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.

---

[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)