AMA
AMERICAN MEDICAL ASSOCIATION

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May 28, 2015

The Honorable Tim Murphy
Chairman
Subcommittee on Oversight and Investigations
Committee on Energy and Commerce
U.S. House of Representatives
2125 Rayburn House Office Building
Washington, DC 20515-6115

Dear Chairman Murphy:

On behalf of the physician and medical student members of the American Medical Association (AMA), I appreciate the opportunity to respond to the additional questions submitted by Representative Michael Burgess, MD as part of the Subcommittee on Oversight and Investigations of the Committee on Energy and Commerce's hearing entitled, "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives."

Questions Posed by the Honorable Michael C. Burgess, MD

1. **The current standard of care for treating pregnant women with opioid dependence, according to the American College of Obstetricians and Gynecologists, is medication assisted therapy, such as buprenorphine or methadone. Medically supervised tapered doses of opioids or abrupt discontinuation are contrary to the current standard of care and are only appropriate in a highly controlled research setting. Dr. Harris, can you tell us more about the standard of care for treating these patients?**

In addition to the increasing numbers of Americans misusing and abusing prescription drugs and dying from unintentional overdose, there are increasing data on the rise of neonatal abstinence syndrome (NAS).[1] As a starting point, it should be noted that substance abuse and addiction is a disease and should be treated as such. This applies to all patients, including women who are pregnant.

Preventing inappropriate opioid use among pregnant women and women of child-bearing age is crucial. For pregnant women who misuse and abuse drugs and alcohol, including prescription opioids, our shared goal must be a healthy outcome for both mother and baby. The AMA recommends that policymakers support the extensive work done on this issue by the nation's leading national medical specialty societies,

[1] Neonatal abstinence syndrome (NAS) is a condition affecting newborns whose mothers used opiates during pregnancy. As detailed in the April 30, 2012 issue of the *Journal of the American Medical Association*, NAS not only can have severe health consequences on fetuses and newborn babies, but NAS raises issues concerning appropriate treatment of pregnant women, Medicaid, and the financial costs to the health care system.

including the American Academy of Pediatrics (AAP), the American Congress of Obstetricians and Gynecologists (ACOG), and the American Society of Addiction Medicine (ASAM). The information from these and other medical societies can help legislators and public health officials design policies that put the interests of the pregnant woman and her baby first and foremost. There are excellent evidence-based practice guidelines (ACOG, AAP, ASAM) that are used today to effectively treat mother and baby. Physicians know how to treat this and are currently doing so across the nation.

However, medically-appropriate opioid use in pregnancy is not uncommon. Opioids are often the safest and most appropriate treatment for a variety of medical conditions and severe pain during pregnancy. The current standard of care for pregnant women with opioid dependence is referral for opioid-assisted therapy with methadone or buprenorphine. Safe prescribing during pregnancy includes opioid-assisted therapy. Medically supervised tapered doses of opioids during pregnancy often result in relapse to former use. Moreover, abrupt discontinuation of opioids in an opioid-dependent pregnant woman can result in preterm labor, fetal distress, or fetal demise. Like diabetes or hypertension, a substance use disorder (such as opioid dependence) is a disease requiring a public health, rather than a punitive response. The same holds true for pregnant women with opioid dependence, who should not be criminalized or face immediate revocation of child custody.

Among its resources, the AAP published "Neonatal Drug Withdrawal,"[2] a clinical report that contains important background on opioids; the clinical presentation of opioid withdrawal; differential diagnosis; assessment and nonpharmacologic treatment; and the rationale and comparative evidence for pharmacologic treatment. There also is information on managing patients, key clinical considerations and an extensive list of references. In short, the AAP report, while not a standard of care, does provide evidence-based information from which medical decisions are made.

Two resources from ACOG's Toolkit on State Legislation[3] may also be of interest. One document highlights the key terms and issues surrounding NAS, including that the "shared goal must be a healthy outcome for both mother and baby" rather than "punitive drug enforcement policies."

ASAM is developing resources as part of the Providers' Clinical Support System for Medication-Assisted Treatment (PCSS-MAT). One part of the PCSS-MAT program is designed to encourage physicians trained in addiction medicine to serve as mentors to other physicians, such as primary care physicians, pediatricians and obstetrician/gynecologists, who may deal with women's issues in addiction, according to ASAM officials.[4]

Finally, the Association of State and Territorial Health Officials (ASTHO), has a comprehensive report on this issue entitled, "Neonatal Abstinence Syndrome: How States Can Help Advance the Knowledge Base

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[2] Clinical Report: Neonatal Drug Withdrawal. Hudak, Mark L., Tan, Rosemarie C. The Committee on Drugs and The Committee on Fetus and Newborn. Pediatrics 2012; 129; e540. Jan. 30, 2012. Available at http://pediatrics.aappublications.org/content/129/2/e540.full.pdf+html

[3] The two documents are "Pregnant Women & Prescription Drug Abuse, Dependence and Addiction" and another document focused on suggested legislation. Both are available from the ACOG Government Affairs division.

[4] Med-Sci: ASAM Steps Up Efforts to Reduce Incidence of NAS. American Society of Addiction Medicine. April 17, 2014. Available at http://www.asam.org/magazine/read/article/2014/04/17/med-sci-asam-steps-up-efforts-to-reduce- incidence-of-nas

for Primary Prevention and Best Practices of Care," which includes information on primary prevention, prenatal care, care of the neonate, and management of NAS.[5]

2. In your testimony, you write that the "American Medical Association (AMA) strongly opposes stigmatizing patients who require opioid therapy." How does this stigma manifest itself and what can be done about it?

As we stated in our written testimony, patients in pain and/or with a substance use disorder deserve compassionate care just like any other patients physicians treat. Language matters, and when we take steps to see those in pain or with a substance use disorder as patients rather than as "junkies," "malingerers," or "drug seekers," we will have taken a great step forward in overcoming the damaging psychological stigma associated with these terms.

Unfortunately, stigma manifests itself in various ways. First, many patients are reluctant to accept that they have a chronic illness and do not seek treatment. Verbal stigma is compounded by social stigma that tends to view someone with a substance use disorder as "weak" or someone who fails to exhibit self-control. Moreover, patients who do seek treatment are often unable to find a provider who offers comprehensive, medical treatment options. SAMHSA estimates that 23 million Americans have a substance use disorder but only 11 percent actually receive treatment. Part of this is likely due to the fact that there are too few providers available to treat this patient population. Yet another component is that some treatment centers do not believe that medication assisted treatment (MAT) should be offered due to the false belief that MAT "trades one addiction for another." The bottom line is that medical science teaches us that MAT, in conjunction with nonpharmacologic treatment, offers patients evidence-based treatment that allows them to lead healthy, productive, fully functioning lives. Finally, patients who are in treatment may find that the prescribed course of treatment may be limited by the type or duration of treatment covered by insurers. For example, many insurers require fail first or step therapy protocols for patients to be approved for either pharmacologic or non-pharmacologic therapies. These administrative barriers serve to effectively deny and delay timely care for patients.

What can be done about the stigma problem? First, the national dialogue should emphasize that patients with a substance use disorder should be treated as any other patient with a chronic disease. The nation experienced a similar stigmatizing debate with HIV/AIDS, and much could be learned from how the country eventually focused on treatment rather than making HIV/AIDS patients feel stigmatized about their medical condition. Second, the AMA will continue to support ONDCP's and SAMHSA's efforts to encourage the use of MAT where appropriate, including in Medicaid and drug courts. The AMA strongly believes that the Administration should continue to assess state Medicaid agencies' efforts to eliminate barriers to accessing MAT and removing prior authorization and other barriers. There also need to be state-by-state efforts to eliminate these barriers in the private and group markets. Finally, the AMA strongly urges increased efforts to encourage physicians and other providers to treat patients with substance use disorders by increasing reimbursement levels for such treatment.

3. In your testimony, you discuss the need for physicians to balance their ethical obligation to treat legitimate patient pain management needs with a responsibility to spot potential misuse or abuse of prescription drugs. I am also a big believer that we MUST not be over reactionary

[5] Neonatal Abstinence Syndrome: How States Can Help Advance the Knowledge Base for Primary Prevention and Best Practices of Care, 2014. Available at: http://www.astho.org/Prevention/NAS-Neonatal-Abstinence-Report/

and deny patient's relief from sometimes unimaginable pain – going backwards and not alleviating human suffering is the last thing we should do.

I believe we need to give doctors the tools they need to stop addiction before it starts. E&C has led this charge and have passed bills that have become law to secure the supply chain and crackdown on rogue Internet pharmacies.

Many times I have spoken about the common sense items Congress could do right now:

- **Help support State PDMPs – fund NASPER and make these systems more interactive, timely, physician friendly, interoperable and real time;**
- **Focus law enforcement efforts not on doctor's who specialize in treating pain or treating painful conditions;**
- **Further crackdown down on rogue distributers and Internet pharmacies; and**
- **Allow coverage of drug monitoring tools to ensure patients are taking their medications (and are processing those medications) as intended.**

Can you share AMA's position on these potential solutions?

The AMA agrees with you that there are several opportunities to take advantage of existing technologies and give physicians, other prescribers, and pharmacists the tools they need to ensure patients are receiving the care they need while working to prevent abuse, misuse, and illegal behavior.

The AMA strongly supports reauthorizing and fully funding NASPER to help states make their PDMPs fully modernized and optimized, with a continued strong public health focus. We are concerned, however, that as introduced, the current NASPER reauthorization bill would allow law enforcement and Justice Department access and engagement with state PDMPs that we cannot support. We do not support law enforcement access to patients' protected health information in a PDMP without a court order.

PDMPs can be helpful clinical tools. But, in order to be most useful, PDMPs need to be able to ensure that the data is available "real-time" at the point of care, that the data is accurate and easy to use, and that it contains all relevant information, including data updated in a timely manner by pharmacists who dispense medications, and potential prescriptions that were dispensed from other states. When PDMPs contain these important elements, we believe that physicians will use them as an important clinical tool to make treatment decisions based on patient-specific needs.

To date, PDMPs mostly have been used to identify so-called "doctor shoppers," but it is unclear whether those efforts are targeting individuals who seek drugs for illegal activities as opposed to patients with a substance use disorder and who need treatment. Although many PDMPs have been used in states for years, there is little data on how to best use these databases to help increase access to treatment. Using these tools as a means to monitor adherence, as you suggest, is one such promising idea. The current focus, however, must be on ensuring that PDMPs are fully funded and modernized so that they can be used in ways that enhance patient care.

The AMA agrees with you that law enforcement efforts should be focused on securing the supply chain and stopping illegal pill mills and rogue, online pharmacies. The AMA has no tolerance for any prescriber or dispenser who engages in illegal activities. There is a difference, however, in appropriate oversight and intrusive investigations not based on probable cause. This is a challenging balance, but the AMA is committed to working with and supporting efforts to help law enforcement get this right. We

also believe that law enforcement, along with first responders and others, should carry Naloxone with them to prevent overdose fatalities. Finally, law enforcement has an important role to play in helping to ensure that suspects and offenders with substance use problems have access to treatment.

Thank you again for the opportunity to testify and to provide these responses for the record. Please do not hesitate to contact me if I can be of further assistance to the Subcommittee. The AMA applauds your leadership in tackling the opioid epidemic and looks forward to working with you and your colleagues to advance public health-focused solutions to prevent and reduce opioid misuse, abuse, overdose, and deaths.

Sincerely,

Patrice A. Harris, MD, MA
Secretary, Board of Trustees

cc: The Honorable Diana DeGette, Ranking Member, Subcommittee on Oversight and Investigations
The Honorable Michael C. Burgess, MD
James L. Madara, MD