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Responses to Questions for the Record
Energy and Commerce Committee, Subcommittee on Health Hearing
June 14, 2013
“Examining the Federal Government’s Response to the Prescription Drug Abuse Crisis”

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 medication to treat opioid addiction. The RFA states “...the number of people who have been inducted to extended release injectable naltrexone remains relatively low” and that “...training in the appropriate use and indications for extended release injectable naltrexone is highly needed.” How does CSAT plan to expand its efforts to increase awareness and knowledge about this medication?**

The new Substance Abuse and Mental Health Services Administration (SAMHSA) Physician Clinical Support System - Medication Assisted Treatment (PCSS-MAT) grant will increase prescribers’ awareness and knowledge about extended release naltrexone (Vivitrol ®) by providing training opportunities that utilize several different formats including online modules, case studies, webinars and others. These activities are expected to reach approximately 30,000 physicians over the three years of the grant period.

- 2. Earlier this year SAMHSA reported that “Hospital emergency department visits linked to buprenorphine have increased 10-fold from 2005 to 2012 with 52 percent of these emergency room cases involving non-medical (illicit) use.” Likewise, the DEA’s Office of Diversion Control reports that buprenorphine is now the 3rd most diverted prescription opioid today, surpassing methadone, and second only to oxycodone and hydrocodone. Given these unintended and other unwelcomed and unanticipated consequences, what is CSAT doing to help reduce the illicit use of this medication?**

Buprenorphine abuse and diversion are measurable; however, the levels of actual abuse (not adjusted for rate of use) and diversion are noticeably less than other opioids. In addition, certain peer-reviewed studies looking at buprenorphine diversion and nonmedical use indicate that some of this use is occurring because people do not have access to substance abuse treatment.

SAMHSA is currently updating the agency’s buprenorphine curriculum. The new curriculum has a specific section addressing the issue of non-medical (illicit) use. The revised curriculum, titled “The DATA 2000 Waiver Course,” will emphasize the importance of using state prescription drug monitoring programs prior to and over the

course of treatment as well as appropriate use of buprenorphine products in the treatment of opioid dependence. The importance of toxicology screening, of requiring psychosocial treatment in addition to medication use, appropriate dose determination, and methods of monitoring progress in treatment which should be considered in setting frequency of office visits and amount of prescribed medication that is provided to a patient will also be emphasized in the curriculum.

- 3. SAMHSA supports a number of web-based treatment locators for the professional community and the general public. We found one that lists methadone clinics and one that lists physicians who offer buprenorphine treatment. 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?**

SAMHSA's Behavioral Health Treatment Services Locator (Locator)¹ currently allows referring professionals and the general public to search for facilities that provide medication-assisted opioid therapy with methadone and buprenorphine. The information in the Locator is collected by the National Survey of Substance Abuse Treatment Services (N-SSATS), an annual census of specialty substance abuse treatment facilities. A question on Vivitrol (extended-release injectable naltrexone) was added to the N-SSATS 2013 survey. Thus, the next time the Locator is updated, currently scheduled for early 2014, it will allow visitors to identify facilities that provide treatment with Vivitrol.

- 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. 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 training activities 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?**

The statute (42 U.S.C. §§ 300x-21 through 300x-66) and implementing regulations (45 CFR 96.120 through 96.137) governing the Substance Abuse Prevention and Treatment Block Grant (SABG) program provide states and jurisdictions with the flexibility to plan, carry out and evaluate activities to prevent and treat substance abuse according to the needs in that state. SAMHSA has provided guidance to the states on the services and levels of care that constitute a full continuum of care which includes medication-assisted treatment. The statute and regulation do not include any prescriptive language regarding any specific service, including pharmacologic therapies. However, in

¹ <http://findtreatment.samhsa.gov>.

the application guidance for the block grant application (Table 4, page 30), under the heading “SAPT Projected Expenditures for Treatment and Recovery” SAMHSA has clarified that up to 10 percent of the funds available can be used for medication management, pharmacotherapy (including all FDA-approved medications for treating substance use disorders), and laboratory services.

- 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. 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 increasing number of opioid overdose deaths?**

The funding for Opioid Treatment Programs (OTP) in FY 2012 totaled \$12.9 million, of which \$8.9 million came from SAMHSA budget authority and \$4 million from the Prevention and Public Health Fund. In FY 2013, SAMHSA’s budget authority for all programs was reduced by 5 percent due to sequestration. However, given the Department of Health and Human Services’ priority on prescription drug abuse prevention and treatment, SAMSHA reallocated funds within its appropriation as displayed on its FY 2013 operating plan to include \$12.4 million for OTPs.

- 6. According to the Drug Abuse Warning Network (DAWN) report released by SAMHSA in July of 2012 emergency department visits for drugs misuse and abuse for pharmaceuticals rose 115% between 2004 to 2010, would you talk about this data and the reason for the increase?**

Over 80 percent of the annual increase of about 720,000 emergency department (ED) visits for misuse and abuse of pharmaceuticals from 2004 to 2010 is due to increases in the misuse and abuse of two types of medications: prescription opiates and opioids, and benzodiazepines. According to the Centers for Disease Control and Prevention (CDC), this increase in ED visits is paralleled by an increase in opioid and benzodiazepine related overdose deaths. Misuse and abuse of prescription opiate and opioid medications (approximately 350,000 more visits in 2010 than in 2004, an increase of about 175 percent) and benzodiazepines (approximately 235,000 more visits in 2010 than in 2004, an increase of about 140 percent) have caused increasing concern over the last decade. Opiates and opioids and benzodiazepines are safe and effective medications when they are used as directed by the people for whom they are prescribed. However, they are also addictive substances with potential for abuse. It is likely that there are multiple causes contributing to the increase in misuse and abuse of these medications. Some portion may be associated with the greater number of prescriptions being written, making prescription drugs more accessible and able to be diverted and used for nonmedical purposes.

- 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?

SAMHSA has partnered with the National Council on Patient Information and Education on the “Not Worth the Risk – Even If It’s Legal” campaign to develop and distribute a comprehensive range of educational and outreach messages encouraging parents to talk to their teens about preventing prescription drug abuse. In addition, SAMHSA has partnered with the Community Anti-Drug Coalitions of America (CADCA) to host Community Prevention Day where participants receive training and technical assistance that is specific to substances abuse prevention including prevention of prescription drug abuse. SAMHSA works with CADCA to get the message out to patients, parents, family members and other involved persons in communities to promote the responsible use of pain medications and other prescription drugs.

SAMHSA’s Strategic Prevention Framework – Partnerships for Success II (SPF-PFS II) grant is designed to address two of the nation’s top substance abuse prevention priorities: (1) underage drinking among persons aged 12 to 20; and (2) prescription drug misuse and abuse among persons aged 12 to 25. The program promotes the alignment and leveraging of prevention resources and priorities at the federal, state, and community levels. SAMHSA’s Drug-Free Communities Support Program grants, in partnership with the Office of National Drug Control Policy (ONDCP), provide funding to support established community-based youth substance use prevention coalitions capable of effecting community-level change.

The SABG is a formula-based grant provided to states and territories to provide financial support for its prevention and treatment programs and services. Federal statute requires states and territories to direct at least 20 percent of the SABG toward substance abuse prevention services. For many states and territories, this funding represents the vast majority of their substance abuse prevention budget. Under the SABG, states are requested to identify the categories of substances, including prescription drugs, they intend to address with the 20 percent set-aside for prevention based on data collected and analyzed from statewide and local needs assessments.

Educating prescribers and dispensers of controlled substance pharmaceuticals on the potential abuse caused by these substances is also critically important as they will, in turn, provide patient education. SAMHSA funded the development of live and online CME courses on Prescribing Opioids for Chronic Pain for providers in consultation with the American Academy of Pain Medicine, Case Western Reserve University School of Medicine, and an independent panel of experts in medical education, pharmacology, pain management, regulation, and addiction. Variations of the course were developed to meet the needs of the Indian Health Service, the military and medical specialties such as emergency medicine.

SAMHSA is working with the Drug Enforcement Administration (DEA) on Take Back programs which provide a safe, convenient, and responsible means of disposing of

prescription drugs. SAMHSA is working with physician and pharmacy groups to promote the adequate education of patients and consumers.

Ultimately, the transformation of attitudes at the local level involves local people. SAMHSA, in conjunction with our colleagues at the National Institutes of Health, the Food and Drug Administration, CDC, and DEA can assist by providing technical assistance to local authorities and local organizations to aid in the shifting in attitudes about the appropriate use, storage and disposal of prescription drugs.

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 the injectable naltrexone?**

The new PCSS-MAT grant will increase prescribers' awareness and knowledge about extended release naltrexone by providing training opportunities that utilize several different formats including online modules, case studies and webinars on the use of naltrexone in both oral and injectable formulations. These activities are expected to reach approximately 30,000 physicians over the three years of the grant period.

- 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?**

It is important to note that two publications² from 2009 address diversion and abuse of buprenorphine and arrived at essentially the same conclusions as the 2006 SAMHSA report. An updated review of diversion and abuse of buprenorphine is being considered by SAMHSA. At this time, SAMHSA notes that, to be most valuable, a review on diversion and abuse of buprenorphine would need to be designed to assess the degree to which previous recommendations have been implemented and the impact of such activity. Given the N-SSATS 2011 shows a significant unmet need for opioid addiction treatment, any new report should also assess the availability and impact of medication assisted treatment not only on diversion and abuse, but also on overdose fatalities.

- 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 opioids-free and medication-free?**

² Johanson CE, Arfken CL, di Menza S, Schuster CR. Diversion and abuse of buprenorphine: findings from national surveys of treatment patients and physicians. *Drug Alcohol Depend.* 2012 Jan 1; 120(1-3):190-5. doi: 10.1016/j.drugalcdep.2011.07.019. Epub 2011 Aug 21.

Center for Substance Abuse Research (CESAR) at University of Maryland, "CESAR Fax Special Series: Buprenorphine," June 13, 2011 – September 12, 2011, available at: <http://www.cesar.umd.edu/cesar/pubs/20110915%20Buprenorphine%20CESAR%20FAX.pdf>.

According to N-SSATS 2011:

- 306,000 persons were receiving methadone for addiction treatment in 2011 through SAMHSA certified OTPs.
- 32,676 persons received buprenorphine through licensed treatment programs. This number includes 7,020 who were in treatment at OTPs and 25,656 who were in treatment at substance abuse treatment facilities that were not OTPs.³

SAMHSA does not collect information on how many individual patients are treated with buprenorphine outside of licensed treatment facilities or with injectable naltrexone.

SAMHSA sponsored programs provide education to physicians on clinical strategies to taper and discontinue opioids including opioid analgesics or heroin, but research consistently indicates high relapse rates after medical withdrawal. Similarly, relapse rates following discontinuation of opioid agonist therapy (methadone or buprenorphine/naloxone) for opioid dependence are very high and associated with significant morbidity and mortality. Research is needed to identify modifiable variables associated with relapse, positive predictors of ongoing remission of addiction after treatment with opioid agonists and optimal time-frames and dosing schedules for titration off of medication as well as the effectiveness of a transition to naltrexone following medical withdrawal.

- 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.**

OTPs are highly regulated and are required by law to provide behavioral therapy and monitor patient toxicology screens which assure maximum benefit of treatment for the patient. To assure safety of the community, patients are not permitted to take medication home for unsupervised self-administration unless they meet specific criteria designed to establish their stability, progress in recovery, and ability to protect their medication from misuse or diversion (42 CFR 8.12(i)(2)). All of these stipulations continue to apply to patients receiving buprenorphine from an OTP. The rule published in December 2012 allows physicians who are treating OTP patients with buprenorphine to dispense buprenorphine for unsupervised self-administration without fulfilling the time-in-

³ OTPs are certified by SAMHSA and are the only kinds of facilities that can legally dispense methadone or buprenorphine for the treatment of opioid addiction. Other substance abuse treatment facilities that are not SAMHSA-certified OTPs can prescribe buprenorphine if they have a specially qualified physician on staff, but they may not dispense buprenorphine or methadone. Only OTPs can dispense these drugs.

treatment requirements which continue to apply to methadone. Based on experience to date with the safety of buprenorphine provided via the less restrictive environment of office-based treatment, allowing earlier and more individualized consideration for take-home dosing was deemed an appropriate measure to reduce the cost of treatment to the patient. Relaxing the need to present daily at the OTP in order to receive buprenorphine reduces distance and time spent traveling and permits a more expeditious reintegration of the recovering individual to family and work life. Finally, as noted that it would in the Final Rule, SAMHSA is sending a formal guidance letter to all OTP Medical Directors encouraging them to complete buprenorphine training and obtain a waiver. In the letter, SAMHSA provided links to Web sites where OTP physicians can complete on-line qualifying training.

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. Specially, what level of patient information will the federal government have access to?

In September 2011, the Centers for Medicare & Medicaid Services (CMS) began working on an approach to help health plans to identify and manage the most egregious cases of opioid overutilization. Comprehensive policy was set forth in a final Call Letter (April 2012) and in more detail in final supplemental guidance (August 2012). In September 2012, CMS issued a memorandum which provided supplemental guidance regarding the section of the Final CY 2013 Call Letter entitled, “Improving Drug Utilization Review Controls in Part D” which sets forth how Medicare Part D sponsors can comply with drug utilization management (DUM) requirements (42 CFR 423.153 *et seq.*) to prevent overutilization of prescribed covered Part D drugs.

As noted in the Final CY 2013 Call Letter, Part D sponsors are, and have been, responsible for establishing reasonable and appropriate drug utilization management programs that assist in preventing overutilization of prescribed medications. Through discussions with the industry, CMS has determined that sponsors need to employ more effective concurrent and retrospective drug utilization review (DUR) programs to address overutilization of medications in order to protect beneficiaries, to comply with DUM requirements and to reduce fraud, waste and abuse in the Part D program. CMS is developing monitoring tools which will identify outliers in opioid use.

SAMHSA is beginning to work with CMS to explore ways to collaborate on addressing the issues of overutilization of opioids and utilizing the capabilities of health information technology (IT) and electronic health records (EHRs). In addition, SAMHSA has focused efforts on HIT to improve access to Prescription Drug Monitoring Programs (PDMPs).

In 2011, SAMHSA initiated the Enhancing Access to PDMPs Project with the goal of using health information technology to improve access to PDMPs in an effort to reduce prescription drug abuse, misuse and overdose in the United States. The project was funded by SAMHSA and managed by the Office of the National Coordinator for Health Information Technology (ONC) in collaboration with SAMHSA, CDC, and ONDCP. During the first part of this two-part project, workgroups of individuals representing state and federal governments as well as industry, trade and advocacy groups, convened to discuss problems related to the transport and use of PDMP data. Recommendations were developed with the aim of facilitating information sharing for healthcare providers in order to make better informed clinical decisions. The second part of the project identified, developed, and implemented pilots that tested linkages between PDMPs and provider EHR systems and pharmacy systems. The results demonstrated the value of increased access to PDMP data at the point of care.

In 2012, SAMHSA provided additional funding to ONC to extend the project for six months to increase the number of pilot sites or the number of states supplying PDMP data in existing pilots and also launch new pilots to test new types of integration. The next phase of the project began in early 2013 and will expand the number of sites (to test scalability) or the number of states supplying PDMP data. Additional pilot sites also tested new types of integration including connecting through a health information exchange and looking at how data can be sent in near real-time from a pharmacy to the PDMP. This phase also focused on work around the goal of creating and disseminating messaging to PDMP stakeholders, especially prescribers and dispensers. Additionally, a “PDMP Resource Center” was developed to enable the entire PDMP community to share its experiences in one location. The Resource Center includes information on an open source reference implementation on PDMP/EHR exchange that can be adopted by PDMPs.

In FY 2012, SAMHSA established the PDMP Electronic Health Record Integration and Interoperability Expansion program, with \$4 million in funding from the Prevention and Public Health Fund. Working collaboratively with the Harold Rogers Prescription Drug Monitoring National Training and Technical Assistance Program at the Department of Justice, this program complements existing federal efforts by improving real-time access to PDMP data through integration into existing technologies, such as EHRs, to improve the ability of state PDMPs to reduce the nature, scope, and extent of misuse. CDC will evaluate the program and report on the best practices developed and impacts of PDMP-EHR integration and how they can be utilized by other states working to link PDMPs to other health IT systems.

In FY 2013, SAMHSA anticipates awarding up to eight grants for EHR and PDMP data integration. The purpose of this program is to reduce prescription drug misuse and abuse by providing healthcare providers with access to PDMP data to make sound clinical decisions without disturbing their regular clinical work.

The PDMP EHR grant cooperative agreement program addresses minimum requirements for security of the database, specifically: “information from the PDMPs must be stored and protected in an electronic manner and must, at a minimum, be equivalent to the standards set forth in regulations promulgated under section 262 of HIPAA. This would include the technical safeguards standards of the HIPAA Security Rule under 45 CFR 164.312. In addition, this program does not supersede the requirements of the Federal substance abuse confidentiality law (42 U.S.C. 290dd-2) and regulations under 42 CFR Part 2.”

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. What tools, programs and grants are available for my community to combat this problem?**

The statute (42 U.S.C. § 300x-22; 42 U.S.C. §300x-27) and implementing regulations (45 CFR 96.124(c)(e) and 45 CFR 96.131) governing the SABG program requires states to focus preventative efforts on substance-using pregnant women and women with dependent children.⁴ In the FY 2013 SABG report, prepared and submitted by the Substance Abuse and Mental Health Program Office of the Florida Department of Children and Families, the state obligated and expended \$12.4 million for services designed for such women and their dependent children. During the state fiscal year 2011-2012, the state served 1,235 pregnant women. The Substance Abuse and Mental Health Program Office of the Florida Department of Children and Families distributes its SABG and state general revenue funds to the state's 20 circuits.

The National Center on Substance Abuse and Child Welfare (NCSACW)⁵ is an initiative of the Department of Health and Human Services and jointly funded by SAMHSA's Center for Substance Abuse Treatment and the Administration on Children, Youth and Families' Children's Bureau's Office on Child Abuse and Neglect. The center provides targeted technical assistance to states and community-based organizations to improve systems and practice for families with substance use disorders who are involved in the child welfare and family judicial systems. NCSACW's goals are to develop and implement a comprehensive program of information gathering and dissemination, to provide technical assistance and to develop knowledge and its application that promotes effective practice, organizational, and system changes at the local, state, and national levels.

SAMHSA's Residential Treatment for Pregnant and Postpartum Women program expands the availability of comprehensive, residential substance abuse treatment, prevention, and recovery support services for pregnant and postpartum women and their minor children, including services for non-residential family members of both the women and children. This program approaches service delivery from a family-centered perspective, meets the multiple individual needs of the population of focus, and considers

⁴ In FY 1994, states were required to expend not less than five percent of the SABG funds to increase the availability of services for women. The women's set-aside is the requirement that states expend a percentage of their annual SABG funds on services designed for pregnant women and women with dependent children. For FY 1995 and subsequent fiscal years, states are required to expend for such services for women not less than an amount equal to the amount expended by states in fiscal year 1994. States are not required to establish additional new programs or expand existing treatment capacity above the capacity developed in FY 1994.

⁵ <http://www.ncsacw.samhsa.gov/>.

the health and well-being of the family members within the context of their families and other important relationships. Most recently, grants were awarded in FY 2011. Depending upon funding availability, another grant announcement may be forthcoming in the future.

SAMHSA efforts to outreach to prescribers and to the public regarding safe and appropriate use of opioid medications also help to prevent the development of addiction and women of childbearing potential are an important focus group for these trainings and materials which are available to individuals and groups in your community.

Finally, the Maternal, Infant and Early Childhood Home Visiting program is authorized by the Affordable Care Act and funded for five years at \$1.5 billion. The program is administered by the Health Resources and Services Administration, in collaboration with the Administration for Children and Families. The Florida Department of Health is the designated lead agency and is working in partnership with the Department of Children and Families to plan and implement the program. The program will identify and focus on communities that have high rates of: premature birth, low birth weight infants, infant mortality; poverty; crime; domestic violence; high school drop-outs; substance abuse; unemployment; and child maltreatment.

2. What changes can we make to our prescription drug laws to make it harder for people to improperly obtain and abuse prescription drugs?

In 2011, ONDCP released the action plan “Epidemic: Responding to America’s Prescription Drug Abuse Crisis” on preventing and reducing prescription drug abuse. The action plan included the following action items that would require a change in Federal law:

- Work with Congress to amend Federal law to require practitioners (physicians, dentists, and others authorized to prescribe) who request DEA registration to prescribe controlled substances to be trained on responsible opioid prescribing practices as a precondition of registration. This training would include assessing and addressing signs of abuse and/or dependence.
- Support reauthorization of the National All Schedules Prescription Electronic Reporting Act, which created a formula grant program administered by SAMHSA that funds state PDMPs. The program outlines specific, uniform criteria states must have in place to be awarded funding, which increases consistency among state PDMPs.
- Work with the Congress on legislation to authorize the Departments of Defense and Veterans Affairs to share patient information on controlled substance prescriptions with state PDMPs.