To: Jennifer Saxe
Director General Health Canada,
Controlled Substances and Cannabis Branch
Jennifer.saxe@Canada.ca

cc: Dr. Stephen Lucas
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Stephen.lucas@hc-sc.gc.ca

The Honourable Jean-Yves Duclos
Minister of Health
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The Honourable Carolyn Bennett
Minister of Mental Health and Addictions
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May 3, 2021

Dear Jennifer Saxe and the Office of Controlled Substances,

We write in reply to your letter dated April 21, 2022 in which you advise of your intention to deny our August 31, 2021 request for a s. 56(1) exemption from the *Controlled Drugs and Substances Act* (CDSA) to operate a Safe Supply Fulfillment Centre and Cocaine, Heroin and Methamphetamine Compassion Clubs in Vancouver, British Columbia.

The essence of our request is that you decriminalize all members affiliated with DULF's compassion club model which is saving lives right now by providing a predictable supply of drugs to people at risk of death due to the toxic supply. Our request has the support of Vancouver Coastal Health, First Nations Health Authority, the City of Vancouver, Portland Hotel Society, the BC Centre on Substance Use and many organizations with expertise in drug policy and substance use.

On March 11, 2022 we reiterated our plea that you take the only action that will save lives right now without requiring us to risk arrest: provide a safe regulated supply of drugs or, failing that, provide us with the authorization and support to do it ourselves.

Our pleas, and our application, align with the findings of the BC's Coroner that: "[t]he primary cause of increased deaths is the growing toxicity and unpredictability of the street supply of drugs. The current drug policy framework of prohibition is the primary driver of this illegal, unregulated and toxic street supply."

As you know, we have proposed two models for the fulfillment centre and compassions clubs: Option 1 is our preferred option, in which pharmaceutical-grade drugs are purchased licitly from a supplier licensed under the CDSA; and Option 2 – the only option available to us in light of Canada's drug laws and policy – is to purchase illegally-produced drugs from unlicensed suppliers off the dark web and then test them to validate their contents. You have stated that

you intend to deny Option 2, and you have implied that we did not include enough detail on Option 1 for you to consider an exemption for that option.

Below, we respond to the positions articulated in your letter with respect to the two options. As a more general response, however, we view your letter as lacking an adequate appreciation that the toxic drug crisis is taking a current and devastating toll on public health and public safety, that the toxic drugs that are killing drug users in such huge numbers are themselves produced and sold illegally, and that currently there are no legal sources for the drugs in sufficient quantity.

This public health crisis demands levels of urgency, commitment and openness to new approaches that are not reflected in your letter. The toxic drug crisis is right now killing thousands of Canadians every year. Indeed, since we submitted our request on August 31, 2021 – eight months ago – there have been **1333 recorded overdose deaths** in British Columbia.[1] This number includes many of our friends and family, including one of VANDU's Board members. We – including you and your minister – cannot simply stand by until all the required conditions are just right to implement a perfect response.

To be clear, obtaining drugs from the dark web is not something we want to do. We do it for two reasons: (1) Canadian drug law and policy prohibits us from obtaining these substances legally; and (2) without a safe, reliable and tested supply of these substances our friends, family and community-members will continue to die.

It cannot be that Health Canada meets its duty to protect and promote public health in the context of this deadly health crisis by taking the purely passive stance of simply approving or denying exemption applications as they come before it, or worse, erecting barriers to programs that work. The urgency of this crisis demands that you collaborate, innovate and work together with us to find solutions. We need you to work with us and with potential drug suppliers to help foster a legal source of non-toxic drugs in sufficient quantities. And until such sources are in place, we need the legal ability to procure drugs from the only source that is practically available to us: the dark web.

We urge you to engage with us with greater frequency and depth than you have done to date. Health Canada characterizes the Section 56(1) exemption process as 'iterative', but since we made our exemption request on August 31, 2021 we have had almost no communication from Health Canada, despite us having reached out to you several times. We received one email on December 14, 2021 asking for clarification on trivial areas of the proposal. After this correspondence we heard nothing back from Health Canada until being told that our Substance Use and Addictions Programming (SUAP) application was being rejected due to the ongoing Section 56 requests associated with it.

[1] B.C. Coroners Service. (2022) Illicit Drug Toxicity Deaths in BC, January 1, 2012 – March 31, 2022. Available at: https://www2.gov.bc.ca/assets/gov/birth-adoption-death-marriage-and-divorce/deaths/coroners-service/statistical/illicit-drug.pdf

We urge you to reconsider your approach to our exemption application in light of those considerations, the rights under sections 7 and 15 of the *Charter of Rights and Freedoms* that are at stake, and the points set out below.

For the sake of clarity, we have divided and sectioned our response in accordance with the two-part response received by your department in relation to **(A) Option 2: The Dark Web Model** and **(B) Option 1: the Pharmaceutical Model**.

(A) <u>Option 2 - The Dark Web Model</u>

Your risk analysis of Option 2 is neither sound nor reasonable. Barring Health Canada's explicit and ongoing support–which we have repeatedly requested–it is not feasible for us to propose and set-up a model of pharmaceutical substance procurement for a model of distribution that is currently illegal and would need a section 56(1) exemption to the CDSA to operate. This paradoxical dilemma is clearly demonstrated by Health Canada's Substance Use and Addictions Programming grant, which rejected a proposal to fund the evaluation of ongoing compassion club operations because "we did not have a section 56(1) exemption". If not even the Canadian government will engage with us in a tangible way, it is an unreasonable and unethical expectation that private industry would be willing to engage with this model without Health Canada preliminary support.

Given the aforementioned lack of support, collaboration, and direction from Health Canada with respect to a licit supply, we have no other choice but to proceed with Option 2 at this time. To that end, we are *seeking a short-term exemption to prevent our actions from being illegal until we have a legal route of access to substances.* We need to save lives now.

Real harm vs. imagined/theoretical harm to Canadian citizens

At the heart of Health Canada's intended refusal of Option 2 of our application lies an assertion that an approval would cause an "unacceptable risk to the health and safety of Canadians." We ask that you clarify how our proposed model is more dangerous than the status quo.

We question the distinctions made between the proposed harms caused by this model of interim regulation versus initiatives that are already supported by Health Canada, such as decriminalization, drug checking, and supervised consumption services, all of which interact with the illicit drug market. All these harm reduction programs are designed to reduce harms associated with drug use and drug policy. Moreover, we have clearly outlined the intended audience for this exemption, which is the same as with all other harm reduction services. This will be a controlled pilot study with participants who already use drugs from the illicit market. With or without our program, drugs will be purchased from the illicit market by these participants, but in the DULF model they will have an accurate understanding of the drugs they consume so they are protected from the poisoned drug supply.

In our original section 56 exemption request we demonstrated, with references to the research evidence, how more harm is being done to people who use drugs and all Canadians by not allowing DULF to operate, and that existing responses to the overdose crisis are insufficient to address existing and emerging problems in the illicit drug supply. Again, we stress that it is the laws of prohibition are driving the illicit supply to ever-more potent substances like fentanyl. [2]British Columbia loses 6 people every day due to illicit opioid overdose death, with 74% of those dying between the ages of 30 to 59[3]. The concerns also extend beyond overdose to the emerging benzodiazepine contamination of the illicit opioid supply chain. The detection rate of benzodiazepines has increased rapidly from 15% of samples in July 2020 to 43% of samples in February 2022.[2] There is clear evidence indicating that overdose deaths continue to be driven by the contamination of the drug supply with illicitly-manufactured fentanyl, related analogues, and benzodiazepines. These contaminated drugs are acquired from street-based sources and are typically not tested for contaminants prior to being consumed. The BC Centre on Substance Use has generated evidence from drug-checking services that reveals large ongoing fluctuations in fentanyl concentrations in illicit drugs, with spikes in fentanyl concentration correlating strongly with spikes in overdose deaths.[4] Further, evidence from the BC Centre for Disease Control has shown the pharmaceutical drugs provided as "safe supply" (e.g., hydromorphone) are not being detected as a major contributor to overdose deaths.[5] Providing quality tested drugs plainly offers a much safer approach than simply allowing people to continue to access the contaminated street-based supply of illicit drugs.

In its recent Report to the Chief Coroner of British Columbia, dated March 9, 2022, the BC Coroners Service Death Review Panel conducted a review of illicit drug toxicity deaths. The Panel's first recommendation is to "Ensure a safer drug supply to those at risk of dying from the toxic illicit drug supply". It goes on to explain:

> Even with the implementation of a safer drug supply the illicit market will not disappear completely. Without broader changes to public policy, as well as increases to currently limited substance services, people who use drugs will still face harms related to criminalization and stigma which limits their ability to access already scarce treatment and recovery services. As such, wider distribution of drug checking technologies can play a role in helping people know the content of the drugs they are purchasing or selling. Wider scale drug checking can also be used as a surveillance tool to detect new analogues and

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[2] Beletsky, L., & Davis, C. (2017). Today's fentanyl crisis: Prohibition's Iron Law, revisited. *International Journal Of Drug Policy*, *46*, 156-159. doi: 10.1016/j.drugpo.2017.05.050

[3] B.C. Coroners Service. (2022) illicit Drug Toxicity Deaths in BC, January 1, 2012 – March 31, 2022. Available at: https://www2.gov.bc.ca/assets/gov/birth-adoption-death-marriage-and-divorce/deaths/coroners-service/statistical/illicit-drug.pdf

[4] BC Centre on Substance Use. (2021). Monthly median fentanyl concentration of drug checking samples overlaying the counts of illicit drug toxicity deaths in Vancouver, BC. [unpublished data; see Appendix A].

[5] BC Centre for Disease Control. Knowledge Update: Post-mortem detection of hydromorphone among persons identified as having an illicit drug toxicity death since the introduction of Risk Mitigation Guidance prescribing: Toxicology supplement. Available at: http://www.bccdc.ca/resource-gallery/Documents/Statistics%20and%20Research/Statistics%20and%20Reports/Overdose/20211209_BCCDC%20Knowledge%20Update_RMG%20Evaluation%20Hydromorphone%20Tox%20Supplement.pdf

toxicity levels of drugs being sold. Investing in an evidence-based continuum of substance use and social services is urgently needed.[6]

As explained in the letter from Vancouver Coastal Health's Deputy Chief Medical Officer Mark Lysyshyn to Jennifer Saxe, which was attached to our original exemption request, the Fulfillment Centre and Compassion Clubs would essentially act as amplifiers of community-based drug checking services, which have previously been granted exemptions by Health Canada.

There is no net change to the illicit market

The response received from Health Canada suggests that the dark net model would result in a net benefit to organized crime and would undermine efforts to stifle global criminal networks. Notably, this assertation was made without reference to any evidence. Respectfully, the suggestion is illogical. The Dark Web Model essentially proposes to act as a harm reduction and drug checking intermediary between people who are already accessing drugs through the illicit market and the people who are already selling substances. The model would not add anything to the market. It is clear that, despite the extreme dangers posed by the illicit drug market, individuals addicted to opioids and stimulants will continue to purchase and consume drugs. This is the consistent with what is known about substance use and addiction,[7] as many people, often in effort to avoid withdrawal, will continue use drugs despite the many risks and threats to personal safety (e.g., overdose, violence, arrest and incarceration) associated with purchasing drugs from illicit street-based drug markets. Further, it well known that for many people, addiction is a chronic relapsing condition, and sustained abstinence is not achievable or desired, especially when people have experienced repeated trauma as a result of drug prohibition. For example, research from British Columbia showed that among people who inject drugs, those who have experienced a recent incarceration event are less likely to stop injecting drugs than those who have not been incarcerated.[8]

The provision of substances through our model will not increase drug market activity, associated crime, or pose a threat to public safety. The research, the long history of the failed war on drugs, and the terrible persistence of the current toxic drug crisis demonstrates, beyond any doubt, that people will continue to purchase and consume contaminated drugs from illicit street-based sources despite the risks. To think or hope otherwise is to be blind to the obvious reality.

It is also clear that not providing access to tested drugs will result in more deaths that could have been prevented. Indeed, there is a large body of evidence demonstrating that interactions with the street-based drug market drastically increases risk to public safety and accounts for a

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6 B.C. Coroners Service. (2022). BC Coroners Service Death Review Panel: A Review of Illicit Drug Toxicity Deaths, March 9, 2022. Available at: https://www2.gov.bc.ca/assets/gov/birth-adoption-death-marriage-and-divorce/deaths/coroners-service/death-review-panel/review_of_illicit_drug_toxicity_deaths_2022.pdf

7 Taylor JL, Samet JH. Opioid Use Disorder.Ann Intern Med. 2022 Jan;175(1):ITC1-ITC16. doi: 10.7326/AITC202201180.

8 DeBeck K, Kerr T, Li K, Milloy MJ, Montaner J, Wood E. Incarceration and drug use patterns among a cohort of injection drug users. *Addiction.* 2009;104(1):69-76.

substantial amount of violence and associated morbidity and mortality.[9,10,11]That is especially the case as people who use drugs are often forced into highly dangerous and visible roles in the drug dealing hierarchy, thus creating further risks to health and the possibility of arrest and incarceration.[12] There is, therefore, a strong basis for expecting that the provision of tested substances through our model will serve to reduce street-based drug market activity and the violence and public disorder associated with it.

The War on Drugs is a Failure

Bad drug policy continues to harm Canadians. Indeed, it has caused the very problem you are asking us to bend ourselves into impossible contortions to solve. As BC's Coroner said in her most recent report, "prohibition is the primary driver of this … toxic street supply" that is killing us. We do not need more evidence that the war on drugs has failed. Currently, overdose is the leading cause of death among people being released from provincial correctional institutions in BC. Persons who have been incarcerated in provincial correctional centers are four times more likely to die of overdose compared to non-incarcerated British Columbians.[13] The impact of prohibition disproportionately impacts Indigenous persons and persons with mental disabilities. You should be accommodating our needs; you should not be asking us to accommodate the needs of a flawed legal and policy framework.

(B) <u>Option 1- Pharmaceutical Supply Model</u>

While the willingness of Health Canada to consider the Pharmaceutical Supply Model is appreciated, the response received suggests that our proposal and attached letters did not propose a coherent model for this option. Specifically, the letter we received states that:

> [the] request does not include information on which to assess a model to purchase legal pharmaceutical-grade substances from a licensed dealer and distribute through compassion clubs. Among other things, such a request would need to include information pertaining to the identification of a licensed dealer willing to sell controlled substances for this purpose and a plan for controls to be in place to protect public health and safety (e.g. secure storage, secure distribution of substances, reporting requirements, etc.).

In the following section, we hope to explain why Health Canada's assertion that we did not provide this information in our proposal and subsequent follow-up letters is inaccurate. In our

9 DeBeck K, Wood E, Zhang R, Montaner J, Buxton JA, Kerr T. A dose-dependent relationship between exposure to a street-based drug scene and health-related harms among people who use injection drugs. Journal of Urban Health. 2011 Aug;88(4):724-35. doi: 10.1007/s11524-011-9575-4
10 DeBeck K, Shannon K, Wood E, Li K, Montaner J, Kerr T. Income generating activities of people who inject drugs. Drug Alcohol Depend. 2007;91(1):50-56.
11 Small W, Maher L, Lawlor J, Wood E, Shannon K, Kerr T. Injection drug users' involvement in drug dealing in the downtown eastside of Vancouver: social organization and systemic violence. Int J Drug Policy. 2013;24(5):479-487.
12 Kerr T, Small W, Johnston C, Li K, Montaner JS, Wood E. Characteristics of injection drug users who participate in drug dealing: implications for drug policy. Journal of psychoactive drugs. 2008;40(2):147-152.
13 Gan WQ, Kinner SA, Nicholls TL, Xavier CG, Urbanoski K, Greiner L, Buxton JA, Martin RE, McLeod KE, Samji H, Nolan S. Risk of overdose-related death for people with a history of incarceration. Addiction. 2021 Jun 1;116(6):1460-71.

submission, there is not a rational basis for refusing to assess the primary component of the application and to focus instead on the alternative back-up model.

As we noted above, without Health Canada's explicit support it is not feasible for us to establish a comprehensive pharmaceutical substance procurement and distribution model that is currently illegal and would require a section 56(1) exemption to the CDSA to operate.

Information Pertaining to Licensed Dealers, Secure Storage and Distribution Were Provided.

In the letter dated September 15, 2021 from Martin T Schechter from Fair Price Pharma Incorporated, the organization confirmed it would be willing and able to provide a supply of pharmaceutical-grade diacetylmorphine provided that an exemption were granted and sanctions provided by the relevant federal and provincial regulators. A subsequent letter is attached to this response, reaffirming Fair Price Pharma Incorporated's willingness to provide diacetylmorphine.

In response to the December 15, 2021 follow-up email to the exemption request, we provided information and relayed the commitment from Dr. Mark Tyndall, the Executive Director of MySafe Society, to utilize the Health Canada SUAP funded MySafe machines that currently store and dispense large amounts hydromorphone tablets across British Columbia. Doctor Tyndall also responded to this email chain on December 17, 2021, which included the following excerpt, addressing security, distribution and records for reporting:

> The technology could address a few of the concerns and challenges with running a buyers club model. Firstly is security – the machine is pretty tamper -proof and we have no issues with this in the 2 years that we have had a machine – it is 800 lbs and bolted to the floor. The case has multiple locks and could not be pried open. We have an external security assessment that was very positive about the security. Secondly, the identification of participants through biometric hand scanning has proven to be very acceptable to the participants and cannot be fooled – no one has the same biometrics. There has been some technical glitches over time but these have been addressed and the software modified. Thirdly, there is real time recording of who and when the product was received. I have access to a dashboard in real time that lets me see when the drugs were picked up. In addition there is a short video record of each pick-up – this is not used routinely but is a back up security feature and discourages anyone from saying that they didn't get their dose when really they did. Although this has never been an issue. Fourthly, the machine is entirely programmable to individualize pick-ups if needed. Fifthly, the machines can be networked so that people could technically get their drugs from more than one machine and still have the same records.

A PDF copy of this email chain is attached to the email referenced above, which is in your records.

Existing Supply Chains are Largely Inaccessible

The DULF model seeks to provide safe supply to our pilot participants as quickly as possible, given the desperate urgency of the current crisis. There are significant barriers to accessing a medical model, which means that a medicalized model cannot reasonably be expected to reach all drug users. This has also been supported by the *BC Coroners Service Death Review Panel Report*, which states:

> Safer supply is a broad concept that exists on a spectrum from a medicalized model treating people with a substance use disorder to a non-prescriber public health model that provides a safer supply of regulated drugs to people. As people use drugs for a variety of reasons, a variety of approaches will be required to provide a safer drug supply to those who need it in the communities where they live. A medicalized model on its own is not sufficient to deliver safer supply to all who need it.[14]

For Health Canada to decide, apparently, that you will not engage in a system outside of the medical model ignores the current reality in which safe supply policies are confused, not comprehensive and cannot support the number of people who need access to safe supply now. The longer we pretend that the medical model alone will stop the overdose crisis the more unnecessary deaths will occur.

Health Canada's Bureaucratic Traps and Abandoned Responsibilities

In your letter you appear to suggest that we should resubmit anew our application for a Section 56(1) exemption for the Pharmaceutical Model. In practice, you are suggesting that, in the midst of this urgent public health crisis a volunteer-run community-based organization must do several months' worth of paperwork; collaborate with multinational and notoriously risk-averse pharmaceutical companies to secure currently highly stigmatized substances to distribute them in a currently illegal model; and then resubmit an application for exemption. Not even a well-resourced organization would be able to overcome these daunting challenges without the expressed support and assistance of the federal government. Why would Health Canada not wish to help us and thereby help protect Canadians from the toxic drug supply? Respectfully, it is not consistent with your mandate and responsibility to look to us to solve all these challenges without assistance from you.

We are bearing the consequences of your inaction. And you are asking us to bear the burden of generating solutions that accommodate Canada's circular, outdated and harmful drug policy.

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[14] B.C. Coroners Service. (2022). BC Coroners Service Death Review Panel: A Review of Illicit Drug Toxicity Deaths, March 9, 2022. Available at: https://www2.gov.bc.ca/assets/gov/birth-adoption-death-marriage-and-divorce/deaths/coroners-service/death-review-panel/review_of_illicit_drug_toxicity_deaths_2022.pdf

There are solutions available to you that do not require our continued deaths or our living in fear of being imprisoned for giving our friends and family what they need to survive. Our s. 56 application is one of them. If you wanted to solve the supply problem, any one of Health Canada's physicians, or Minister Bennett herself, could obtain an exemption from the College of Pharmacists to allow you to sign a non-patient specific ward prescription to ensure supply until a more long-term non-medical solution is found. You have more power and more resources than we do. And it is your responsibility.

Conclusion

As you can tell, we have serious concerns with your letter. We do wish express our appreciation for the work your department has done in service provision and policy and program development. We urgently need and rely upon the efforts and leadership of your department. We welcome – indeed, we request – collaboration with and further discussion on any additional ideas you may have.

After waiting **245 days** and witnessing **1,333 British Columbians die** since we first requested this exemption, we ask that you act with urgency to do the right thing – the thing that will actually protect the health and safety of Canadians: follow the evidence, follow the recommendations of countless experts including BC's Coroner and work with us instead of against us to enable a safe supply to those at risk of dying from the toxic supply.

The undersigned,

Jeremy Kalicum
Co-founder, Drug User Liberation Front

Eris Nyx
Co-founder, Drug User Liberation Front

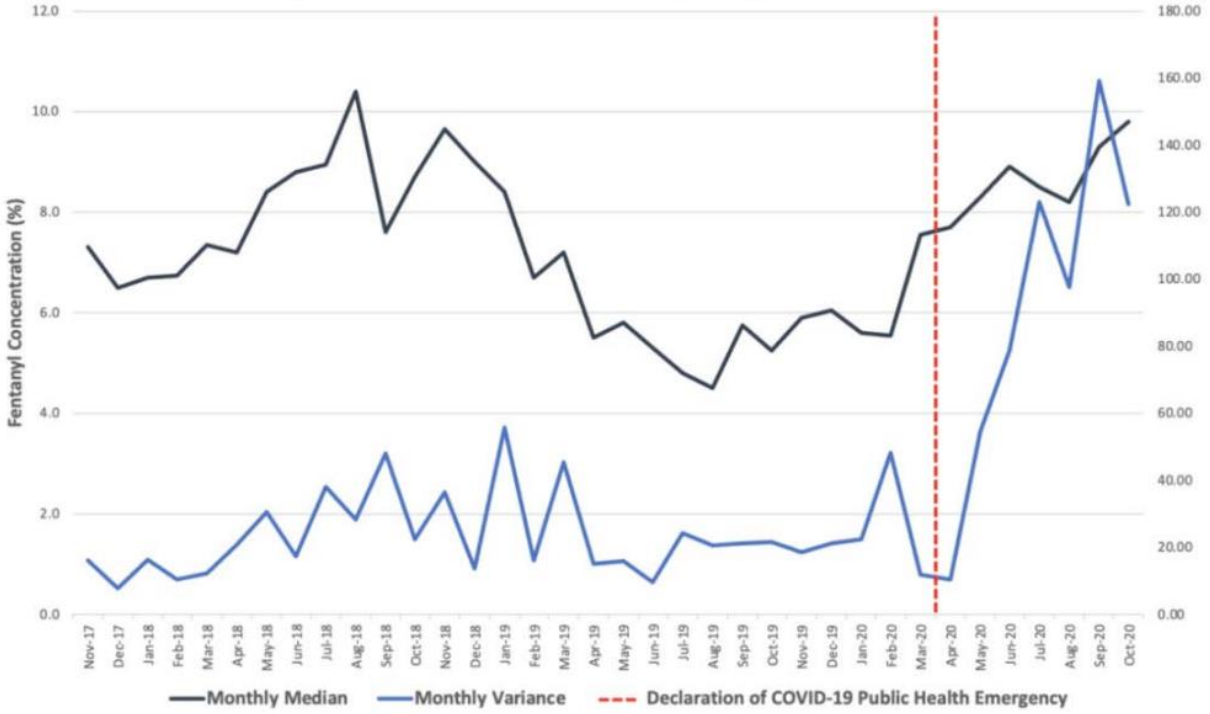
Brittany Graham
Executive Director, Vancouver Area Network of Drug Users

Copies to:
The Honouralbe Sheila Malcomson, Minister of Mental Health and Addictions, BC
The Honourable Adrian Dix, Minister of Health, BC
Lisa Lapointe, Chief Coroner, BC

Dr. Bonnie Henry, Provincial Health Officer, BC
Mark Lysyshyn, Deputy Chief Medical Office, Vancouver Coastal Health
Dr. Shannon McDonald, Acting Chief Medical Officer, First Nations Health Authority
Mayor Kennedy Stewart, City of Vancouver
Adam Palmer, Chief Constable, Vancouver Police Department

Appendix A: BC Centre on Substance Use. (2021). Monthly median fentanyl concentration of drug checking samples overlaying the counts of illicit drug toxicity deaths in Vancouver, BC.

Figure 2. Monthly median fentanyl concentration and monthly variance of fentanyl concentration of fentanyl-positive opioid drug checking samples in Vancouver, BC.



- After the declaration of the COVID-19 public health emergency, the variability in fentanyl concentration of opioids purchased from the unregulated drug supply increased dramatically. This is despite seeing the fentanyl concentration relatively unchanged and continuing to follow a cyclical pattern.
- It cannot be confirmed whether this was a result of COVID-19 border restrictions or if something else caused this effect.

Citation: BC Centre on Substance Use. (2021). Monthly median fentanyl concentration and monthly variance of fentanyl concentration of fentanyl-positive samples in Vancouver, BC. [unpublished data].