

**Testimony before the House Energy and Commerce
Oversight and Investigation Subcommittee
U.S. House of Representatives**

Hearing on

**“Examining the Growing Problems of Prescription Drug and Heroin Abuse:
State and Local Perspectives.”**

Statement of

Sarah T. Melton, PharmD,BCPP,BCACP,CGP,FASCP

Chair, One Care of Southwest Virginia

Associate Professor of Pharmacy Practice

East Tennessee State University Gatton College of Pharmacy

March 26, 2015

INTRODUCTION

Chairman Murphy and members of the Subcommittee, thank you for this opportunity to examine the growing problems of prescription drug and heroin abuse from the state and local perspectives.

My name is Sarah Melton, and I chair One Care of Southwest Virginia.¹ One Care serves as a consortium of 16 substance abuse coalitions working throughout the 21 counties and cities in the southwestern region of the Commonwealth of Virginia. The 28-member Board of Directors includes representatives from community service boards, faith based organizations, social services, health care, higher education, law enforcement, business, and recovery communities. The One Care of SWVA Board operates collaboratively and has committed to undertaking a broad based strategic planning initiative - a blueprint for the control and mitigation of substance abuse and misuse in southwest Virginia facilitated by the Healthy Appalachia Institute and with the encouragement of the Southwest Virginia Health Authority, regional partners and elected officials.²

I serve as associate professor of pharmacy practice at the East Tennessee State University Gatton College of Pharmacy and am an active member of the Prescription Drug Abuse and Misuse Working Group.³ This working group is interdisciplinary and is doing extensive research and outreach in the areas of prescriber education, neonatal abstinence, and appropriate storage and disposal of controlled substances.

¹ One Care of Southwest Virginia; <http://www.onecareva.org/home> . Accessed March 21, 2015.

² One Care of Southwest Virginia. Blueprint for Substance Abuse and Misuse Prevention, Treatment and Control. August 2011. Available at <http://www.appalachianaware.org/uploads/content/201107281627076950.pdf> Accessed March 21, 2015.

³ East Tennessee State University Prescription Drug Abuse and Misuse Working Group; <http://www.etsu.edu/cph/pdam/> . Accessed March 21, 2015.

I serve on the Virginia Task Force on Prescription Drug and Heroin Abuse established by Governor Terry McAuliffe in September 2014. I serve as co-chair of the Education Subcommittee and work closely with the other subcommittees of Treatment, Enforcement, Data and Monitoring, and Disposal. I am a board certified psychiatric pharmacist and work clinically with patients with the disease of addiction to heroin and prescription medications on a daily basis.

During my testimony, I will address key areas relating to state and local initiatives that are making an impact in the area of heroin and prescription drug abuse. I will also address key areas where the federal government can assist in these areas.

EDUCATION OF PRESCRIBERS

Students and residents in healthcare professions often have limited exposure to curricula on identifying and treating substance use disorders. In addition, experiential clinical training on appropriate prescribing and dispensing of controlled substances is lacking. Inappropriate prescribing and an inability to identify patients at risk of substance abuse have played a tremendous role in the abuse of prescription medications and the development of substance use disorders. In Virginia, we are working together to bring leaders from schools of medicine, pharmacy, nursing, and physician assistants together to assure our prescribers and dispensers of controlled substances have received adequate education on addiction and treatment of chronic pain.

A recent comprehensive report by the National Center on Addiction and Substance Abuse (CASA) at Columbia University found that most doctors fail to identify or diagnose substance

abuse “or know what to do with patients who present with treatable symptoms.”⁴ Addiction is linked to more than 70 diseases or conditions and accounts for a third of inpatient hospital costs, according to CASA, but addiction medicine is rarely taught in medical school or residency training. This 5-year study found that, despite the prevalence of addiction, the enormity of its consequences, the availability of effective solutions and the evidence that addiction is a disease, both screening and early intervention for risky substance use are rare, and only about 1 in 10 people with addiction involving alcohol or drugs other than nicotine receive any form of treatment. Of those who do receive treatment, few receive anything that approximates evidence-based care. Overall, more funding is needed from the federal level to provide expanded graduate medical education opportunities for training in the identification, referral, and treatment of substance use disorders. As changes in federal funding allocated for graduate medical education is currently being discussed, this is an opportune time to assess how funding can best address training in addiction medicine. In addition, interdisciplinary training among health care providers is a necessity so that providers are not working in silos of care.

Tennessee has a mandated annual continuing education requirement on appropriate prescribing. Virginia does not have this requirement, and multiple attempts to have his requirement legislated have failed. However, One Care of Southwest Virginia joined with the Medical Society of Virginia and the Virginia Department of Health to provide no-cost continuing medical education to over 2,000 prescribers and dispensers over the past 3 years. Topics for education include universal precautions when prescribing controlled substances, the prescription drug monitoring program, neonatal abstinence syndrome, and opioid risk, evaluation and

⁴ CASAColumbia. Addiction Medicine: Closing the Gap between Science and Practice. Published June 2012. Available at <http://www.casacolumbia.org/addiction-research/reports/addiction-medicine>. Accessed March 21, 2015.

mitigation strategies. We are evaluating data on changing of prescribing habits and attitudes, registration to the prescription monitoring program, and other outcomes at this time.

In Virginia, a letter was sent directly from Secretary of Health and Human Services, Dr. William Hazel, to all prescribers in January of 2015. The letter specifically addressed new legislation requiring prescribers to be registered with the prescription monitoring program (PMP) in 2016. However, the letter also provided education about the prescription monitoring program and how it should be integrated into clinical care. As a result of that letter, prescription drug monitoring program registrations dramatically increased, and we are seeing a steady increase in inquiries for PMP reports being used in the clinical setting. A similar letter to all pharmacists will be sent in the next month.

Access to Naloxone

Naloxone is a medication called an “opioid antagonist” that is used to counter the effects of opioid overdose. Naloxone is used in opioid overdoses to counteract life-threatening depression of the central nervous system and respiratory system, allowing an overdose victim to breathe normally. Naloxone works only if a person has opioids in their system; the medication has no effect if opioids are not present. Naloxone can be administered by minimally trained laypeople, making it ideal for treating overdose in people who have overdosed on prescription opioids or heroin in the community. Naloxone has no potential for abuse.

Both Virginia⁵ and Tennessee⁶ have recently passed legislation that provides for widespread access to naloxone for lay rescuers. The legislation provides Good Samaritan

⁵ Commonwealth of Virginia, HB 1458. Naloxone or other opioid antagonist; pharmacist may dispense in cases of opiate overdose. Available at <http://lis.virginia.gov/cgi-bin/legp604.exe?151+sum+HB1458> Accessed March 21, 2015

protection in the form of immunity from civil liability for licensed healthcare practitioners who prescribe or dispense naloxone or any person who administers naloxone in good faith belief that the other person is experiencing an opioid related drug overdose, and the person exercises reasonable care in administering the naloxone.

One Care has worked extensively with the Virginia Department of Behavioral Health and Developmental Services to provide training on the appropriate administration of naloxone to lay rescuers through Project REVIVE!⁷ Last summer, Senator Tim Kaine attended one of these trainings in Lebanon, Virginia. As a result of his training, Senator Kaine introduced legislation through the *Opioid Overdose Reduction Act of 2015* to offer the same kind of “Good Samaritan” protection to protect first responders, health professionals, and family members who are educated in administering overdose prevention drugs from being sued.⁸ It is my hope that Congress will pass this legislation in order to provide consistent “Good Samaritan” protection across the nation. This legislation will allow naloxone to be used to save as many lives as possible from opioid overdose while limiting fears of civil liability.

A barrier we have encountered in providing naloxone to lay rescuers is the cost associated with obtaining the medication. While some insurance companies will cover the cost of naloxone, the majority do not. Mandatory coverage of this life-saving medication through all prescription insurance plans would allow this medication to reach key populations at risk.

⁶ State of Tennessee, Public Chapter No. 623, Senate Bill No. 1631. Available at <http://state.tn.us/sos/acts/108/pub/pc0623.pdf> Accessed March 21, 2015

⁷ Project Revive! Available at <http://www.dbhds.virginia.gov/individuals-and-families/substance-abuse/revive> Accessed March 21, 2015

⁸ S.707 - Opioid Overdose Reduction Act of 2015, 114th Congress (2015-2016). Available at <https://www.congress.gov/bill/114th-congress/senate-bill/707/text> Accessed March 21, 2015

TREATMENT

The Substance Abuse Prevention and Treatment Block Grant funds treatment services for indigent people. However, the funding is not sufficient to address the prescription drug epidemic in Tennessee and Virginia. It is recommended that additional funding be allocated to fund treatment services for the uninsured, undersinsured, and indigent populations.

Medication-assisted treatments with methadone, buprenorphine, or naltrexone have become an essential component of a comprehensive treatment plan for opioid use disorders, allowing patients to regain control over their health and lives. The Substance Abuse and Mental Health Services Administration (SAMSHA) has published evidenced-based guidelines on the use of these medications to treat opioid addiction.⁹ The development of buprenorphine and its authorized prescribing from physicians' offices has expanded access to treatment dramatically, especially in remote and rural areas of the country. However, modernization of federal law is needed to further expand access to these life-saving treatments prescribed by trained prescribers, to decrease stigma associated with medication-assisted treatment, and to promote research on best-practices when these medications are prescribed. More specific best-practice requirements and recommendations are needed for prescribers and insurers, including Medicaid and Medicare, to make certain patients are receiving comprehensive care by competently trained healthcare providers. Also critical is provision of reimbursement for the provision of essential components of the comprehensive treatment plan including psychotherapy and urine drug screening.

Women with children need specialized treatment services tailored to meeting their needs as well as the needs of their children. These services include a full continuum of treatment

⁹ Center for Substance Abuse Treatment. *Medication-Assisted Treatment for Opioid Addiction in Opioid Treatment Programs*. Treatment Improvement Protocol (TIP) Series 43. DHHS Publication No. (SMA) 12-4214. Rockville, MD: Substance Abuse and Mental Health Services Administration, 2005.

services as well as other wraparound services to assist mothers in caring for their children. These services include safe drug-free housing and aftercare services to ensure recovery is maintained and support is offered when required. While some services are being offered to meet the needs of this specialized population, there is still considerable unmet need.

MONITORING

The prescription drug monitoring programs (PDMPs) collect data from pharmacies on dispensed controlled substance prescriptions and make it available to authorized users through a secure, electronically accessible database. Research strongly suggests that PDMPs serve essential functions in combating the prescription drug abuse epidemic through identifying major sources of prescription drug diversion such as prescription fraud, forgeries, doctor shopping, and improper prescribing and dispensing. PDMPs have become essential tools in patient care by providing providers with information is crucial for providing good medical care and ensuring patient safety. Both Virginia and Tennessee participate with the National Association of Boards of Pharmacy InterConnect Program.¹⁰ This program facilitates the transfer of PDMP data across state lines to authorized users. It allows participating state PMPs across the United States to be linked, providing a more effective means of combating drug diversion and drug abuse nationwide. Allocation of federal funding to help achieve participation from all states with PDMP programs to achieve a national PDMP program should be considered.

A concern encountered daily in clinical practice is that methadone treatment facilities are not required to report dispensing of methadone to prescription drug monitoring programs. Therefore, patients receiving methadone for an opioid use disorder who do not disclose this to

¹⁰ National Association of Boards of Pharmacy InterConnect Program. Available at <http://www.nabp.net/programs/pmp-interconnect/nabp-pmp-interconnect> Accessed March 21, 2015

their other health care providers are at risk of receiving other medications that may interact with methadone and cause significant toxicity or death. Federal regulations at 42 CFR Part 2 concern the confidentiality of alcohol and drug abuse treatment records.¹¹ Section 2.1 states "records of the identity, diagnosis, prognosis, or treatment of any patient which are maintained in connection with the performance of any drug abuse prevention function conducted, regulated, or directly or indirectly assisted by any department or agency of the United States shall, except as provided in subsection (e) of this section, be confidential and be disclosed only for the purposes and under the circumstances expressly authorized under subsection (b) of this section." In contrast, buprenorphine dispensed for opioid dependence is reported to the state PDMP programs, which allows better monitoring for safety and appropriate use.

DISPOSAL AND STORAGE

In recent years, the topic of pharmaceutical waste has become a public health issue of increasing urgency. The Drug Enforcement Administration (DEA), Environmental Protection Agency (EPA), Centers for Medicare and Medicaid Services (CMS), and Food and Drug Administration (FDA) have all taken steps to address pharmaceutical waste in both the community and institutional settings. However, these efforts have not been coordinated and have in some cases conflicted with one another.

Tennessee and Virginia have made great strides in bringing stationary disposal units to many locations across the states. Increased federal funding made available to states in order to place a stationary disposal unit in each county would be optimal. However, we are encountering significant barriers associated with the disposal of the medications placed in these stationary

¹¹ Electronic Code of Federal Regulations, 42 CFR Part 2. Available at <http://www.ecfr.gov/cgi-bin/text-idx?c=ecfr&sid=3b047be10bbce7b3854b2e4067207222&rgn=div8&view=text&node=42:1.0.1.1.2.1.1.1&idno=42> Accessed March 21, 2015

units. There are very high costs associated with incineration of the medication wastes often associated with air-quality control measures mandated by the EPA. In October, the U.S. Drug Enforcement Administration (DEA) finalized rules for the Secure and Responsible Drug Disposal Act of 2010¹² that allow hospitals and pharmacies to be collectors; however, there is no funding for this. During the same time period, the DEA ended sponsorship of its highly successful medication take-back events.

CONCLUSION

Those of us who work in addiction medicine and mental health will continue to work with our local, State, and Federal partners to continue to prevent and reduce the devastating consequences of prescription drug and heroin abuse. There is tremendous work being done on the local and state levels that is clearly making a difference, but we have a tremendous amount of hard work in front of us to end this epidemic. Thank you for the opportunity to testify and for the subcommittee's ongoing commitment to address this public health crisis.

Additional Resources of Information: Prescription for Success: Statewide Strategies to Prevent and Treat the Prescription Drug Abuse Epidemic in Tennessee¹³ and National Governors Association Policy Academy: Virginia Prescription Drug Abuse Reduction Plan¹⁴

¹² Department of Justice, Drug Enforcement Administration. 21 CFR Parts 1300, 1301, 1304, 1305, 1307, and 1317 [Docket No. DEA-316] RIN 1117-AB18. Disposal of Controlled Substances. Available at http://www.deadiversion.usdoj.gov/fed_regs/rules/2014/2014-20926.pdf. Accessed March 21, 2015

¹³ Prescription for Success: Statewide Strategies to Prevent and Treat the Prescription Drug Abuse Epidemic in Tennessee. Available at <http://tn.gov/mental/prescriptionforsuccess/> Accessed March 21, 2015

¹⁴ National Governors Association Policy Academy: Virginia Prescription Drug Abuse Reduction Plan. Available at https://www.dhp.virginia.gov/dhp_programs/pmp/docs/PrescriptionDrugAbuseReductionPlan.pdf Accessed March 21, 2015