



Quantitative Analysis of Fentanyl/Seized Drugs

Henderson Forensic Laboratory response to proposed Senate Bill 35

Impact Presentation

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Topics to Cover

- Background
- Safety Concerns
- Costs
- Increased turn-around times and increased backlogs
- Testing limitations
- Unknowns



Qualitative Analysis vs. Quantitative Analysis

- Qualitative Analysis: Can tell you the identity of a controlled substance at any quantity in a material. (Qualitative analysis can tell you that a pill contains oxycodone.)
- Quantitative Analysis: The percentage of that material that is the controlled substance. (Quantitative analysis can tell you that only 20% of that pill is actually oxycodone.)



Background

- To date, quantitative analysis for the detection of controlled substances have focused on analyses in blood, urine or other biological matrices. These techniques are used to detect substances after the drug has already been consumed.
- Our research failed to locate any U.S. labs performing quantitative analysis for criminal/legal use. Some analytical or clinical labs quantitate for research purposes.
- One open project announcement was found for a Kosovo Agency who are conducting a worldwide search to for experts on 'Quantitative Analysis of Narcotics.'
 - Their lab consists of several PhD Chemists/Scientists working in their chemical analysis of narcotics section
 - Problem description states the fact that the laboratory lacks fundamental training in the quantitative analysis of drugs (reference Fulbright Open Project Announcement #8696)
 - Their goal is to establish technical and scientific protocols that describe the steps and processes involved in the quantitative analysis of narcotic substances
 - Looking for experts to design and implement a validation plan for the methods in a manner that enables them to perform



Current Method

- We conduct Qualitative Analysis on all seized drugs. For example, if we have evidence suspected to contain fentanyl, the chemist takes a small sample to pulverize for testing utilizing proper PPE and a small containment hood.
- Working with very small quantities allows for the safe handling and minimizing exposure and contamination.



Facts about Fentanyl

- Counterfeit pills are not produced using exact science
 - Analysis has found some pills can range from .02 mg to 5.1 mg of fentanyl per counterfeit pill (https://www.dea.gov/resources/facts-about-fentanyl)
 - As little as 2 mg of fentanyl can be fatal
 - A single grain of table salt is approximately 0.3 mg
 - Approximately 6-7 grains of salt worth of fentanyl can be fatal
 - According to the DEA's website and facts about fentanyl, one kilogram
 of fentanyl has the potential to kill 500,000 people
 (https://www.dea.gov/resources/facts-about-fentanyl)



Facts about Fentanyl

- HPD Forensic Laboratory has received a brick of fentanyl for examination with a net weight of approx. 2.2 pounds, or 1 kilogram
- For quantitative analysis, this entire brick would need to be pulverized into a fine airborne powder creating safety hazards for:
 - Testing, Clean-up, Repackaging, Storage, Disposal, Transportation,
 Presentation in Court



According to Lexipol:

- Leading science organizations advise that incidental skin contact with dry fentanyl products is not likely to cause toxicity.
- The most concerning route of fentanyl exposure is inhalation of airborne powder or aerosolized fentanyl

https://www.lexipol.com/resources/blog/first-responder-fentanyl-exposure-what-you-need-to-know/



Proposed Safety Requirements for Pulverizing Fentanyl Products in the Laboratory:

- Personal Protective Equipment (PPE)
- Building Safety
- Storage Safety
- Disposal Safety
- Transportation Safety



National Institute for Occupational Safety and Health (NIOSH)

The National Institute for Occupational Safety and Health
 (NIOSH) recommends that environments with suspected large quantities
 of fentanyl powder require a Self-Contained Breathing Apparatus (SCBA)
 with a Level A protective suit.

https://www.lexipol.com/resources/blog/first-responder-fentanyl-exposure-what-you-need-to-know/



Level A Protection

- The United States Environmental Protection Agency (EPA) recommends the following for Level A protection:
 - self-contained breathing apparatus (SCBA)
 - totally encapsulated chemical- and vapor-protective suit
 - inner and outer chemical-resistant gloves, and
 - disposable protective suit, gloves, and boots.

https://www.epa.gov/emergency-response/personal-protective-equipment



Fentanyl in fine, particulate form would require more than just a hood to guarantee laboratory safety. The aerosolized form would require the **3C** safety approach for the testing environment:

- 1. Containment: contain high risk work areas within walled labs. Separate these environments from other areas to reduce airflow/venting contamination.
- **2. Control:** control airflows to move powdered fentanyl to areas that are safe. Powders need to be controlled with properly designed HVAC systems and air movement to move loose powder to a safe location.
- **3. Capture:** capture powdered substances with HEPA pre-filtered returns that can be disposed of properly and not become airborne. These filters would be close to the flow and pull in powders to their locations to keep them away from staff.



Building Safety

- Construction of a separate fentanyl lab designed to meet SB35 requirements:
 - Safety to reduce dermal, ingestion, inhalation, and ocular exposure of fentanyl powder to *all* staff
 - Completely independent from the forensic laboratory to minimize exposure risk
 - All MEP/FP would be independent. No cross-over utilities or waste to eliminate cross contamination to remainder of staff
 - Negative pressure lab with adjoined neutral pressure vestibule



Building Safety

- Construction of a separate fentanyl lab designed to meet SB35 requirements (continued):
 - Walls to be full height and airtight
 - Vestibule will act as a cleanroom air wash to remove any fentanyl from PPE
 - 12 fresh air exchanges per hour
 - Air to be supplied for minimal air disturbances to prevent blowback from hoods.
 - Mechanical returns to be low to the floor with a filter
 - Sealed concrete floors, epoxy paint and ceiling, no hard corners/texture



Building Safety

- Construction of a separate fentanyl lab designed to meet SB35 requirements (continued):
 - Equipment: 4 powder hoods, 4 fume hoods, and 4 bio safety cabinets
 - Separate Instrumentation Lab
 - Provide HEPA pre-filter on exhaust fans which can be disposed
 - All lab returns to be low with pre-filter which can be disposed
 - Lab system separate from office system
 - Provide lab exhaust with vibration isolation on roof with screening

 Approximate cost for Fentanyl Quantitation Laboratory Addition: \$26M



Impact - Safety

- With the potential of ventilation from the lab of airborne fentanyl, questions arise for neighborhood safety
 - Would the EPA need to perform an EIS or Hazardous Dust Assessment to determine the safety of a facility of this nature?
- Vendor, custodial, and repair personnel safety that need to enter the laboratory space
- OSHA study for more guidance on protection of employee health and safety
- Worker's compensation analysis/study due to increased risk of injury or death of a laboratory employee due to fentanyl exposure



Storage and Disposal Safety

- Safety issues for storage of packages containing pulverized fentanyl powder
- Waste storage there would need to be a specific room for waste storage and disposal for items possibly contaminated from pulverized fentanyl exposure (gloves). The room would require safety features with a separate HVAC design
- Fentanyl clean-up for non-disposable glassware and other laboratory instruments, nonconsumables, and cleaning outside of the vented hood area
- Safety issues for transportation or handling of packages containing pulverized fentanyl powder currently must transport in confined vehicle for disposal or court
- Fentanyl disposal our current contract for disposal will not allow the incineration of plastic; larger quantities would pose safety issues for disposal - would possibly need to provide our own incinerator on site for disposal



Additional Instrumentation Needed

- Purchase of two LC/MS Q-trap or Q-TOF instruments for testing
 - \$500,000 to \$800,000/instrument
- Validation of methods (unknown cost/time)
- Yearly Preventative Maintenance Costs
 - \$46,000/instrument



Additional Personnel Needed

- A minimum of three (3) additional FTE would be needed for new facility
 - Safety requires at least two (2) employees in the building at all times
 - For PTO, would need three for minimum coverage
- Approximately 40% of all cases currently submitted contain fentanyl
- Recurring costs of \$420,000 ± year
 - Plus, additional training, proficiency testing, PPE, and consumables of approximately \$30,000/year per FTE
 - Possible hazard pay



Case Impact – Turn-around and backlogs

- The Henderson Forensic Laboratory currently has 1 ½ FTE in the Seized Drug Section
 - 2023 average backlog: 44 cases
 - 2023 average turnaround time: 45 days
- Toxicology (only current section performing quantitative analysis (one sample per case, one matrix, 37 drugs):
 - 2023 average backlog: 60 cases
 - 2023 average turnaround time per sample: 231 days
- Proposed quantitative analysis of seized drugs = (unlimited samples per case, unlimited matrices, upwards to 200/300 different drugs)
 - Increased backlogs and increased turnaround times greater than Toxicology



Case Impact – Examples

Qualitative Analysis of a single case	Quantitative Analysis of a single case
Exhibit of evidence is weighed, and a very small amount is tested	The entirety of each exhibit is pulverized to homogenize it (more time consuming), weighed, and tested
	Exhibits containing multiple populations (example: multiple bags each containing pills) would each need to be pulverized to homogenize it, and each tested separately and weighed
If there is one test per exhibit the case can be completed in a day or two	If there is one test per exhibit the case can be completed in (estimate 2 weeks)
If there is more than one drug in the exhibit, minimal extra time is needed for testing, typically just a few hours additional per drug	If there is more than one drug in the exhibit, the time for testing is multiplied and can take a few months or more
If there are multiple populations, the time to complete a case is multiplied, and can take up to a month or more	If there are multiple populations, the time for testing could span a year or more
	If there is more than one population with more than one drug, the time for testing would be well over a year



Testing Limitations – Matrix Matching

- To conduct quantitative analysis, a standard of the drug in the same matrix needs to be utilized as a control to test against
- In seized drugs, there are many matrix variations
 - A tablet from a pharmaceutical production lab is formed when an active drug is embedded in an inert material. This is not the same for clandestine production labs that have no QC checks in place.
 - Drugs can be mixed in many matrix materials: wax, liquid, pills, powders, edibles, blotter paper, biologicals/plants, etc.
 - Must be able to matrix match to test/separate the drug from the inert material
 - Currently only relatively pure powders on the market through limited vendors
 - Each matrix variation would need to be validated



Projected Financial Impact

- \$26 M for lab building addition
- \$1.1 M for instrumentation
 - \$100,000 annual preventative maintenance costs after 3 years
- \$500,000 for personnel and training (annual)
- Method development and matrix matching unknown cost
- Increased PPE unknown cost
- Safety studies unknown cost



Many Unknowns...

- Quantitative Analysis of seized drugs, including fentanyl, is not performed in other laboratories (not an industry standard)
 - Therefore, there are no standards, no protocol, no guidelines, no training, no one to assist or answer questions
 - From the Kosovo Open Project, it appears there is a worldwide search for such expertise
 - Unknown safety risks to scientists, other laboratory personnel, evidence custodians, building maintenance, and possibly the surrounding neighborhood



Questions?