“Examining Legislative Proposals to Combat Our Nation’s Drug Abuse Crisis”

Questions for the Record

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American Society of Addiction Medicine

The Honorable Representative Tim Murphy

1. **In your testimony you cite research from the University of Kentucky about the motivation to use diverted buprenorphine was the inability to find treatment. Are you aware that the research abstract clearly states: “Results: Lifetime buprenorphine use “to get high” was 70.1%. Nearly half (46.5%) [of the patients in the study] used diverted buprenorphine over the 6-month follow-up period.” Doesn’t the use of buprenorphine to “get high” suggest that this medication is being used recreationally, and doesn’t recreational use suggest to you that diverted buprenorphine is helping to spread and maintain addiction?**

   Thank you for this question. As with all opioids, buprenorphine is sometimes used recreationally. While 70.1% of participants in this study reported using buprenorphine “to get high” at least once in their lifetime, which could be as little as once over the last decade, less than half (46.5%) had used diverted buprenorphine at all during the 6-month study period, yet all (100%) participants reported non-medical prescription opioid use “to get high” in the past 30 days, indicating that opioids other than buprenorphine are far more likely to be used “to get high.”

   However, the authors’ main finding, which is insightful as Congress considers how to increase access to addiction treatment while mitigating diversion risk, is that the “strongest predictor [of diverted buprenorphine use] was attempting but failing to access buprenorphine treatment.” Based on this finding, the authors conclude that “increasing, not limiting, buprenorphine treatment access may be an effective response to buprenorphine diversion among persons not in treatment.”

   Moreover, no research has shown buprenorphine as a “first drug” or even a first opioid, so the assertion that it is spreading addiction is baseless. Given that addiction is a chronic neurobiological disorder, it is “maintained” on its own without any need for help from buprenorphine. In fact, the contrary could be said, given that when a patient uses buprenorphine they are much less likely to use heroin or other opioids. This decreases the risk of overdose, HIV, hepatitis C and overall criminogenic behavior.

   No one is more worried about the specter of the possible diversion and misuse of buprenorphine products than the addiction treatment field. We are also the most trained to identify it and prevent it. With evidence based dosing, regular follow-up appointments and prudent toxicological evaluations, we can mitigate the risk of diversion and misuse of buprenorphine so that the benefit continues to far outweigh any harm.

The Honorable Representative Gus Bilirakis

Dr. Waller, ASAM has concerns that HR 2872, the Opioid Treatment Modernization Act, will unintentionally lead to reduced access to treatment. However, I have heard several concerns aligned with Dr. Sledge’s testimony, which is that there is no one size fits all approach and that simply raising the caps could lead to the unintended consequence of increased diversion and prescription drug abuse if other services, such as counseling and patient monitoring, are not mandated.

1. **Can you provide some detail about ASAM's recommendations for preventing diversion if requirements, such as those included in HR 2872, are not enacted?**

Thank you for this question. ASAM shares concerns about buprenorphine diversion and the quality of addiction treatment that patients receive. ASAM also believes that patients should have treatment options and supports access to the right medication at the right time for each patient. That is why ASAM has developed Standards of Care for Addiction Physician Specialists, accompanying performance measures, and, most recently, a National Practice Guideline on the Use of Medications for the Treatment of Addiction Involving Opioid Use (available here: http://www.asam.org/practice-support/guidelines-and-consensus-documents/npg) which provides clinical guidance for the use of all three FDA-approved medications for the treatment of opioid use disorder as well as the use of naloxone to treat opioid overdose, including what strategies are recommended to mitigate buprenorphine diversion risk. Specifically, ASAM's practice guideline recommends that physicians see patients weekly at the beginning of their treatment until they are determined to be stable, access PDMP data to check for other medications the patient may be receiving, and conduct urine drug testing to assess medication adherence and the use of other controlled or illicit substances. It recommends physicians take steps to reduce the chance of diversion, including strategies such as frequent office visits, urine drug testing, observed dosing, and recall visits for pill counts. It further recommends patients be counseled on safe storage and disposal. As with most other clinical practice guidelines issued by national medical specialty societies, state medical boards, rather than the federal government, are best poised to issue regulations to encourage the adoption of its recommendations, and state Medicaid programs as well as commercial insurers have the authority to choose which services and what level of quality they will pay for. It is worth noting that full enforcement of the Mental Health Parity and Addiction Equity Act could help mitigate diversion and other poor treatment practices by ensuring that patients' receive coverage for evidence-based, comprehensive care.

Moreover, ASAM shares concerns about lifting the DATA 2000 prescribing limits without simultaneously implementing measures to ensure patients receive high-quality care. That is ASAM recommends specific and extensive training requirements for practitioners who would be permitted to treat more than 100 patients, as well as ongoing continuing medical education (CME) and random site audits by the Substance Abuse and Mental Health Services Administration (SAMHSA) for practitioners who treat more than 100 patients. These recommendations are detailed in ASAM's July 2014 letter to Secretary Burwell (available here: http://www.asam.org/docs/default-source/advocacy/letters-and-comments/opioid-epidemic-recommendations_secy-burwell_2014-07-31.pdf?sfvrsn=4). ASAM feels that these training requirements and oversight structure are sufficient to ensure patients receive high-quality care without dis-incentivizing those physicians who currently treat fewer than 100 patients from continuing to offer this valuable treatment service, as we feel the mandates included in HR 2872 would do. In particular, as your question suggests, mandating counseling services is especially concerning, as many patients' insurance plans do not cover counseling services and counseling services are simply unavailable in many parts of our country. While psychosocial interventions are recommended for patients receiving buprenorphine, they should not be required, especially for stable patients who have been in recovery for many years, for patients whose insurance plans do not cover counseling, and for patients living in areas where such services are unavailable. Tying such a mandate to the ability to offer treatment with buprenorphine would most certainly restrict access to what has been proven to be an effective treatment even without concurrent counseling.

2. **How will ASAM's proposals not only prevent diversion, but also ensure patients receive comprehensive, effective treatment?**

ASAM believes that ensuring physicians and other health care providers who treat patients with opioid addiction are sufficiently educated about the disease of addiction is the most effective way to ensure patients receive comprehensive, effective treatment. That is why ASAM's recommendations for increasing the prescribing limit include detailed training requirements, so that prescribers have a solid understanding of:

1. The chronic disease of addiction
2. The nature of the continuum of care and ASAM Criteria (choosing the correct level of care)
3. The use of the full range of FDA-approved medication options for all addictive disorders with special attention to controlled substances
4. The behavioral interventions required to stabilize and maintain a patient in long term recovery including but not limited to: Mutual help models of recovery, Cognitive Behavioral Therapy, Motivational Enhancement Therapy, Trauma Informed Care, Contingency Management and the team based approach to care with integrated and/or off-site behavioral therapist
5. Development and use of treatment plans
6. Use of and interpretation of drug screens and tests
7. Diversion control: random call backs, drug screens, and medication counts
8. Medical and Psychiatric comorbidities and the coordination of care
9. Use of prescribed or illicit drugs of abuse while in buprenorphine treatment: integrating the roles of PDMPs, care coordination, contingency management, treatment plans, family sessions, and the continuum of care
10. Medico-legal and ethical issues in addiction treatment with buprenorphine

ASAM has also advocated for mandatory education related to pain management and addiction for all prescribers of controlled substances, which we feel will lead to more judicious prescribing of medications with addictive potential (including opioids and other prescription drugs such as benzodiazepines, which contribute to overdose deaths), reduced stigma of both pain and addiction, and increased screening for the risk factors for addiction and referrals to treatment when indicated. Such legislation has been introduced by Rep. Yvette Clark (HR 3889) and ASAM encourages the Energy and Commerce Committee to consider it and report it out.

The Honorable Representative Frank Pallone, Jr.

The Controlled Substances Act currently prohibits the transportation of controlled substances outside of registered locations, making it illegal for physicians to transport controlled substances from one practice setting to another. At the hearing, we heard from a witness about the problems this creates for team physicians who need to transport controlled substances from one state to another for an athletic game or tournament. However, at the same time, we heard from you and other witnesses

that the substance abuse epidemic this country is facing is fueled in part by diversion of prescribed opioid medicines.

1. **Please discuss any issues or potential unintended consequences the Committee should think about when considering legislation to facilitate the ability of doctors to transport controlled substance pain medications with them when they travel with sports teams, or otherwise need access to such controlled substance medicines. What additional safeguards, if any, should be put in place to allow for the safe transport of these substances in the instance of sports travel or for disaster assistance?**

My concern is that there is no shortage of opioids in any State or in any city where an NFL or other professional sports team plays. There only needs to be a better contractual relationship between team doctors so that the prescriptive liability is waived to the away team's physician. Also, it is well documented that there is a significant opioid overuse issue in the NFL. As a Pain and Addiction Physician I would be concerned about the routine use of opioids for standard game related trauma. As an aside, opioids also significantly mask concussion symptoms and would make it difficult to do an accurate post-game assessment.

We already have many ways to transport opioids and other pain relievers. This is accomplished via the Red Cross, the National Guard, local hospitals, FEMA and local ambulance companies. Each of these has to account for every dose given and is responsible for the appropriate and safe storage of the controlled substances.

I see nothing but risk with this bill, especially given the very plausible alternatives and current pathways.