



# THE COMMITTEE ON ENERGY AND COMMERCE

## MEMORANDUM

June 12, 2013

To: Members of the Subcommittee on Health

From: Majority Committee Staff

Re: Examining the Federal Government's Response to the Prescription Drug Abuse Crisis

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On June 14, 2013, at 9:30 a.m. in 2123 Rayburn House Office Building, the Subcommittee on Health will hold the first in a series of hearings on the nation's prescription drug abuse crisis. This hearing is entitled "Examining the Federal Government's Response to the Prescription Drug Abuse Crisis." The following memorandum provides background on the hearing witnesses and federal efforts to address the prescription drug abuse crisis.

### **I. WITNESSES**

Mr. R. Gil Kerlikowske  
Director  
Office of National Drug Control Policy (ONDCP)

Dr. Doug Throckmorton  
Deputy Director  
Regulatory Programs  
Center for Drugs Evaluation and Research  
Food and Drug Administration (FDA)

Dr. H. Westley Clark  
Director  
Center for Substance Abuse Treatment  
Substance Abuse and Mental Health Services Administration (SAMHSA)

### **II. BACKGROUND**

Prescription drug abuse has plagued the U.S. for many years and continues to be a growing problem. The Centers for Disease Control and Prevention (CDC) classified prescription painkiller abuse as a health epidemic and determined that this is the fastest growing drug problem in the U.S. Over the past decade there has been a more than fourfold increase in opioid overdose deaths as well as increase in sales of these drugs.<sup>1</sup> The direct health care cost of prescription drug abuse exceeds \$70 billion every year.<sup>2</sup>

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<sup>1</sup> Substance Abuse and Mental Health Services Administration. "Results from the 2010 National Survey on Drug Use and Health: Detailed Tables." U.S. Department of Health and Human Services. [September 2011]. Available:

In August 2005, Congress enacted the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER, P.L. 109-60), a bipartisan effort of the Energy and Commerce Committee led by Mr. Whitfield and Mr. Pallone. The law fostered the implementation and enhancement of State prescription drug monitoring programs, which are used to track controlled substances prescribed by doctors and dispensed by pharmacists.

In 2011, the Administration released a prescription drug abuse plan, entitled “Epidemic: Responding to America’s Prescription Drug Abuse Crisis,” which outlines proposals in four areas to address the prescription drug abuse crisis: education, monitoring, proper disposal, and enforcement.<sup>3</sup>

On July 9, 2012, President Obama signed the Food and Drug Administration Safety and Innovation Act (FDASIA, P.L. Law 112-144) into law. FDASIA includes several provisions regarding prescription drug abuse.<sup>4</sup> First, under section 1122 of FDASIA, the Secretary of Health and Human Services (HHS) must review Federal programs and identify gaps regarding prescription drug abuse and treatments for those with prescription drug dependence. The Secretary of HHS must release this report no later than July 2013. Further, section 1122 requires FDA to issue guidance on developing abuse-deterrent products. In January, to its credit, FDA issued the guidance as required. It is entitled “Abuse Deterrent Opioids – Evaluation and Labeling.”<sup>5</sup>

Second, section 1139 of FDASIA requires FDA to hold a public meeting on the scheduling of hydrocodone. FDA held the meeting in January 2013. Third, under section 1141 of FDASIA, the Secretary of HHS must issue a report on enhancing the interoperability of State prescription drug monitoring programs. This report is due no later than July 2013.

This hearing provides an opportunity for the Subcommittee to hear from FDA, SAMHSA, and ONDCP on the current federal efforts to fight prescription drug abuse.

### **III. STAFF CONTACTS**

If you have any questions regarding the hearing, please contact Carly McWilliams, Brenda Destro, Paul Edattel or Katie Novaria at (202) 225-2927.

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<http://www.samhsa.gov/data/nsduh/2k10NSDUH/tabs/LOTsect7pe.htm#TopOfPage>

<sup>2</sup> Drug Enforcement Administration. “Prescription for Disaster: How Teens Abuse Medicine 2nd Edition.” U.S. Department of Justice. [Revised August 2012]. Available: [http://www.justice.gov/dea/pr/multimedia-library/publications/prescription\\_for\\_disaster\\_english.pdf](http://www.justice.gov/dea/pr/multimedia-library/publications/prescription_for_disaster_english.pdf)

<sup>3</sup>For more information please go to: [http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx\\_abuse\\_plan.pdf](http://www.whitehouse.gov/sites/default/files/ondcp/policy-and-research/rx_abuse_plan.pdf)

<sup>4</sup> The text of FDASIA can be found here: <http://www.gpo.gov/fdsys/pkg/PLAW-109publ60/pdf/PLAW-109publ60.pdf>

<sup>5</sup> The guidance document can be found here:

<http://www.fda.gov/NewsEvents/Newsroom/PressAnnouncements/ucm334785.htm>