescription, in line with the CDC's opioid prescribing guidelines, and to require e-prescriptions of opioids and other controlled substances to reduce abuse and diversion.

"I applaud Walmart's decision to proactively implement policies that will change the way they prescribe opioids and improve their prescription verification system. These changes will not only help us decrease the number of prescription opioids that make it to the street, but will help us crack down on fraudulent prescriptions. While I'm glad that there is a growing a coalition of companies that are proactively implementing changes to fight the opioid epidemic, there is more that has to be done. Physicians, pharmacies, community leaders, law enforcement, and countless others all must come together to find common sense solutions to this problem. It is my hope that other stakeholders take notice and engage in similar practices," Senator Manchin said.

Walmart and Sam's Club will restrict initial acute opioid prescriptions to no more than a seven-day supply, with up to a 50 morphine milligram equivalent maximum per day. Starting in 2020, Walmart and Sam's Club will require e-prescriptions for controlled substances because they are harder to tamper with.

U.S. Senator Joe Manchin applauded First Lady Melania Trump's "Be Best" initiative, which in part focuses on how the opioid epidemic impacts children and highlighted Huntington's Lily's Place, a facility that provides short-term medical care to babies born addicted to drugs.

"I applaud the First Lady for choosing to focus on how one of the biggest challenges facing our country, the opioid epidemic, impacts the most vulnerable among us, our children. The First Lady also highlighted Lily's Place in Huntington, which is doing crucial work to help our communities and families overcome opioid use disorder. I'm glad the First Lady is bringing national attention to this crisis and the tireless work West Virginians are doing to fight the opioid epidemic. I look forward to continuing to work with the First Lady, President Trump and his administration to protect our children from this horrible public health emergency," Senator Manchin said.

The First Lady rolled out the "Be Best" initiative, which includes helping children dealing with the opioid epidemic and preventing cyberbullying. The First Lady mentioned Lily's Place in her speech. Lily's Place provides treatment for infants with neonatal abstinence syndrome (NAS), a syndrome that occurs after birth in infants suffering from opioid withdrawals. West Virginia has the highest rate of NAS in the country, and Lily's Place handles overflow from hospitals in the Huntington area. The nonprofit is also the first clinic of its kind to provide counseling and treatment to parents.

U.S. Senators Joe Manchin , Dick Durbin (D-IL) and Ed Markey (D-MA) urged U.S. Food and Drug Administration (FDA) Commissioner Scott Gottlieb to remove ultra-high dose opioids removed from the market.

The Senators said in part: "A particular concern with ultra-high dose opioids is accidental ingestion, borrowed medication, and recreational use. Studies have shown that 12 million Americans misuse prescription opioids annually, and more than half of all misuse originates with a prescription opioid from a friend or relative. It is our understanding that the FDA may have evidence and adverse events data to understand the scope of misuse from ultra-high dose opioids.

"Last year, the National Academy of Sciences issued a report outlining a new framework for the FDA's opioid approval and removal decisions. We were pleased by your endorsement of this new approach that takes misuse potential into account when weighing the risks and benefits of opioid formulations. Given that palliative and cancer-related pain patients who require high opioid doses could still receive adequate treatment with multiple pills, patches, or other formulations, we believe these ultra-high dose opioids can be removed from the market without imposing hardship on those with legitimate pain needs."

Dear Commissioner Gottlieb:

Our nation's unprecedented opioid epidemic, which is killing 115 Americans every day, requires a comprehensive response from all stakeholders. Under your leadership, the U.S. Food and Drug Administration (FDA) has taken positive steps to reduce opioid addiction and overdose, including by expanding the Risk Evaluation and Mitigation Strategy (REMS) to immediate-release opioids, exploring ways to expand provider education, making packaging and labeling changes to protect against overconsumption, and requesting removal of Opana ER from the market due to its abuse potential. We commend you for spearheading these important initiatives. Today, we write to urge you to take additional action to protect Americans from unsafe products that pose disproportionate overdose risk by removing ultra-high dosage opioids from the market.

Ultra-high dose opioids are those which, when taken as directed by the label, exceed the Centers for Disease Control and Prevention's (CDC) threshold for dangerously high daily opioid intake of 90 morphine milligram equivalents. For example, the OxyContin 80mg tablet, can cause fatal respiratory depression when taken by a person without a high opioid tolerance—it is as powerful as 24 tablets of Vicodin. Additionally, the Subsys fentanyl spray comes in doses equal to 58 Vicodin tablets. Given the strength of a single dose of one of these opioids, it is shocking that such products remain on the market in the midst of our nation's opioid epidemic.

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Last year, the National Academy of Sciences issued a report outlining a new framework for the FDA's opioid approval and removal decisions. We were pleased by your endorsement of this new approach that takes misuse potential into account when weighing the risks and benefits of opioid formulations. Given that palliative and cancer-related pain patients who require high opioid doses could still receive adequate treatment with multiple pills, patches, or other formulations, we believe these ultra-high dose opioids can be removed from the market without imposing hardship on those with legitimate pain needs.

We understand that several medical and public health stakeholders have submitted a citizen petition under Section 355(e) of the Federal Food, Drug, and Cosmetic Act, asking the FDA to remove these high-dose opioid pills from the market given their outsized risks. We urge you to heed this important, potentially life-saving request. We appreciate your commitment to using all tools at the FDA's disposal to help address the opioid crisis.