

ONE HUNDRED THIRTEENTH CONGRESS  
**Congress of the United States**  
**House of Representatives**  
COMMITTEE ON ENERGY AND COMMERCE  
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July 9, 2013

Dr. H. Westley Clark  
Director  
Center for Substance Abuse Treatment  
Substance Abuse and Mental Health  
Services Administration  
1 Choke Cherry Road  
Rockville, MD 20857

Dear Dr. Clark:

Thank you for appearing before the Subcommittee on Health on Friday, June 14, 2013, to testify at the hearing entitled "Examining the Federal Government's Response to the Prescription Drug Abuse Crisis."

Pursuant to the Rules of the Committee on Energy and Commerce, the hearing record remains open for ten business days to permit Members to submit additional questions for the record, which are attached. The format of your responses to these questions should be as follows: (1) the name of the Member whose question you are addressing, (2) the complete text of the question you are addressing in bold, and (3) your answer to that question in plain text.

To facilitate the printing of the hearing record, please respond to these questions by the close of business on Tuesday, July 23, 2013. Your responses should be mailed to Sydne Harwick, Legislative Clerk, Committee on Energy and Commerce, 2125 Rayburn House Office Building, Washington, D.C. 20515 and e-mailed in Word format to [Sydne.Harwick@mail.house.gov](mailto:Sydne.Harwick@mail.house.gov).

Thank you again for your time and effort preparing and delivering testimony before the Subcommittee.

Sincerely,  
  
Joseph R. Pitts  
Chairman  
Subcommittee on Health

cc: The Honorable Frank Pallone, Jr., Ranking Member, Subcommittee on Health

Attachment

## Attachment—Additional Questions for the Record

### The Honorable Joseph R. Pitts

1. The Center for Substance Abuse Treatment (CSAT) recently released an RFA for a “Physician Clinical Support System – Medication Assisted Treatment” to support physician education on the use of medications to treat opioid addiction. The RFA states “...the number of people who have been inducted on extended release injectable naltrexone remains relatively low” and that “...training in the appropriate use and indications for extended release injectable naltrexone is highly needed<sup>1</sup>.” How does CSAT plan to expand its efforts to increase awareness and knowledge about this medication?
2. Earlier this year SAMHSA reported that “Hospital emergency department visits linked to buprenorphine have increased 10-fold from 2005 to 2010 with 52 percent of these emergency room cases involving non-medical (illicit) use.”<sup>2</sup> Likewise, the DEA’s Office of Diversion Control reports that buprenorphine is now the 3<sup>rd</sup> most diverted prescription opioid today, surpassing methadone, and second only to oxycodone and hydrocodone<sup>3</sup>. Given these unintended and other unwelcomed and unanticipated consequences<sup>4,5,6</sup> what is CSAT doing to help reduce the illicit use of this medication?
3. SAMHSA supports a number of web-based treatment locators<sup>7</sup> for the professional community and the general public. We found one that lists methadone clinics<sup>8</sup> and one that lists physicians who offer buprenorphine treatment<sup>9</sup>. Does SAMHSA have a similar locator for patients who are seeking extended release naltrexone? What plans does SAMHSA have to provide, on an equal basis, information for accessing all FDA-approved medications to treat opioid dependence?
4. In Administrator Hyde’s testimony before the Energy and Commerce Committee on Oversight and Investigations Hearing on May 22, 2013, she stated that much of SAMHSA’s funding goes to the block grants, which are passed on to the states to fund substance abuse treatment – which is about \$1.8 billion for substance abuse prevention and treatment. We understand that a significant portion of addicted individuals relapse to drug use.<sup>10,11,12</sup> Further, we understand that, for the treatment of opioid dependence, SAMHSA dedicates a great deal of funding, time and effort on the development and delivery of education and

<sup>1</sup> See: FY 2013 Cooperative Agreement for the Physician Clinical Support System – Medication Assisted Treatment at: <http://www.samhsa.gov/grants/2013/ti-13-003.aspx> [accessed June 10, 2013]

<sup>2</sup> See: <http://www.samhsa.gov/newsroom/advisories/1301293122.aspx>

<sup>3</sup> See: [http://www.deadiversion.usdoj.gov/nflis/2011annual\\_rpt.pdf](http://www.deadiversion.usdoj.gov/nflis/2011annual_rpt.pdf)

<sup>4</sup> Goodnough & Zezima. When Children’s scribbles hide a prison drug. *New York Times*, May 26, 2011 Accessed January 16, 2012 at <http://www.nytimes.com/2011/05/27/us/27smuggle.html>.

<sup>5</sup> Bazazi, A.R., Yokell, M., Fu, J.J., Rich, J.D., Zaller, N.D., “Illicit Use of Buprenorphine/Naloxone Among Injecting and Noninjecting Opioid Users,” *Journal of Addiction Medicine*. Volume 5, Number 3, September 2011.

<sup>6</sup> <http://www.samhsa.gov/newsroom/advisories/1301293122.aspx>

<sup>7</sup> See: <http://www.samhsa.gov/treatment/index.aspx> [accessed June 10, 2013]

<sup>8</sup> See: <http://dpt2.samhsa.gov/treatment/directory.aspx> [accessed June 10, 2013]

<sup>9</sup> See: [http://buprenorphine.samhsa.gov/bwns\\_locator/](http://buprenorphine.samhsa.gov/bwns_locator/) [accessed June 10, 2013]

<sup>10</sup> Weiss, R. et al. (2011). Adjunctive Counseling During Brief and Extended Buprenorphine-Naloxone Treatment for Prescription Opioid Dependence. *Archives of General Psychiatry*. 68(12):1238-46

<sup>11</sup> Fudala, P. (2003). Office-Based Treatment of Opiate Addiction with a Sublingual-Tablet Formulation of Buprenorphine and Naloxone, *New England Journal of Medicine*, 349 (10); 949-958.

<sup>12</sup> Johnson, R. et al. (2000). A controlled trial of levomethadyl acetate, buprenorphine, and methadone for opioid dependence. *New England Journal of Medicine*; 343: 1290-1297

training activities<sup>13, 14</sup> with respect to substitution, or replacement therapies. Is it within the authority of SAMHSA to provide stronger guidance to states to use some percent of their block grant funds on FDA-approved non-addictive medications?

5. Over the last two fiscal years, SAMHSA has reduced funding of its Opioid Treatment Programs from \$12.8 million in FY 2012 to \$8.746 million in FY 2014 – including a proposed \$200,000 reduction in the coming fiscal year<sup>15</sup>. While we applaud the fiscal restraint, we are concerned that funding is being reduced from the Opioid Treatment Programs initiatives in particular. Is there a rationale for this particular reduction in light of the prescription drug epidemic and the increasing number of opioid overdose deaths?
6. According to the Drug Abuse Warning Network (DAWN) report released by SAMHSA in July of 2012 emergency department visits for drug misuse and abuse for pharmaceuticals rose 115% between 2004 to 2010, would you talk about this data and the reasons for the increase?
7. SAMHSA's National Survey on Drug Use and Health revealed an estimated 54% of the prior-year non-medical users of prescription pain relievers obtained the drugs for free from a friend or relative where less than 1% reported receiving them from the Internet. How do we solve a problem that is primarily happening at home?

### **The Honorable Phil Gingrey**

1. Over the past decade, SAMHSA has expended substantial resources in the development and implementation of training, education and demonstration programs with respect to buprenorphine. What plans does SAMHSA have for comparable education and training programs on injectable naltrexone?
2. On November 30, 2006, SAMHSA released a report entitled “**Diversion and Abuse of Buprenorphine: A Brief Assessment of Emerging Indicators Final Report.**” At that time, the Summary of the Report stated “*The phenomenon [of diversion] may reflect lack of access to addiction treatment, as some non-medical use [of buprenorphine] appears to involve attempts to self-medicate with buprenorphine when formal treatment is not available.*” As of today, however, buprenorphine appears to be widely available, with well over a million people dosed and sales in the U.S. over \$1 billion annually. Given the recent reports by the DEA and others, do you agree that an updated review of buprenorphine diversion and abuse is warranted?
3. How many patients are currently treated each year with the three medications approved by the FDA for the treatment of opioid addiction: buprenorphine, methadone, and injectable naltrexone? Is the “exit strategy” for transitioning opioid dependent Americans who are currently being treated with opioid dependence therapies from physical dependence on opioids to opioid-free and medication-free?

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<sup>13</sup> See: SAMHSA Justification of Estimates for Appropriations Committees, FY 2013 accessed June 4, 2013 at: <http://www.samhsa.gov/Budget/FY2013/SAMHSAFY2013CJ.pdf>

<sup>14</sup> SAMHSA Justification of Estimates for Appropriations Committees, FY 2014 accessed June 4, 2013 at: <http://www.ihs.gov/BudgetFormulation/documents/FY2014BudgetJustification.pdf>

<sup>15</sup> Health & Human Services, Substance Abuse and Mental Health Services Administration, Justification of Estimates for Appropriations Committees, FY 2014, pp.

4. In December 2012, SAMHSA issued new regulations that expanded the use of buprenorphine in opioid treatment programs (OTPs), or what formerly were referred to as methadone clinics. In the section of this Regulations labeled “Costs and Benefits,” it states “There may be additional diversion and abuse risks associated with the possible expansion of treatment, but the Secretary believes that the benefits of increased flexibility and increased access to care in OTP settings outweighs these possible risks.” Please elaborate on the risk/benefit analysis undertaken, as referred to in this regulation.

**The Honorable Bill Cassidy and H. Morgan Griffith**

In your oral testimony, you indicated that the federal government is moving toward using electronic health records (EHRs) to develop algorithms to identify outliers of physicians prescribing large amounts of controlled prescription drugs. Please define precisely how the federal government plans on using EHRs for this purpose, including the scope of information the federal government will have access to. Specifically, what level of patient information will the federal government have access to?

**The Honorable Gus Bilirakis**

1. Recently, there was a drug summit in Pasco County, FL where public health officials were talking about the growing problem of babies born addicted to prescription drugs. The Pasco-Pinellas area ranks first in the state for babies born addicted. What tools, programs and grants are available for my community to combat this problem?
2. What changes can we make to our prescription drug laws to make it harder for people to improperly obtain and abuse prescription drugs?