ASAM The Voice of Addiction Medicine
American Society of Addiction Medicine

Testimony of David Kan, MD, DFASAM
Before the Energy and Commerce Committee Subcommittee on Health
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Executive Summary

My name is Dr. David Kan, and I'm the President of the California Society of Addiction Medicine, a Chapter of the American Society of Addiction Medicine (ASAM), which represents more than 5,000 of our nation's addiction specialist physicians and other clinicians.

My testimony today will focus on the following facts:

1. Addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions, and we have published standards and guidelines that detail best practices for the use of these medications.
2. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.
3. Changes to the Controlled Substances Act to facilitate the use of telemedicine and new medication formulations can expand access to evidence-based treatment options and help close the addiction treatment gap.

Opioid addiction is taking a devastating toll on our families, friends, and neighbors across the country, but there is hope when patients can access effective treatment services. ASAM is honored today to offer its thoughts and expertise on how we can close the treatment gap, improve the quality of care, and ultimately save lives.

Introduction

Chairman Burgess and Ranking Member Green, thank you very much for inviting me to participate in this important hearing. I'm grateful to you and the other Members of the Subcommittee for your leadership in addressing the epidemic of opioid addiction currently ravaging our country.

My name is Dr. David Kan, and I am the President of the California Society of Addiction Medicine, a Chapter of the American Society of Addiction Medicine, also known as ASAM. This testimony is offered on behalf of ASAM, myself as a practicing addiction specialist physician, and my patients. I am board-certified in both Addiction Medicine and General and Forensic Psychiatry, and I'm the Medical Director of Bright Heart Health, which provides telemedicine addiction treatment services in 21 states across the United States, and of which I have a 3.5% ownership interest. I have dedicated my entire career to treating patients with opioid addiction and have spent more than a decade treating addiction at the Veterans Administration Medical Center in San Francisco, where I used telemedicine to treatment patients. I am also a faculty member at the UCSF Department of Psychiatry.

Established in 1954, ASAM is a national medical specialty society of more than 5,000 physicians and allied health professionals who specialize in the treatment of addiction. Its mission is to increase access to and improve the quality of addiction treatment; to educate physicians, other health care providers and the public; to support research and prevention; and to promote the appropriate role of the physician in the care of patients with addictive disorders.

My testimony today will focus on the following three facts:

1. Addiction involving opioid use can be successfully treated with a combination of medications and psychosocial interventions, and we have published guidelines that detail best practices for the use of these medications.
2. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.
3. Changes to the Controlled Substances Act to facilitate the use of telemedicine and new medication formulations can expand access to evidence-based treatment options and help close the addiction treatment gap.

Addiction Involving Opioid Use Can Be Treated Successfully

The medical literature is clear, and as a practicing addiction specialist with more than a decade of experience I can confirm, that addiction involving opioid use can be treated successfully with a combination of medication and psychosocial interventions.

There are currently three medications that are FDA-approved to treat opioid addiction: methadone, which has been used in highly regulated opioid treatment programs since the 1960s; buprenorphine, which has been used since 2002 by specially trained physicians in their offices; and naltrexone, which is not a controlled substance and can be administered by any licensed prescriber. Given the bills being considered by the Subcommittee today, I will focus my remarks on the safety and effectiveness of buprenorphine, although it is important to note that all three medications have been proven to be safe and clinically effective for the treatment of addiction involving opioid use.

The benefits of buprenorphine in the treatment of opioid dependence and opioid use disorder are well documented. A 2013 review of the scientific literature found substantial, broad and conclusive evidence for the effectiveness of all three medications.[1] Several studies of office-based treatment with buprenorphine found it improves treatment engagement; reduces cravings, illicit opioid use, and mortality; and improves psychosocial outcomes. Compared to full opioid agonists like methadone, buprenorphine offers an improved safety profile, with significantly lower related overdose deaths and adverse events after treatment discharge.[2,3,4] Moreover, the direct health care savings per opioid dependent patient per year exceed $20,000,[5] with total economic savings stretching beyond just health care costs to the criminal justice and social services sectors as well.

Finally, we have clear standards of care for clinicians treating patients with addiction, as well as comprehensive guidelines for how to use medications effectively in the clinical care of persons with addiction involving opioid use. ASAM's *Standards of Care for the Addiction Specialist Physician*, which apply to any physician assuming the responsibility for caring for patients with addiction and related disorders, address expected physician competencies and actions with the ultimate purpose of improving patient outcomes. ASAM's *National Practice Guideline for the Use of Medications in the Treatment of Addiction Involving Opioid Use* was developed to promote evidence-based clinical treatment of opioid use disorder and to assist clinicians in the decision-making process for prescribing medications to patients with opioid use disorder. It offers specific clinical recommendations on the assessment and diagnosis of opioid use disorder, treatment options, managing withdrawal, initiating medication treatment, and psychosocial treatment.[6] I will return to the Standards and the Guideline's recommendations shortly when I discuss the in-person physical examination requirement stipulated by the Ryan Haight Act.

There are Significant Barriers to Access these Medications Leading to a Major Treatment Gap

Despite the strong evidence base for the use of buprenorphine and the clinical guidance available, very few eligible patients are offered medication to help treat their disease. Indeed, a 2015 study published in the Journal of the American Medical Association found that 80% of Americans with opioid addiction don't receive treatment.[7] Part of the treatment gap is attributable to lack of access to DATA-waived clinicians who can prescribe buprenorphine. A 2015 study co-authored by the Assistant Secretary for Mental Health and Substance Use Dr. McCance-Katz that estimated national and state need and capacity for opioid agonist medication-assisted treatment (both methadone and buprenorphine) found that, "among states and the District of Columbia, 96% had opioid abuse or dependence rates higher than their buprenorphine treatment capacity rates." The authors concluded, "Significant gaps between treatment need and capacity exist at the state and national levels. Strategies to increase the number of [opioid agonist-MAT] providers are needed."[8]

Other barriers preventing patients from accessing this life-saving treatment include transportation difficulties, limited hours of operation, and few prescribers who accept Medicaid or Medicare. Individually, these barriers prevent access. However, patients often encounter multiple barriers making access to treatment next to impossible.

- Whether rural or urban, many individuals struggle with attending appointments due to functional ability and transportation issues related to bus schedules, costs of travel, and ability to adjust work and life schedules around appointments.
- Many providers only offer limited hours or weekday schedules. Many individuals seeking treatment for addiction involving opioid use are employed by retail, restaurant,

construction, or similar industries with limited flexibility to attend frequent medication and behavioral health appointments in accordance to their treatment plan.

- Finally, the scarcity of Medicaid-eligible and enrolled practitioners and programs that could provide medications for the treatment of addiction involving opioid use to Medicaid patients limits geographic access for Medicaid beneficiaries with addiction involving opioid use, requiring long commutes and/or Medicaid-paid transportation, whose costs are rising substantially as a result. Many physicians choose to offer cash only practices, restricting access to care to only individuals who can pay out-of-pocket.

Changes to the Controlled Substances Act to Facilitate Treatment Via Telemedicine and New Medication Formulations Can Help Close the Treatment Gap

While not a silver bullet that will solve our current opioid addiction crisis or fully close the treatment gap, making smart and targeted changes to the Controlled Substances Act to facilitate treatment with buprenorphine for addiction involving opioid use via telemedicine and the use of new implantable and injectable buprenorphine formulations are steps this Congress should take to expand treatment access.

Telemedicine

Telemedicine provides significant opportunities to reach more patients in urban, peri-urban, and rural communities. However, the current restrictions on internet prescribing under the Ryan Haight Act and the seven, specific “practice of telemedicine” exceptions it provides for are of limited utility for expanding access to treatment with buprenorphine for addiction involving opioid use via telemedicine. As you know, the Ryan Haight Act generally requires an “in-person medical evaluation” in the physical presence of the prescribing clinician for the prescription to be

considered valid. The “practice of telemedicine” exceptions to this requirement provide for circumstances in which the patient is being treated by, and physically located in, a DEA-registered hospital or clinic, or in which the patient is being treated by and in the physical presence of another DEA-registered practitioner. It generally does not allow for circumstances in which a patient may have received a medical evaluation by another qualified practitioner but is not physically present in a DEA-registered hospital or clinic or with another DEA-registered practitioner.

ASAM’s Standards of Care and National Practice Guideline make it clear that patients presenting for treatment of addiction involving opioid use should receive a physical examination by a qualified and appropriately licensed healthcare professional as part of a comprehensive assessment process. However, they specifically allow for this examination to be conducted by a healthcare professional other than the prescriber, as long as the prescriber “ensure[s] that a current physical examination is contained within the patient medical record before a patient is started on a new medication for the treatment of his/her addiction.”[9] **Accordingly, ASAM recommends that the requirement for an in-person physical exam by the prescribing clinician be revised to allow for the physical exam to be conducted by another appropriately licensed healthcare professional and documented in the patient’s medical record.** Completion of the patient’s medical history should include screening for concomitant medical conditions, including infectious diseases (hepatitis, HIV, and tuberculosis [TB]), acute trauma, and pregnancy. Initial laboratory testing should also include a complete blood count and liver function tests.

Additionally, ASAM recommends limiting this exception to the in-person physical exam requirement for patients who will be treated with buprenorphine for opioid addiction only to those physicians who hold “additional certification” or who practice in a “qualified practice setting” per

the definitions in the 2016 SAMSHA rule that raised the DATA-2000 prescribing limit. Specifically, only physicians who hold board certification in addiction medicine or addiction psychiatry by the American Board of Addiction Medicine or the American Board of Medical Specialties, or certification by the American Society of Addiction Medicine, or those who practice in settings that provide professional coverage for patient medical emergencies when the practice is closed, provide access to case management services, are registered with their state PDMP, and are able to accept third-party insurance, should be allowed to prescribe buprenorphine via telemedicine with an in-person evaluation conducted by another appropriately licensed healthcare professional and documented in the patient's medical record.

These changes would allow for highly skilled addiction specialists to treat patients who might otherwise face insurmountable geographic, logistical, or financial barriers to in-person treatment, and would make progress toward closing the addiction treatment gap while still ensuring patients are receiving high-quality care from competent healthcare providers.

New Formulations

Secondly, ASAM encourages Congress to move expeditiously to amend the Controlled Substances Act to allow for specialty pharmacies to deliver new injectable and implantable buprenorphine formulations directly to the administering clinician's practice, rather than requiring the clinician to rely on the "buy and bill" method for obtaining and being reimbursed for the medications.

Foremost to ASAM's mission is a goal to increase access to and improve the quality of addiction treatment. The introduction and use of novel addiction medications supports this goal. Addiction patients, like all patients, should have available to them a robust and varied array of treatment

options, as no one treatment modality is appropriate or therapeutic for everyone. The recent approval of implantable and injectable buprenorphine formulations expands treatment options for patients. No product will be suitable for all patients, and many will still be best-served by oral formulations, other medications, or no medication at all, but they may help improve treatment adherence and reduce diversion among certain patients for whom they are indicated. However, these options are only valuable if patients can access them. A change to the Controlled Substances Act, as has been proposed in Senate bill 916, would facilitate access to these new products by allowing them to be delivered to administering practitioners on a patient-by-patient basis rather than requiring the practitioners anticipate demand, buy the medication in advance, store it on site, and hope they estimated the correct number of doses needed to meet demand and avoid waste. This is not a new pathway for medication delivery but would allow for these controlled substances to be delivered as many non-controlled substances are already. It is a technical, common-sense fix to the law that will expand treatment access while potentially reducing the buprenorphine diversion, and ASAM urges this Subcommittee to advance a bill to approve it.

Thank you, again, for the opportunity to present here today. ASAM looks forward to a continued collaboration on this and other addiction-related issues, and I look forward to your questions.

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Appendix: ASAM Position on Other Bills under Consideration

Bill	ASAM Position
H.R. 2063, the Opioid Preventing Abuse through Continuing Education (PACE) Act of 2017	The dramatic increase in the prescription of opioid medications has played a significant role in rise of opioid addiction and development of the opioid overdose epidemic in the United States. To address this epidemic, we must take a comprehensive approach to strengthening treatment, prevention, and recovery services for patients with addiction, including strategies to ensure safe and responsible prescribing of opioids. This bill would help reduce unnecessary exposure to addictive medications by requiring prescribers to be educated on safe prescribing practices and addiction, and ASAM is pleased to endorse it. In addition, ASAM offers these additional recommendations for consideration: • Make the new training requirement a condition of registration to prescribe or dispense benzodiazepines in addition to opioids for the treatment of pain. • Streamline federal efforts to promote safe opioid prescribing by incorporating the recommendations included in the CDC Guideline for Prescribing Opioids for Chronic Pain. There is no need for duplicative federal recommendations on opioid prescribing; in fact, duplicative efforts may only confuse practitioners and

	further clutter an already-crowded educational space on this topic. • Offer a “test-out” option that would give practitioners the opportunity to demonstrate their knowledge and “test-out” of this mandatory training requirement.