



Proceedings from the 2017 Fentanyl Working Meeting

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Proceedings
from the
2017 Working Meeting

Protecting First Responders[±] on the Frontlines of the Fentanyl^{±±} Epidemic

September 6-7, 2017

Executive Summary

The Department of Homeland Security (DHS), Countering Weapons of Mass Destruction, Office of Health Affairs, in collaboration with the Department of Transportation, National Highway Transportation Safety Administration, Office of Emergency Medical Services, sponsored a two-day working meeting on September 6 and 7, 2017, entitled “*Protecting First Responders on the Frontlines of the Fentanyl Epidemic.*” These proceedings summarize the key messages of the meeting and provide scientifically derived, evidence-based, and practitioner-informed recommendations. These will serve as a guide to inform strategy, policies and procedures to prevent and mitigate unintended fentanyl exposures across first responder occupations. The proceedings also include information obtained from relevant events that have occurred since the meeting and additional research.

Approximately 100 policy makers, leaders, and science and medical experts participated in the two-day meeting to address the ongoing and rapidly evolving fentanyl threat to the nation’s first responders. Attendees represented subject matter experts from law enforcement, fire, emergency medical services (EMS), occupational safety and health, emergency medicine physicians and medical toxicologists, and public health entities from across the Federal, State, Local, Tribal and Territorial (FSLTT) communities.

The immediate goals of the working meeting were several: provide current, evidence-based information regarding fentanyl detection, recognition, exposure and exposure control to improve first responder protection across the FSLTT; dispel misinformation regarding suspected first responder exposures and intoxication; and, to provide information on intoxication signs, symptoms and countermeasures. Ultimately, these proceedings represent the initial steps in uniting the FSLTT first responder community to ensure consistent, updated, and informed policy, guidance, messaging and procedures with the common goal of protecting the nation’s first responders on the frontlines of the fentanyl epidemic, without degradation to mission. These proceedings include 18 recommendations that DHS distilled from 40 key messages associated with the working meeting. A copy of the agenda is included as Appendix A.

[±]For purposes of these proceedings, the term “first responders” includes law enforcement, fire, and emergency medical services personnel.

^{±±}For purposes of these proceedings, the term “fentanyl” refers to illicit non-pharmaceutical fentanyl and its high-potency analogs.

RECOMMENDATIONS

Recommendation 1. The FSLTT first responder community should establish a community of practice with the common goal of protecting the nation's first responders. This group would develop and maintain consistent and informed policy, guidance, messaging and procedures, adapted to fit unique missions of frontline first responders. In the future, such a community of practice can also serve as a unified information resource to address other legacy and emerging issues affecting the nation's responders.

Recommendation 2. First responders can and should incorporate into their operations an initial visual assessment of the response environment for the presence of free powder to determine necessary protective measures. Where suspicious free powder is present, first responders need to make every effort not to disturb the powder to avoid aerosolizing potential fentanyl and creating a risk of inhalation.

Recommendation 3. The FSLTT community should leverage all communication avenues available to reassure first responders that incidental dermal contact alone with fentanyl is unlikely to result in intoxication during routine first responder operations. The use of gloves as standard operating procedure, such as those used for protection against blood borne pathogens, would go a long way towards ensuring basic exposure protection.

Recommendation 4. The FSLTT first responder community of practice should educate first responders that inhalation and mucous membranes remain the routes of exposure of most concern for fentanyl intoxication. First responders should avoid disturbing suspicious free powder, which could create an inhalation hazard and should avoid direct skin contact that could result in transfer from skin surface to mucus membranes (eyes, nose, and mouth). The FSLTT first responder community should incorporate these considerations into policy, guidance, messaging, and procedure development.

Recommendation 5. Occupational exposure experts across the FSLTT should collaborate to develop strategies that include comprehensive data collection and sharing, and research in the area of first responder fentanyl exposure for both humans and canines.

Recommendation 6. The FSLTT first responder community of practice should develop a set of standardized Job Hazard Analyses (JHAs), representing the most common first responder work tasks. JHAs should be a key element for any first responder safety and health program and incorporate both human and working canine first responders. Any workplace controls, including Personal Protective Equipment (PPE), are based on, and identified in, the JHA.

Recommendation 7. First responders should remove suspected fentanyl from skin surfaces with soap and water and *must avoid* entirely the use of alcohol-based hand sanitizers, alcohol wipes, liquid bleach and bleach wipes for fentanyl-contaminated skin cleansing since alcohol and bleach enhance fentanyl skin absorption.

Recommendation 8. First responder departments should equip and train their frontline personnel in the use of Personal Protective Equipment (PPE) that protects them from ingestion, inhalation or other contact with fentanyl, with the appropriate level of PPE based on a JHA.

Recommendation 9. First responder departments should educate frontline personnel on signature fentanyl intoxication symptoms: slowed or no breathing, drowsiness or unresponsiveness, and constricted or pinpoint pupils.

Recommendation 10. The FSLTT first responder community of practice should develop a consensus guideline that establishes a case definition and provides recommendations to improve use of, and access to, bio-specimen laboratory confirmation and a means by which to collect laboratory-confirmed case reports from across the FSLTT first responder community.

Recommendation 11. First responder departments across the FSLTT should establish automatic mechanisms for bio-specimen collection and analysis for first responders after suspected exposures and intoxication.

Recommendation 12. Medical toxicologists should conduct additional research to confirm or refute signs and symptoms anecdotally associated with fentanyl exposure and intoxication and which do not represent the signature opioid toxidrome. Clinicians should consider the possibility of drug mixtures - that may or may not include opioids - and which could result in other, non-opioid intoxication signs and symptoms when treating first responders and when validating exposure via laboratory confirmation.

Recommendation 13. First responder departments should educate the frontline to immediately self-administer or administer naloxone to others when there is suspected opioid intoxication. First responders should also be trained and prepared to initiate rescue breathing per Basic Life Support (BLS) or Advanced Cardiac Life Support (ACLS) guidelines in the absence of naloxone or when naloxone administration does not yield the expected outcome. In either instance, first responders should seek definitive medical care.

Recommendation 14. First responder departments should develop and expand CPR and AED programs.

Recommendation 15. First responders should feel confident to administer naloxone, without hesitation, in the event of an occupational fentanyl intoxication.

Recommendation 16. First responder departments must address the care and storage of naloxone, particularly those with missions conducted in uncontrolled climate conditions. Factors for consideration include time-sensitive issuance and turn-in procedures at muster, to sustain long-term product viability.

Recommendation 17. First responder departments should develop and train their personnel on treatment protocols for the administration of naloxone.

Recommendation 18. The FSLTT first responder community of practice should develop a consensus guideline on the ideal naloxone countermeasure program that the FSLTT can disseminate across the first responder community nation-wide.

INTRODUCTION

Fentanyl: An Evolving Threat

The United States is in the midst of an epidemic of deaths due to opioid overdoses.¹ Opioids are a large class of highly potent substances that provide analgesia but can also lead to sedation and respiratory depression. They are associated with a high abuse potential. The misuse and abuse of opioid drugs, including legally prescribed painkillers, illegal narcotics such as heroin, and illegally made or sold opioids such as the increasingly prevalent fentanyl, pose a serious and growing threat to public health.^{2,3}

How Bad is the Problem?

According to the Centers for Disease Control and Prevention (CDC), drug overdoses have become the leading cause of unintentional injury death in adults under the age of 50 in the United States.⁴ Overdose deaths involving opioids nearly tripled between 2002 and 2015.⁵ Today, opioid overdoses take the lives of almost 64,000 Americans per year – 175 people per day, with approximately 54 of those dying from fentanyl and its analogs.⁴ In 2013, the number of Americans aged 12 or older who either abused or were dependent on opioids exceeded two million.⁴ The opioid crisis is so acute as to warrant a Presidential declaration of a Public Health Emergency on October 26, 2017.⁶

What is Fentanyl?

Fentanyl is a rapid-acting pain reliever that is 50 to 100 times more potent than morphine and can be hundreds of times⁷ stronger than heroin. Fentanyl has the potential to be lethal to humans at a much smaller dosage (1-2 mg dose range)⁸ than other opioids, such as heroin (50 mg dose),^{9,10} with the analog carfentanil having an even smaller reported estimated lethal dose (two one-hundredths of a milligram).^{11,12} For purposes of these proceedings, the term “fentanyl” refers to illicit non-pharmaceutical fentanyl and its high-potency analogs.

What is a Fentanyl Analog?

An analog is a structurally related but not identical chemical, versus a derivative chemical produced from a parent chemical. Fentanyl analogs retain functional similarity and are important because, like fentanyl, they are pharmacologically active at the same opioid receptor(s) sites.¹³ Chemically, there are over 1,000 possible analogs to fentanyl,¹⁴ and, to date, of these, only a limited number have been identified as actual manufactured products found on the street.¹⁵

Why is Fentanyl so Dangerous?

Illegally produced fentanyl is sold through illegal drug markets for its heroin-like effect and is often mixed with heroin to increase its potency and euphoric effects. Imprecision in working with sub-milligram (i.e., microgram) amounts of fentanyl during illicit manufacture and distribution of product for the street, as well as the unknown nature of fentanyl and fentanyl analogs in what drug abusers consume, results in drastically reduced margins of safety with illicit drug use than previously encountered by the end-user, dealers and buyers. Combined, these factors may partly explain the rising numbers of citizen deaths, and give rise to significant first responder uncertainty and concerns regarding their own potential exposures and necessary protective measures during response activities.

The Rise of Fentanyl

In recent years, the dangers of synthetic opioids such as fentanyl have gained increasing recognition among both public health and law enforcement officials. The nature of this risk has recently changed due to the re-emergence of illicit fentanyl, on the national scene, among drug abusers, starting with the first recognized overdose cases of fentanyl and its analogs in 2013.^{2,3} While the annual number of deaths of our citizens from prescription opioids tripled from 1999 to 2011, the period of 2011 to 2015 saw a tripling of deaths from illicit drugs including fentanyl.¹⁶ This rapidly increasing morbidity and mortality resulting from fentanyl abuse among drug users occurs as a direct result of intravenous injection, inhalation or oral consumption of a drug which can be lethal at very small doses, as documented in post-mortem and post-morbidity specimens. Intravenous injection, inhalation and oral consumption of any drug which has the potential to cause respiratory depression has a range of predictable outcomes including death from overdose. Unfortunately, this drug-related epidemic has resulted in increased morbidity and mortality for thousands of our citizens each year from this crisis. All too commonly, the daily video and photographic images of drug abusers who have overdosed have now become commonplace in the national media¹⁷— bearing witness to the dangers of fentanyl use and the national scope of the problem.

Naloxone

The opioid epidemic has led to widespread administration of the drug naloxone in its three FDA approved formulations as the prime countermeasure to fentanyl intoxication. Naloxone is a fast-acting, safe, and highly effective antidote that can block and reverse the effects of opioid medications. Naloxone displaces (or “kicks out”) the opioids from the receptors and then blocks the receptors (and the effects of the opioid) for roughly 30-90 minutes. Naloxone can be quickly administered and has no reported risk of abuse or dependency.

Until recently, most states required non-healthcare providers be trained to administer naloxone and only allowed them to administer naloxone under the supervision and authority of a licensed physician. However, more and more states are relaxing these controls and are reducing liability associated with naloxone administration by untrained non-health care providers. It is still prudent practice for non-healthcare first responders to understand proper naloxone use.

Naloxone “resistance” is a potential misnomer used in the media. “Resistance” is a medical term normally used to quantify antibiotic susceptibility patterns of bacteria, and may not be the most accurate nomenclature used to describe instances in which naloxone does not work against fentanyl overdoses or occupational intoxications. A more accurate term may be naloxone “ineffectiveness” or “failure” based on any of several factors, such as a delay in administration or an inadequate absorbed dose.

The Impact of Fentanyl on the Nation's First Responders

Recently, drug trafficking organizations have adopted dynamic trafficking tactics, techniques, and procedures, further confounding the challenges of responding to fentanyl-related activities. Ever expanding profits and increased freedom to conduct their illicit business fuels the trade of this potentially fatal drug. Additionally, individuals outside of the classic drug trafficking trade now have the potential to make millions of dollars in profit from a several thousand dollar investment by purchasing sub-kilogram amounts of fentanyl from illicit manufacturers in China over the dark web and utilizing the parcel mail system for distribution.² While the volume of law enforcement seizures of fentanyl remain relatively small compared to heroin and other illicit drugs, fentanyl has become the most frequently seized illicit synthetic opioid. For example, the quantity of fentanyl DHS Customs and Border Protection (CBP) seized in fiscal year 2013 was approximately two pounds; the amount increased to approximately 440 pounds in fiscal year 2016.¹⁸

First responder missions have traditionally placed first responders in situations and environments that leave them at risk of potential exposure to various health and safety threats, such as: injury from physical assaults and weapons, needle sticks, exposure to body fluids, vehicular accidents, etc. First responder risk has recently evolved with the resurgence of opioid use among drug users nation-wide, further confounded with the first recognized overdose cases from fentanyl and its analogs in 2013.^{2,3} Complicating factors that further affect the impact of the fentanyl trade on the first responder community include:

- The rapidity by which fentanyl and its analogs have re-entered the illicit drug market;
- The lack of experience and data available with regard to fentanyl, particularly as it concerns fentanyl analogs and its effects to both humans and canines;
- The lack of experience, data, and evidence-based medicine with regard to treatment and the management of persons overdosed, or intoxicated, with fentanyl;
- A shift towards commercial mail-order shipment for drug trafficking to include high-order purity levels of product shipped via commercial mail-order; and,
- Misinformation message distortion within the press and other media.

The First Responder Exposure Challenge

Ensuring the health and safety of the nation's first responder workforce, both human and canine, is of paramount importance. In the course of day-to-day operations, law enforcement, fire, and EMS personnel could unknowingly be exposed to fentanyl or other opioids.

Fentanyl emerges as a routine contraband that brings with it the risk of potential lethality from occupational exposure. Prior to fentanyl, concern regarding inadvertent inhalation and mucosal absorption of contraband drugs, such as cocaine and heroin and other illicit drugs, was limited to emergency operations targeting clandestine production labs and related industrial-level criminal drug activities where there was a large amount of drug-related particulates in the environment. While these types of scenarios continue to pose an exposure threat to law enforcement, exposure risk for the overall first responder community has expanded from the more classic frontline

point-of-care emergency medical providers to now include non-medical first responders, such as law enforcement. The overdose epidemic requires, with increasing frequency, that first responders be vigilant in self-protection and must now incorporate naloxone administration as part of their routine first responder function.

The science of first responder fentanyl exposures is limited. Current strategies to respond to occupational fentanyl exposures are mostly informed by observational data.¹⁹ Human fentanyl exposure studies are limited to two studies performed in bulk pharmaceutical production environments.^{20,21} Of note, the pharmaceutical exposure studies are outdated and have minimal applicability to incidental exposure scenarios that most first responders would experience. Data also exists from the animal experience with the fentanyl analog carfentanil.²² Limited evidence exists in the literature regarding the human and canine effects from fentanyl exposure or the management of overdosed, or intoxicated individuals, affected by fentanyl analogs.²³ Recent press releases^{24,25} provide anecdotal descriptions of the problem, but do not provide evidence-based science or medicine to inform and guide policy and procedure regarding management of potential first responder fentanyl exposures.

KEY MESSAGES

1. Fentanyl Represents a Watershed Moment in the History of Occupational Threats to First Responders

Fentanyl has been disruptive and transformative, driving the first responder professions to adjust course and develop entirely new policies and procedures, with an impact that is broad and reaches every segment of the FSLTT first responder community. Fentanyl represents a significant shift in trafficking patterns and business models, from the macro- to the micro-criminal organization, with individuals and small networks purchasing small amounts of the drug over the internet for distribution in the illicit drug trade, with consignment and express mail becoming their means of enterprise, operating outside the normal channels of the historical drug trade.^{18,26} Fentanyl also emerges as a contraband which brings with it the risk of potential intoxication from incidental occupational exposures. Prior to fentanyl, concern regarding inadvertent inhalation and mucosal absorption of cocaine, heroin, and other illicit drugs, was limited to law enforcement operations targeting clandestine drug labs and related industrial-level criminal drug activities. In these environments, there could be a large quantity of substrate drug, which, if not handled properly, holds the potential for dermal contamination or airborne particulate concentrations such that symptom-producing exposures are possible in the absence of careful handling and appropriate use of personal protective equipment (PPE).

Fentanyl has created a heightened concern for potential exposure during routine law enforcement operations, such as apprehension and search of subjects, vehicle and vessel searches, express mail and consignment processing, and assessment and care of individuals requiring medical assistance. Fentanyl is also the first of its drug-class to require the average frontline law enforcement officer to have a working medical knowledge of a specific occupational exposure/intoxication, as well as a working occupational knowledge of the use of its medical antidote -- naloxone. Fentanyl now joins firearms, knives, motor vehicle accidents, and other threats that can harm first responders in the field, while naloxone now joins body armor, tourniquets, and Individual First Aid Kits (IFAKs) on the list of items that can protect first responders in the field. For the first time, perhaps, since the 1980s when HIV/AIDS came on the scene, first responders must now rethink their approach to how they perform their duties through the lens of potential fentanyl exposure when interacting with the public on a daily basis.

2. The Fentanyl Crisis in America Has Disproportionate Impact on the Citizen Population versus First Responders.

Rapidly increasing morbidity and mortality directly resulting from fentanyl use among drug abusers typically occurs via intravenous injection or oral consumption, which can be highly lethal at very small doses,¹¹ as documented in post-mortem and clinical specimens.²⁷ Intravenous injection, inhalation or insufflation (i.e., blowing the drug into a body cavity), and oral ingestion of any drug which sedates and suppresses respirations have expected outcomes including death from overdose. Tragically, we are losing thousands of Americans each year.

The impact on first responders, however, is not the same. First responders face the potential threat of inadvertent exposure to fentanyl in the occupational setting, during which inadvertent

contact with and absorption into the bloodstream through the lungs, mucus membranes, or skin would have to occur for intoxication and its effects to occur.

PPE selection and usage provide effective controls against such occupational exposures. Overall, the risk of fentanyl occupational intoxication to first responders is elevated, but is still relatively low and remains predictable. The risk of morbidity and mortality among drug users is different from that of first responders and should not be compared to the average citizen experience.

3. Misinformation in the Media Has Had a Significant Impact on the Perception of the Fentanyl Problem and Affected the Development of Protective Measures for First Responders

One recognized hallmark of the fentanyl crisis has been the abundance of misinformation and non-expert testimony, which, along with anecdotal accounts, promoted and perpetuated mixed and inaccurate messaging. This has been especially true of media reporting that incidental skin exposure from fentanyl resulted in first responder intoxications and has the potential to be fatal.²⁸ The information void was a result of the rapidly evolving fentanyl crisis, compounded by limited definitive knowledge and expert messaging, to provide the appropriate evidence-informed communications. Additionally, the concept that fentanyl is 50-100 times more potent than morphine when injected intravenously was confused with a belief that fentanyl was absorbed through the skin at a rate 50-100 times in excess of that of the previously known absorption rate of opioids, which is not supported by available evidence.²⁹ The end result, in some instances, was that policy, guidance, messaging and procedure to protect frontline first responders across the FSLTT has been hindered by inaccurate or incomplete information. Misinformation and absent information related to this drug has significantly altered the trajectory of the initial fentanyl response.

4. First Responders Can Perform Their Jobs Safely and Effectively in the Face of a New and Challenging Threat Environment

This message is critical at this time in our nation's response to the emerging fentanyl threat. We know that first responders, including our canine workforce, either knowingly or unknowingly, encounter fentanyl on a routine basis. For example, some DHS personnel,¹⁸ routinely encounter fentanyl powder and pills during vehicle or vessel searches, apprehension and arrests of persons, inspection of express and consignment mail, and during chemical analyses in the laboratory. It is reassuring that they have been able to conduct their jobs safely and effectively despite the occupational risk, with no federal cases of occupational fentanyl intoxications to date.²³

5. First Responders Share a Common Risk Despite Different Missions

In just two years, fentanyl has become a universal problem with global implications.² Both its victims and promoters reside in multiple countries. Fentanyl is, and is likely to remain, an occupational threat to the FSLTT first responder community. While first responder missions differ, they share common risk in terms of potential fentanyl exposures, as they may encounter fentanyl in the context of interacting with individual persons and vehicles as part of their daily duties. Fentanyl response represents an ideal model of the ways in which first responders can establish successful partnerships amidst shared risk and common goals. The fentanyl exposure challenge provides a critical opportunity for the FSLTT first responder community to unite and collaborate in the development and implementation of comprehensive, robust, and unified

protective policies and procedures. A consolidated strategy, to include a communications strategy, must occur in order to quickly and successfully counter fentanyl's growing effects.

6. The Average Law Enforcement Officer Has Not Been Trained on Occupational Fentanyl Exposure Prevention or Intoxication Countermeasures

Just a few years ago, fentanyl occupational exposure and related naloxone countermeasure training did not exist in the law enforcement community, since there was simply no apparent need. Currently, many first responder organizations and departments are beginning to provide training on naloxone administration as part of workforce health protection. Comprehensive training on fentanyl exposure avoidance and protection and naloxone administration needs to occur early in a first responder's career, such as at the law enforcement academy level, and needs to continue across the life cycle of the first responder career. Rescue breathing, as taught in basic CPR and BLS training, is valuable in the fentanyl response and should always be performed to provide life-sustaining treatment until definitive help arrives in the form of additional naloxone or EMS personnel and further resources.

7. Rural and Small Law Enforcement and EMS Departments Remain Especially Vulnerable to the Threat of Fentanyl

Fentanyl represents an emerging threat to first responders, at all levels, and in every segment of our nation. Fentanyl policy development, training, and naloxone acquisition all require substantial investments of human capital, time, money, and other resources that may not be available to rural and smaller first responder departments. Without these resources to support robust workforce health protection, first responder departments remain vulnerable to fentanyl occupational exposures. Data, strategy, policy, and procedure sharing from larger departments and the Federal government must continue. State law enforcement fusion centers³⁰ play an enormous role in this respect, and are the conduit, along with FSLTT first responder organizations, for distribution and rapid release of counter-fentanyl products with far-reaching impact.

8. Standardized, Consistent and Expertly-informed Policy, Guidance, Messaging and Procedures are the First Line of Defense in the Protection of First Responders

Prior to the summer of 2017, there existed a clear lack of information and guidance for first responder communities regarding the risk of occupational exposure to fentanyl and use of naloxone. This was due largely to the novelty of fentanyl as an exposure risk and a lack of information resources for the chain-of-command to distribute. The scarcity of information was especially acute in the law enforcement community. Inaccurate media reporting and the lack of evidence-based information led to widespread perception of significant risk from exposure to fentanyl.

In today's information technology era, there are multiple communication channels to enable rapid and wide information dissemination. Leveraging an array of communication channels in a volatile and threatening situation is critical to maintaining job performance at its optimal level, especially in the face of first responder fear, uncertainty, and confusion. Clear, timely, informed, and consistent messaging regarding fentanyl continues to be of paramount importance and is still evolving. In response to the information crisis, a number of national-level experts published first responder fentanyl protective guidelines to include:

- *Fentanyl Guide for First Responders*, Drug Enforcement Administration, June 2017;
- *Position Statement: Preventing Occupational Fentanyl and Fentanyl Analog Exposure to Emergency Responders*, American College of Medical Toxicologists and American Association of Clinical Toxicologists, June 2017;
- *Fentanyl: Preventing Occupational Exposure to Emergency Responders*, National Institute for Occupational Safety and Health, Centers for Disease Control and Prevention, August 2017;
- *Recommended Best Practices to Minimize Emergency Responder Exposures to Synthetic Opioids, Including Fentanyl and Fentanyl Analogs*, Interagency Board, October 2017; and,
- *Fentanyl Safety Recommendations for First Responders*, National Security Council, November 2017 (See Appendix B).

9. Nomenclature Is Important for Consistent Policies, Procedures and Messaging to Counter the First Responder Fentanyl Threat

Accurate, standardized and consistent nomenclature matters at both the headquarters level and on the frontlines. A common lexicon drives effective strategy and policy at the headquarters level, and drives confidence and correct procedure on the frontlines. It also promotes understanding and uniformity across occupations and agencies. Examples of accurate nomenclature include the following:

Fentanyl		
Analog (or “analogue”). A chemical similar in structure and effect at a common receptor. Fentanyl analogs are not derived from fentanyl but share the same basic chemical structure as fentanyl and exert their effect at the same opioid receptor as fentanyl.	vs	Derivative. A derivative is a chemical that is synthesized or produced from a parent chemical.
Intoxication. Occupational exposure. A symptomatic, toxic and inadvertent exposure. Not all exposures result in intoxication, whereas all intoxications first require exposure.	vs	Overdose. Non-occupational exposure. A symptomatic toxic and intentional exposure as seen in drug abusers.
Potency. Potency is the measure of a drug’s effect relative to its dose amount.	vs	Lethality. Measure of a drug’s deadliness relative to its drug effect.
Incidental Exposure. A small, brief, unintentional exposure which occurs during routine first responder job tasks such as vehicle and person searches, suspect apprehensions, express mail and consignment processing, and assessment and care of individuals requiring medical assistance. It does not include operations such as entry into manufacturing and large-scale distribution sites such as clandestine labs, pill mills, and other locations where large amount of substrate product or powder is present.		
Naloxone		
Failure. Used to describe naloxone ineffectiveness.	vs	Resistance. A medical term normally used to quantify antibiotic susceptibility patterns of viruses and bacteria.

10. Fentanyl Response is an Ideal Prototype Model for the Development of Policy, Guidance, Messaging and Procedures-related Protection of First Responders Against Contaminants of Concern in the Workplace

Fentanyl as both a chemical and an occupational threat cannot be viewed in isolation. It is one of many chemicals and contaminants of concern in the workplace. Fentanyl represents an opportunity for the FSLTT first responder community to develop a universal approach to comprehensive and consistent policy, guidance, messaging and procedure development, in a standardized and easily reproducible manner, for both legacy and emerging threats. Universal substance isolation becomes the standard process to address unknown substances, so that first responders can be trained to respond to any potential agent, such as fentanyl, anthrax, ricin, etc. Such an all hazards approach provides a simplified and easy method that is easy to train and highly reliable in the field. First responders have become accustomed to treating every white powder and unknown substance as if it were fentanyl with its associated risks for intoxication, and further accustomed to everyday use of PPE (gloves, mask, and eye protection). Repetitive use of PPE becomes automatic and predictable, which is both the goal and the hallmark of a successful occupational risk mitigation program.

Recommendation 1. The FSLTT first responder community should establish a community of practice with the common goal of protecting the nation's first responders. This group would develop and maintain consistent and informed policy, guidance, messaging and procedures, adapted to fit unique missions of frontline first responders. In the future, such a community of practice can also serve as a unified information resource to address other legacy and emerging issues affecting the nation's responders.

FENTANYL DETECTION AND RECOGNITION

11. Staying Ahead of Fentanyl Analogs Remains Problematic

An *analog* is a structurally related but not identical chemical; whereas a *derivative* is a chemical produced from a parent chemical. Fentanyl analogs retain functional similarity and are important because, like fentanyl, they are pharmacologically active at the same opioid (mu) receptor(s).¹³ Chemically, there are over 1,000 possible analogs to fentanyl,¹⁴ and, to date, of these, only a limited number have been identified as actual manufactured products found on the street, with an even smaller number having been previously placed into drug schedule and classified as illegal by the Drug Enforcement Administration.¹⁵

Criminals have had the advantage of pivoting to the next unclassified analog in the long list of analogs which are candidate for manufacture —once one analog is no longer viable for illicit manufacture and distribution, they simply switched to another. Law enforcement has had the disadvantage of having to detect a new analog on the street, identify the chemical structure of the analog in the laboratory, formally declare the analog a threat to public safety in order to add it to the list of scheduled drugs in the U.S., and then enforce the drug's scheduled status. Emergency scheduling of new analogs has been a lengthy legal process that can take up to six months to complete.³¹ On February 6, 2018, the DEA issued a temporary scheduling order to schedule all fentanyl-related substances not currently listed in any schedule of the Controlled

Substances Act (CSA) and their isomers, esters, ethers, salts and salts of isomers, esters, and ethers into Schedule I. The DEA took this action to “avoid an imminent hazard to the public safety” and will enable law enforcement to “impose upon persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle fentanyl related substances” the requisite “regulatory controls and administrative, civil, and criminal sanctions applicable to Schedule I controlled substances.”³² This temporary scheduling order is effective until February 6, 2020.

12. Fentanyl Analytical Laboratory Capabilities Require Further Development at Many Levels

A comprehensive and true description of the fentanyl problem in the United States remains elusive because our detection of fentanyl remains limited across the spectrum of compartments involved in its response. Law enforcement personnel in the field lack universally robust, safe, accurate and specific point-of-contact fentanyl testing to expedite criminal investigations.¹⁵ Medical examiners and coroners lack the wide-spread capability for accurate and sensitive post-mortem fentanyl detection to support accurate cause-of-death reporting.²⁷ Hospital emergency rooms lack rapid fentanyl drug screening to aid diagnosis and treatment of overdose or intoxication victims.³³ Improved reliable field detection capabilities are key to an effective and sustainable comprehensive counter-fentanyl program.

13. Hand Held Detection Technology Is Still Evolving

Hand-held spectroscopy-based analyzers such as TruNarc^{TM 34} and Gemini^{TM 35} provide point-of contact testing and enhance mobility and response capabilities for first responders in the field. Both are limited to detection of purity levels of fentanyl exceeding 10 percent,¹⁵ which makes both analyzers potentially insensitive for scenarios where purity levels are between 7-10%. Both also require field-sampling specimens that are adequate and have volumes large enough to provide detection. Emerging or newly applicable spectroscopy methods, including Thermal Desorption Direct Analysis in Real-time Mass Spectrometry (TD-DART-MS), and Ion Mobility Spectrometry (IMS), which involve swabbing the outside of a package for minuscule amounts of fentanyl residue, while not hand-held, address this issue, providing rapid and sensitive (i.e., nanograms to picograms) detection of fentanyl.³⁶ The logistics of providing these devices and training personnel in their use across a large organization could be difficult and resource-intensive.

14. Recognition and Assessment of the Form of Fentanyl, Quantity and Degree of Disturbance Should be Used to Gauge Potential Fentanyl Exposure Risk and Determine Necessary Protective Measures

While fentanyl can be encountered in the form of solution, spray, on blotter paper, etc.,^{37,38} the majority of expected occupational encounters with fentanyl in the near future will likely be in powder or pill (tablet or capsule) form, both of which carry the risk of powder absorption from inhalation or mechanical transfer to mucus membranes from skin or other contact.² Fentanyl powder has low volatility and does not spontaneously volatilize,²⁹ but does have the potential to be aerosolized if free powder is disturbed. Visible free powder, or powder residue from pills, correlates with occupational risk, with the risk increasing as the amount of visible free powder, or degree of disturbance, also increases.³⁹ The amount of visible free powder can be used to guide effective PPE posture.³⁹

Recommendation 2. First responders can and should incorporate into their operations an initial visual assessment of the response environment for the presence of free powder determine necessary protective measures. Where suspicious free powder is present, first responders need to make every effort not to disturb the powder to avoid aerosolizing potential fentanyl and creating a risk of inhalation.

EXPOSURE ROUTES

15. Fentanyl Incidental Dermal Exposure Is Unlikely to Result in Intoxication during Routine First Responder Operations

Skin contact is a potential and likely exposure route; human skin is not entirely impervious to fentanyl.²⁹ However, physiologically, fentanyl intoxication via incidental intact skin exposure during routine first responder operations is not likely to occur, despite media reports to the contrary,²⁸ since fentanyl is not, under routine conditions, absorbed quickly enough, and is not typically present on the skin in sufficient quantities to result in intoxication. This statement is based on known skin physiology and absorption dynamics,⁴⁰ a limited number of experimental trials,²⁹ data extrapolated from established and extensive research on the legal pharmaceutical fentanyl analgesic medication patch,^{41,42} evidence from occupational exposures of industry pharmaceutical production workers,^{20,21} and expert opinion.²⁹

First responders should still be trained to remove visible fentanyl from skin by washing with cool or room temperature water (and soap, if available), to prevent mechanical transfer of fentanyl from skin to mucus membranes, where absorption is more likely to occur. Broken skin or skin that is otherwise not fully intact (such as inflamed or abraded skin) will have different absorption characteristics than intact skin and remains a site of possible enhanced absorption.²⁹

Percutaneous exposures such as inadvertent needle sticks increase the risk of intoxication, but do not represent “incidental” non-penetrating surface dermal exposures as discussed here.

Recommendation 3. The FSLTT community should leverage all communication avenues available to reassure first responders that incidental dermal contact with fentanyl is unlikely to result in intoxication during routine first responder operations. The use of gloves as standard operating procedure, such as those used for protection against blood borne pathogens, would go a long way towards ensuring basic exposure protection.

16. Inhalation and Mechanical Transfer of Fentanyl from Skin to Mucus Membranes (Eyes, Nose, Mouth, etc.) Remain the Exposure Routes of Highest Concern for Intoxication During First Responder Daily Operations

Significant absorption of fentanyl can occur in the lungs and mucus membranes,²⁹ making these exposure routes the major concern for potential intoxication from fentanyl exposure(s). The lungs and mucus membranes are rich in surface blood vessels and, physiologically, represent a better absorptive surface area than intact skin. Fentanyl can be inhaled into the lungs. It can also be mechanically transferred to the eyes, nose or mouth from the skin and other surfaces during inadvertent contact (i.e., when a person wipes their eyes without first washing fentanyl residue

from their fingers or when removing their gloves). For instances where skin contamination is suspected or confirmed, first responders must be educated to avoid touching their mouth, nose, eyes, or other skin; not to eat, drink, smoke, or use the toilet during or after contact or contamination; and to always wash their hands – with soap and water -- at the end of any tour during which potential contact or contamination may have occurred.

Recommendation 4. The FSLTT first responder community of practice should educate first responders that inhalation and mucous membranes remain the more significant routes of exposure for fentanyl intoxication. First responders should avoid disturbing suspicious free powder, which could create an inhalation hazard and should avoid direct skin contact that could result in transfer from skin surface to mucus membranes (eyes, nose, and mouth). The FSLTT first responder community should incorporate these considerations into policy, guidance, messaging and procedure development.

EXPOSURE ASSESSMENT AND EVALUATION

17. There Currently Exists a Lack of High Grade and Extensive Evidence-based Information Regarding the Human and Canine Effects of Fentanyl and its Occupational Exposure Risk

In the medical world, levels of evidence driving the principles and practice of medical care range from the most robust evidence (1A), which is a systematic review of randomized controlled studies, to the least robust (5), which is expert opinion alone, with various intermediate levels, including level (4) evidence from case studies.⁴³ There currently exists only level 4 and 5 evidence regarding human occupational illicit fentanyl exposures, which represents a significant gap in our understanding of the occupational fentanyl problem and a limitation to policy and procedure development for workforce health protection.²³ Similar to the situation of their human co-workers, there is a void of data regarding canine workforce occupational fentanyl exposures and intoxication.⁴⁴

Recommendation 5. Occupational exposure experts across the FSLTT should collaborate to develop strategies that include comprehensive data collection and sharing, and research in the area of first responder fentanyl exposure for both humans and canines.

EXPOSURE PREVENTION AND MITIGATION

18. First Responder Workforce Protection is Integral to Successful Mission Execution

Workforce safety and successful mission execution are not mutually exclusive in a counter-fentanyl world. First responders, especially law enforcement on the frontlines, understand that evidence collection, apprehensions and arrests, drug interdiction, and public safety must be preserved and remain robust in any workforce health protection scenario. First responders must be able to conduct their day-to-day jobs in a permissive environment, with fentanyl policy and procedure shaped in a way that wholly supports mission completion.

19. A Job Hazard Analysis (JHA) is an Essential Requirement in the Development of Safety and Health Policy and Procedures Related to Fentanyl

The most definitive and accurate way to quantify the risk to first responders for any mission evolution, in any organization, is to conduct a Job Hazard Analysis (JHA). A JHA is a detailed assessment of the risks of any given hazard in relation to the tasks and sub-tasks of a specific job.⁴⁵ Once the sub-tasks are identified, associated hazards and protective measures are defined. Safety and health policy, procedure and protective measures, including training and education, must be firmly rooted in JHA(s).

First responders can also utilize JHAs to stratify, for example, the risk of fentanyl exposures into high and low risk categories based upon factors such as the presence or absence of free particulate powder, etc. To further illustrate this concept, job tasks such as clandestine lab entry, where large amounts of free fentanyl powder or pills may be expected to be found can be easily identified and classified as high-risk, while routine law enforcement searches of detained individuals, during which small amounts/ numbers of contained powder and pills maybe expected to be found, can be classified as low-risk.^{39,46}

An essential component of any comprehensive counter-fentanyl and naloxone countermeasures program is the accurate assignment and understanding of risk as related to specific job tasks. JHAs need to also address risks in related tasks such as fentanyl evidence collection, field-testing and transport as well as appropriate management of contaminated uniforms and field gear.

Recommendation 6. The FSLTT first responder community of practice should develop a set of standardized Job Hazard Analyses (JHAs), representing the most common first responder work tasks. JHAs should be a key element for any first responder safety and health program and incorporate both human and working canine first responders. Any workplace controls, including Personal Protective Equipment (PPE), are based on, and identified in, the JHA.

20. Alcohol-based Hand Sanitizers, Alcohol Wipes, Liquid Bleach and Bleach Wipes Have the Potential to Enhance the Fentanyl Skin Absorption and Should Not be Used to Clean Skin

Alcohol promotes enhanced skin absorption, which is why it is used by the pharmaceutical industry in various topical medications, including the fentanyl analgesic medication patch, to aid in delivery.²⁹ Alcohol-based hand sanitizers and wipes, if used, have the potential to increase fentanyl absorption from skin during incidental exposures, and should be avoided.²⁹ Bleach and related products should not be used to sanitize hands, since the chlorine in bleach converts fentanyl salts (hydrochloride and citrate—forms of illicit product on the street) to their base, which can be absorbed from skin at a faster rate than the salts themselves.⁴⁷ Washing hands

with soap and water (or water alone) remains an elegant low-tech, low-cost, but still very effective safety procedure.²⁹

Recommendation 7. First responders should remove suspected fentanyl from skin surfaces with soap and water and *must avoid* entirely the use of alcohol-based hand sanitizers, alcohol wipes, liquid bleach and bleach wipes for fentanyl-contaminated skin cleansing since alcohol and bleach enhance fentanyl absorption.

21. First Responder Use of Personal Protective Equipment (PPE) Can be Highly Effective in the Prevention of Inhalation, Mucous Membrane, and Skin Exposure and Potential Intoxication

For incidental exposure scenarios, standard personal protective equipment (PPE) is focused on inhalation, mucous membrane, and skin protection and includes:

- A NIOSH-approved, properly fitted respirator mask (e.g., air-purifying half-masks with elastomeric face piece);
- Non-powdered nitrile (or other chemical resistant) gloves (minimum 4 mil);
- ANSI-approved eye protection (non-vented safety goggles); and,
- Sleeve or other garment-type protectors (if needed for additional protection of exposed skin).

This basic level of protection will go far to prevent absorption through the exposure routes of most concern and should be made readily available to all first responders as a critical tool for safe operations.²⁹ Decontamination procedures should be used for visible contamination of clothing and equipment.

Recommendation 8. First responder departments should equip and train their frontline personnel in the use of Personal Protective Equipment (PPE) that protects them from ingestion, inhalation or other contact with fentanyl, with the appropriate level of PPE based on a JHA.

22. N/P/R-95 Respirator Masks Have the Same Assigned Protection Factors as N/P/R-100 Respirator Masks

Both the N95 and P100 respirator masks are rated with the same assigned protective factor of 10, which means that both masks, under expected conditions, provide equivalent protection and safety in the working environment.⁴⁸ At present, universal agreement is lacking among experts regarding selection of the N/P/R-95 versus -100 mask for routine protection against inhalation of free fentanyl powder.

First responders should follow their own organization's internal PPE recommendations and protocols. Resources are available to guide respirator selection for operations other than routine or lower-risk that require higher levels of respiratory protection.^{37,39,46,48,49} Fit-testing remains an integral requirement of any comprehensive occupational health and safety program. Individual fit-testing for any respirator is crucial to its performance; protection may be compromised when a poorly fitting mask is utilized.⁴⁸

FENTANYL INTOXICATION

23. Fentanyl Intoxication Produces the Classic Opioid Toxidrome of Slow or No Breathing, Drowsiness or Unresponsiveness, and Constricted or Pinpoint Pupils

A toxidrome (short-hand combination of the words “toxic” and “syndrome”) is a group of tell-tale signs and symptoms in a person that are present as a result of intoxication with a specific

Recommendation 9. First responder departments should educate frontline personnel on signature fentanyl intoxication signs and symptoms in themselves and others: slowed or no breathing, drowsiness or unresponsiveness, and constricted or pinpoint pupils.

drug(s) or toxin(s). Fentanyl, like most opioids, produces a toxidrome which includes three signature elements: slowed or no breathing, drowsiness or unresponsiveness, and constricted or pinpoint pupils.⁵⁰ Key message #27 addresses other commonly reported intoxication signs and symptoms that require further research and confirmation.

24. To Date, There Have Been Zero Laboratory-confirmed Intoxications from Fentanyl Among Non-Federal First Responders and There have Been Zero Reported Intoxications Among Federal First Responders

Anecdotal reports in the media^{25,51} of purported or suspected fentanyl intoxications nationally are numerous yet are without basis due to lack of an established case definition and the absence of confirmation through post-exposure laboratory drug testing. Outside of the Federal government, there have been cases of non-federal first responders reporting certain signs and symptoms after exposure or suspected exposure to fentanyl, but there have been no available laboratory confirmations of true fentanyl intoxication in any of these cases.²³ As such, there exists no reliable picture of the true risk to first responders from fentanyl. The absence of confirmed and reported intoxications amongst the non-federal and federal first responder workforce, respectively, are substantiated in a review of available literature, as well as open and closed source reporting.²³

25. First Responder Fentanyl Intoxication Incidence and Prevalence Rates Are Unknown.

Currently, we have neither the numerator (number of persons with confirmed fentanyl occupational intoxications) nor the denominator (number of persons with confirmed or suspected fentanyl occupational exposures) in the equation (case rate of fentanyl occupational intoxications). Incidence and prevalence rates for fentanyl occupational intoxications among first responders are, consequently, unknown.²³

26. A Case Definition with Confirmatory Lab Testing for Occupational Fentanyl Intoxications is a Critical Missing Element in Accurate Depiction of Fentanyl Exposures

A critical data point missing from our current understanding of the occupational fentanyl threat is the concept of the case definition—an essential element to understanding fentanyl and its occupational risk. A case definition is a set of criteria used to establish the probability of a disease or injury in an exposed person. With respect to potential fentanyl occupational exposure and intoxication, an appropriate case definition would include:

- Documented evidence of the presence of fentanyl on the job (e.g., evidence that fentanyl was the specific drug interdicted, seized, sampled, or encountered during a search, or the etiology of toxicity in a victim whom the first responder treated or otherwise interacted with;
- A completed exposure pathway (e.g., lack of adequate PPE; no respiratory protection in the circumstance of gross airborne contamination);
- The presence in a first responder of signs and symptoms consistent with opioid (fentanyl) intoxication (suspect case);
- Post-exposure testing of bio-specimens (i.e., blood or urine) confirming the presence of fentanyl or its metabolites (confirmed case); and,
- Reversal of the opioid toxidrome with administration of naloxone.

The first four criteria are needed to confirm a definitive occupational exposure and intoxication have occurred. Reversal of the opioid toxidrome with administration of naloxone is a supporting criterion, but not necessary for a confirmed case. Bio-specimen laboratory confirmation of fentanyl (or its analogs) is critical in documenting and providing evidence of confirmed rather than just suspected cases. The current lack of laboratory fentanyl case confirmation nationally is likely driven by several factors:

- Absence of a true fentanyl intoxication;
- The lack of an emergency room clinical requirement for fentanyl-specific opioid identification
- The long turn-around time for confirmatory laboratory testing; and,
- The lack of re-imbursement capability for laboratory testing that does not inform acute treatment of patients.

Ultimately, collective reporting of laboratory-confirmed cases from across the FSLTT will provide a more accurate picture of first responder fentanyl exposure risk.

Recommendation 10. The FSLTT first responder community of practice should develop a consensus guideline that establishes a case definition and provides recommendations to improve use of, and access to, bio-specimen laboratory confirmation and a means by which to collect laboratory-confirmed case reports from across the FSLTT first responder community.

Recommendation 11. First responder departments across the FSLTT should establish automatic mechanisms for bio-specimen collection, and analysis, for first responders after suspected exposures and intoxication.

27. More Research Is Needed on Whether Other Signs and Symptoms Such as Dizziness, Rapid Heart Rate, Nausea and Vomiting, or Feelings of Impending Doom Can Be the First Signs of a Significant Fentanyl Intoxication

There have been anecdotal reports in the media of first responders experiencing a range of symptoms after suspected fentanyl exposures that do not fit into the classic toxidrome of opioid intoxication,⁵¹ creating some confusion regarding identification of the presence of true fentanyl intoxication. This includes signs and symptoms such as: dizziness, rapid heart rate,

nausea and vomiting, or feelings of impending doom which can be observed with other unrelated medical conditions such as heat injury, dehydration, the adrenaline response, etc. These signs and symptoms have been reported as resulting from fentanyl exposure but without subsequent laboratory confirmation of actual exposure to, or intoxication from, fentanyl exposure as the cause. This has resulted in difficulty identifying a causal effect or establishing a true diagnosis of occupationally related fentanyl exposure and intoxication. Systemic opioids can routinely trigger histamine release in the body, producing dizziness, nausea, and other symptoms, although controlled use of fentanyl in the hospital setting has been previously established to have a favorable side effect profile which includes less histaminic effects than others in its class.⁵² Very limited data from small cohorts of drug abusers, ingesting oral tablets or using nasal spray solution containing fentanyl, or one of its analogs, suggests that true fentanyl intoxications have the potential to produce signs and symptoms beyond the classic opioid toxidrome.^{53,54} In the future, case experience over time along with post-exposure blood testing will provide the answer to this question. More research is required to confirm this, with consideration also given to multiple drug mixtures that are also prevalent in the illicit drug trade and their associated intoxication characteristics.

Recommendation 12. Medical toxicologists should conduct additional research to confirm or refute signs and symptoms anecdotally associated with fentanyl exposure and intoxication and which do not represent the signature opioid toxidrome. Clinicians should consider the possibility of drug mixtures - that may or may not include opioids – and which could result in other, non-opioid intoxication signs and symptoms when treating first responders and when validating exposure via laboratory confirmation.

INTOXICATION COUNTERMEASURES

28. First Responders Must Render Immediate Care in the Event of Known or Suspected Fentanyl Intoxication

Whenever a first responder suspects he/she or others are displaying signs and symptoms of a fentanyl intoxication, time is of the essence. If a first responder experiences directly or observes in others slowed or no breathing and/or drowsiness or unresponsiveness, naloxone should be administered, without hesitation, with its administration repeated every 2-3 minutes until adequate breathing is restored, or the first responder runs out of naloxone, or EMS arrives on scene and assumes care of the patient. Subsequent doses of naloxone are administered in the opposite nostril,⁵⁵ to ensure complete absorption of the medication. First responder personnel who work alone can self-administer naloxone if they experience any signs and symptoms of suspected fentanyl intoxication.

First responders on-scene should initiate rescue breathing per Basic Life Support (BLS) or Advanced Cardiac Life Support (ACLS) guidelines in the absence of (sufficient) naloxone when an affected person continues to have inadequate or no respirations, despite (prior) naloxone administration. When other worrisome symptoms are present in the context of uncertainty, naloxone should still be administered, unless directed otherwise by higher medical authority, in conjunction with evacuation and close monitoring of the symptomatic first responder, and simultaneous with calls for (additional) EMS response.

Recommendation 13. First responder departments should educate the frontline to immediately self-administer or administer naloxone to others when there is suspected opioid intoxication. First responders should also be trained and prepared to initiate rescue breathing per Basic Life Support (BLS) or Advanced Cardiac Life Support (ACLS) guidelines in the absence of naloxone or when naloxone administration does not yield the expected outcome. In either instance, first responders should seek definitive medical care.

29. Cardiopulmonary Resuscitation (CPR) and Automated External Defibrillator (AED) Capacity Remain Important to Any Comprehensive Fentanyl Response

Fentanyl intoxication has the capacity to cause slowed or no breathing in humans. In situations in which naloxone or sufficient amount of naloxone is not available, or in which a person has suffered a respiratory arrest from prolonged fentanyl intoxication, rescue breathing, as taught in basic CPR and BLS training, will provide life-sustaining treatment until definitive help arrives in the form of additional naloxone or EMS personnel and further resources. In a situation in which a person has suffered a cardiac arrest from prolonged fentanyl intoxication, use of an AED may facilitate successful resuscitation. First responder agencies should fund, and support, the parallel development and expansion of CPR and AED training and acquisition of resources, along with the development and deployment of a successful naloxone program. All naloxone training should emphasize that rescue breathing is an effective bridge to definitive treatment by experienced medical personnel, with this imperative as equally relevant for our canine workforce.

Recommendation 14. First responder departments should develop and expand CPR and AED programs.

30. Nasal Naloxone is an Effective, Safe, Inexpensive, and Easy-to-Train Countermeasure That Can Be Successfully Used by Non-Healthcare Providers in the Field

Naloxone is an opioid reversal agent which works by competitively blocking fentanyl binding at the (mu) opioid receptor sites in the body.⁵⁵ It saves lives because it reverses the fatal respiratory depression which can occur as a result of fentanyl effects on the brain and central nervous system.⁵⁵ The immediate goal of naloxone administration is restoration of adequate respirations, with improvement in mental status or level of consciousness as a secondary priority. Under normal circumstances, naloxone is a safe drug with limited reported side effects and no reported abuse potential.⁵⁶

While it is true that use of naloxone can precipitate withdrawal in a person who is opioid dependent and overdosed, it has few side effects when used in non-opioid dependent persons who are acutely intoxicated, and is unlikely to result in harm or effect if given to a person without true opioid overdose or intoxication.⁵⁶ Naloxone is safe to use in pregnant women and children, although it is contraindicated in infants younger than 28 days old.⁵⁵ Nasal naloxone can be successfully self-administered by symptomatic individuals.⁵⁷

The Food and Drug Administration (FDA) approved the use of NARCAN® nasal spray to reverse slowed or no breathing and/or drowsiness or unresponsiveness associated with opioid

overdose.⁵⁵ The NARCAN[®] nasal naloxone spray, when purchased in bulk, currently costs under \$100 for a 4 mg nasal spray two-unit pack.⁵⁸ The pre-filled syringe of intravenous naloxone for (off label) use with a mucosal atomizer device together as an improvised nasal spray is comparably priced.⁵⁹ The Evzio[™] naloxone auto-injector is also available. NARCAN[®] (and, similarly, the improvised, off-label nasal spray) is a simple delivery device which requires little or no technical knowledge or skill in administration requiring insertion of the tip of either device into the affected person's nostril followed by device actuation by compressing the unit between the 2nd and 3rd fingers, using the thumb to actuate the plunger for delivery of the spray.⁵⁵ This delivery device has a proven track record of successful use of the spray by non-healthcare providers with no previous medical training.⁶⁰

The Evzio[™] auto-injector⁶¹ is a device intended for intramuscular injection and has a mechanism which includes a needle, therefore necessitating a potentially a higher level of first responder education and training. Ease of use and more simplified education and training makes nasal naloxone an ideal countermeasure.

31. Withdrawal Does Not Occur in Persons Who Are Not Opioid Dependent

Chronic opioid users, who overdose on fentanyl and receive naloxone for resuscitation, may experience signs and symptoms of acute opioid drug withdrawal, such as severe nausea and agitation, etc., as a result of the rapid opioid reversal effects.⁵⁰ Naloxone-induced withdrawal in chronic drug users is typically uncomfortable but not life threatening, and rarely results in serious complications.^{50,55} First responders who are not opioid dependent will not experience opioid withdrawal symptoms from naloxone administration, although adverse side effects from naloxone administration can occur.^{50,55,56}

Recommendation 15. First responders should feel confident to administer naloxone, without hesitation, in the event of a fentanyl intoxication.

32. Establishing Naloxone Countermeasure Programs for the Frontline First Responders, Human and Canine, at Risk of Fentanyl Exposure is a Priority

The starting point, following implementation of appropriate administrative and engineering controls, for any first responder organization addressing the threat of potential fentanyl exposure and intoxication should be the acquisition and distribution of naloxone. A JHA will enable first responder departments to develop a risk-based approach to identify those work tasks with the greatest potential to result in exposure, with the priority naloxone distribution going to those identified as having the highest risk.

33. It is Important to Understand the Specifications Regarding Naloxone and its Use

- The immediate goal of naloxone administration is restoration of adequate respirations--improvement in mental status or level of consciousness is secondary;
- Naloxone is not a substitute for definitive medical care by experienced medical professionals or basic supportive care within their scope of practice from any responder;
- First responder personnel experiencing signs and symptoms of a suspected fentanyl intoxication or anyone who has been given naloxone should be evaluated by higher medical authority as soon as safe and possible to do;

- First responder organizations should track all workforce health naloxone administrations to their personnel; and,
- A naloxone program should, ideally, be overseen by a physician for medical direction and prescription ordering of bulk doses.

34. Naloxone Nasal Spray Has Specific Requirements for Storage and Maintenance

Naloxone manufacturers recommend that naloxone nasal spray be stored at temperatures between 59-77 degrees Fahrenheit.⁵⁵ Exposures to routine excursions outside this temperature range are permissible for 24 hours without significant product degradation occurring.⁵⁸ Product exposed to temperatures greater than 104 degrees Fahrenheit for any period of time is considered unusable and should be discarded due to concerns over loss of efficacy.⁵⁸ Freezing causes naloxone to crystallize and decreases the chance of effective delivery of the spray, and product exposed to freezing temperatures should be discarded.⁵⁸ NARCAN® currently has a two-year shelf life.⁵⁸ An additional factor which needs to be considered in the distribution and storage of naloxone nasal spray is the potential for uncontrolled climate conditions for product stored in vehicles and vessels, particularly in non-temperate geographic regions and challenging conditions. Commercial products including a personal belt nasal spray carrier pouch with wireless temperature monitoring⁶² are available to mitigate loss of naloxone product due to uncontrolled climate conditions.

Recommendation 16. First responder departments must address the care and storage of naloxone, particularly those with missions conducted in uncontrolled climate conditions. Factors for consideration include time-sensitive issuance and turn-in procedures at muster, to sustain long-term product viability.

35. First Responder Departments Should Have Established Treatment Protocols for the Administration of Naloxone

Algorithm-driven protocols are the standard of care for safe and appropriate naloxone administration. Algorithms are instructions that prompt action. A typical naloxone algorithm prompts naloxone administration in a suspected fentanyl victim who is breathing less than 8-10 times per minute and is drowsy or unresponsive.²³ The endpoint and goal of any algorithmic approach is the restoration of normal breathing to a rate of 10-12 times per minute. A sample algorithm is included as Appendix C.

Recommendation 17. First responder departments should develop and train their personnel on treatment protocols for the administration of naloxone.

36. There Are Essential Clinical Considerations Regarding the Use of Naloxone for Persons Suspected of Fentanyl Intoxication or Overdose

- Naloxone is a competitive antagonist and works in the body primarily by blocking the (mu) opioid receptor at which fentanyl is pharmacologically active, so that the effects of fentanyl are reversed by antagonism alone—naloxone does not affect metabolism or elimination of fentanyl itself, but instead buys time for the body to rid itself of fentanyl⁵⁵ through physiologic breakdown and excretion of the drug.

- Naloxone is FDA indicated to be used to restore breathing and/or consciousness in a person who has slowed or no breathing and/or drowsiness or unresponsiveness due to the effects of an opioid.⁵⁵
- The NARCAN[®] naloxone nasal spray delivers a one-time dose of 4 mg, and is not intended for re-use⁵⁵ improvised nasal spray devices deliver dose(s) of 2-4 mg and are also not intended for re-use. In January 2017, the FDA approved a 2 mg version of NARCAN[®].
- The contraindications to naloxone use are a known allergy to naloxone or lack of nasal absorption of naloxone as may be seen with nasal trauma, nose bleeds, excessive mucus, and septal deviation; naloxone spray administration is not recommended in these instances.⁵⁵
- Successful resuscitations from fentanyl intoxications, and overdoses, may require typical dosages of nasal naloxone in the range of 2-10 milligrams.⁵⁰ More than one nasal spray may be required and the total milligrams of naloxone may be higher than traditional dosing. This may be due to incomplete absorption through the nose, higher culprit drug concentrations, or combinations of multiple factors.
- The dose of naloxone required for successful resuscitation is influenced by many factors including the fentanyl dose exposure, body weight of the affected individual, duration of intoxication, alteration in breathing and circulation of the affected individual, etc.⁵⁰
- A total or cumulative dosage of more than 10 mg of naloxone administered to a symptomatic individual without improvement in symptoms may suggest a diagnosis other than fentanyl or opioid intoxication alone.⁵⁰
- The onset of naloxone's effects should occur on the order of minutes.⁵⁰
- A single naloxone dose continues to have clinical effects against fentanyl for up to a maximum of approximately 90 minutes, after which time a return of the toxic effects of fentanyl may occur from fentanyl still active in the body.^{50,55}
- Because of the approximately 90 minute window of action for naloxone, and because fentanyl may last longer than the clinical effect of naloxone, individuals with suspected occupational fentanyl intoxications should be observed in an hospital setting for a minimum of 4 hours or longer,⁵⁰ even if no longer symptomatic, to ensure no sudden relapse occurs which requires repeat naloxone administration.

37. Naloxone Resistance is a Potential Misnomer Used in the Media/Press

“Resistance” is a medical term normally used to quantify antibiotic susceptibility patterns of viruses and bacteria, and may not be the most accurate nomenclature used to describe instances in which naloxone does not work against fentanyl overdoses or occupational intoxications. A more accurate term may be naloxone “ineffectiveness” or “failure”. There is also no current evidence that fentanyl or its analogs irreversibly binds to the mu opioid receptor. Although there is no current evidence in the literature that naloxone completely loses competitive inhibition with fentanyl or any of its analogs,²³ there are several circumstances in which naloxone will not reverse respiratory depression or sedation caused by a fentanyl overdose or intoxication, such as:

- An irreversible respiratory or cardiac arrest from prolonged fentanyl intoxication;
- Inadequate dosage of naloxone;
- A diagnosis other than opioid overdose or intoxication;
- A mixed overdose or intoxication with another agent causing persistent effects despite successful reversal of fentanyl; and
- Lack of nasal absorption of naloxone, as may be seen with nasal trauma, nose bleeds, excessive mucus, and septal deviation.⁵⁵

38. Establishment and Management of a Naloxone Countermeasure Program Requires a Comprehensive Strategy

Launching a successful operational naloxone countermeasure program requires a comprehensive strategy that incorporates policy, procedure, acquisition, and distribution. Specific considerations of such a strategy includes:

- Physician oversight;
- Designated local and regional coordinators;
- Enterprise-wide naloxone integration;
- First responder education and training;
- Data management including the creation, tracking and analysis of metrics;
- Supply chain and product tracking and management to include stock rotation of nasal sprays and oversight of lost and degraded product;
- Planning for future opioid related workforce threats; and,
- Resource management and conservation to optimize naloxone countermeasure programs.

Over time, data tracking -- to include data on prevalence of first responder exposure and intoxication data -- will improve knowledge and management of naloxone countermeasures programs, predicated on data collection and trend analysis.

Recommendation 18. The FSLTT first responder community of practice should develop a consensus guideline on the ideal naloxone countermeasure program that the FSLTT can disseminate across the first responder community nation-wide.

39. Naloxone Nasal Spray Which is Stored Out of Immediate Reach of First Responders is Rendered Useless as a Countermeasure.

In determining operational deployment, access to the nasal spray in the event of a sudden emergency is the factor that drives where naloxone nasal sprays are pre-positioned: the nasal spray must be within safe time and distance from first responder personnel and their location, to resuscitate a person who has stopped breathing from a fentanyl intoxication. If not carried on a person or in patrol/rescue vehicle, naloxone must be readily on hand to be administered within the 3-5 minute window of opportunity for successful resuscitation and rescue from irreversible brain injury due to lack of oxygen in a person not breathing. In the absence of naloxone, or if naloxone administration does not yield expected results, first responders must be ready and able to provide supportive care with basic life support such as CPR.

40. First Responder Working Canines Share the Same Risk but Not the Data or Experience in Nasal Naloxone Administration

While human experience with naloxone nasal spray is known and safe, data in the veterinary world is currently lacking to support the safe use of nasal spray in working canines,⁴⁴ with concerns about the efficacy of nasal administration in canines, and with the potential for the nasal formulation to alter working canine olfactory sensitivity. Future research may address these important questions. Currently, canine handlers carry naloxone auto-injectors for use against potential canine fentanyl intoxications. Local veterinarians typically prescribe naloxone as part of an on-going veterinarian-patient-client-relationship.

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APPENDICES

Appendix A



PROTECTING FIRST RESPONDERS ON THE FRONTLINES OF THE FENTANYL EPIDEMIC

September 6-7, 2017

Department of Homeland Security,
Office of Health Affairs

in collaboration with

Department of Transportation,
National Highway Traffic Safety Administration,
Office of Emergency Medical Services



Homeland
Security



AGENDA

Wednesday September 6, 2017

- 08:00 – 08:30 **Onsite Registration**
- 08:30 – 08:35 **Welcome: Linda Holifield-Kennedy, MD, MPH**, Senior Medical Advisor for Occupational Health, US Department of Homeland Security's Office of Health Affairs
- 08:35 – 8:40 **Opening Remarks: Larry D. Fluty**, Acting Assistant Secretary for Health Affairs and Chief Medical Officer, US Department of Homeland Security's Office of Health Affairs
- 08:40 – 09:00 **Overview: Fentanyl and Opioid Crisis in the United States, Evidence-based Approaches to Reduce Harm to First Responders: Lee Pietrangelo, MD**, Medical Liaison Officer Program Manager, Department of Homeland Security's Office of Health Affairs
- 09:00 – 09:20 **EMS/HAZMAT Perspective on Fentanyl Risk to First Responders: Jon Krohmer, MD**, Director, Office of Emergency Medical Services, National Highway Traffic Safety Administration
- 09:20 – 09:50 **Featured Speaker: Fentanyl: The Next Wave of the Opioid Crisis: Kemp Chester**, Associate Director, National Heroin Coordination Group, Office of National Drug Control Policy
- 09:50 – 10:00 **Q & A**
- 10:00 – 10:20 **Ultra-Potent Synthetic Opioid Pipeline: Stephen D. McConachie**, Chief Operations Manager, US Department of Homeland Security's Customs & Border Protection, Liaison to the Office of National Drug Control Policy (ONDCP)
- 10:20 – 10:30 **Q & A**
- 10:30 – 10:45 **Break**
- 10:45 – 11:05 **Clinical Effects of Fentanyl: Andrew Stolbach, MD, MPH**, Associate Professor, Emergency Medicine and Medical Toxicology, Johns Hopkins University, Baltimore, MD
- 11:05 – 11:15 **Q & A**
- 11:15 – 11:35 **Science of Naloxone: Andrew Stolbach, MD, MPH**, Associate Professor, Emergency Medicine and Medical Toxicology, Johns Hopkins Hospital, Baltimore, MD
- 11:35 – 11:45 **Q & A**
- 11:45 – 12:05 **Chemistry of Fentanyl and its Analogs, Dispelling the Myths: Mike McCormick, PhD**, Science Officer, Laboratories & Scientific Services, US Department of Homeland Security's Customs and Border Protection
- 12:05 – 12:15 **Q & A**
- 12:15 – 1:15 **LUNCH – ON YOUR OWN**
- 1:15 – 1:35 **The New Jersey Fusion Center Experience: CAPT Juan Colon**, NJ State Police and NJ Fusion Center; **Diane Calello, MD**, Medical Director, NJ Poison Information and Education System, New Jersey Medical School of Rutgers University, Newark, NJ
- 1:35 – 1:45 **Q & A**
- 1:45 – 2:05 **Preventing Occupational Fentanyl and Fentanyl Analog Exposure to First Responders, A Modular Training Approach: Chuck McKay, MD**, Medical Toxicologist, Associate Director Connecticut Poison Control Center
- 2:05 – 2:15 **Q & A**

2:15 – 2:30	Break
2:30 – 2:50	Naloxone Treatment Algorithms and Administering a Naloxone Program: Nick Hanke , Office of Field Operations, US Department of Homeland Security's Customs and Border Protection
2:50 – 3:00	Q & A
3:00 – 3:20	Law Enforcement Training Pilot: Mark Kirk, MD , Director, Chemical Defense Program, US Department of Homeland Security's Office of Health Affairs
3:20 – 3:30	Q & A
3:30	Adjourn

Thursday September 7, 2017

08:00 – 8:30	Recap of Day One
08:30 – 8:50	Potential Routes of Fentanyl Exposure: CAPT Michael Schwartz, MD , Deputy Director, Chemical Defense Program, US Department of Homeland Security's Office of Health Affairs
8:50 – 09:00	Q & A
09:00 – 09:20	Technologies for Detecting Fentanyl and Its Analogs: Mike McCormick, PhD , Science Officer, Laboratories & Scientific Services, US Department of Homeland Security's Customs and Border Protection
09:20 – 09:30	Q & A
09:30 – 09:50	Naloxone Use in Working Canines - The Veterinary Experience: Marvin Meinders, DVM , Veterinary Medical Officer, US Department of Homeland Security's Office of Health Affairs
09:50 – 10:00	Q & A
10:00 – 10:15	Break
10:15 – 10:45	Synthesizing and Managing Gaps and Misinformation: Amber Williams-Allen, Rachel Campbell , National Biosurveillance Integration Center, US Department of Homeland Security's Office of Health Affairs
10:45 – 11:45	Working Group Breakouts: Group A – Educational Awareness & Training Module Group B – Protective Guidelines Group C – Establishing a Naloxone Program Group D – Communications Strategies
11:45 – 1:00	LUNCH – ON YOUR OWN
1:00 – 2:00	Working Groups
2:00 – 3:00	Working Group Report Outs (15 Mins. Each)
3:00 – 3:30	Future Direction and Adjournment

Larry (Dave) Fluty

Acting Assistant Secretary for Health Affairs and Chief Medical Officer
US Department of Homeland Security's Office of Health Affairs



Dave Fluty is the Acting Assistant Secretary for the Office of Health Affairs (OHA) in the Department of Homeland Security (DHS). In this position, he leads a multi-disciplinary professional and technical staff that anticipates the public health impact of biological attacks, chemical releases, pandemics, and disasters, and helps prepare the nation and the DHS workforce to respond and rebound.

Mr. Fluty previously served as the Principal Deputy Assistant Secretary for OHA, following a 22 year tenure with U.S. Customs and Border Protection (CBP), where he most recently served as the CBP Area Port Director for the Houston/Galveston Seaport. Prior to this assignment, Mr. Fluty was the Deputy Assistant Commissioner of the CBP Office of Training and

Development, a senior executive position responsible for ensuring that all employee training and development efforts support CBP's mission and meet the needs of a diverse and dispersed workforce of over 60,000 employees.

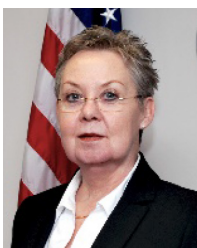
Mr. Fluty previously served as the Director of the CBP Southwest Regional Science Center in Houston, TX, where he was responsible for providing CBP and DHS law enforcement officers with frontline technical assistance and scientific services in many diverse areas that include WMD threats, trade enforcement, forensic analysis, and crime scene investigation. Additionally, he worked closely with the petroleum industry measurement community to develop uniform guidelines and streamline technical reporting requirements for the approval of petroleum measurement systems for CBP custody transfer purposes.

Mr. Fluty began his federal career with U.S. Customs in 1994 as a forensic chemist in the San Francisco Laboratory, where he worked extensively in the country-of-origin analysis of petroleum products. He rapidly assumed positions of increased responsibility, serving at CBP Headquarters as the Director of Scientific Services providing operational and administrative management of the CBP laboratory system and as the Deputy Assistant Director of Operational Support at the DHS Domestic Nuclear Detection Office, where he helped develop the inter-agency nuclear decision protocols to adjudicate nuclear detection events at our nation's borders and abroad.

Mr. Fluty is a graduate of the CBP SES Candidate Development Program. He holds a bachelor's degree in Chemistry from the University of the Pacific and is a Senior Executive Fellow at Harvard University's John F. Kennedy School of Government.

Leslie H. Holland

Deputy Director, Workforce Health and Medical Support Division
Office of the Assistant Secretary for Health Affairs



Leslie Holland is the Deputy Director of the Workforce Health and Medical Support Division of the Office of Health Affairs in the Department of Homeland Security (DHS). The Office of Health Affairs serves as the Department's principal agent for all medical and public health matters. Ms. Holland brings 25 years of federal service spanning five federal agencies to this position to lead DHS workforce health protection and medical services oversight and coordination activities. She directs a team of experts in medicine, public health, emergency response, and preparedness to manage the delivery of DHS medical services, coordinate the DHS EMS response with state and local EMS systems, and develop programs to protect the DHS workforce from threats they may face in the line of duty.

Prior to joining the DHS Office of Health Affairs, Ms. Holland served as Director of Occupational Safety and Health in the Office of the Assistant Secretary of the Navy (Energy, Installations & Environment). In this position she led the strategic advancement of the Department's safety program and established a safety career development program

as part of the Defense Department's Strategic Human Capital Planning initiative. For her efforts, Ms. Holland was awarded the Navy Superior Civilian Service Award, the second highest honorary award under the Department of the Navy Civilian Awards program.

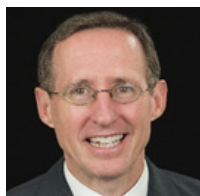
Ms. Holland led the United States Coast Guard's (USCG) Safety and Environmental Health Program from 2007 to 2011. As Chief, she directed the USCG's Aviation, Afloat and Shore Safety and Environmental Health programs. Her most significant accomplishments include driving a marked decline in USCG off-duty motor vehicle accidents and establishing a novel approach to managing operational risk before and during USCG missions.

Prior to the USCG, Ms. Holland served at the Department of State from 2000 to 2007, where she traveled to 60 American embassies and consulates worldwide conducting safety, occupational health, and environmental assessments. Ms. Holland has also served with the U.S. Army Corps of Engineers and the National Aeronautics and Space Administration. She began her civil service career in 1987 at the Naval Security Station, now home to DHS headquarters in Washington, DC.

Ms. Holland holds a Master of Science Degree in Environmental Health from Old Dominion University and is a Certified Industrial Hygienist (CIH) and Certified Safety Professional (CSP).

Lee A. Pietrangelo, M.D.

Medical Liaison Officer (MLO) Program Manager
US Department of Homeland Security's Office of Health Affairs



Lee A. Pietrangelo, M.D., M.S. is the Medical Liaison Officer (MLO) Program Manager in the Office of Health Affairs within the Department of Homeland Security. Prior to joining DHS and federal service, Dr. Pietrangelo was a full-time internist and hospital physician, serving as an attending physician in several hospitals in the northeast Ohio area, working most recently for the Cleveland Clinic Foundation and prior for Fisher-Titus Medical Center in Norwalk and the Ohio Permanente Medical Group in Maple Heights. Previous U.S. government experience included a tour as a Navy officer, serving as staff physician in the Office of Attending Physician to U.S. Congress, providing medical, occupational, and emergency services to Members of Congress, Justices of the Supreme Court, and staff and visitors on Capitol Hill.

Prior to his work as a full-time hospital physician, Dr. Pietrangelo retired from the U.S. Military after 23 years serving in both the U.S. Navy and the U.S. Army, having spent the majority of that time on the operational side in the United States, Iceland, Europe, and the Middle East including service in Operations Southern Watch, Iraqi Freedom, Enduring Freedom, and Joint Guardian.

Early in his military career he graduated from the U.S. Navy's Flight Surgeon Training Program, including completing primary flight training with aviation candidates at the Naval Aviation Schools Command at Naval Air Station Pensacola, earning his flight surgeon wings. Dr. Pietrangelo eventually became qualified as both an Army and Navy flight surgeon, with several hundred flight hours in rotary and fixed wing aircraft. He served in a variety of roles during his career as Medical Officer and Flight Surgeon, including serving as an emergency room physician at the U.S. Naval Hospital Keflavik, Iceland where he also flew search and rescue missions in the North Atlantic with the U.S. Air Force's 56th Rescue Squadron; serving as the Command Element Surgeon for the 24th Marine Expeditionary Unit (Special Operations Capable) based out of Camp Lejeune, deploying to the Mediterranean Sea and Arabian Gulf areas of responsibility with the U.S.S. Guam Amphibious Ready Group; serving as squadron flight surgeon for Marine Tactical Electronic Warfare Squadron One (VMAQ-1) and later as Group Surgeon for Marine Air Group Fourteen (MAG-14) at Marine Corps Air Station Cherry Point; and deploying to Camp Bondsteel in Kosovo in support of the NATO KFOR mission where he flew search and rescue and medevac missions as well as provided flight surgeon and internal medicine support to NATO forces.

Dr. Pietrangelo also completed combat tours to Iraq and Afghanistan, working at front line battalion aid stations, shock trauma field units, and emergency room and clinic settings, serving with the 2nd Battalion 24th Marine Regiment, the 173rd Airborne, and the 144th and 684th Area Support Medical Companies.

Dr. Pietrangelo received his undergraduate degree in Classics and Pre-Med at the College of the Holy Cross in Worcester, MA, and his Masters of Science in Public Health Nutrition and his Doctor of Medicine at Case Western Reserve University in Cleveland, Ohio. He completed both an internship in Family Medicine and his residency in Internal Medicine at Fairview Hospital in Cleveland, Ohio. Dr. Pietrangelo also completed an academic fellowship in Patient Safety at the VA Pittsburgh Health System. He is a diplomat of the American Board of Internal Medicine.

Kemp L. Chester

Associate Director and Chief of the NHCG, Office of National Drug Control Policy



Kemp L. Chester is Associate Director and Chief of the National Heroin Coordination Group (NHCG) within the Office of National Drug Control Policy. In this capacity, Mr. Chester leads the inter-agency effort to reduce the availability of heroin in the United States by disrupting its global supply chain. Mr. Chester leads a diverse, multi-disciplinary team of subject matter experts, and works closely with the National Security Council staff to manage a network of partnerships across the inter-agency community focused on the heroin problem.

Prior to joining the ONDCP, Mr. Chester was the Director of National Security and Intelligence for McKenna Principals, a private sector consulting firm, where he managed a program bringing state of the art information sharing and safeguarding technologies to the Department of Homeland Security. Mr. Chester's prior government experience was as the Chief of the Office of Counternarcotics Worldwide (CNW) at the Defense Intelligence Agency from 2011-2014. At DIA, Mr. Chester was responsible for defense intelligence collection and analysis on global narcotics issues, and for the management of all funding for the intelligence analysis effort in support of Department of Defense counternarcotics activities. He also served as the Executive Agent of the Consolidated Counterdrug Database, the government's primary source on the global movement of drugs from source country to destination.

During a 27 year career as a US Army Intelligence Officer, Mr. Chester served in a variety of command and staff positions in the United States, Europe, and the Middle East, including service in Operations Desert Shield and Desert Storm, Iraqi Freedom, and Enduring Freedom. During his time in Afghanistan, from 2010-2011, then-Colonel Chester served as the Chief of the Ministry of the Interior Intelligence Advisory Team for the NATO Training Mission-Afghanistan. Working closely with coalition partners and the European Union Police Mission in Afghanistan (EUPOL), Mr. Chester designed and built an enduring police intelligence capability for the Islamic Republic of Afghanistan, which included the Afghan National Intelligence Training Center (ANITC), the Network Targeting and Exploitation Center (NTEC), and the full staffing of an 1100-person Directorate of Police Intelligence within the Ministry. He also served as the mentor and advisor to Afghanistan's Director of Police Intelligence.

Mr. Chester earned a Bachelor of Arts in Political Science from The Citadel, a Master of Arts in International Relations from the University of South Carolina, a Master of Arts in National Security and Strategic Studies from the Naval War College, a Master of Military Arts and Sciences from the School for Advanced Military Studies, and a Master of Arts in National Strategy from the National War College. Mr. Chester and his wife currently live in Lorton, Virginia and they have three children.

Jon R. Krohmer, MD

Director, Office of EMS, NHTSA, DOT



Jon R. Krohmer, M.D., F.A.C.E.P. is the Director of the NHTSA Office of EMS in the Department of Transportation. Immediately prior to that, he was the Assistant Director of the ICE Health Service Corps at the Department of Homeland Security. Previously, he was the principal deputy assistant secretary for OHA and DHS deputy chief medical officer. He entered the Senior Executive Service and began serving in that position with DHS in September 2006 and served as the acting assistant secretary for health affairs and DHS chief medical officer from August 2008 to August 2009. He is also currently the EMS Medical Director of the Caroline County, MD Department of Emergency Services.

Prior to his work at DHS, Dr. Krohmer was an attending physician and director of emergency medical services (EMS), emergency medicine residency and the Department of Emergency Medicine at the Spectrum Health Butterworth Campus in Grand Rapids, Mich. In addition, he was an associate professor of emergency medicine at the College of Human Medicine at Michigan State University in East Lansing, Mich. He is the former EMS medical director of Kent County Emergency Medical Services and was the medical director for the West Michigan Metropolitan Medical Response System, the Kent County Medical Reserve Corps and the Michigan Region 6 Bioterrorism Preparedness Consortium. He has been active in local, regional, state and national domestic preparedness activities for many years.

Dr. Krohmer received his undergraduate degree at Ferris State College, School of Pharmacy in Big Rapids, Mich., and is a graduate of the University of Michigan Medical School in Ann Arbor, Mich. He completed his emergency medicine residency at Wright State University in Dayton, Ohio and was chief resident there from 1985 to 1986. Dr. Krohmer also completed a fellowship in EMS and research at Wright State University. He currently is a fellow of the American College of Emergency Physicians and a diplomat of the American Board of Emergency Medicine.

Dr. Krohmer has been active with both the American College of Emergency Physicians where he chaired the EMS Committee and the Trauma Care and Injury Control Committee, as well as the Michigan College of Emergency Physicians where he was president of the organization and chaired the EMS Committee. He has been associated with the National Association of EMS Physicians since 1986 and served as president of the organization. He was a founding member and a past president of Advocates for EMS. He is active in numerous other professional associations.

Linda Holifield-Kennedy, MD, MPH

Workforce Health and Medical Support Division
US Department of Homeland Security's Office of Health Affairs



Dr. Linda Holifield-Kennedy is Senior Medical Advisor for Occupational Health, Office of Health Affairs for US Department of Homeland Security. She previously served as Medical Officer for Civilian Employee Health Services at the Pentagon. In this capacity, Dr. Holifield-Kennedy provided full range clinical occupational health services to the Pentagon Workforce. Participated in policy development and implementation for employee medical surveillance programs. Conducted risk analysis surveys to reduce work related injuries and illnesses. Concomitantly served as Chief Medical Officer for Occupational Health Services at The U.S. Army Research Laboratory/Adelphi Laboratory Center. Served as a First Responder at the Pentagon on September 11, 2001.

Dr. Holifield-Kennedy co-authored publications in the Journals of Preventive Medicine and Hypertension. She has presented topics, related to workforce health and safety, at various organizations/agencies. Including the American Occupational Health Conference, Democratic National Committee, Pentagon, Department of Labor and US Army

Research Laboratory/Adelphi Laboratory Center. She is a past member of the Board of Directors for the Washington Metropolitan Chapter of the American College of Occupational and Environmental Medicine and currently serves on the Board of Directors for Four Corners International Missions (FCIM) Inc. She oversees annual free clinic services in the East African Villages of Kenya and Uganda.

Dr. Holifield-Kennedy received her Bachelor of Science Degree, in Psychobiology, from UCLA; Master's Degree in Public Health from The Johns Hopkins School of Public Health; and Doctoral Degree in Medicine from the State University of NY, Brooklyn. She completed her Internship at the George Washington University Medical Center; Internal Medicine Residency at the Greater Baltimore Medical Center and Postdoctoral Fellowship in Occupational & Environmental Medicine at the Johns Hopkins School of Public Health.

Stephen D. McConachie

Chief Operations Manager
US Department of Homeland Security's Customs and Border Protection



Stephen McConachie is a Chief Operations Manager at US Customs and Border Protection (CBP) Headquarters in Washington, DC. He manages programs involving Counternarcotics and Illicit Trafficking, Gangs and Transnational Organized Crime, Weapons of Mass Destruction (WMD), and Medical Countermeasures. He also serves as a liaison to the Office of National Drug Control Policy and the Threat Mitigation Working Group for Combating Transnational Organized Crime.

Mr. McConachie entered on duty as an Inspector with the former U.S. Customs Service in October of 1999, and earned the Distinguished Graduate Award in U.S. Customs Service Inspector class 0101. In October of 2002, he was promoted to Senior Inspector and served as the Cargo Office Manager for the Port of Pittsburgh. In June of 2005, he completed the Master Trainer Program at the CBP Academy in Glynnco, Georgia, and served as an Instructor/Course Developer for the Hazardous Materials Operations Training Program. He also served on three occasions as a Visiting Instructor with the CBP Firearms and Tactical Training Division at Ft. Benning, Georgia.

From October of 2006 to January of 2011, Mr. McConachie served as a Hazardous Materials Specialist and Special Mission Planner with the Federal Bureau of Investigation (FBI), Critical Incident Response Group at Quantico, Virginia. While with the FBI, Mr. McConachie coordinated the staff training and exercise program for the WMD Render Safe Mission, including the Marble Challenge Exercise Series.

Mr. McConachie has been a volunteer firefighter since he was 16, and has held leadership roles as an engine company Lieutenant and Captain. He joined the Allegheny County Hazardous Materials Team at 18 and rose to the rank of Commander of the Silver Team, leading over 60 HAZMAT Operators and Technicians. He also served on the Allegheny County Local Emergency Planning Committee, the Region 13 Counterterrorism Task Force, and as President of the Pennsylvania Association of Hazardous Materials Technicians.

Mr. McConachie has developed and taught numerous hazardous materials courses for the Allegheny County Fire Academy, and had articles published in Firehouse Magazine and the Journal of Emergency Medical Services. From 2007 to 2008, he served on the Intelligence/Investigations Working Group for the National Incident Management System (NIMS) Integration Center, where he represented the FBI in writing the NIMS Intelligence/Investigations Function Guidance and Field Operations Guide.

A native of Pittsburgh, Pennsylvania, Mr. McConachie is a graduate of West Liberty University and is a certified Master Exercise Practitioner. He is married, and has a son and a daughter.

Andrew Stolbach, MD, MPH

Associate Professor, Emergency Medicine and Medical Toxicology
Johns Hopkins University, Baltimore, MD



Andrew Stolbach, MD, MPH, FAACT, FACEP, FACMT, is board certified in emergency medicine and medical toxicology. He leads our toxicology training curricula and works clinically at The Johns Hopkins Hospital. He serves as a consultant to the Maryland Poison Center, is a member of the Johns Hopkins Hospital Pharmacy and Therapeutics Committee and is a Johns Hopkins Institutional Review Board co-chair.

He was a magna cum laude graduate of Pennsylvania State University with a bachelor's degree in life science and a minor in history. He furthered his education at the University of Maryland School of Medicine and earned his MD in 2002. Dr. Stolbach completed his emergency medicine residency at St. Luke's-Roosevelt Hospital Center in New York City from 2002 to 2005, where he was Chief Resident. He completed his fellowship in medical toxicology at Bellevue Medical Center and New York University School of Medicine.

Dr. Stolbach has received honors and awards, including the University Honors Medal for Scholarship in History (1998), Phi Beta Kappa Honor Society (1998), a 2010 American College of Medical Toxicology/McNeil Products Award for Acetaminophen-Related Research, and a grant from the Agency for Toxic Substances and Disease Registry for airborne particulate matter education.

He is a member of the board of directors of the American College of Medical Toxicology. He is recognized as a fellow of the American College of Emergency Medicine, American College of Medical Toxicology and American Academy of Clinical Toxicology.

Dr. Stolbach has developed a 15-part online toxicology training program that is used by 25 emergency medicine residency programs.

He is Co-Chair of the GETUP (Global Emergency Toxicology Uniting Program) toxicology course. The GETUP program links countries with and without toxicology services to provide education in the management of poison and overdose. The overall goals of the program are to educate clinicians who care for poisoned patients and to connect people throughout the world with an interest in poisoning education.

He also created toxicology webinars and online modules for the American College of Medical Toxicology and the Agency for Toxic Substances and Disease Registry.

Mike McCormick, PhD

Science Officer, Laboratories & Scientific Services
US Department of Homeland Security's Customs and Border Protection



Dr. Mike McCormick is a Science Officer for US Customs and Border Protection Laboratories and Scientific Services Directorate (LSSD) in Washington D.C. Dr. McCormick graduated summa cum laude with his bachelor's degree in chemistry from Michigan Tech University. He received his PhD from the University of Virginia, where he synthesized new anti-cancer drugs and synthesized chemicals that make fireflies emit red light. After a brief post-doctorate at the University of Utah, Dr. McCormick spent four years teaching organic chemistry and general chemistry at Boise State University, while continuing to research anti-cancer drugs and perform research in the area of chemical education. Discouraged by the lack financial incentives in academia, Dr. McCormick joined the federal government as a narcotics chemist and digital forensics scientist at LSSD's Chicago field laboratory. After a few years on the bench, Dr. McCormick was able to move up the government ladder and relocated to LSSD headquarters in Washington, D.C. where his primary responsibilities are program management for LSSD's designer drug program, pharmaceutical safeguard program, and remote narcotics triage program which he designed and developed. While not on the job, Dr. McCormick enjoys fishing, cycling, and breaking clays with his wife.

Juan Colon, Captain

New Jersey State Police



Captain Juan Colon is a 24 1/2 year veteran of the New Jersey State Police and he is currently assigned to the New Jersey Attorney General's Office under the Office of Drug Addiction Control working on drug policy. As the architect of the Drug Monitoring Initiative, he maintains oversight of the initiative and is also involved in several state working groups to drive state level counter-drug efforts.

During most of his career, he has focused on the intelligence function and he has extensive experience with street gangs and organized crime. As an intelligence collector targeting these groups, he managed numerous informants and has conducted several undercover operations.

He has received several awards for his accomplishments and was nominated for the 2014 Trooper of the Year Award. He holds a Bachelors degree in Public Administration from Fairleigh Dickerson University.

Diane P. Calello, MD

Executive and Medical Director, New Jersey Poison Information and Education System
New Jersey Medical School of Rutgers University, Newark, NJ



Dr. Diane Calello is the Executive and Medical Director of the New Jersey Poison Information and Education System at the New Jersey Medical School of Rutgers University. She received her Bachelor of Arts from the College of William and Mary in Virginia and her medical degree from the New Jersey Medical School, which she now calls home. Her residency and fellowship training was conducted at the Children's Hospital of Philadelphia.

She is board certified in Pediatrics, Pediatric Emergency Medicine, Medical Toxicology, and Addiction Medicine. Dr. Calello is a national expert on toxico-surveillance for emerging threats through the Poison Control System, as well as multidisciplinary collaborations, such as the New Jersey Drug Monitoring Initiative to combat evolving overdose outbreaks.

Charles A. McKay, MD, FACMT, FACEP

Medical Director (Interim), Connecticut Poison Control Center



Dr. McKay is a medical toxicologist at Hartford Hospital and the University of Connecticut School of Medicine. His training has been in Pathology, Internal Medicine, Emergency Medicine, and Medical Toxicology. Dr. McKay is the Medical Director (Interim) of the Connecticut Poison Control Center. He provides toxicology consultation at two hospitals and was also the Medical Director of Occupational Health Services for Hartford Hospital and Connecticut Children's Medical Center. He was the Medical Toxicology Fellowship Director at Hartford Hospital/University of Connecticut School of Medicine for 20 years. He is the Principal Investigator for several laboratory-based clinical studies. Under contract to DHS, he led the American College of Medical Toxicology's (ACMT's) development of a practical toxicology principles course for law enforcement and participates in ACMT's contracts and cooperative agreements with the CDC and DHS regarding chemical and environmental exposures. He lectures widely on chemical terrorism and risk communication, including the ACMT Chemical Agents of Opportunity Course -- provided to more than 10,000 participants in the last 13 years. He provides medical-legal consultation and education in both civil and criminal matters. He is on the Executive Board of Directors of the American College of Medical Toxicology, currently serving as President.

Nicholas E. Hanke

Chief CBPO/Program Manager, National EMS Coordinator
US Customs and Border Protection, Office of Field Operations, Incident Management Division



Chief CBPO/Program Manager Nick Hanke has returned to OFO Headquarters, Incident Management Division (IMD) in 2016 after serving at the Advanced Training Center since 2014 as a Course Developer/Instructor for the Emergency Preparedness Branch. Part of his duties include continuing the coordination and implementation of the OFO Emergency Medical Services program which he spearheaded during his previous tenure with IMD. Additionally, he serves as the program manager for the OFO Naloxone Pilot Program and assists with contraband safe-handling policies, procedures, and techniques. He served as the Acting Director for IMD from January through May 2017. This included planning and operations in support of the Presidential Inauguration, for which he served as the CBP Incident Commander over the deployed personnel supporting the US Capitol Police.

Nick joined the legacy US Customs Service in 2000, after having served as a Police Officer with the US Department of Defense, in Boston, MA. Later he was transferred to Connecticut where from 2007, he served as the Port Director for the ports of Bridgeport, New Haven, and New London. This included oversight of all CBP operations in coastal Connecticut, including close coordination with the US Coast Guard, the US Navy, and other agencies. Highlights of his tenure there include deployment to Houston as part of CBP's response to Hurricane Ike and working with other Federal law enforcement agencies and the U.S. Attorney's office in relation to inspection operations and testimony in a major narcotics case.

In 2010, Nick accepted a position with the Office of Field Operations, Headquarters, Incident Management Division, assisting in the management of all OFO emergency preparedness and response programs and planning. This included the strategic coordination of component response to numerous natural disasters (e.g. Sandy, Irene, the Japan earthquake/tsunami), Commissioner Designated Events, and National Special Security Events (e.g. Presidential Inauguration, Republican/Democratic National Conventions, and NFL Super Bowls). Additionally, Nick spearheaded the concept, development, drafting, and negotiations for the National OFO Emergency Medical Services Program and assisted in the development of an OFO Geospatial Information Systems program.

Concurrent with his career with CBP, Nick has served as a volunteer firefighter and emergency medical technician since 1989, serving in various roles as a training officer, rescue officer, battalion and assistant chief.

Nick is a Nationally Registered Emergency Medical Technician, Heavy Rescue Technician, Public Safety Diver, Hazardous Materials Technician, Master Exercise Practitioner, and received a Bachelor's Degree in Sociology from Fairfield University in 1995.

Mark Kirk, MD

Director, Chemical Defense Program
US Department of Homeland Security's Office of Health Affairs



Mark Kirk, MD directs the OHA Chemical Defense Program. He is an emergency physician and medical toxicologist with extensive field experience in prehospital medicine, emergency medicine, critical care toxicology and large-scale hazardous materials and chemical terrorism incident response.

He has over 25 years of "in the field" experience in a spectrum of provider and emergency management roles. Beyond being a nationally recognized clinical expert in emergency medicine and medical toxicology, he practiced as an emergency medical technician (first responder for 4 years) and served as the assistant medical director for a large EMS system, the medical advisor to an urban fire department hazardous materials team, as a team member in a Disaster Medical

Assistance Team that responded to Hurricane Andrew, as a community emergency response coordinator through the Local Emergency Planning Committee (LEPC) and Regional Poison Center and as a subject matter expert for local, state and federal responses to real events or large scale exercises. Such “real world” experiences at nearly every level of emergency response to disasters and specifically chemical incidents is necessary to appropriately engage the emergency response and public health communities who are the front line in responding to these events.

He is a nationally recognized educator and thought leader in his medical specialties and most specifically in the emergency response to large-scale chemical incidents. He is widely published in this area with many peer reviewed articles and textbook chapters. Frequently, national and international conferences invite him to share his insights and expertise about responding to chemical incidents. In addition, he still actively teaches prehospital care providers, nurses and physicians, mostly using of high-fidelity simulation, the essential procedures and critical decision-making skills for responding to chemical incidents. With over 20 years as an educator, he embraced simulation education as a teaching tool in 2003. He helped lead the development of the UVA Medical Simulation Center in the UVA School of Medicine and served as the Co-Medical Director of the Center until March 2013. He is Associate Professor in the School of Medicine’s Department of Emergency Medicine

Michael Schwartz

Deputy Director, Chemical Defense Program
US Department of Homeland Security’s Office of Health Affairs



CAPT Michael Schwartz, USPHS, is an emergency physician and medical toxicologist and is the Deputy Director of the Chemical Defense Program at the US Department of Homeland Security’s Office of Health Affairs. Prior to his transfer to DHS, Dr. Schwartz served for 13 years as a medical officer at the Centers of Disease Control and Prevention. At CDC, he was primarily responsible for CBRNe preparedness and planning, outbreak investigations involving chemical exposures, medical countermeasures research, and surveillance of chemical threats.

Dr. Schwartz is a graduate of Cornell University and Oxford; he completed his medical training in Cincinnati, Ohio, and his medical toxicology fellowship at Emory University in Atlanta.

Marvin Meinders

Veterinary Medical Officer, Epidemiology
Chief, Food, Agriculture and Veterinary Defense (FAVD) Branch
US Department of Homeland Security’s Office of Health Affairs



Dr. Marvin Meinders joined the Office of Health Affairs (OHA) Health Threats Resilience Division as the Veterinary Medical Officer in Epidemiology and is Chief of the Food, Agriculture and Veterinary Defense (FAVD) Branch. He brings 40 years of experience in veterinary and public health to OHA. Dr. Meinders began his career as a veterinarian in a rural practice focuses on large animal and has expanded his expertise to include environmental health, medical readiness and medical epidemiology. Dr. Meinders has led many medical readiness programs, including Medical Plans and Logistics at HQ USAF in Germany and the Medical Readiness Division for the Joint Staff, Pentagon. Dr. Meinders served as an officer in the Air Force and retired as a Colonel in 1999.

Appendix B

FENTANYL†

SAFETY RECOMMENDATIONS FOR FIRST RESPONDERS

† For the purposes of this document, fentanyl, related substances, and synthetic opioids (herein after referred to as fentanyl†) includes fentanyl analogues (e.g., acetylfentanyl, acrylfentanyl, carfentanil, furanylfentanyl), novel synthetic opioids (e.g., U-47700), and other drugs that may be laced with these substances.

- ▶ **The abuse of drugs containing fentanyl† is killing Americans. Misinformation and inconsistent recommendations regarding fentanyl† have resulted in confusion in the first responder community.**
- ▶ You as a first responder (law enforcement, fire, rescue, and emergency medical services (EMS) personnel) are increasingly likely to encounter fentanyl† in your daily activities (e.g., responding to overdose calls, conducting traffic stops, arrests, and searches).
- ▶ This document provides scientific, evidence-based recommendations to protect yourself from exposure.

WHAT YOU NEED TO KNOW

- ▶ Fentanyl† can be present in a variety of forms (e.g., powder, tablets, capsules, solutions, and rocks).
- ▶ Inhalation of airborne powder is MOST LIKELY to lead to harmful effects, but is less likely to occur than skin contact.
- ▶ Incidental skin contact may occur during daily activities but is not expected to lead to harmful effects if the contaminated skin is promptly washed off with water.
- ▶ Personal Protective Equipment (PPE) is effective in protecting you from exposure.
- ▶ Slow breathing or no breathing, drowsiness or unresponsiveness, and constricted or pinpoint pupils are the specific signs consistent with fentanyl† intoxication.
- ▶ Naloxone is an effective medication that rapidly reverses the effects of fentanyl†.

Actions to take...

To protect yourself from exposure

- ▶ Wear **gloves** when the presence of fentanyl† is suspected.
- ▶ **AVOID actions that may cause powder to become airborne.**
- ▶ Use a properly-fitted, NIOSH-approved **respirator ("mask")**, wear **eye protection**, and minimize skin contact when responding to a situation where small amounts of suspected fentanyl† are visible and may become airborne.
- ▶ Follow your department guidelines if the scene involves large amounts of suspected fentanyl† (e.g., distribution/storage facility, pill milling operation, clandestine lab, gross contamination, spill or release).

When exposure occurs

- ▶ Prevent further contamination and notify other first responders and dispatch.
- ▶ Do not touch your eyes, mouth, nose or any skin after touching any potentially contaminated surface.
- ▶ Wash skin thoroughly with cool water, and soap if available. **Do NOT use hand sanitizers as they may enhance absorption.**
- ▶ Wash your hands thoroughly after the incident and before eating, drinking, smoking, or using the restroom.
- ▶ If you suspect your clothing, shoes, and PPE may be contaminated, follow your department guidelines for decontamination.

If you or other first responders exhibit

- **Slow Breathing or No Breathing**
- **Drowsiness or Unresponsiveness**
- **Constricted or Pinpoint Pupils**
- ▶ Move away from the source of exposure and call EMS.
- ▶ Administer naloxone according to your department protocols. Multiple doses may be required.
- ▶ If naloxone is not available, rescue breathing can be a lifesaving measure until EMS arrives. Use standard basic life support safety precautions (e.g., pocket mask, gloves) to address the exposure risk.
- ▶ If needed, initiate CPR until EMS arrives.



Collaborative Support From:

- American College of Emergency Physicians
- American College of Medical Toxicologists
- American Industrial Hygiene Association
- Association of State and Territorial Health Officials
- Association of State Criminal Investigative Agencies
- Fraternal Order of Police

- International Association of Chiefs of Police
- International Association of Fire Chiefs
- International Association of Fire Fighters
- Major Cities Chiefs Association
- Major County Sheriffs of America
- National Alliance of State Drug Enforcement Agencies

- National Association of Counties
- National Association of County and City Health Officials
- National Association of Emergency Medical Technicians
- National Association of EMS Physicians
- National Association of State EMS Officials

- National Governor's Association
- National HIDTA Directors Association
- National Narcotic Officers' Associations' Coalition
- National Sheriffs' Association
- National Volunteer Fire Council
- Police Executive Research Forum
- Police Foundation

<https://www.whitehouse.gov/ondcp/key-issues/fentanyl>

Appendix C

Suspected Opioid Overdose

Algorithm for Non-Healthcare Providers

