Statement of

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Deadly Synthetic Drugs: The Need to Stay Ahead of the Poison Peddlers

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Chairman Grassley, Ranking Member Feinstein, and distinguished committee members, my name is Dr. Sullivan Smith, M.D., F.A.C.E.P. I would like to sincerely thank you for the opportunity to provide this written testimony concerning illicit synthetic drugs. It is indeed an honor and a privilege to testify today at this hearing, "Deadly Synthetic Drugs: The Need to Stay Ahead of the Poison Peddlers."

The synthetic drug problem is a fairly recent development. Over the past several years, these previously unseen and unknown drugs have surfaced in our communities at convenience stores, head shops, and on the Internet. They have rapidly become popular, widely available and just as widely abused. These drugs have resulted in far too many violent acts, injuries, illnesses, trips to the emergency department, lengthy stays in the intensive care unit, and deaths across our nation.

The class of synthetic drugs consists of several different types of substances. First, there are cannabinoids. The original compounds in this group were first synthesized at Clemson University in an attempt to find better pharmaceutical agents for legitimate medical purposes. While they have a variety of chemical structures, they all bind to the same marijuana (THC) receptors in the brain with an affinity that is sometimes several hundred times stronger than THC. Sold by names such as Diablo, 7H, Diesel XXX, SenorLoko, Blue Magik, Scooby Snax, and Killer Buzzz, these compounds have been very effectively marketed by drug dealers who target our youth and young adults. Typically, these compounds are simply sprayed onto inert plant materials in order to be smoked. More recently, liquid forms of these compounds have been sold to be used in electronic cigarettes called "vaping." These drugs are well known to cause alarming effects such as hallucinations, paranoia, seizures, violent behaviors, kidney damage, and hemodynamic effects such as dangerously high blood pressure, heart rates, and body temperatures. These drugs have both directly and indirectly resulted in many deaths. The use of these compounds is widespread and growing rapidly.

The second group of drugs are cathinones, which are stimulants. They have effects that mimic those of methamphetamine, cocaine, and ecstasy, or a combination thereof. These compounds affect serotonin and dopamine receptors in the brain. They often have somewhat similar chemical structures, and most can be characterized as phenylethylamines. Also effectively marketed by drug dealers targeting our youth and young adults, these drugs are sold by names such as Molly's Plant Food, Ultra Molly, Kamikaze, XTC, SkarFace, and Space Dust. These drugs appear in a variety of forms, but most commonly are sold as a powder or perhaps a powder filled capsule. These drugs are consumed by smoking, snorting, swallowing, but most commonly by intravenous injections. Intravenous use of these drugs is also associated with all of the typical intravenous drug risks such as hepatitis, endocarditis and HIV/AIDS. "Vaping" these compounds is a new and growing method of consumption. These drugs cause alarming effects such as hallucinations, paranoia, seizures, violent acts and hemodynamic effects such as dangerously high blood pressures, heart rates, and body temperatures. The use of these drugs is well known to directly and indirectly result in death. As these compounds affect serotonin and dopamine receptors in the brain, they are also associated with a condition known as excited delirium. Excited delirium is suspected to be the result of defective dopamine and serotonin receptors in the brain. Individuals who suffer excited delirium display bizarre and often very violent behavior in a hyper dynamic state of physical activity. Body temperatures, heart rates, and blood pressures soar to critical and immediately dangerous levels. Left untreated, and even at times with the best of treatment, these

individuals suddenly become very still and quiet as they collapse and very quickly deteriorate on to cardiorespiratory arrest and death. The use of these compounds is widespread and growing.

The problems posed by these first two groups of drugs are difficult problems to address for a number of reasons. There are new and unique compounds hitting the market weekly. Some of these compounds have never been synthesized before and as such are completely unknown. These new compounds are different in terms of chemical structure by subtle alterations in their chemical structures. This happens for two reasons. First, it is an attempt to dodge existing laws such as the Controlled Substance Analogue Enforcement Act. This act requires that the compound must be "substantially similar' to the parent controlled substance prompting technical arguments over nuances in minute chemical compound structure and pharmacologic effects. Many of the compounds in these groups are largely or completely unknown in terms of both scientific data and human experience. Additionally, the packages of these drugs are labeled as "Not for Human Consumption." The Controlled Substances Analogue Enforcement Act states that the analogue compound may be controlled "to the intent intended for human consumption." Second, these compounds are altered in order to find a more intense high, a better euphoria, decreased time of onset, or longer duration of effect. As these compounds are new and changing continuously, there is little if any meaningful medical testing available to determine the levels let alone the mere presence of these compounds in the user. Currently, the list of these compounds for which meaningful testing exists varies depending upon local medical resources but there are only couple of dozen at best. The number of compounds known to be available in the United States presently is in excess of four hundred and new compounds are appearing at times weekly. Considerable drift has been identified in the products being sold. It is not uncommon for product in identical packaging to vary in actual chemical content and amount from batch to batch and purchase to purchase. The chemical content may vary not only by actual drug sold but also by the addition of various adulterants which are sometimes pharmacologically active and or toxic by themselves. As the result of this combination of the chemicals, amount of those chemicals, other pharmacologically active compounds, and any number of adulterants, the effects of these identically packaged products may vary considerably while remaining extraordinarily dangerous.

Last January, the American College of Emergency Physicians (ACEP) surveyed its membership about the emergency care issues associated with the cathinones and cannabinoids. More than 1500 emergency physicians representing every state in the Union and the District of Columbia responded to the survey. The questions asked were framed for consideration of the patients seen from 2014 to 2015. The responses were startling. According to the survey:

- More than 95% of the responding physicians said that the number of patients that they treated for synthetic drug use had either increased (61%) or remained the same (35%).
- 72% of responding physicians saw an increase in the use of cannabinoids.
- When asked what specific drug was being used, respondents commonly answered "Don't know," or "Mixed."
- Many respondents reported seeing and expressed concerns about "vaping" liquid forms of these drugs.

- Demographically, respondents categorized those using these drugs as 55% teenagers and 35% middle aged, 54% white and 25% African American.
- Most alarming, 87% of responding emergency physicians reported seeing violent acts and 42% had seen staff injured within the last year by patients using these drugs.

The costs associated with the medical care of these individuals using these drugs are enormous. Cookeville Regional Medical Center (CRMC), a 228 bed facility in my home town of Cookeville, Tennessee, reviewed the records of patients admitted to the intensive care unit (ICU) while using the cathinone and cannabinoid drugs. Most but not all of the patients who used these synthetic drugs required admission to the ICU. The average hospital cost to care for these patients in intensive care was $29,000. It should be noted that this figure represents only the fixed costs, not charges, incurred by the hospital. It does not represent so many other costs of the patients' care such as physician expenses, pharmaceuticals, and any necessary follow up care. Over the last three years, CRMC has admitted 198 patients who have battered by these drugs to the ICU. This represents an estimated cost of $5,742,000. Of those 198 patients, only 3 have had medical insurance of any sort.

The third class of the synthetic drugs to consider is opioids. It is no secret that a terrible opioid epidemic is sweeping the nation and killing our citizens. For quite some time, much attention has been paid to the prescription opioids. While efforts to combat the abuse of prescription drugs were underway, a new class of opioids, synthetic opioids, has rapidly emerged. These synthetic and significantly more potent opioids such as fentanyl have become common street drugs. These drugs cause euphoria and sedation, but also vomiting, respiratory insufficiency and failure, low blood pressure, and all too often--death. The mechanism of death is usually respiratory depression and failure. The increased potency of these compounds is terrifying. Understanding the potency of these drugs is critical to understanding the dangers they pose. For example, consider that a grain of table salt represents the approximate volume of a milligram. Most medications used in medical therapy are dosed in milligram or multiples of milligram quantities. With that in mind, these synthetic opioids are dosed using micrograms, not milligrams. For reference, one microgram is one thousandth of a milligram. Minimal variations, by amounts that represent tiny fractions of a grain of salt, can, and do, produce significant and deadly changes in the effects on the user.

Recently, chemical structure manipulation similar to what has been seen with cathinones and cannabinoids has been identified in opioids. Acetyl fentanyl, butyrl fentanyl and b-hydroxythiofentanyl, all compounds where the basic fentanyl structure has been altered, have received emergency scheduling by the DEA. Commonly, these synthetic opioids are used to "improve" an existing, but less potent product such as heroin. By the addition of these synthetic opioid compounds, the weaker drug now becomes more potent, has a greater effect, and is more dangerous, but also preferentially sought by the user.

The addition of microgram quantities of these drugs is very risky business. Small variations in quantity result in profound and all too often deadly effects. Across the United States there have been many documented deaths attributed to abuse of these synthetic opioids. In Putnam County, Tennessee, a rural Tennessee county of approximately 70,000 people, we have recently identified a series of four

deaths directly caused by counterfeit Percocet tablets in one two-month period alone. These counterfeit Percocet tablets, which should contain oxycodone and acetaminophen, actually contained deadly amounts of fentanyl. In Sacramento, California, over a two week period in late March and early April, there were 52 individuals who overdosed on fentanyl laced counterfeit hydrocodone tablets. Fourteen of those 52 individuals died. In 2014, a federal grand jury returned a 23-count indictment, charging 22 people with multiple offenses related to a conspiracy to distribute large amounts of heroin and fentanyl responsible for multiple overdoses and deaths in the Middle District of Tennessee. According to the indictment, the defendants were undeterred after finding out about the overdoses and continued to distribute the drugs.

Unfortunately, testing for synthetic opioids is rather limited much like the other synthetic drugs. Most drug screens used in clinical settings only provide results for older and better known drugs that are present in a patient's system in much greater quantities than these newer synthetic opioids. It is unknown if the newer synthetic opioids are even detected on standard drug testing and screening methodology. Because of the limited testing and accuracy, the magnitude of this synthetic opioid abuse epidemic and the number of related deaths is likely underrepresented. In Putnam County, Tennessee, additional deaths are currently being investigated for suspected ties to synthetic opioids. Similar counterfeit Percocet tablets were identified as being responsible for several deaths in Sumner and Franklin counties in Tennessee. Large quantities of tablets, identical in appearance and composition, have recently been seized in Mobile, Alabama and Cleveland, Ohio.

Because of the national opioid epidemic, the widespread use of naloxone, the antidote for opioid overdose, has received much attention. In Cookeville, Tennessee, the police department has carried naloxone for about a year. While not a unique program, in this first year of naloxone deployment alone, our police officers are credited with saving the lives of at least four individuals who had suffered life threatening opioid overdoses. The most recent save occurred six days ago.

In my capacity as Director of the Cookeville Regional Medical Center Emergency Department, I have encountered numerous patients suffering the effects of synthetic drugs. The first known emergency department (ED) experience at Cookeville Regional Medical Center with a patient using cannabinoids was a young female college student brought to the ED by her friends after consuming a product purchased at a convenience store. She was writhing and thrashing about continuously and could not stay on the bed. She was hallucinating and seeing demonic images. Her heart was racing and her blood pressure was dangerously high. In order to control her signs and symptoms she was given large amounts of intravenous Ativan (lorazepam), a medication similar to Valium (diazepam). Usual adult doses of Ativan to control life threatening seizures are 2-4 milligrams intravenously for an average sized adult. This patient required a total of 28 milligrams, which is six to fourteen times the usual dose range, in order to keep her on the bed and to control her hallucinations, dangerous blood pressure, and heart rate. She was admitted to the ICU where she recovered over a period of days except for the persistent serpentine body movements. At the time of her discharge from the hospital, these persistent movements were thought by her neurologists to be a permanent effect. At last contact, there was little, if any, improvement of this disabling movement disorder.

In a more violent episode, a young man in his twenties who reportedly consumed the synthetic narcotic "Molly's Plant Food," was admitted to the ED. He was sweating profusely, had dangerously high blood pressure, temperature, and heart rate. He was actively hallucinating and very agitated. During the initial attempts to approach and treat this patient, he suddenly jumped from the stretcher and attacked the ED staff trying to help him. It was a most violent struggle where he displayed true superhuman strength. Though of medium build, he threw numbers of ED and EMS staff about with little effort though several of them weighed well over two hundred pounds. He had absolutely no perception of pain, as evidenced by the complete indifference to the several facial fractures he incurred during the struggle when he and those trying to control him fell to the floor. The struggle eventually spilled into the room of another ED patient who was being treated for cardiac-related chest pain. Several ED staff were injured in the fight. This author suffered broken ribs as a result of the altercation. Another ED staff member injured his back as he was thrown against a counter and was unable to return to work for several months. Once admitted to the ICU, this hepatitis C positive patient slung feces into the face and eyes of a nurse during another violent outburst.

In the CRMC ICU, two nurses have been assaulted by patients who were being treated for ingestions of these synthetic drugs. One nurse was beaten so severely with a metal pole used to hang intravenous fluids that he was rendered unconscious.

One recent patient presented to the ED after a confrontation with local law enforcement. Extraordinary physical efforts of multiple officers, including the use of a Taser were required to subdue and control him for transport to the hospital. During the struggle, he broke the leg of one of the officers. While being handcuffed, this subject displayed such strength the he actually bent a set of handcuffs to the point they are no longer serviceable. Because of the recent spike in violent behavior displayed by these individuals using these synthetic drugs, the ED has added additional security staff which now also includes uniformed law enforcement officers. Additionally, my physician group now pays for and offers Jiu Jitsu training to our staff. This martial arts training has helped to more effectively control these violent patients while minimizing injuries to patients and staff alike.

A 14-year-old male presented to the ED with his parents after exhibiting agitation and bizarre behavior at home. He was delusional and hyperactive to the point that delivering medical care was next to impossible. In order to treat his drug ingestion, as well as to control his behavior, he was sedated. Sedation and intravenous fluid resuscitation are common treatment protocols for patients who use these drugs. There is no antidote for these drugs. Weighing approximately 140 pounds, he required 140 milligrams of Versed (midazolam), a powerful sedative drug in the same class as Valium (diazepam). This incredibly large amount of medication only kept him on the bed and little more. He remained awake and conversant. To put that dose into perspective, it is 44 to 88 times the usual dosing range for an adolescent of similar weight. An ordinary individual not under the effects of these drugs if given this amount of Versed would require mechanical ventilation and blood pressure support simply to stay alive. He required an additional 100 milligrams of Versed en route to the pediatric ICU at a hospital in another town. He eventually recovered.

A female patient presented to the CRMC from the county jail under the influence of a cathinone after becoming combative with the jail staff while being processed into the jail. She was actively hallucinating. Her skin was hot to the touch. Her temperature on arrival was 102 degrees. Her heart rate was dangerously fast. She eventually died in the ICU some 10 days after presentation to the ED. Despite optimized medical therapy which included cooling blankets, sedation and intravenous fluids, the intensive care staff were unable to control her body temperature, which remained at or near 107 degrees for several days. She ultimately succumbed to multi-organ failure as the result of that extreme body temperature. She was a 28-year-old mother of a 6-year-old little girl.

Finally, there was an adult male subject in a motel room who was delusional after consuming cathinones who was trying to defend himself from individuals that he perceived were attacking him. Thank goodness, he did not own a firearm. Instead, he pepper sprayed those attacking him. After using the pepper spray to try to stop the attack, he resorted to other means of defense. Recognizing his violent delusional state, his girlfriend called 9-1-1 and asked for help from the police. As the first officer on the scene entered the motel room, the subject was retrieving his axe to use in his defense against his attackers. The older of his 2 attackers was two years old. They were the children of his girlfriend.

In closing, the magnitude and scope of the problems created by the synthetic drugs we face today are difficult to meaningfully describe in a document such as this. A far better understanding of the problem comes only from understanding the personal experiences, stories, and anguish of those who face these issues every day. The toll of these drugs on human life and health in America is extraordinary. The costs associated with the medical care of these patients represent a significant economic burden. These drugs are readily available, widely used, and growing in popularity. People are dying, often in the prime of their lives, because of these drugs. Given the lack of accurate testing, many cases and deaths caused by synthetic narcotics go unclassified and undiagnosed. As such, we are unable to fully quantify the enormity of this deadly issue. As bad as the numbers are, we know they are actually bigger and growing.

The landscape of the synthetic drug problem is changing rapidly and outpaces the ability of legislation to keep up as it exists today. We must take a multifaceted approach to combatting synthetic narcotics. Part of this solution must be legislative. While it is absolutely essential to control these drugs by scheduling, the process of classifying each new synthetic substance is inadequate and will never keep pace with the continually emerging narcotics. The need for action to effectively address the growing threat to our nation posed by these drugs is absolute, critical, and immediate. I am available to assist you at any time and by any means which you feel might be beneficial as you address this or any other issue.

Respectfully Submitted,

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