Statement

of the

American Medical Association

to the

Committee on Energy & Commerce
Subcommittee on Oversight and Investigations
United States House of Representatives

Re: "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives"

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

April 23, 2015

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Summary of the American Medical Association's Statement

- There is no question that we are in the midst of an epidemic of prescription drug opioid misuse, abuse, overdose, and deaths from such drugs. At the same time, we are seeing an alarming related trend, with patients turning to illicit drugs such as heroin as the supply of prescription drugs decreases.
- The issues are complex and there is no one answer or solution, but we must approach the problems with a public health focus.
- As physicians, we need to take ownership and responsibility for prevention. We need to ensure that patients experiencing pain are appropriately treated, and that patients who abuse or misuse opioids are referred to and have access to treatment programs.
- The American Medical Association is providing leadership and working on a number of fronts 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.
- We have specific recommendations to address solutions. First, 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. We are developing new training materials on responsible opioid prescribing through a SAMHSA grant.
- We need to ensure that patients in pain receive the care they need and reduce the stigma associated with many such patients. We must change the tone of the debate to pay more attention to multi-disciplinary, patient-centered approaches to pain management, including ensuring insurance coverage for evidence-based alternative pain management treatments.
- We need to recognize that opioid use disorder is a medical condition and increase coverage for and access to medication assisted treatment and other treatment programs. We need more resources devoted to ensure that evidence-based treatment is available and accessible.
- We need to increase access to naloxone and other overdose prevention measures, and enact Good Samaritan laws to provide protection from liability for bystanders who witness overdoses.
- We need to modernize and fully fund prescription drug monitoring programs. PDMPs can serve as a helpful clinical tool, but to increase their use, they need to be real-time, interoperable, and available at the point-of-care as part of a physician's workflow.
- Physicians want to be engaged and be part of the solution.

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On behalf of the American Medical Association (AMA), I commend the Subcommittee on Oversight and Investigations of the Energy & Commerce Committee for conducting this hearing to address "Combatting the Opioid Abuse Epidemic: Professional and Academic Perspectives." 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. The AMA appreciates having the opportunity to testify at today's hearing.

There is no question that we are in the midst of a public health epidemic. According to the Centers for Disease Control and Prevention (CDC), the rate of fatal prescription drug overdoses involving opioids almost quadrupled from 1999 to 2011. The rate of emergency department visits involving prescription drug misuse—primarily of opioid, antianxiety, and insomnia medications—more than doubled from 2004 to 2011. The CDC reports that while deaths involving prescription opioids declined for the first time in a decade in 2012, they once again increased in 2013, with more than 16,000 lives lost annually. More recently, there has been a substantial increase in deaths from heroin. The CDC recently reported that 8,257 people died of heroin-related deaths in 2013—a 39 percent increase from 2012. Total drug (illicit and prescription) overdose deaths in 2013 rose to 43,982, up six percent from 2012. We are deeply disturbed about the rise in overdoses from prescription opioids and that deaths from heroin-related overdoses are rapidly increasing. While public and media attention has focused on several recent overdose deaths of high-profile celebrities, communities across the U.S. have seen a tragic rise in heroin-related deaths. Some suggest this is due to restrictions on prescribing prescription opioids, or the lower

cost and easier accessibility of heroin. There may be other reasons as well, and we need the data to help guide our interventions, but it is clear that we need to act.

The numbers are sobering and the AMA is working on a number of fronts to implement specific strategies to reduce prescription opioid misuse, abuse, overdose, and overdose deaths. The AMA brings a critical perspective to this public health crisis as physicians are on the frontlines and fully understand the human cost and the toll it can take on patients and their families, as well as on whole communities. Physicians work hard to balance their ethical obligation to treat patients with legitimate pain management needs against their legal responsibility to identify patients who may be misusing or abusing drugs, and prevent abuse, misuse, overdose, and death from prescription drugs. Under the Controlled Substances Act (CSA), physicians have a legal responsibility to ensure that a prescription for a controlled substance is "issued for a legitimate medical purpose by an individual practitioner acting in the usual course of his professional practice." This legal responsibility underscores our ethical obligations to our patients, and the AMA is committed to helping physicians meet their responsibilities.

The AMA believes that it is up to physicians to be leaders in preventing and reducing abuse, misuse, overdose and death from prescription drugs through ensuring appropriate prescribing practices as one part of a multi-pronged public health strategy. At the same time, the AMA is strongly committed to ensuring that patients experiencing pain receive appropriate treatment with opioids, if necessary, and that patients with opioid use disorders have access to treatment.

We need a comprehensive public health approach to combatting the nation's prescription opioid abuse and growing heroin epidemic. These are complex problems, and the AMA is working with multiple stakeholders to effectuate change in how to address these issues. We believe the following critical components are necessary: enhancing education for physicians and patients about appropriate prescribing practices; increasing access to treatment programs for opioid use disorders, including medication assisted treatment programs (MAT); ensuring that patients in pain receive the care they need and reducing the stigma of pain; recognizing that opioid use disorder is a medical condition, reducing the stigma of this disorder, and increasing coverage for and access to medication assisted treatment and related services; increasing access to naloxone and other overdose prevention measures, and expanding Good Samaritan laws; and increasing funding and staffing for up-to-date, interoperable, at the point-of-care prescription drug monitoring programs (PDMPs) that are integrated into a physician's workflow. Each of these components is discussed in further detail below.

Enhancing education for physicians and patients

The AMA strongly supports physicians and other prescribers relying on the most up-to-date education and training when it comes to pain management, prescribing opioid analgesics, and other pain medications. We must take increased responsibility for solving this national epidemic. 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 address over-prescribing of opioids while ensuring

appropriate treatment of patients with acute or chronic pain. The AMA is working with the National Association of Boards of Pharmacy (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.

Ensuring that patients in pain receive the care they need and that they are not stigmatized as "malingerers" or "drug seekers"

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. For example, many patients must face step therapy, fail first, and prior authorization protocols by insurers that limit a physician's ability to prescribe a non-opioid treatment such as physical or occupational therapy. Despite the substantial burden of chronic pain in the U.S., access to multidisciplinary care and reimbursement for non-pharmacologic approaches is inadequate and needs to be addressed.

Furthermore, objective tests for the presence or absence of pain or pain intensity are still at a basic stage of development, and in most circumstances, the best clinical approach is to assume that the patient is reporting a true experience. While accepting a patient's complaint of pain as valid does not demand that a specific treatment be initiated, it does provide a foundation for assessment and the basis of developing an effective patient-physician dialogue and relationship, which is key to enabling the physician to provide the best possible care.

Recognizing that opioid use disorder is a medical condition and increasing coverage for, and access to, medication assisted treatment and related services

Similar to patients in pain, 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. 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.

We are deeply concerned by the barriers faced 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. A profound need exists to address the workforce limitations and the lack of accessible and affordable treatment programs.

Making certain prescription drugs less accessible, however, does not stop prescription drug misuse, abuse, diversion, overdose, and death. In fact, making these drugs less accessible without policies and strategies to provide treatment and recovery merely changes the drug of choice from legal prescription drugs to illegal drugs 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 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 major tool to 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 and the patient limits serve as barriers to increase capacity to treat opiate addiction and the availability of suboxone to opiate-addicted patients, particularly those patients in jurisdictions that have adopted a law enforcement approach (as opposed to a public health approach) to combat prescription drug abuse. 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 opiate addiction.

Several options exist to expand the current capacity to treat opiate addiction. First, suboxone training could be offered free-of-charge to prescribers with either renewal or initial application of a prescriber's DEA number. Second, the initial patient cap could be increased with a waiver option after 6 months instead of one year. In addition, Medicare reimbursement rates for suboxone treatment and counseling could be increased as an incentive for prescribers to treat opiate-addicted patients.

Increasing access to overdose prevention measures such as naloxone and enhancing Good Samaritan protections

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 who use these drugs, 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.

Modernizing and fully funding prescription drug monitoring programs

We acknowledge that physicians and other prescribers must take charge of this epidemic by carefully examining prescribing practices. Physicians need to be sure that they are prescribing appropriately and taking necessary precautions, including consulting PDMPs when clinically indicated. PDMPs have the potential to serve as a helpful clinical tool in the fight against prescription drug misuse.

As a result of years of concerted advocacy from the AMA and other national medical specialty societies, the National All Schedules Prescription Electronic Reporting Act of 2005 (NASPER) was signed into law. Although $52 million was authorized over a five-year period, it was not until 2009 that federal funds were appropriated to support the state adoption of PDMPs.

PDMPs can provide reliable and actionable information. It has been only in the past several years that almost all states (e.g., with the exception of Missouri) have finally passed state legislation establishing PDMPs. In order to increase the use of PDMPs, the AMA supports PDMPs that are real-time, interoperable, and available at the point-of-care as part of a physician's workflow. Currently, 28 states can share data through NABP's Pharmacy Interconnect platform. When PDMPs are available at the point-of-care, with up-to-date information, and integrated into physician workflow, their efficacy is remarkable. A growing body of evidence suggests that PDMP data can help inform sound clinical decision-making; however, there also is a growing body of evidence suggesting that PDMPs—by themselves—are not the panacea to reducing prescription drug abuse, misuse, overdose or death.

Modernized PDMPs can provide physicians with a basic tool to make treatment decisions based on patient-specific needs. This not only includes helping detect so-called "doctor shoppers," but also providing information on whether a patient might need counseling for a potential opioid use disorder. In short, PDMP data can be helpful to form a diagnosis and treatment plan, but it is not a stand-alone solution.

However, full funding for PDMPs is needed to ensure that physicians across the country have this effective tool at the point-of-care to combat prescription drug abuse while ensuring that patients with legitimate need for pain management continue to have access. Unfortunately, the appropriations to fully fund, modernize, and optimize the PDMPs have not kept pace with the rapid escalation in abuse and diversion of prescription drugs. We support full appropriations with a continued strong emphasis on the public health focus of NASPER.

Working with stakeholders at the federal and state levels

The AMA has worked closely with federal and state policymakers and with a diverse array of stakeholders for many years to address this growing public health crisis. At the federal level, the AMA is a founding member of the Alliance to Prevent the Abuse of Medicines (the Alliance), a non-profit partnership of key stakeholders in the prescription drug supply chain—e.g., manufacturers, distributors, pharmacy benefit managers, pharmacies, physicians—established to develop and offer policy solutions aimed at addressing the prescription drug abuse epidemic. In addition, the AMA participated in a diverse coalition of stakeholders convened by the National Association of Boards of Pharmacy (NABP), to discuss key issues and develop recommendations related to the safe prescribing and dispensing of controlled substances. The AMA Board of Trustees recently joined NABP and 15 medical, pharmacy, and other organizations to issue a consensus document, "Challenges and Red Flag Warning Signs Related to Prescribing and Dispensing Controlled Substances," that represents the culmination of several meetings and collaborative work by the stakeholder organizations.

Over the past year, the AMA has brought together representatives from more than 40 medical specialty and state medical associations, as well as the American Dental Association, to discuss strategies and develop recommendations to prevent and reduce opioid abuse and misuse. The AMA Task Force to Reduce Opioid Abuse is focused on ensuring that physicians and other prescribers take on an increased leadership role to address the nation's epidemic of prescription drug misuse, unintentional overdoses, and death, while also ensuring access to legitimate treatment for pain, as well as opioid use disorders.

At the state level, the AMA and our state medical societies have worked closely to ensure that new policies have a direct impact on this national epidemic. Nearly every state legislature is considering one or more pieces of legislation concerning prescription drug abuse, misuse, overdose, and death, including bills on PDMPs, continuing medical education requirements for licensing, restrictions on prescribing opioids, and electronic prescribing of controlled substances. It is important to note, as recognized by CDC, that different regions of the nation have different problems, and a one-size-fits-all approach is not the optimal method of attack. For example, the nation's heroin epidemic has gripped the Northeast in different ways than in other parts of the nation, and that region has made efforts to greatly expand access to naloxone. Similarly, states have begun to use county-level data to understand prescribing patterns, overdose and death patterns, and other key data to determine how to best target public health

interventions. The interventions needed in more rural parts of Kentucky and Tennessee, for example, might differ from what is needed in the Chicago, Philadelphia, or Denver suburbs.

One of the most promising interventions has been new laws focused on overdose prevention, increased access to naloxone, Good Samaritan protections, and treatment of opioid use disorders. The AMA has worked hand-in-hand with many state medical societies to help enact these laws throughout the nation, and our goal is for every state in the land to support this life-saving approach.

But we can't stop there. In addition to state legislative advocacy, the AMA remains engaged with the National Conference of Insurance Legislators (NCOIL), National Alliance for Model State Drug Laws, the National Governors Association (NGA), and other legislative-focused organizations. Outreach also continues with patient-focused organizations, including the HARM Reduction Coalition, National Safety Council, and others in an effort to balance the national discussion of prescription drug abuse, misuse, overdose, and death to one that appropriately emphasizes overdose prevention and treatment for opioid use disorders.

Conclusion

As the foregoing initiatives demonstrate, the AMA is strongly committed to combatting opioid drug misuse, abuse, overdose, and death while simultaneously ensuring access to treatment for pain and opioid use disorders. The AMA appreciates the opportunity to provide our comments on this critical health policy matter, and we look forward to working with the Subcommittee, Committee, and Congress to address the scourge of prescription opioid and heroin abuse and overdose, while ensuring that patients with legitimate pain management needs and opioid use disorders have access to treatment. Our patients deserve no less.