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OCTOBER 20, 2015

# EXAMINING LEGISLATIVE PROPOSALS TO COMBAT OUR NATION'S DRUG ABUSE CRISIS

HOUSE OF REPRESENTATIVES, COMMITTEE ON ENERGY AND COMMERCE

ONE HUNDRED FOURTEENTH CONGRESS, FIRST SESSION

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*WITNESS TESTIMONY*

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Dean
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Indiana University

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Cumberland Heights

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Chair, Legislative Advocacy Committee
American Society of Addiction Medicine

Dr. Allen Anderson *[view pdf]*
President
American Orthopedic Society for Sports Medicine

Dr. Kenneth Katz *[view pdf]*
Department of Emergency Medicine
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*AVAILABLE WEBCAST(S)*:*

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**Testimony to the U.S. House of Representatives' Committee on Energy and Commerce**

**Paul K. Halverson**

**Founding Dean**

**Indiana University Richard M. Fairbanks School of Public Health**

**Indianapolis, Indiana**

**October 20, 2015**

## SUMMARY

- Prescription opioid abuse is a rapidly escalating public health issue across the country. Opioid abuse leads to many health problems including heroin use, drug overdose and death.
- Indiana's mortality rate from drug overdose, at 14.4 per 100,000, has quadrupled since 1999, according to a report by Trust for America's Health.
- Opioid abuse is the cause of an HIV outbreak in a small rural county in Indiana. As of June, the county of 25,000 had 169 confirmed cases in 2015. Prior to this year, there have never been more than 5 cases for the entire southeastern district of the state (12 counties).
- Infants exposed to opioids in utero often experience Neonatal Abstinence Syndrome at birth. They experience irritability, feeding and digestive issues, and respiratory distress. Their hospitalizations are complicated and costly.
- Addiction is a challenging public health problem, due to the lack of consensus about the cause of the problem, i.e., biological/genetic vs. lack of character and will power.
- Although many people who use illegal drugs and become addicted are prosecuted and sentenced to jail, drug abuse continues to grow. We cannot incarcerate our way out of the problem. New approaches our needed.

**Testimony to the U.S. House of Representatives' Committee on Energy and Commerce**

**Paul K. Halverson**

**Founding Dean**

**Indiana University Richard M. Fairbanks School of Public Health**

**Indianapolis, Indiana**

**October 20, 2015**

I'm before you today to discuss a very important and far reaching public health issue, the heroin and prescription drug abuse epidemics, and their deleterious effects, that we're experiencing across the country and in my home state of Indiana.

We know that addiction is not a tragedy for the addicted person alone. It is a tragedy for individuals, families and entire communities. The effects are cumulative, and contribute significantly to costly social, physical, mental, and public health problems. Addiction contributes to teenage pregnancy, harms unborn babies, fuels domestic violence and child abuse and contributes to the spread of sexually transmitted diseases. It leads to missed work, problems holding a job and sometimes to homelessness. Addiction is a major cause of motor vehicle crashes, crime, gun violence, homicide and suicide. As if the public health and social costs are not enough, the financial costs of drug addiction to our state alone, for health care, criminal justice, education and more, are estimated at $7.3 billion annually.

Opioid abuse is particularly pernicious because it can be the precursor to heroin use. A study from the Substance Abuse and Mental Health Services Administration found that nearly 4 out of every 5 new heroin users took non-medical prescription pain medication before taking up heroin.

The end result is that people are dying. Forty-four people die each day in our country from an overdose of pain medication, according to the Centers for Disease Control and Prevention. Nationally heroin-related deaths have escalated from 5,300 to more than 8,200 between 2012 and 2013, a 39% increase.

In Indiana, we have the 17th highest drug overdose mortality rate in the United States, 14.4 per 100,000 people, according to a report from Trust for America's Health (TFAH). The majority of these deaths were from prescription drugs. Since 1999, when the rate was 3.2 per 100,000, our morality rate has quadrupled. Although mortality rates are up in many states in the country, Indiana is one of only 4 states where the rate quadrupled in 14 years. The TFAH report also states that Indiana had only five out of 10 possible indicators for promising strategies to help curb prescription drug abuse. Nationally, 28 states and Washington, D.C. scored six or less, placing us squarely in the bottom half of states.

Indiana made the national news this past summer with its public health crisis related to opioid abuse. Scott County, with a population of less than 25,000 people, had an unprecedented outbreak of HIV related to needle sharing among intravenous drug users who were injecting a prescription opioid. As of June 2015, there were 169 confirmed cases in the county. The entire southeastern region of Indiana has never had more than 5 cases annually prior to this year. Significant cuts in an already chronically underfunded public health infrastructure have hit communities hard, and left them without important public health services such as education on how to protect themselves against life threatening diseases and confidential HIV testing and treatment. As a result, this small county led the entire state in both drug overdose deaths in 2009-2013 (42.66/100,000) and non-fatal emergency department visits due to opioid overdose in (75.28/100,000) in 2009-2013.

Neonatal Abstinence Syndrome (NAS) is another serious crisis unfolding throughout the country. NAS appears in newborns who have been exposed to opiates in utero. The symptoms include increased irritability, hypertonia (spasticity), tremors, feeding intolerance, vomiting, watery stools, seizures and respiratory distress. NAS infants are likely to have significantly longer, more complicated and very expensive hospitalizations at birth. The incidence of NAS has *quintupled* between 2000 (1.20/1,000) and 2012 (5.8/1,000) and mirrors the surge in opioid abuse over the same time period. The percentage of NAS infants covered by Medicaid has risen from 68.7% in 2000 to 81.5% in 2013. Hospital charges for NAS infants in 2013 were estimated at $1.5 billion, placing a significant burden on governmental budgets and the health care system.

Opioid abuse and heroin use indeed have serious consequences for the country, not only in terms of morbidity and mortality, but in the fraying of the social fabric of our communities. Individual attitudes and political responses to illegal drug consumption combine to make substance abuse one of the toughest of all public health challenges. It is often a primary focus for discussions about social values. The bottom line is that we don't have consensus on whether substance abuse is a biological or genetic disease or a matter of personal choice. People sometimes assume incorrectly that drug abusers don't have strong moral principles or willpower. They believe users can stop taking drugs simply by changing their behavior. In reality, drug addiction is a complicated disease, and recovery takes more than good intentions or willpower. Because drugs change the brain in ways that foster compulsive drug abuse, quitting is extremely difficult even for those who desperately want to do so.

By the same token, substance abuse is often a lightning rod in the criminal justice system. However, we have learned that we can't incarcerate our way out of this problem. We already have prisons full of people debilitated by substance abuse problems, and yet still the problem grows. We have to find a new approach.

For all these complex and costly reasons, we are grateful to Representative Brooks for shedding light on the very serious problems of opioid abuse and heroin use, which are becoming more pervasive with each passing day. It is clear we need to effectively attack these problems and prevent further destruction of our public's health due to opioid abuse.

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Statement

Of Chapman Sledge, MD

Chief Medical Officer

Cumberland Heights Foundation

Nashville, Tennessee

to the

United States House of Representatives

Committee on Energy & Commerce

Subcommittee on Health

Re: “Examining Legislative Proposals to Combat our Nation’s Drug Abuse Crisis.”

October 20, 2015

## Summary

The following is a summary of my statement:

- An overview of my background and qualifications to testify
- A brief description of Cumberland Heights, the addiction treatment facility where I serve as Chief Medical Officer
- The opioid problem in Nashville, Tennessee
- The challenges and process of abstinence from opioids
- The course of opioid detoxification and treatment
- Support for the H.R. 2872: The Opioid Addiction Treatment Modernization Act
- Support for H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015

I want to thank the Committee for holding this important hearing on legislative solutions to combat the worsening drug crisis that has swept across our country. Like all of us, I am deeply concerned about what I see happening with regard to the opioid epidemic, in particular, and I am grateful to have this opportunity to share with you my observations and thoughts.

I am Chief Medical Officer of Cumberland Heights, a private not-for-profit addiction treatment center on the banks of the Cumberland River in Nashville, TN. I previously served as Medical Director of Addiction Treatment Services at Pine Grove Behavioral Health in Hattiesburg, MS. I am certified by the American Board of Addiction Medicine, and I am a Fellow of the American Society of Addiction Medicine. I represented Mississippi, Alabama, Florida, Tennessee, and Kentucky on the Board of Directors of the American Society of Addiction Medicine from 2005 until 2009, and served as Secretary of ASAM from 2009 until 2011.

Cumberland Heights will celebrate it's fiftieth anniversary of treating addiction in 2016. We provide addiction treatment to men and women, both adults and adolescents. Though most of our patients are working class and insurance dependent, we also treat a fair number of patients with the resources to pay for treatment out of pocket, and we treat a number of patients dependent upon scholarships to fund their treatment.

A watershed moment in my career as an Addiction Medicine physician came around 2006. On a Saturday morning I was making rounds on our twenty-five bed detox unit. At the end of the day, I realized that every one of the twenty-five patients had a diagnosis of Opioid Dependence. Some of those patients had other substance use disorders as well, but every single patient had a diagnosis of Opioid Dependence. Every one of those patients was dependent upon

prescription opioids. Over the years I have seen our most commonly occurring diagnosis shift from Alcohol Dependence to Opioid Dependence. Of the more than 1,500 admissions to Cumberland Heights in the past year, the most common diagnosis is Opioid Dependence, particularly in young adult patients. Heroin addiction has become more and more prevalent as access to prescription opioids becomes more limited through less abusable formulations, monitoring of controlled substance prescription databases, and education.

My expertise is based in direct patient care. I am an expert in what my patients disclose to me, face to face, in my office.

In 2008, at the ASAM Medical Scientific Conference in Miami, I was asked by a colleague if I used Buprenorphine to treat Opioid Dependence. I replied that we utilized Buprenorphine to detox from Opioids. He remarked that he had never seen a patient recover without Buprenorphine. I told him that I had recovered from Opioid Dependence without Buprenorphine. He said, "Yes, but you weren't using intravenously". He appeared incredulous when I told him that indeed recovered from IV Opioid Addiction without Opioid Agonist Therapy. I am appalled when an addiction treatment provider makes recommendation based on his or her personal experience in treatment; that is not what I am saying. My experience is that there are multiple paths to recovery; there is no one size fits all approach.

Over the years, I have been amazed at the stories of diversion and abuse of Buprenorphine among patients presenting to Cumberland Heights for treatment. Buprenorphine may be used sublingually as designed, used intranasally, or injected. Motivations include "to get high" as well as to treat withdrawal. Of course, some patients with Buprenorphine diversion and abuse take it with the motivation to get off other opioids.

A typical 8 mg dose of Buprenorphine costs $20 in Middle Tennessee, and as much as $40 per 8 mg dose in East Tennessee. The street value supports the level of diversion and abuse. In fact, Buprenorphine has been identified as the third most diverted medication in the United States by the DEA.

My attraction to Cumberland Heights was the ability of the organization to honor tradition while maintaining an innovative approach to treatment. Rarely are patients naïve to Buprenorphine treatment when they present to Cumberland Heights for evaluation. Often, Opioid Dependent patients have failed Buprenorphine or Methadone treatment. During the course of evaluation, the patient identifies a desire to be free of opioids. We have developed a bit of a niche in the local addiction treatment community by using pharmacotherapy to support abstinence from opioids while provided psychosocial treatment to promote ongoing recovery. The most effective technique is residential treatment, detox from opioids, and initiation of long acting naltrexone through injection. We completely understand that addiction is a chronic medical illness, and ongoing recovery requires ongoing treatment. Upon discharge from residential treatment, patients are referred for ongoing psychosocial treatment as well as ongoing administration for extended release naltrexone, Vivitrol.

I am very enthusiastic about two of the bills that are currently under consideration.

The first is the bill that was introduced by Dr. Larry Bucshon and Congressman Womack, titled “H.R. 2872: The Opioid Addiction Treatment Modernization Act.” This bill would require that doctors who obtain certification to prescribe buprenorphine be trained on the use of all FDA-approved treatments for opioid addiction; and they would be required to offer directly, or by referral, all treatment options, based on the individualized needs and preferences of the patient.

Likewise, I like that the bill would require that buprenorphine practices conduct drug screens to ensure patients are actually taking their medication, and not just selling them on the street. Another important provision of this bill is the requirement that these practices maintain diversion control plans. Simply giving opioid dependent individuals a 30-day supply of buprenorphine to take home with them is a prescription for disaster. I am not at all opposed to buprenorphine treatment, but I am opposed to poor and irresponsible treatment. HR 2872 would ensure that individualized, professional treatment is offered based on the needs of the patient, including the option to get off of all opioids.

I understand that HHS is planning on lifting the cap on buprenorphine practices. I do not see how we are ever going to end this opioid epidemic by simply increasing the amount of opioids being prescribed. Quality care and treatment options for patients should be priority number one, not the advancement of the current one-size-fits-all approach that is dominating today's treatment landscape. It is in this context that lifting of the caps should be considered.

There has been a lot of misinformation spread about how liberal access to buprenorphine in Baltimore, or in France, reversed the number of heroin overdoses. However, the data paints a different picture. Heroin overdose rates in Baltimore are at an all-time high, and the numbers of opioid overdoses in France are increasing steadily too.

Lastly, I also want to applaud Congresswoman Brooks and Congressman Kennedy for introducing "H.R. 2805, the Heroin and Prescription Opioid Abuse Prevention, Education, and Enforcement Act of 2015." This bill calls for the formation of a "Pain Management Best Practices Inter-Agency Task Force" to develop recommendations for appropriate training in pain management; and a plan for disseminating the Task Force recommendations. In addition, it

would strengthen prescription drug monitoring programs so that providers can access for the early identification of patients at risk for addiction in order to initiate appropriate interventions.

Our country has to try and eliminate the irresponsible prescribing of opioids, and I support efforts at helping people get off of opioids whenever possible. These two bills do that and for that reason I hope you will give them your thoughtful consideration.

ASAM The Voice of Addiction Medicine
American Society of Addiction Medicine

Testimony of Robert Corey Waller, MD, MS
Before the Energy and Commerce Committee Subcommittee on Health
October 20, 2015

**Executive Summary**

My name is Dr. Corey Waller, and I'm the Chair of the Legislative Advocacy Committee of the American Society of Addiction Medicine (ASAM), which represents more than 3,700 of our nation's addiction specialist physicians and other clinicians.

My testimony today will focus on the following facts:

1. Addiction is a chronic disease of the brain that leads to characteristic biological, psychological, social and spiritual manifestations.
2. 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.
3. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.

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.

**Written Statement**

Chairman Pitts 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. Corey Waller, and I am the Chair of the Legislative Advocacy Committee 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, who are unable to speak before this committee themselves. I am board certified in both addiction medicine and emergency medicine, and I'm the Medical Director of the Spectrum Health Medical Group Center for Integrative Medicine, the Medical Staff Chief of Pain Medicine to the Spectrum Health Hospital System, as well as Substance Use Disorder Medical Director at Lakeshore Regional Partners in Grand Rapids, MI.

Established in 1954, ASAM is a national medical specialty society of more than 3,700 physicians and allied health professionals, including a growing number of nurse practitioners and physician assistants. 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 is a chronic disease of the brain that leads to characteristic biological, psychological, social and spiritual manifestations.

2. 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.
3. There are significant barriers to access these effective medications, resulting in a significant addiction treatment gap in our country.

**Addiction is a Chronic Brain Disease**

We're here today to provide recommendations on how best to respond to the epidemic of prescription opioid and heroin misuse, addiction and related overdose deaths, which, according to the Centers for Disease Control (CDC), have reached epidemic levels in our country. We've all seen the data and heard the shocking statistics. But what's not said or heard enough is that the 2.3 million people who need treatment for opioid addiction have a chronic disease of the brain. While we need to prevent other Americans from developing addiction, these 2.3 million people need treatment.

Like other chronic diseases, such as hypertension and diabetes, addiction is the result of a combination of biological (genetic) and environmental factors. Rather than affecting the circulatory or endocrine system, however, addiction affects areas of the brain involved in reward, motivation and memory, and leads to characteristic biological, psychological, social and spiritual manifestations. This is reflected in an individual pathologically pursuing reward and/or relief by substance use and other behaviors.

Addiction is characterized by inability to consistently abstain, impairment in behavioral control, cravings, diminished recognition of significant problems with one's behaviors and interpersonal relationships, and a dysfunctional emotional response. Like other chronic diseases, addiction

often involves cycles of relapse and remission. Without treatment or engagement in recovery activities, addiction is progressive and can result in disability or premature death.

Also like other chronic diseases, addiction can be treated, but it requires long-term management. Historically, we've treated addiction in this country acutely, expecting patients to recover after relatively short stints in detox or rehabilitation programs. Unfortunately, this model of care isn't working, and it's putting patients at heightened risk for overdose when they return to their communities with a reduced opioid tolerance.

Instead, these patients need ongoing chronic disease management, the goal of which is to reduce morbidity and mortality related to their disease, improve functioning, and use the lowest dose of medication possible. Rather than considering whether or not a patient still needs medication to manage his or her illness, we should be looking for treatment outcomes like reduced incidence of infectious disease, increased employment, housing stability, and reduced involvement with the criminal justice system, among other indicators of a return to physical, mental, social and spiritual health.

**Addiction Involving Opioid Use Can Be Treated Successfully**

These outcomes are not unattainable for a person suffering from opioid addiction. Indeed, addiction involving opioid use can be treated successfully with a combination of medication and psychosocial services.

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 physicians who complete a special

training in their offices; and naltrexone, which is not a controlled substance and can be administered by any licensed prescriber.

All of these medications have proven to be clinically effective. A 2013 review of the scientific literature found substantial, broad and conclusive evidence for the effectiveness of all three medications, and for methadone in particular.[1] Notably, the literature on the efficacy of these medications is not new - there are now eight large-scale, rigorously conducted, reviews of the literature on these medications since the early 1980's. In particular, treatment with methadone has been shown to reduce opioid use, criminal justice involvement, drug-related deaths, unemployment and HIV risk behavior. Several studies of office-based treatment with buprenorphine have found it improves treatment engagement; reduces cravings, illicit opioid use, and mortality; and improves psychosocial outcomes. While there were comparatively fewer studies of naltrexone available at the time of the review, the available research did suggest that it is safe, generally well tolerated and results in immediate and complete blockade of opioid receptors and thus discontinuation of self-administered opioids. Additional research is needed to determine whether early experience with extended-release injectable naltrexone, which suggests greater retention in treatment, reduced craving, and lower opioid use, will result in greater patient willingness to continue the monthly injections and the protection from opioid relapse afforded by those injections. It's important to note, as we consider how to expand access to these medications, that naltrexone cannot be administered to pregnant women; only methadone and buprenorphine are safe to use with expectant mothers.

Finally, we have clear and comprehensive guidelines for how to use these medications effectively in the clinical care of persons with addiction. 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 physicians in the

decision-making process for prescribing pharmacotherapies to patients with opioid use disorder. It's the first guideline to address all the FDA-approved medications available to treat addiction involving opioid use and opioid overdose - methadone, buprenorphine, naltrexone and naloxone. The guideline offers specific clinical recommendations on the assessment and diagnosis of opioid use disorder, treatment options, managing withdrawal, initiating treatment and switching between medications, psychosocial treatment, and special considerations for populations such as pregnant women, adolescents, and persons involved in the criminal justice system.[2]

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

However, despite the strong evidence base for the use of these medications and the clinical guidance available, very few eligible patients are offered medication to help treat their disease. Less than 30% of treatment programs offer medications and less than half of eligible patients in those programs receive medications.[3] Indeed, a study published just last week in the Journal of the American Medical Association found that 80% of Americans with opioid addiction don't receive treatment.[4]

This treatment gap is attributable to many factors, some more complex than others. Research has demonstrated significant access barriers to methadone, including waiting lists for treatment entry, limited geographic coverage, limited insurance coverage, and the requirement that many patients receive methadone at the OTP daily.

The Drug Addiction Treatment Act of 2000 (DATA 2000) was intended to expand access to addiction treatment across geographies and populations by integrating it into the general

medical setting. However, there are also barriers to accessing buprenorphine, including provider willingness and limited insurance coverage. Particularly among specialists like myself and other physicians with advanced training in the treatment of addiction, the limit on the number of patients an individual physician can treat with buprenorphine is a significant barrier to access. ASAM surveyed its members regarding their buprenorphine prescribing practices, in 2013. The results illustrate the difficulties even addiction medicine specialists are having in meeting patient demand. Over 90% of respondents reported having a DEA waiver to prescribe buprenorphine to at least 30 patients with three quarters of those prescribing buprenorphine certified to treat up to 100 patients. However, nearly half reported patient demand in excess of 100 individuals.

In recent months my practice has had to turn away many patients due to the 100 patient limit for buprenorphine. This includes pregnant patients as well as the children of my friends and has resulted in at least 2 overdose deaths. If I am out of town or unavailable, my Physician Assistants are unable to see the patients who need an urgent intake, due to the restrictions on PAs and NPs writing for buprenorphine, which exists even if they are under the guidance of a physician who is board certified in Addiction.

It's important to note that the entire purpose of DATA 2000 was to make opioid addiction treatment available outside OTP settings in traditional physicians' offices, both to increase access in areas where OTPs may be physically inaccessible and to reduce the stigma and patient burden associated with visiting an OTP for treatment on a daily basis. Federal regulation of OTPs is significant, as is state oversight of these facilities. For example, these facilities are required to employ counselors and must be accredited by the Joint Commission or CARF. Regulating individual physician practices in such a manner would undoubtedly overburden smaller practices and drive individual physicians away from offering addiction treatment

services, reducing the already-limited addiction treatment workforce and exacerbating the treatment gap.

This is not to say that the quality of office-based buprenorphine treatment services available is of uniformly high quality. We recognize that diversion of buprenorphine is a problem in many areas and agree that it's a concern. Moreover, due to lack of insurance coverage or lack of qualified providers, some patients don't receive high quality psychosocial support in addition to their medication. That's why our recommendations to lift the patient limits under DATA 2000 include required training on diversion control techniques such as call-backs, pill counts and urine drug screens, as well as comprehensive education on psychosocial supports.

While increased diversion is often cited as a chief concern related to raising the patient limit, research suggests that the relationship between treatment access and diversion is an inverse relationship, meaning greater access may even reduce diversion. Highlighting this is a study out of the University of Kentucky that found an inability to access treatment was a risk factor for using diverted buprenorphine.[5] This finding aligns with what many addiction treatment providers know from experience: when patients cannot access treatment, either due to wait lists or lack of insurance, they may purchase diverted buprenorphine to self-medicate. Additionally, some patients will share their prescription with loved ones who cannot access treatment or sell part of their prescription to cover the expense of the office visit for their addiction treatment if their insurance coverage does not pay for (or does not pay adequately for) the physician's services or the cost of the medication.

Still, because diversion and quality of care remain legitimate concerns, ASAM has proposed a gradual and limited lifting of the DATA 2000 limits. Our recommendations would allow specialists and physicians with additional training to treat up to 500 patients, while being subject

to quality checks by SAMHSA (See Attachment 1). Specifically, ASAM proposes that either Congress or the Secretary of the Department of Health and Human Services (HHS) increase the limit as follows:

- Over a two-year phase-in, increase the limit for prescribing physicians to 250 patients in year 1 and 500 patients in year 2. Prescribers seeking an increase in patient limit must satisfy additional addiction treatment training requirements approved by the Substance Abuse and Mental Health Services Administration (SAMHSA) that covers prescribing, counseling, treatment planning, drug testing, pill recall, etc. This training would be in addition to the buprenorphine certification requirement currently required to qualify for the 30/100 patient prescribing limit.

- Prescribing physicians who are expert in treating addiction as evidenced by board certification by ABAM in addiction medicine or the American Board of Psychiatry and Neurology (ABPN) in addiction psychiatry shall not be required to obtain the additional training, including training on diversion control techniques and psychosocial interventions.

- Additionally, we recommend there be a follow up study on the impact of increasing the limit on diversion rates and treatment access. Specifically, after year 2 of the increased prescribing limit, HHS, in consultation with the Drug Enforcement Administration (DEA), and CDC, should determine what impact, if any, the increase in access to opioid addiction medications has had on: decreasing deaths due to opioid overdose; decreasing diversion rates; and improving patient access to the Food and Drug Administration (FDA)-approved opioid addiction pharmacotherapies.

By coupling a lifting of the patient limit with increased training requirements and accountability for those physicians treating large numbers of patients, we feel we can expand access while also ensuring a certain quality of care. Still, this single strategy should be just one part of broader federal efforts to ensure safe prescribing of opioids for pain, alternate pain therapy options and early identification of and treatment for addiction.

Pain and addiction education should be required curriculum in medical school and encouraged as continuing medical education throughout a physician's career. Communities should have the resources to educate their citizens about these issues and the outreach and surveillance resources necessary to better understand their unique issues and needs.

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

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**Appendix: ASAM Position on Bills under Consideration**

| Bill | ASAM Position |
|---|---|
| HR 2536, the Recovery Enhancement for Addiction Treatment Act | ASAM strongly supports this bill as a means of improving patient access to life-saving medications that treat opioid addiction through a strategy that supports improved prescriber education, diversion control and expansion of qualified buprenorphine treatment providers. The current opioid epidemic is compounded by a documented gap in access to evidence-based treatment, including buprenorphine treatment. Expanding the prescribing limit for qualified addiction treatment providers will have an immediate, positive impact on expanding opioid addiction patient access to a clinically and cost-effective addiction pharmacotherapy.<br><br>ASAM has also recommended an approach to expand the DATA 2000 patient limits that would gradually increase the limits for board-certified specialists and other physicians who have completed additional training requirements (40 hours of addiction treatment training initially and 36 hours of addiction-related CME every three years thereafter). These recommendations propose expanding the patient limit to 250 in the first year of prescribing and 500 thereafter. Physicians prescribing to more than 100 patients under this approach would be subject to random audits by SAMHSA to ensure they are adhering national standards of care and national medical |

| | |
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| | practice guidelines for the treatment of opioid addiction with agonist, partial-agonist and antagonist medications (for example, the establishment of individual treatment plans; use of individual, family and group psychosocial services; and use of diversion control strategies). This recommended approach would also expand prescribing authority to nurse practitioners and physician assistants who complete additional training (40 hours of addiction treatment training initially and 36 hours of addiction-related CME every three years thereafter) and practice under the supervision of a physician qualified under these recommendations to treat more than 100 patients. |
| HR 2805, the Heroin and Prescription Opioid Abuse Prevention, Education and Enforcement Act | ASAM supports this bill but notes that the section directing the establishment of a Pain Management Best Practices Inter-Agency Task Force to develop best prescribing practices may be redundant to efforts currently underway by the CDC. Still, ASAM supports the reauthorization of the Byrne Justice Assistance Grant program, the advancement of public education and awareness campaigns, and the development of naloxone demonstration grants to improve naloxone access. |
| HR 2872, the Opioid Treatment Modernization Act | ASAM has several concerns with this bill and believes it will have significant unintended consequences on access to addiction treatment involving buprenorphine. Dramatically reducing access to evidence-based addiction treatment at a time when our nation is experiencing an epidemic of prescription opioid and heroin overdose deaths is misguided |

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| | policy. This bill would create several new barriers to treatment by placing unnecessary and excessive administrative burdens on physicians to prescribe buprenorphine, as well as by creating new, additional barriers to becoming certified to prescribe this medication in the first place. In effect, it would reduce the addiction treatment workforce and further restrict already limited access to care for patients in need, particularly in rural and underserved areas where there are already access issues.<br><br>Moreover, since the bill only amends the section of the Controlled Substances Act governing the use of Schedule III-V narcotics to treat addiction in physicians' offices, it by default only applies to the use of one of the three FDA-approved medications for opioid addiction treatment. It therefore will not be able to have its intended effect of ensuring "the full range of science- and evidence-based treatment options for opioid addiction are fully integrated into treatment," because it narrowly targets only one treatment option. |
| HR 3014, the Medical Controlled Substances Transportation Act | ASAM is concerned this bill would create significant loopholes that could be exploited by those wishing to transport controlled substances for illicit purposes and undermine local law enforcement agencies' ability to interrupt drug trafficking. |
| HR 3537, the Synthetic Drug Control Act | ASAM supports the careful regulation of dependence-producing substances. Additionally, ASAM recommends that |

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| | law enforcement measures aimed at interrupting the distribution of illicit drugs should be aimed with the greatest intensity at those causing the most serious acute problems to society. The balance of resources devoted to combating these problems should be shifted from a predominance of law enforcement to a greater emphasis on treatment and prevention programs, as well as programs to ameliorate those social factors that exacerbate drug dependence and its related problems.<br><br>ASAM would also recommend either a delayed effective date or additional funding for DEA to process research approvals for those scientists currently conducting research on these specific substances. |
| HR 3680, the Co-Prescribing to Reduce Overdoses Act | ASAM supports efforts to increase co-prescribing of naloxone to patients receiving high-potency, long-acting opioids, so that naloxone is available for home use in the event of an overdose situation experienced by the patient or by any others in the household. |
| Draft Bill, the Improving Treatment for Pregnant and Postpartum Women Act | ASAM supports efforts to increase access to opioid addiction treatment services for pregnant and postpartum women. |

**Attachment 1: ASAM Letter to Secretary Burwell, July 31, 2014**

July 31, 2014

The Honorable Sylvia Burwell
Secretary, US Department of Health and Human Services
200 Independence Avenue, SW
Washington, DC 20201

Dear Secretary Burwell,

On behalf of the members of the American Society of Addiction Medicine (ASAM), the nation's largest medical professional society representing addiction physician specialists and affiliated addiction health professionals, we respectfully submit to you our recommendations for urgently addressing the opioid epidemic. These recommendations are informed by our members' collective expertise and reflect their myriad specialty backgrounds, the diverse patient populations they serve, and the wide range of clinical settings in which they practice.

Opioid addiction does not discriminate: regardless of income, education level or social standing, opioid addiction looks the same to the practicing addiction doctor. It leads to severe impairment and, far too often, to death. Fortunately, like other chronic diseases, opioid addiction can be prevented and the millions of Americans now suffering from this disease can be treated. As with other chronic illnesses, treatment does not consist of only one simple treatment for all sufferers. Treatment often requires multiple, overlapping therapies that may include medication, behavioral therapy, family therapy, and ongoing recovery support.

With that framework in mind, we urge the Administration to consider proposals that focus holistically on provider and community education, overdose death prevention and increased access to treatment, in order to effectively manage the epidemic. We hope the following recommendations inform and support the critical work you are doing to address this issue.

Sincerely,

Stuart Gitlow, MD, MPH, MBA, FAPA
President, American Society of Addiction Medicine

Attachment: ASAM Recommendations to Address the Opioid Epidemic

CC:
Pamela Hyde, JD, Administrator, Substance Abuse and Mental Health Services Administrator (SAMHSA)
Elinore McCance-Katz, MD, PhD, Chief Medical Officer, SAMHSA
H. Westley Clark, MD, JD, MPH, Director, SAMHSA Center for Substance Abuse Treatment
Michael M. Botticelli, Acting Director, Office of National Drug Control Policy

**Overdose Prevention and Opioid Addiction Treatment Recommendations**

**Section I: Education**

Physicians receive little training about pain management or addiction treatment in medical school or in residency programs. As a result, there is a general lack of understanding and experience among most physicians related to these diseases. This lack of education reinforces the prevailing modes of practice: prescription opioids for pain management and an antiquated view of addiction as an acute behavioral problem for which treatment is only self help or weeks of inpatient rehabilitation.

It is the opinion of ASAM that a lack of education among most physicians about the proper treatment of chronic pain and chronic opioid addiction disease is a considerable contributing factor to the current opioid addiction epidemic. ASAM offers the following recommendations, in an effort to address these problems:

1. Mandatory prescriber education on addiction prevention/treatment tied to DEA certificate to prescribe controlled substances.

a. Applies to all prescribers of controlled substances including, but not limited to, physicians, nurse practitioners, and physician assistants, as well as to pharmacists.
b. Education would also be required for recertification.

2. Mandatory medical school education on addiction (minimum 12 hours)
    a. Schools not in compliance with requirement would be unable to accept students using federal financial aid
3. Community Education Grants on proper use of naloxone, and the continuum of care for treatment of addictive disease

**Section II: Prevention**

Building on the infrastructure of the Drug Free Communities (DFC) program is a cost effective way to invest minimal federal dollars to prevent prescription drug abuse at the community level and get positive results. ASAM recommends:

1. New funding to allow current and past DFC grantees to apply for supplemental grants of up to $75,000, on a dollar for dollar matching basis, to deal with their community's prescription drug epidemic in a comprehensive, community wide fashion. ($5 million)

**Section III: Overdose Prevention**

ASAM supports the increased use of naloxone in cases of opioid overdose. Naloxone has been proven to be an effective, fast-acting, inexpensive and non-addictive opioid antagonist with minimal harmful side effects, when used to prevent the often fatal respiratory arrest which characterizes the advanced stages of prescription or illegal "opioid" overdose. Naloxone can be

administered quickly and effectively by trained professionals and by lay individuals who observe the initial signs of an opioid overdose.

Persons provided with naloxone supplies for use in the event of drug overdose, including known illicit opioid users who are provided with these supplies under a public health program of harm reduction, should be educate about the prevention, detection, and appropriate response to drug overdose, for example, how to recognize opioid overdose symptoms and how to refer to emergency medical services. Lay persons offered prescriptions for naloxone at medical visits, or provided with nasal naloxone delivery devices through public health agencies, should also be provided education on proper use of these devices and information on accessing addiction treatment.

Therefore, ASAM recommends:

1. Increase naloxone access with recommended training including: pharmacist training; package inserts appropriate to the patient's level ; and/or community-based training and education about both opioid overdose treatment and about opioid addiction treatment options.

**Section IV: Treatment**

A key mission statement of the American Society of Addiction Medicine is, "to increase access to and improve the quality of addiction treatment." A 2013 survey of ASAM's membership revealed that the 100-patient prescribing limit on buprenorphine was considered a major barrier to patient access to care. Furthermore, ASAM public policy specifically recommends against laws, regulations or health insurance practices that impose arbitrary limits on the number of

patients who can be treated by a physician or the number and variety of pharmacologic and/or psychosocial therapies that may be used for treatment. No other disease, no other specialty, and no other medication are limited in this manner.

Fundamentally, the following recommendations are intended to address an escalating opioid epidemic by addressing a policy that significantly limits patient access to a clinically and cost-effective treatment by proposing alternatives that would increase access to pharmacotherapies to treat opioid addiction in a thoughtful, judicious way.

ASAM's recommendations are also supported by the development of an ASAM clinical guideline on pharmacological therapies for opioid use disorders that will establish very clear boundaries around the proper use of buprenorphine in managing opioid addiction, including strategies for mitigating diversion like the establishment of treatment plans and routine random drug screens, pill counts, and prescription drug monitoring program reviews. Recognizing that best practice of chronic diseases requires attention to all elements of a biopsychosocial approach, the guideline also specifically addresses the utility of psychosocial supports in the treatment plan by doing a literature review of all the existing clinical evidence regarding these modalities in the context of medication management of opioid addiction.

Given these considerations, ASAM recommends:

1. Increase of buprenorphine prescribing limit, phased in over 2 years (250 patient limit per physician for year 1, then a 500 patient limit per physician for year 2)
    a. Prescribing physicians who are expert in treating addiction as evidenced by addiction medicine certification by the American Society of Addiction Medicine (ASAM), board certification in addiction medicine by the American Board of Addiction Medicine (ABAM) , subspecialty board certification in addiction

psychiatry from the American Board of Psychiatry and Neurology (ABPN), or a subspecialty board certification in addiction medicine from the American Osteopathic Association (AOA) shall qualify for an increased limit, to 250 in year 1 and 500 in year 2.

b. Non-addiction specialist physicians seeking an increase in patient limit must satisfy additional addiction treatment training requirements as follows:
    i. Additional training requirements for non-addiction physician specialists will be developed by the American Society of Addiction Medicine, the American Academy of Addiction Psychiatry, the American Osteopathic Academy of Addiction Medicine, or any other organization that the Secretary determines is appropriate for purposes of this subclause, in consultation with the Substance Abuse and Mental Health Services Administration (SAMHSA).
    ii. Such training will consist of a minimum of 40 hours including both didactic and skills-based training based in the standards of high quality care using buprenorphine, as delineated in national medical practice guidelines related to the treatment of opioid addiction with pharmacotherapy (ASAM practice guidelines, to be released in Spring 2015).
    iii. Training must include at least 2 hours each, in the following areas:
        1. The chronic disease of addiction
        2. The nature of the continuum of care and ASAM Criteria (choosing the correct level of care)
        3. 12 step models of recovery
        4. Individual, group and family education and counseling
        5. Motivational enhancement theory and skill development
        6. Contingency management techniques

7. Development and use of treatment plans
8. Use of and interpretation of drug screens and tests
9. Diversion control: random call backs, drug screens, and medication counts
10. Medical and Psychiatric comorbidities and the coordination of care
11. 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
12. Medico-legal and ethical issues in addiction treatment with buprenorphine

c. Advance-practice providers (APPs, e.g., nurse practitioners, physician assistants) who meet the requirements to obtain a waiver to prescribe buprenorphine can only do so under the supervision of a physician who is certified to treat over 100 patients (see #1a, 1b above)
    i. APPs may not exceed the 100-patient limit.
    ii. APPs must complete the training course as described in 1b above in order to prescribe buprenorphine to treat addiction.
    iii. The 100 patients treated by an APP will not be counted as part of their supervising physician's limit.
d. All prescribers are required to complete 36 hours of continuing medical education related to addiction medicine every 3 years.
    i. Physician specialists, as defined in 1a, could be waived from the ongoing education requirement if they can prove ongoing participation in their board's Maintenance of Certification requirements.

ii. Physicians practicing under the 100-patient limit would be required to satisfy 9 hours of continuing medical education related to addiction medicine, every 3 years.

2. All practitioners who are certified to treat 250 or 500 opioid-dependent patients with buprenorphine may be subject to random site audits by the Substance Abuse and Mental Health Services Administration (SAMHSA), in order to assure that high-level prescribers are adhering to national addiction medicine standards of care and to national medical practice guidelines related to the treatment of opioid addiction with opioid agonist, partial-agonist and antagonist pharmacotherapies.
   a. Audits by SAMHSA shall be in lieu of audits by the Drug Enforcement Administration (DEA).
   b. Practitioners prescribing to over 100 patients who do not comply with a SAMHSA audit will be subject to an audit by the DEA.
   c. Physicians prescribing within the parameters of the 30-patient and/or 100-patient waiver will not be subject to SAMHSA or DEA audits.
   d. Non-physician prescribers shall be subject to audit as part of the audit of their physician supervisors.
   e. In order to meet audit requirements, prescribers should include the following, as part of their office-based opioid treatment program protocols:
      i. bio-psycho- social admission assessments, including appropriate physical examination and laboratory testing
      ii. Formal treatment planning and regular treatment plan updates
      iii. Screening for medical and psychiatric co-morbidities and referral for treatment

iv. Utilization of individual, family, and group psycho-education and counseling modalities consistent with guidelines and treatment of other chronic behavioral health disorders

v. Utilization of both scheduled and random drug screens, scheduled and random drug tests when appropriate, and Prescription Drug Monitoring Program checks

vi. Use of contingency management protocols, with repercussions for failed drug screens/ failed PDMPs consistent with harm-reduction treatment of opioid dependence approach

3. Follow-up study on impact of increase on diversion rates (DEA) and impact on treatment access (HHS/ASPE).
   a. There is evidence indicating that geographic areas of low access to buprenorphine treatment have higher levels of buprenorphine diversion. After year 2 of the increased prescribing limits, HHS, in consultation with the DEA, will determine what impact, if any, the increase in access to opioid addiction medications has had on diversion rates and whether there has been improved patient access to the FDA-approved opioid addiction pharmacotherapies.

4. Remove restriction on initiation of buprenorphine for the treatment of opioid addiction in hospitals.
   a. Under current regulations, physicians who initiate patients for the first time on buprenorphine for the treatment of opioid addiction in hospitals are unable to have the prescription filled by a hospital inpatient pharmacy. Hospitals are currently being told, in writing, that they cannot let their inpatient DEA registration

and their inpatient medication administration procedures apply to the initiation of buprenorphine for opioid addiction.

5. $50 million in increased Substance Abuse Prevention and Treatment block grant funding for dissemination of evidence-based models for preventing and treating opioid dependence

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The American Orthopaedic Society for Sports Medicine

*A world leader in sports medicine education, research, communication, and fellowship.*

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OCTOBER 20, 2015

Testimony of

**ALLEN F. ANDERSON, M.D.**
**PRESIDENT**
**AMERICAN ORTHOPAEDIC SOCIETY FOR SPORTS MEDICINE**

Before the

**US HOUSE OF REPRESENTATIVES**
**COMMITTEE ON ENERGY AND COMMERCE**
**SUBCOMMITTEE ON HEALTH**

I'd like to thank you Mr. Chairman, and all of the honorable members of this subcommittee, for the opportunity to testify here today. My name is Allen Anderson, and I am an orthopaedic surgeon specializing in sports medicine. I am also president of the American Orthopaedic Society for Sports Medicine or AOSSM. AOSSM is a 501(C)(3) nonprofit educational organization for orthopaedic surgeons specializing in the care of athletic injuries at every level of competition – youth, collegiate, elite and professional. 60 percent of our members take care of high-contact/collision sports like football or ice hockey, where a serious injury can occur. A team physician must have an unrestricted medical license and be a medical doctor or doctor of osteopathy in good standing. He or she must have a fundamental knowledge of on-field medical emergency care and a working knowledge of musculoskeletal injuries, medical conditions and psychological issues affecting the athlete. The most important responsibility of the team physician is the medical care of athletes of all ages and all levels of competition, whether it be amateur or professional, grade school children or the master athlete.

Today I want to discuss the need for a team physician to be able to carry controlled substances when travelling with the team. I will explain the problems with current law, describe the fact that work-arounds are not practical, and why HR 3014, the Medical Controlled Substances Transportation Act will enable the team physician to provide the best quality medical care to an injured athlete.

In emergencies or disasters when there is significant trauma it is critical that a physician have immediate access to controlled substances in order to adequately treat the patient. Athletes who play contact sports and then fly home on the same day are at much greater risk of having an urgent medical problem than is the usual flying public secondary to recent strenuous activity. There are times, such as during air travel or on a bus, when the team physician is the only medical person available to render care. There are documented cases of players having seizures on a flight, and in such a situation, controlled substances are needed to stop the seizure and save the players life. Additionally, it is humane care to allow a player to take a pain pill in the event that he/she has a broken bone and is flying back home.

One or more athletes are injured in almost every collegiate game you watch on Saturday. These players who are your constituents come from almost every state in the Union. The team physician, who is probably a member of AOSSM, is there on the sideline to render aid and take responsibility for the athletes' wellbeing. This aid is severely restricted by current law.

Currently, the Controlled Substances Act of 1970 prohibits the transportation and storage of controlled substances away from the site of storage that is registered with the Drug Enforcement Agency (DEA) making it illegal for team doctors to transport a limited quantity of critical medications that might be needed for pain control or emergency management while travelling with their teams. This is highly problematic for athletic team physicians who need the ability to maintain a limited supply of controlled substances for those instances where a player is injured during games that are away from home. The DEA and federal law is quite strict concerning the transportation and

dispensing of prescription drugs, and especially controlled substances, in states where the physician is not licensed. A physician may only store, dispense or administer controlled substances at a physical location and address registered with the DEA. Therefore a doctor dispensing or administering controlled substances at multiple practice locations must do so at each location under that location's specific DEA registration number. This applies whether the controlled substances are transported within the same state or across state lines. Most states similarly require physicians to dispense under a state controlled substances registration. Additionally, federal law requires that registrants complete specific DEA forms and invoices for the purposes of each registered location's required records.

The current work-arounds for this are problematic for several reasons. Current options for a team's medical staff include pre-dispensing medication to specific athletes prior to travel, or delegating the dispensing of controlled substances to the home medical state in the state of entry. Travel schedules and limited availability of local physicians to prescribe/dispense controlled substances is an issue. The local physician needs to independently examine the patient, and the local physician has limited ability to follow the patient after they leave the area. There are privacy concerns – the local physician is generally caring for a competing team. The local physician also has competing demands to treat players with his/her primary team.

HR 3014, the Medical Controlled Substances Transportation Act, would address these concerns. It provides the physician who is traveling with a team with a construct in which he/she can appropriate manage the injury – short of surgery or hospitalization – in a similar fashion to when they are at their home sports facilities, including prescribing and dispensing of controlled substances when medically appropriate. It does not diminish the need or requirement for controlled substances to be monitored to a lesser extent than at the primary area of practice; nor does it limit the accountability of the physician. The team physician will be responsible for the security of the controlled substances throughout the entire time the team will be traveling.

Specifically HR 3014 requires the physician to enter into a specific agreement with the DEA in order to transport a controlled substance. The agreement includes the controlled substance to be transported, the practice setting from which the controlled substances will be transported, the practice setting or disaster area to which controlled substances are transported, the dates of transport, the anticipated travel time and the intended mode of transport. The duration of transport is limited to 72 hours and records of the controlled substances dispensed are maintained. It should be noted that these medications are registered and subject to inspection by the DEA at any time.

Thank you for your consideration of this important measure that would allow the highest level of care for an injured athlete.

Military flight surgeons and rural large animal veterinarians have exemption and are able to carry the medications they need. Team contact sports can be much more perilous than non-combat military maneuvers or treating large animals.

This legislation would also benefit rural physicians who travel long distances to see patients, physicians whose practices lie on a state line, and physicians who donate their time to assist patients in declared disaster areas.

The AOSSM appreciates the opportunity to discuss this matter with you today, and I'm happy to answer questions.

Statement of

Kenneth D. Katz, M.D., F.A.C.M.T., F.A.A.E.M.

Section of Medical Toxicology
Department of Emergency Medicine
Lehigh Valley Health Network

Allentown, Pennsylvania

On behalf of the
American College of Emergency Physicians (ACEP)

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

Hearing on

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

Presented
October 20, 2015

I. Introduction

The drug epidemic confronting this nation has been significantly transformed in recent years due to the accessibility of cheaply made, mass-produced, deadly synthetic drugs. The use of these dangerous compounds has directly led to violence, hospitalizations, and deaths. For example, in both the adult and pediatric intensive care units in Allentown, Pennsylvania this spring, I spent countless hours at the bedside caring for many patients suffering from the toxic effects of synthetic cannabinoids. Most notably, there were 11 individuals who tested positive for a novel, potent synthetic cannabinoid, named MAB CHMINACA. This exposure was further corroborated when the identical compound was found in drug material packages found on their persons.

Sadly, the majority of these patients were adolescents who required ventilators to breath and administration of potent sedatives to calm them. Several of these patients experienced seizures, and one teen even suffered irreparable brain damage and died. Needless to say, the impact on the lives of these patients and their families has been incalculable.

During this time, I worked with the Lehigh County district attorney, the Pennsylvania Department of Health, National Medical Services Laboratories and the Philadelphia Poison Control Center to try and rapidly identify the poison which ripped through eastern Pennsylvania, leaving in its wake multiple patients in emergency departments, hospitals and, unfortunately, morgues.

Mr. Chairman and members of the subcommittee, my name is Dr. Kenneth D. Katz, M.D., F.A.C.M.T., F.A.A.E.M., and I would like to thank you for allowing me to testify today on behalf of the American College of Emergency Physicians (ACEP) to discuss the dangers posed by synthetic drugs and to advocate for enactment of H.R. 3537, the "Synthetic Drug Control Act of 2015."

ACEP is the largest specialty organization in emergency medicine, with more than 34,000 members committed to improving the quality of emergency care through continuing education, research, and public education. ACEP has 53 chapters representing each state, as well as Puerto Rico and the District of Columbia and a Government Services Chapter representing emergency physicians employed by military branches and other government agencies.

In addition to my work in the Department of Emergency Medicine and Section of Medical Toxicology at Lehigh Valley Health Network in Allentown, Pennsylvania; I am also an Assistant Professor of Emergency Medicine with the Philadelphia College of Osteopathic Medicine. I am board certified in emergency medicine, medical toxicology and internal medicine.

II. What are synthetic drugs?

In every community across the nation, my colleagues and I are treating more and more patients who have experienced synthetic drug toxicity or poisoning. It's important to understand that the term "synthetic drugs" we are using here today describes substances that are primarily manufactured in clandestine Chinese laboratories and actually represents a nimiety of chemical combinations that are designed to mimic the effects of illegal chemicals with stimulant,

depressant or hallucinogenic properties. They are non-organic, chemically synthesized, unsafe recreational drugs that produce psychoactive, or mind-altering, effects, and they fall into two main categories: cathinones and cannabinoids.

Cathinones are stimulants with effects similar to cocaine and amphetamine, while cannabinoids are forms of synthetic marijuana that consists of lab-manufactured THC (tetrahydrocannabinol). Many of these substances are marketed as innocuous products such as incense, plant fertilizer or air freshener and then sold in convenience stores, gas stations, or online. Because of their commercial availability, many users presume they must be safe. They are labeled "not for human consumption" to mask their intended purpose and avoid Food and Drug Administration (FDA) regulatory oversight, and they have been given street names such as "Scooby Snacks," "Smiley," "Cloud Nine," and "Vanilla Sky" to make them more attractive and less threatening.

However, the public should not be fooled. Even though these products may be hiding in plain sight, they are colorfully packaged poisons.

III. Why are synthetic drugs so dangerous?

Most illicit drug manufacturers aim to refine the purity of their products in order to increase the street value and profit margin. However, regarding synthetic drugs, individual products can contain a vast array of different chemicals with varying potencies. For example, synthetic cannabinoids may contain compounds two to 500 times more powerful than THC. In many cases, the manufacturers' only goal is to alter the chemical compound in such a way to technically create a "new" compound, allowing them to circumvent legislative and regulatory

bans. Furthermore, detection of substances such as synthetic cannabinoids is literally impossible using either standard or even advanced drug testing in a hospital laboratory. It can only be performed by sending samples to specialty labs outside of the hospital and, even in these cases, confirmation of a novel compound can take weeks due to the subtle changes made by the chemists producing them.

This modification process poses increasing risks to users who are unaware of the reactions the new chemicals or formulations may cause. It is not until these substances are ingested or inhaled that some, or all, of the following symptoms can occur: hyperthermia; elevated blood pressure and pulse; severe, uncontrollable agitation; seizures; coma; muscle breakdown; kidney injury; and, ultimately, death. Because there is no standard for manufacturing these drugs, the potency of each batch is different, which greatly increases the risk of toxicity. Unfortunately, at that point, it may be too late for either my emergency medicine colleagues, or even me, as a medical toxicologist, to save them.

IV. Synthetic drug use increasing

While there is an increasingly expanding array of synthetic drugs being manufactured, of particular concern to ACEP is the availability and high use of synthetic cannabinoids. According to the latest data available from SAMHSA's Drug Abuse Warning Network, the number of emergency department visits involving synthetic cannabinoids increased by nearly 70% between 2010 to 2011 (11,406 to 28,531). Furthermore, the number of emergency department visits for patients aged 12 to 17 doubled from 3,780 to 7,584 during that same timeframe while visits for patients aged 18 to 20 increased fourfold (from 1,881 in 2010 to 8,212 in 2011). There is a

highly disproportionate use of these drugs by males as well who accounted for nearly 80 percent of the 2011 visits.[i]

The 2013 National Drug Threat Assessment Summary notes that the number and type of synthetic cannabinoids have increased exponentially as evidenced by the number of reports submitted to the National Forensic Laboratory Information System (NFLIS). There were 29,467 synthetic cannabinoid drug reports in 2012, which was an increase of 1,402 percent from 2009 when there were only 21.[ii] According to the 2014 NFLIS midyear report, there were already 19,838 synthetic cannabinoid drug reports in the first six months of 2014.[iii]

In addition, the American Association of Poison Control Centers reported 5,230 total synthetic marijuana exposures in 2012. Through September 30 of this year, there have been 6,310 exposure reports, and these numbers do not account for ED presentations and hospital admissions of which the poison control centers are unaware.[iv]

My home state of Pennsylvania has been especially hard hit by the increasing use of synthetic marijuana, trailing only New York, Mississippi, and Texas in the number of reported exposures this year.

V. What has been done at the federal and state levels?

Synthetic drugs first appeared in the United States around 2009, and prior to 2010, they were not controlled by any federal or state statute. As these drugs quickly grew in availability, popularity,

and use, the medical community witnessed the terrible effects these drugs had on the lives of their victims, their families, and the communities in which they lived.

In an effort to curb access to these toxic substances, ACEP was proud to work with Representative Dent and Senators Grassley, Feinstein, Klobuchar and Portman to enact the "Synthetic Drug Abuse Prevention Act" as part of the "Food and Drug Administration Safety and Innovation Act" (P.L. 112-144) in 2012. The provisions of that law permanently placed 26 types of synthetic cannabinoids and cathinones into Schedule I of the Controlled Substances Act (CSA) and extended the period of time that the U.S. Drug Enforcement Administration (DEA) may administratively schedule substances under its emergency scheduling authority from 18 to 36 months.[v]

Currently, all 50 states have banned some cannabinoids and cathinones, with the majority doing so through legislation. Since synthetic compounds are easily manipulated to make new drugs, many states have passed laws targeting entire classes of substances or use broad language to describe the prohibited drugs. The intent of these general bans is to prevent new forms of synthetic drugs from remaining unregulated, while still allowing use for approved medical and research purposes.[vi]

VI. What more can Congress do?

While our combined effort to modify the CSA in 2012 was a good first step, federal statutes must be updated to meet this constantly evolving challenge and restrain these dangerous products. The Federal Analogue Act[vii] provides that any chemical that is "substantially similar" to a

controlled substance listed in Schedule I or II of the CSA is to be legally treated as though it were also listed in that schedule.

However, in order to obtain a successful conviction under the Federal Analogue Act, the prosecutor must demonstrate to the jury that the chemical in question: (1) is substantially similar to the chemical structure of a controlled substance; AND (2) causes a stimulant, depressant, or hallucinogenic effect that is substantially similar to that of a controlled substance. The courts have maintained a very high bar for the interpretation of "substantially similar" and cases involving the Analogue Act often turn into courtroom battles of chemists debating the minutiae of molecular structure and endocrinology.

The "Synthetic Drug Control Act of 2015" (H.R. 3537), sponsored by Representatives Charlie Dent (R-PA) and Jim Himes (D-CT), would amend the Analogue Act to strike "substantially" from the analogue definition and allow for a substance to be treated as an analogue if it is chemically similar OR produces a similar clinical effect. This legislation is targeted at the manufacturers and distributors of synthetic drugs, not the end-users. It would amend the Analogue Act so that it would only apply to the sale, manufacture, import, and distribution of drugs -- not simple possession. Furthermore, H.R. 3537 would add more than 200 known synthetic drugs to Schedule I of the CSA.

Enactment of H.R. 3537 is critical, but improved public awareness regarding the risks associated with using synthetic drugs is equally so. ACEP has a long history of conducting public awareness campaigns related to injury prevention and public safety issues, such as: wearing

bicycle and motorcycle helmets, texting while driving, child passenger safety, drunk driving and firearm safety, just to name a few. It has been our experience that these efforts help avert emergency department visits and save lives.

## VII. Conclusion

The easy access to, and thoughtless use of, synthetic drugs by those who are unaware of their dangerous toxicities not only places their health and lives at risk, but can have a profound impact on my ability to care for all of my patients. When users of synthetic drugs need emergency medical attention, they are utilizing precious resources, such as ambulances, emergency department beds, hospital personnel, and limited health care dollars.

It is both my opinion, and that of the American College of Emergency Physicians, that this critical issue must be addressed through the enactment of H.R. 3537 and supplemented by a national campaign to educate Americans about the dangers of using synthetic drugs.

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[i] Substance Abuse and Mental Health Services Administration (SAMHSA); Drug Abuse Warning Network; The CBHSQ Report; "Update: Drug-Related Emergency Department Visits Involving Synthetic Cannabinoids;" 10/16/2014

[ii] American College of Emergency Physicians Public Health & Injury Prevention Committee; "Synthetic Drug Overdose: An Information Paper"

[iii] Drug Enforcement Administration; Office of Diversion Control; National Forensic Laboratory Information System; 2014 Midyear Report

[iv] American Association of Poison Control Centers; Alerts; Synthetic Cannabinoids

[v] Office of National Drug Control Policy; Synthetic Drugs (a.k.a. K2, Spice, Bath Salts, etc.); Government Efforts to Ban Synthetic Drug Products

[vi] National Conference of State Legislatures; "Synthetic Drug Threats;" 1/13/2015

[vii] Federal Analogue Act (21 U.S.C. §813)