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OBAMA ADMINISTRATION RELEASES ACTION PLAN TO ADDRESS NATIONAL PRESCRIPTION DRUG ABUSE EPIDEMIC; ANNOUNCES FDA ACTION REQUIRING DRUG MAKERS TO DEVELOP EDUCATION PROGRAM FOR PRESCRIBERS ABOUT SAFE USE OF OPIOIDS

New Strategy Strikes Balance between Cracking down on Drug Diversion and Protecting Delivery of Effective Pain Management

Washington, D.C.—Today, Gil Kerlikowske, White House Director of National Drug Control Policy; Assistant Secretary for **Health and Human Services**, Howard Koh, M.D.; Food and Drug Administration Commissioner, Margaret A. Hamburg, M.D.; and DEA Administrator, Michele M. Leonhart released the Obama Administration's comprehensive action plan to address the national prescription drug abuse epidemic and announced new Federal requirements aimed at educating the medical community about proper prescribing practices.

The Administration's *Epidemic: Responding to America's Prescription Drug Abuse Crisis* provides a national framework for reducing prescription drug diversion and abuse by supporting the expansion of state-based prescription drug monitoring programs, recommending more convenient and environmentally responsible disposal methods to remove unused medications from the home, supporting education for patients and healthcare providers, and reducing the prevalence of pill mills and doctor shopping through enforcement efforts. The plan is the culmination of six months of collaboration across the Federal government, with agencies including the Departments of Justice, Health and Human Services, Veterans Affairs, the Department of Defense, and others.

In support of the action plan, the Food and Drug Administration (FDA) today announced that it is requiring an Opioids Risk Evaluation and Mitigation Strategy (REMS). The new program will require manufacturers of long-acting and extended-release opioids to provide educational programs to prescribers of these medications, as well as materials prescribers can use when counseling patients about the risks and benefits of opioid use. The Food and Drug Administration Amendments Act of 2007 gave FDA the authority to require manufacturers to develop and implement a REMS to ensure the benefits of a drug or biological product outweigh its risks.

"Today we are making an unprecedented commitment to combat the growing problem of prescription drug abuse," said Vice President Biden. "The Government, as well as parents, patients, health care providers, and manufacturers all play a role in preventing abuse. This plan will save lives, and it will substantially lessen the burden this epidemic takes on our families, communities, and workforce."

"The toll our Nation's prescription drug abuse epidemic has taken in communities nationwide is devastating," said Director Kerlikowske. "We share a responsibility to protect our communities from the damage done by prescription drug abuse. This plan will build upon our already unprecedented efforts to coordinate a national response to this public health crisis by addressing the threat at the Federal, state, and local level."

"Abuse of prescription drugs, especially opioids, represents an alarming public health crisis," said Howard K. Koh, M.D., M.P.H. Assistant Secretary for Health. "This Plan, which coordinates a public health approach with a public safety approach, offers hope and health to our Nation."

"Unintentional drug overdose is a growing epidemic in the US and is now the leading cause of injury death in 17 states," CDC Director Dr. Thomas Frieden said. "There are effective and emerging strategies out there to address

this problem. Support for this action plan will help us implement those strategies which will go a long way to save lives and reduce the tremendous burden this problem has on our healthcare system and our society."

"Long-acting and extended-release opioid drugs have benefit when used properly and are a necessary component of pain management for certain patients, but we know that they pose serious risks when used improperly, with serious negative consequences for individuals, families, and communities," said FDA Commissioner Margaret A. Hamburg, M.D. "The prescriber education component of this Opioid REMS balances the need for continued access to these medications with stronger measures to reduce their risks."

"DEA is committed to implementing this important and much needed action plan to reduce the demand for prescription drugs, enforce our nation's drug laws, and take back unneeded prescription drugs," said DEA Administrator Michele M. Leonhart. "When abused, prescription drugs are just as dangerous and just as addictive as drugs like methamphetamine or heroin. The more we can do to stop the abuse of prescription drugs, the more effective we will be in reducing the death, destruction and despair that accompanies all drug abuse."

Prescription drug abuse is our Nation's fastest-growing drug problem. The number of people who have unintentionally overdosed on prescription drugs now exceeds the number who overdosed during the crack cocaine epidemic of the 1980's and the black tar heroin epidemic of the 1970's combined. In 2007, approximately 27,000 people died from unintentional drug overdoses, driven mostly by prescription drugs. Additionally, according to the Substance Abuse and Mental Health Services Administration, the number of Americans in 2009 aged 12 and older currently abusing pain relievers has increased by 20 percent since 2002. Further, visits by individuals to hospital emergency rooms involving the misuse or abuse of pharmaceutical drugs have doubled over the past five years.

ONDCP is coordinating an unprecedented government-wide public health approach to reduce drug use and its consequences in the United States. This effort includes requesting an increase in funding for drug prevention by \$123 million and treatment programs by \$99 million dollars for Fiscal Year 2012, to train and engage primary health care to intervene in emerging cases of drug abuse, expand and improve specialty care for addiction—including care for families and veterans, and to better manage drug-related offenders in community corrections.

To read the full Action Plan, [click here](#).

To read the FDA's Opioids Risk Evaluation and Mitigation Strategies (REMS), [click here](#).

To get involved in DEA's National Prescription Drug Take-Back Initiative, [click here](#).

For more information on National efforts to reduce drug use and its consequences visit: www.WhiteHouseDrugPolicy.gov

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