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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



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 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.



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.)



<https://www.dea.gov/press-releases/2019/11/07/dea-issues-warning-over-counterfeit-prescription-pills-mexico>

Potential Accidental Absorption Exposures in the Laboratory:

- Inhalation
- Mucosal contact
- Dermal

LETHAL DOSE

**Fake pills often contain fentanyl
and are more lethal than ever before.**



<https://www.dea.gov/press-releases/2019/11/07/dea-issues-warning-over-counterfeit-prescription-pills-mexico>

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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>)



HPD Forensic Laboratory has received bricks of fentanyl for examination with a net weight of approx. 2.2 pounds.

For quantitative analysis, **this entire brick would need to be pulverized into a fine airborne powder and homogenized (mixed evenly)** creating safety hazards for:

- Testing
- Clean-up
- Emergency response (if needed)
- 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.
 - Handling pills or bricks with proper PPE is not concerning in that state
- **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 powder 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.



Current Henderson Laboratory

- In a 4700 sq. ft. retrofitted building – new building scheduled for completion in 2024
- Approximately 40% of all drug cases currently submitted contain fentanyl
- 3 FTE (plus 1) in training in Chemistry Section
 - 1 ½ in Seized Drugs
 - ½ dedicated as LIMS Administrator
 - 1 in Toxicology (blood alcohol and blood drug) with 1 in training
- 3 FTE in Impression Evidence Section (latent prints and footwear/tire track)
- 1 FTE in 10-prints
- 1 FTE Evidence Processing Technician
- 4 FTE Administrative Staff

13 Employees total



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
 - To reduce cross-contamination in other sections of the laboratory
 - Highly sensitive instruments
 - Possible false positives due to contamination



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, non-consumables, 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
- Development and 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
 - Safety requires at least two (2) employees in the building at all times
 - For PTO, would need three for minimum coverage
- Recurring costs of \$420,000 ± year
 - Plus, additional training, proficiency testing , PPE, and consumables of approximately \$30,000/year per FTE



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



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



Case Impact – Examples

Qualitative Analysis of a single case	Quantitative Analysis of a single case
<p>Exhibit of evidence is weighed, and a very small amount is tested</p>	<p>The entirety of each exhibit is pulverized to homogenize it (more time consuming), weighed, and tested</p> <p>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, or each pill individually tested/weighed.</p>
<p>If there is one test per exhibit the case can be completed in a day or two</p> <p>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</p>	<p>If there is one test per exhibit the case can be completed in (estimate 2 weeks)</p> <p>If there is more than one drug in the exhibit, the time for testing is multiplied and can take a few months or more</p>
<p>If there are multiple populations, the time to complete a case is multiplied, and can take up to a month or more</p>	<p>If there are multiple populations, the time for testing could span a year or more</p> <p>If there is more than one population with more than one drug, the time for testing this one case would be well over a year</p>



Legal Patient

FDA states a tolerant user (can be prescribed 80 mg of oxycodone per day. The M/30 tablets are said to contain 30 mg of Oxycodone. So that would be 2.6 tablets per day.

	Highest prescribed dosage	# of tablets	1 month supply (# of tablets*30)	Weight of 1 month supply**
Legal Patient	80mg/day	2.6/day	78 tablets	7.8 grams

**one M/30 tablet typically weighs 0.1 grams (78 tablets/0.1 grams=7.8 total grams)



Comparison the legal patient to someone who can be charged with possession or trafficking at **current Qualitative NV weight thresholds.**

	Quantity	# of tablets	# of bottles**
Legal Patient	7.8 grams	78 tablets (1 month supply)	1 bottle
Current PCS (Possession of Controlled Substance) Class C Felony	14 grams	140 tablets	1.8 bottles
Current Lowest Trafficking in Fentanyl	28 grams	280 tablets	3.5 bottles

**Assuming 78 tablets per bottle (equivalent to a month's supply for a tolerant user)



Quantitation numbers for Possession of a Controlled Substance (under Class C Felony) and Trafficking using Current Thresholds and under Colorado Revised Thresholds:

	Lowest weight threshold	DEA range**	# tablets	# of bottles needed for charge
PCS (Class C Felony)	14 grams	0.02 mg	700,000	8,974 bottles
PCS (Class C Felony)	14 grams	5.1 mg	2,745	35 bottles
Trafficking	28 grams	0.02 mg	1,400,000	17,948 bottles
Trafficking	28 grams	5.1 mg	5,490	70 bottles
Colorado	1 gram	0.02 mg	50,000	641 bottles
Colorado	1 gram	5.1 mg	196	2.5 bottles
Colorado	4 grams	0.02 mg	200,000	2,564 bottles
Colorado	4 grams	5.1 mg	7,843	10 bottles

**DEA website states the range of tablets that have been quantitated range from 0.02 mg to 5.1 mg



Conclusion

- Quantitative Analysis of seized drugs, including fentanyl, is not an industry standard
 - Therefore, there are no standards, no protocol, no guidelines, no training, no one to assist or answer questions
 - NRS allows for mixtures so that quantitation is not needed
- Sentences for possession/trafficking are not mandatory and are at the discretion of the court
 - If exigent circumstances exist, such as victim not knowing that their product contained fentanyl, that can be worked out in the courtroom
- Unknown safety risks to scientists, other laboratory personnel, evidence custodians, building maintenance, and possibly the surrounding neighborhood



Conclusion (continued)

- Colorado Bureau of Investigation (CBI) is to perform all testing for local labs throughout the State of Colorado for fentanyl quantitative analysis (QA).
 - Trafficking thresholds changed and they are only concerned with cases containing 1 to 4 grams at 60% purity or higher
 - A Nevada State Laboratory is being proposed for 2027 and they have indicated that they will be able to perform quantitative analysis
 - If all three labs are tasked with changing testing protocol, we will have three different methods and 3x the cost to retrofit or equip each of the labs properly
 - Recommend following Colorado and have all QA performed at one central, state lab facility = pooling of resources in one location and development of one method of testing



Questions?

The Henderson Forensic Laboratory would also like to extend an invitation for tours of our laboratory to learn more about our operations.

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