

TESTIMONY

of the

American Medical Association

before the

U.S. House of Representatives Committee on Energy and Commerce Subcommittee on Health

Re: Examining Legislative Proposals to Combat our Nation's Drug Abuse Crisis

October 8, 2015

Division of Legislative Counsel

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STATEMENT

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for the Record

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The American Medical Association (AMA) commends the U.S. House of Representatives Committee on Energy and Commerce's efforts, through its Subcommittee on Health and Subcommittee on Oversight and Investigations, to address our nation's drug abuse crisis. As the largest professional association for physicians and the umbrella organization for state and specialty medical societies, the AMA is dedicated to promoting the art and science of medicine and the betterment of public health. As part of this mission, the AMA believes that it is up to physicians to be leaders in preventing and reducing abuse, misuse, overdose, and death from prescription drugs and that we need a comprehensive, multi-pronged public health approach to combatting the nation's prescription opioid abuse and growing heroin epidemic. This approach must balance the treatment needs of pain patients with efforts to promote appropriate prescribing, reduce diversion and misuse, promote an understanding that substance use disorders are chronic conditions that respond to treatment, and expand access to treatment for individuals with substance use disorders. These are complex problems with no single solution, and the AMA is working on multiple fronts through the AMA Task Force to Reduce Opioid Abuse as well as our ongoing efforts with Congress and the Administration, our work with the nation's state and specialty medical societies, and through additional efforts with stakeholders in both the private and public sectors to effectuate change in how to address these issues. We welcome the opportunity to submit this statement for the record in the Subcommittee on Health's hearing today.

Physicians are on the frontlines and fully understand the human cost and the toll this growing epidemic is having on patients and their families, as well as on whole communities, across the country. Physicians must take ownership and responsibility for prevention. The AMA is providing leadership and working to offer and implement specific strategies to deal with this epidemic. We are working with a diverse array of stakeholders at the federal and state levels to effect change.

The AMA strongly supports the following legislative reforms, which we believe would help to reduce prescription opioid misuse, abuse, overdose, and overdose deaths: 1) increasing coverage for and access to treatment programs, including medication assisted treatment (MAT); 2) increasing access to overdose prevention measures, such as naloxone, and expanding Good Samaritan protections; and 3) reauthorizing and fully funding the National All Schedules Prescription Electronic Reporting Act (NASPER) to enable modernizing prescription drug monitoring programs (PDMPs). In addition, we support funding to enable expanded public education campaigns to prevent diversion and misuse of prescription drugs. Each of these reforms is discussed in further detail below.

Increasing Coverage for and Access to Treatment Programs

Opioid use disorder is a chronic disease that can be effectively treated but it requires ongoing management. **However, more resources need to be devoted to ensure availability of, and access to, evidence-based treatment.** A public health-based approach to harmful drug use requires having both broad-based treatment services available for those with opioid use disorders, as well as MAT, and insurance coverage for such treatment. MAT is the use of medications, commonly in combination with counseling, behavioral therapies, and other recovery support services to provide a comprehensive approach to the treatment of opioid use disorders. Food and Drug Administration (FDA) approved medications used to treat opioid addiction include methadone, buprenorphine (alone or in combination with naloxone), and naltrexone. Types of behavioral therapies include individual therapy, group counseling, family behavioral therapy, motivational incentives, and other modalities. MAT has been shown to be highly effective in the treatment of opioid addiction.

However, we are deeply concerned by the barriers faced by patients who need treatment and by physicians in finding and placing patients in addiction treatment and recovery programs. Many physicians regularly face this dilemma because there is inadequate capacity to refer patients for treatment and recovery programs. There are too few physicians and programs offering treatment and recovery services. Physicians who are on the frontlines of this crisis, particularly those in primary care and emergency departments, continue to report challenges in making referrals to meet patients' needs. As noted by the *Washington Post* in a front-page article focused specifically on the heroin epidemic, which was published on Sunday, October 4, 2015:

Treatment centers are often prohibitively expensive, overcrowded, underfunded and subject to byzantine government rules. Health insurance coverage is stingy to nonexistent. And the social stigma of heroin addiction is still so potent that many users and their families are reluctant to seek help in the first place.

Many states do not offer a full range of MAT for patients in Medicaid programs, or subject Medicaid patients to various prior authorization requirements. Even if a state does cover MAT, some states impose limits on the length of time a patient may receive such treatment. And, despite parity rules for mental health and substance use disorders, some private insurance coverage also imposes limits on treatment, especially long-term coverage. Community-based programs are lacking, and mental health networks and pain or addiction specialists are nonexistent in many areas. In addition, legislative efforts designed to reduce supply or impose restrictions on treatment can make treating patients with a substance use disorder demonstrably more difficult for physicians.

Making certain prescription drugs, including those used in MAT, less accessible, however, without policies and strategies to provide treatment and recovery, merely pushes patients out of treatment and toward illegal drugs, such as heroin, that have no legitimate medical use. If the ultimate goal is to provide comprehensive care to our patients and ensure we are doing everything we can as a profession and a society to stop addiction, overdose, and death, a far greater effort is needed to focus on the treatment and recovery side of this crisis.

For example, the AMA strongly supports increased access to <u>and coverage for</u> treatment for drug addiction and physician office-based treatment of opioid addiction. The Drug Addiction Treatment Act of 2000 provided for an office-based option for opiate treatment utilizing buprenorphine (a potent synthetic compound that acts on the same opiate receptors as morphine and methadone). However, limits remain on the number of patients a physician may treat utilizing buprenorphine, a drug that can be used to facilitate recovery from opiate addiction. There is broad consensus in the medical community that

buprenorphine is a successful tool to help fight addiction. Lifting the cap would enable physicians to treat more patients with this highly-effective drug.

In addition, suboxone, a combination of buprenorphine and naloxone (an inhibitor of the opiate receptor), is very safe to be administered on an outpatient basis and is available to be prescribed by any licensed practitioner after completing a training curriculum that focuses on the pathophysiology of opiate addiction, screening of patients, symptom identification and management, and prescribing of the medication. Becoming certified as a prescriber for suboxone requires a fee for completion of the training, registration with governmental entities, and after a waiting period, the ability to prescribe suboxone to 30 patients for the first year. The prescriber may submit a waiver request to treat up to 100 patients after the first year.

The regulatory process for becoming a prescriber combined with the patient limits serve as barriers to increase capacity to treat opiate addiction. The advantages of reducing the regulatory burdens to prescribing suboxone would not only increase the availability of suboxone treatment for patients with opiate addiction, but would also increase clinical identification, awareness, and acceptance of opiate addiction as a disease and reduce the stigma associated with it. Several options exist to expand the current capacity to treat opiate addiction: 1) suboxone training could be offered free-of-charge to prescribers with either renewal or initial application of a prescriber's Drug Enforcement Agency (DEA) number; 2) the initial patient cap could be increased with a waiver option after six months instead of one year; and 3) Medicare reimbursement rates for suboxone treatment and counseling could be increased as an incentive for prescribers to treat opiate-addicted patients.

Increasing Access to Naloxone and Expanding Good Samaritan Laws

The AMA strongly supports the national trend of states enacting new laws to increase access to naloxone, which is a safe and effective FDA-approved medication that reverses prescription opioid and heroin overdose and saves lives. Naloxone has no psychoactive effects and does not present any potential for abuse. AMA advocacy has supported new state laws to put naloxone into the hands of appropriately trained first responders and friends and family members who may be in a position to help save lives. **The AMA encourages physicians to co-prescribe naloxone to their patients at-risk who are taking opioid analgesics.**

Since the mid-1990's, community-based programs have been offering naloxone and other opioid overdose prevention services to persons at risk for overdose, their families and friends, and service providers (e.g., health care providers, homeless shelters, and substance abuse treatment programs). These services include education regarding overdose risk factors, recognition of signs of opioid overdose, appropriate responses to an overdose, and administration of naloxone. It is well documented that naloxone has saved thousands of lives across the nation. Despite this progress, however, barriers still exist to optimal use of naloxone in preventing overdose deaths. One way to reduce barriers to the use of naloxone is passage of Good Samaritan laws to protect from liability first responders, friends and family members, or bystanders who may witness an overdose and have access to naloxone. We urge Congress to provide increased funding for increased access to naloxone overdose prevention programs and to encourage the adoption of broad Good Samaritan protections.

Fully funding and modernizing PDMPs

The AMA strongly encourages physicians and other prescribers to register for and use PDMPs. PDMPs have the potential to serve as a helpful clinical tool in the fight against prescription drug misuse.

The AMA applauds the committee for taking up H.R. 1725, the "National All Schedules Prescription Electronic Reporting Reauthorization Act (NASPER)," and seeing it passed by the House of Representatives earlier this year. The reauthorization of NASPER and full appropriations are urgently needed to ensure that physicians across the country have patient-specific information through PDMPs at the point-of-care and to incentivize further implementation of best practices and information sharing between states. Fully funded and modernized PDMPs that contain relevant clinical information and are available at the point of care have been shown to be an effective tool to help physicians and other providers make appropriate prescribing decisions and ensure that patients with legitimate pain management needs continue to have access to medically necessary care.

Increased Education for Physicians/Prescribers and Patients

We support enhancing education and training of physicians, prescribers, and patients to ensure informed prescribing decisions to prevent and reduce the risks of opioid abuse. The AMA strongly supports physicians and other prescribers relying on the most up-to-date education and training to ensure that if opioid analgesics are clinically indicated, physicians and other prescribers have the education and training to do so safely and appropriately. Enhanced education—beginning in medical, physician assistant, nursing, dental, and pharmacy schools and continuing throughout one's professional career—can help all prescribers, pharmacists, and patients identify and address the risks of prescription drug misuse and prevent diversion and overdoses. Physicians must take the lead in training and educating themselves and their colleagues to ensure they are making informed prescribing decisions, considering all available treatment options and data for their patients, reducing inappropriate prescribing of opioids, making appropriate referrals for patients with opioid use disorders, and taking other steps to ensure appropriate treatment of patients with acute or chronic pain. The AMA is working with the NABP, National Association of Chain Drug Stores, Federation of State Medical Boards, and other associations on this effort.

In addition, the AMA, along with several other medical organizations, is a partner in the Prescriber Clinical Support System for Opioid Therapies (PCSS-O) funded by the Substance Abuse and Mental Health Services Administration (SAMHSA) and administered by the American Academy of Addiction Psychiatry. PCSS-O is a national training and mentoring project developed in response to the prescription opioid overdose epidemic. As part of this collaborative, the AMA is developing new training materials on responsible opioid prescribing and a focused educational module on opioid risk management for resident physicians, and is seeking to engage selected states and state medical associations on collaborative approaches to address opioid-related harms.

We also must confront stigma. Patients in pain deserve compassionate care just like any other patient physicians treat, and the AMA strongly opposes stigmatizing patients who require opioid therapy. In medicine, we do not use terms such as "malingerer" or "drug seeker" because these terms carry with them damaging psychological stigma. Patients who need care are simply "patients," and we should seek to change the tone of the debate toward more attention on multidisciplinary, patient-centered approaches to pain management and ensuring that evidence-based alternative pain management treatments and strategies are covered by insurance, while supporting opioid-based therapies when clinically appropriate and effective. In a similar vein, we should not use terms such as "addict" or "junkie" or "user" because these terms carry with them damaging psychological stigma. Patients who need care are "patients," and deserve our care and compassion. Opioid use disorder is a chronic disease that can be effectively treated but it requires ongoing management. This educational aspect includes, but goes much further than, simply health care professional education.

Another key part of education should be focused on prevention, including public campaigns about safe practices for unused medications. Adequate funding is needed to implement public education campaigns

about how to properly store and dispose of unused opioid medication. The AMA supports the DEA's efforts to promote National Take Back Day and similar efforts to provide a safe and legal way for people to dispose of prescription drugs they do not need.

Improving Treatment for Pregnant and Postpartum Women

We also concerned by the data showing an increase in the incidence of NAS in newborns. 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. But we also must caution against policies that could lead to ineffectual treatment of pain for women, particularly those who are pregnant. Like diabetes or hypertension, a substance use disorder 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. **Therefore, the AMA recommends that policymakers support the extensive work done on this issue by the nation's leading national medical specialty societies, 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.**

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. We urge Congress to provide more resources for treatment programs specifically focused on pregnant/post-partum women and infants born with NAS.

Conclusion

As physicians, we need to be equipped to balance our ethical obligation to treat patients with pain alongside the need to identify signs of diversion. However, we also need coordinated, constructive programs that support education, treatment, and prevention. The AMA is committed to working with Congress and the Administration to address the many facets of this complicated epidemic.