

## POSITION STATEMENT

# Stopping the Opioid Epidemic: Integral Role of Clinical Laboratorians

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## Introduction

The creation and availability of synthetic opioids have intensified an already extraordinary public health crisis. In 2017, 28,869 people died from synthetic opioid related overdoses, a 46 percent increase from the year before (1). Laboratories are often the first to identify synthetic drugs circulating on the streets and can provide insight into their variety and the frequency of their use in local communities (2). Leveraging the expertise of clinical laboratory professionals to identify the use of synthetic opioids can help clinicians and first responders make informed treatment decisions and help public health and safety officials identify the cause of overdose outbreaks and coordinate a response.

## Background

Local markets for synthetic opioids are diverse and continually changing. Highly potent opioids such as fentanyl and new-generation varieties like U-47700 are easily trafficked. Slight modifications to their chemical structure can produce a variety of derivatives, also known as analogs, which produce similar effects with substantial differences in potency and toxicity (2). Completely novel analogs can circumvent legal restrictions, and new iterations are often produced faster than they can be regulated by the Drug Enforcement Administration (DEA). Cheaper and more powerful than their traditional counterparts, synthetic opioids have exploded in prevalence and are commonly mixed with heroin or

### AACC POSITION:

AACC supports efforts to address the opioid crisis through greater collaboration between laboratories, healthcare personnel, and public health and safety agencies. Laboratory expertise can help clinicians monitor pain management and addiction treatment patients to prevent illicit opioid usage. Laboratories generate data that can support the timely assessment of drug trends and facilitate a faster response to overdose outbreaks.

cocaine or pressed into counterfeit pills and sold as prescription pain medication (3).

The rise of synthetic opioids is increasing the rate of overdose deaths because users are often unaware of the true composition of the drugs they have taken. Clinicians and first-responders frequently encounter patients who require multiple doses of the opioid antidote naloxone to reverse an overdose caused by exposure to highly potent synthetic opioids. The effects of these opioids can be long-lasting, and patients who initially respond well to naloxone may need additional doses after the initial reversal to prevent overdose symptoms from returning. High doses of potent synthetic opioids have been known to overwhelm the effects of

opioid antidotes to the point that patients require a ventilator to breathe (4). Detecting when these drugs first begin to circulate in a community is critical to prevent a potential overdose outbreak and save lives. Laboratory professionals such as toxicologists and those who specialize in drug monitoring are experienced with identifying chemicals, drugs, and other substances. Their expertise can support the identification of synthetic opioids and enable a timely public health response.

## Considerations

### Test Utilization

Sophisticated test procedures are required to detect synthetic opioids. Commonly used tests, known as immunoassays, can identify a limited range of synthetic opioid analogs that may vary depending on the manufacturer (5). These tests can be performed quickly but are often of limited utility when evaluating an overdose due to a lack of sensitivity and specificity. A positive result would not necessarily specify the drug to which a patient was exposed, and a negative result may not indicate a lack of exposure since a compound could be present but undetected. Close collaboration is required between laboratories and the physicians ordering tests, especially when the results have implications for critical treatment decisions (6). Clinical laboratorians who are familiar with the limitations of certain screening methods, such as board-certified toxicologists or clinical chemists with a focus in toxicology and therapeutic drug monitoring, should be included on clinical care teams to help clinicians order and interpret tests, and to help educate patients about the danger of local synthetic opioid varieties.

### New Test Methods

Laboratories that use sensitive analytical technologies are always working on new protocols to detect and confirm synthetic opioids and designer drugs. The rapid pace at which the synthetic opioid landscape evolves makes new testing panels obsolete by the time they receive FDA approval. In order to stay ahead, clinical laboratories develop specialized mass spectrometry assays. These laboratory developed tests can accurately identify novel synthetic drugs at extremely low concentrations. The timeliness and accuracy of testing for synthetic opioids could improve further if forensic, public health, and clinical laboratories collaborate to build shared libraries

of chemical structural and mass spectral data. Laboratories that lack access to mass spectrometry methods could benefit from an expedited regulatory approval pathway for commercial availability of test panels for synthetic opioids.

### Opioid Surveillance

Overdose outbreaks involving novel synthetic opioids are unpredictable and often deadly. Improving the timeliness and scope of opioid surveillance is crucial since local patterns of usage can change significantly in a short period of time. Expanding laboratory capacity to conduct comprehensive testing for synthetic opioids in both fatal and non-fatal cases could help public health and safety officials rapidly identify changes in the local supply of synthetic opioids and coordinate targeted prevention measures. Laboratories that detect new compounds could report them to a public health surveillance system focused on tracking opioid usage, similar to the reconstituted Drug Abuse Warning Network (DAWN). The information could then be disseminated to the relevant stakeholders. If a particularly deadly opioid such as carfentanil is reported, clinicians, public health officials, and law enforcement could be notified to take precautions or mobilize a response.

### Public Health and Safety Partnerships

Greater collaboration between laboratories, public health and law enforcement agencies could facilitate a more effective response to the synthetic opioid crisis. The Drug Enforcement Administration monitors geographic trends in the illicit opioid supply and collects drug chemistry data from a network of laboratories through its National Forensic Laboratory Information System. This information could be made available to assist laboratories with chemical characterization of novel synthetic opioids and to augment public health surveillance data.

### Regional Stakeholder Communication

Regional and community stakeholder partnerships that promote information sharing could benefit areas where clinical and laboratory resources are unevenly distributed. This sharing could be facilitated through a live database developed by stakeholders to distribute information about which laboratories have comprehensive testing capabilities, what compounds have been encountered and where, and how to contact those involved in the collection, analysis, treatment, and dissemination processes in the region.

State Health Laboratory and Poison Control Center information could also be made readily available for quick reference and communication when necessary.

## Positions

AACC supports efforts to address the opioid crisis through greater collaboration between laboratories, healthcare personnel, public health and safety agencies, and other stakeholders. In particular, the Association recommends the following actions.

### Laboratories and the Healthcare Community

- ▶ Laboratory experts should be included on clinical care teams to assist with test ordering and interpretation.
- ▶ Laboratory directors should provide detailed interpretive comments and consultative services for sophisticated tests as warranted.
- ▶ Clinicians should consult with experts in their laboratories to ensure patients in pain treatment and opioid dependency programs are effectively monitored for illicit synthetic opioid usage.
- ▶ Overdose patients should be educated about precautions to take with synthetic opioids and provided access to medication-assisted treatment.

### Congress & Federal Agencies

- ▶ Congress should provide funding to scale-up the number of hospitals, and clinical and public health laboratories that can identify novel synthetic drugs at the state and local level.
- ▶ Congress should provide funding to develop stakeholder partnership networks that facilitate rapid information sharing to target synthetic opioid response and prevention resources.
- ▶ Congress should provide funding to expand opioid surveillance programs for synthetic drugs, such as DAWN, to leverage timely de-identified data from a greater number of clinical and public health laboratories.
- ▶ The Drug Enforcement Administration should provide access to analysis of seized materials to clinical and public health laboratories to assist with the timely identification of novel synthetic opioids.
- ▶ The Food and Drug Administration should expedite the regulatory approval of testing panels developed for the rapid detection of synthetic opioids.

## References

1. Rich, S., Itkowitz, C., Crites, A., Hanssen, S., Higham, S., Horwitz, S., & Zezima, K. (2019, March 13). [The Fentanyl Failure](#). *The Washington Post*. Retrieved April 10, 2019
2. Morrow, J. B., Roper-Miller, J. D., Catlin, M. L., Winokur, A. D., Cadwallader, A. B., Staymates, J. L., ... Goldberger, B. A. (2018). The Opioid Epidemic: Moving Toward an Integrated, Holistic Analytical Response. *Journal of Analytical Toxicology*, 43(1), 1-9. doi:10.1093/jat/bky04
3. Bonnie, R. J., Ford, M. A., & Phillips, J. (2017). [Pain management and the opioid epidemic: Balancing societal and individual benefits and risks of prescription opioid use](#). Washington,,: National Academies Press.
4. Rzasalynn, R., & Galinkin, J. (2018). Naloxone dosage for opioid reversal: current evidence and clinical implications. *Therapeutic Advances in Drug Safety*, 63–88. doi.org/10.1177/2042098617744161
5. Warrington, J. S., Walsh, A., Baker, E., Lozier, D., & Belec, A. (2018). Keeping Up with Fentanyl: Failure to Do So Is Not an Option. *The Journal of Applied Laboratory Medicine*, 3(1), 148-151. doi:10.1373/jalm.2017.025510
6. Fishman, S. M., Wilsey, B., Yang, J., Reisfield, G. M., Bandman, T. B., & Borsook, D. (2000). Adherence Monitoring and Drug Surveillance in Chronic Opioid Therapy. *Journal of Pain and Symptom Management*, 20(4), 293-307. doi:10.1016/s0885-3924(00)00195-0