

## Submission to Health Canada on a proposal to control the derivatives and analogues of 4-piperidone and its salts under the Controlled Drugs and Substances Act

November 27, 2023

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The [Canadian Drug Policy Coalition \(CDPC\)](#) is a national, non-partisan organization seeking to end the harms of Canada's century-old regime of drug prohibition through evidence-informed drug policies. We collaborate with dozens of civil society and human rights groups across the country, focusing on public education, consultation with communities most impacted, academic research, and robust engagement with diverse stakeholders. CDPC's head office is located at Simon Fraser University in Vancouver, British Columbia, in the Faculty of Health Sciences.

CDPC suggests that ongoing scheduling and prohibition of substances under the *Controlled Drugs and Substances Act* (CDSA) and *Precursor Control Regulations* (PCR) is having unintended negative effects, and alternative models for regulating all substances should be sought to balance the need to protect the health of Canadians against the negative effects of prohibition.

### Background

On October 28, 2023, Health Canada [solicited comments](#) and published a [Notice of Intent](#) proposing to amend item 27 of Schedule VI to the CDSA and item 28 of the Schedule to the PCR by expanding the existing listings of the fentanyl precursor 4-piperidone and its salts to include its derivatives and analogues under the CDSA.

Under this proposal, the existing listing for 4-piperidone and its salts would be expanded to include its derivatives and analogues, including 1-boc-4-piperidone, 3-methyl-4-piperidone, and 1-benzyl-4-piperidone. Evidence shows that these

substances are being imported into Canada and/or detected in clandestine laboratories and being used to synthesize fentanyl and fentanyl analogues.

This submission considers the current legal framework and lessons from previous and ongoing scheduling of substances. CDPC is concerned about the health and societal risks created by the current regulatory environment. We suggest that the persistent and growing scheduling of substances and pre-cursors does not achieve the intended outcome of reducing the use of substances and has unintended negative consequences, especially for people who use drugs. In Canada, in the last decade, heroin has almost entirely been replaced by numerous fentanyl analogues – but fentanyl may not have proliferated had we sensibly regulated, instead of prohibited, heroin.

CDPC encourages a more fulsome discussion of the models and options available to regulate all substances, drawing on lessons learned from other public health policy issues.

### **Health Canada's Drug Analysis Service data**

Health Canada's [Drug Analysis Service](#) (DAS) and Cannabis Laboratory (CL) operates laboratories across Canada that analyze suspected illicit substances seized by Canadian law enforcement agencies. DAS data demonstrates the unintended consequences of scheduling substances: new and different substances continually emerge such as novel synthetic opioids (different fentanyl analogues and nitazene compounds) and other depressant type drugs such as a range of illicit benzodiazepines.

From [July to September 2023](#), a total of 28,666 samples (including Cannabis) were submitted for analysis:

- There was a total of 6,819 identifications of opioids where 75% were fentanyl or fentanyl analogues (Fentanyl; Para-fluorofentanyl; Bromofentanyl; 4-anilino-n-phenethylpiperidine; Acetyl Fentanyl; Methoxyacetyl Fentanyl; Para-chlorofentanyl). From all samples containing heroin, 20% also contained fentanyl.
- There was a total of 2,798 identifications of benzodiazepines during that period which represents a 36% increase over the same period last year.
- There was a total of 242 identifications of nitazenes during that period which represents a 44% increase over the same period last year.
- Newly identified depressant class substances included: Ethyleneoxynitazene; N-boc fluroro Norfenrtanyl.

From [April to June 2023](#), a total of 25,352 samples (including Cannabis) were submitted for analysis:

- There was a total of 6,896 identifications of opioids where 75% were fentanyl or fentanyl analogues (Fentanyl; Para-fluorofentanyl; Carfentanil; Bromofentanyl). From all samples containing heroin, 27% also contained fentanyl.
- There was a total of 2,976 identifications of benzodiazepines during that period which represents a 15% increase over the same period last year.
- There was a total of 234 identifications of nitazenes during that period which represents a 36% decrease over the same period last year.
- Newly identified depressant class substances included: N-propionyl Fluoro Norfentanyl; Despropionyl Fluorofentanyl; N-pyrrolidino Protonitazene; Metizolam.

From [January to March 2023](#), a total of 26,517 samples (including Cannabis) were submitted for analysis:

- There was a total of 6,143 identifications of opioids where 75% were fentanyl or fentanyl analogues (Fentanyl; Para-fluorofentanyl; Carfentanil; Bromofentanyl; Acetyl Fentanyl; Furanyl Fentanyl; Methoxyacetyl Fentanyl). From all samples containing heroin, 25% also contained fentanyl.
- Newly identified depressant class substances included: N-desethyl Isotonitazene.

DAS published a [March 2023 report](#) “*Spotlight: The evolution of Fentanyl in Canada over the past 11 years*”. The report states:

- Fentanyl was first identified in Canada in 1989 in exhibits submitted by law enforcement agencies. Since 2016, there has been a sharp increase in the number of Fentanyl identifications in Canada. Between January 2012 and December 2022, Fentanyl has been identified in 77,141 exhibits submitted for analysis.
- Fentanyl is a major contributor to the opioid crisis in Canada; in 2021, 86% of all accidental apparent opioid toxicity death involved Fentanyl and 32% of all opioid-related poisoning hospitalizations involved Fentanyl or Fentanyl analogues.

Previous efforts to schedule and prohibit fentanyl and fentanyl precursors have not stopped people using substances, rather they have increased the number of fentanyl analogues and other novel opioid or depressant type contaminants in the drug supply. This has increased the volatility, danger, and toxicity of the unregulated drug supply. Over the last several years there has been an exponential increase in fatal and non-fatal overdoses, hospitalizations, and the attendant need for emergency health responses such as naloxone distribution, supervised consumption spaces, safe supply initiatives. In addition, scheduling substances further complicates law enforcement efforts.

## **Toxic drug deaths are primarily from the unregulated supply.**

Health Canada's Notice of Intent to control the derivatives and analogues of the fentanyl precursor 4-piperidone and its salts under the CDSA notes:

- "Between January 2016 and March 2023, there were a total of 38,514 apparent opioid toxicity deaths in Canada. Fentanyl and fentanyl analogues continue to be major drivers of the opioid overdose crisis, with 81% of all accidental apparent opioid toxicity deaths from January to March 2023 involving fentanyl".
- For a full list of opioids involved, see Appendix A.

Current [Health Canada reporting](#) also notes:

- Of all accidental apparent opioid toxicity deaths so far in 2023 (January-March), 81% involved fentanyl. This percentage has increased by 42% since 2016 when national surveillance began but appears to have stabilized in recent years.
- Of all accidental apparent opioid toxicity deaths so far in 2023 (January-March), 77% involved opioids that were only non-pharmaceutical. This percentage has increased by 17% since 2018 when national surveillance began but appears to have stabilized in recent years.
- There was a total of 37,697 opioid-related and 16,231 stimulant-related poisoning hospitalizations from January 2016 to March 2023 in Canada (excluding Quebec)
- A total of 1,309 opioid-related poisoning hospitalizations occurred so far in 2023 (January-March). This is an average of 15 hospitalizations per day.
- For opioid-related poisoning hospitalizations, fentanyl and its analogues were involved in 36% of accidental opioid-related poisoning hospitalizations, compared to 19% of intentional opioid-related poisoning hospitalizations so far in 2023 (January-March). The percentage of all opioid-related poisoning hospitalizations that involved fentanyl and its analogues has increased 106% since 2018 when national surveillance began, but appears to have stabilized in recent years.
- Note: Prior to 2018, the percentage of deaths involving fentanyl and/or fentanyl analogues represented a single category. For data reported for 2018 to 2023 (Jan to Mar), some provinces and territories did not report fentanyl analogue information or required additional information to differentiate fentanyl from fentanyl analogues until investigations were completed. Therefore, deaths involving fentanyl analogues may be included in the fentanyl percentages for some jurisdictions.

## Canada

[November 2022: Opioids \(Canadian Drug Summary\)](#), Canadian Centre on Substance Use and Addiction

Noted in the summary:

- Most opioid-related deaths involve opioids that were nonpharmaceutical in origin and often involve other substances (e.g., nonmedical benzodiazepines or stimulants).
- The unpredictability and toxicity of the illegal drug supply have increased since the start of COVID-19, and new synthetic opioids have recently been detected (e.g., nitazenes), which have the potential to increase opioid-related harms among people who use drugs.

## British Columbia

[November 1, 2023 Report to the Chief Coroner of British Columbia](#): BC Coroners Service Death Review Panel: An Urgent Response to a Continuing Crisis

The report notes:

- On April 14, 2016, in response to an alarming increase in drug-related emergencies and deaths in British Columbia, the provincial health officer declared the province's first-ever public health emergency. More than seven years later, the emergency remains in place, and more than 13,000 people have died.
- These deaths are largely preventable, and yet, in 2023, British Columbians are being lost to unregulated drug supply at twice the rate they were when the emergency was first declared. With the passing of each day, week, month, and year, we risk becoming numb to the scale of this emergency as the current devastation becomes the norm. Any response to addressing the magnitude and severity of the emergency will experience challenges but the current system of prohibition is failing badly, and the status quo is no longer acceptable.
- The primary driver of death is the increased toxicity, volatility, and unpredictability of the unregulated drug supply. Various synthetic opioids and other adulterants including benzodiazepines and other substances are often found in toxicological testing and in drug sample testing, but the one constant throughout the emergency is illicitly produced fentanyl, a powerful synthetic opioid. The cause of death in nearly all instances is mixed drug toxicity, with fentanyl present in more than 85% of deaths in 2022.
- “These drug poisoning deaths have been primarily driven by an increasingly toxic illicit drug supply, exacerbated by under-resourced health and social

supports that have been unable to keep up with increasing demands and complexities.” - Minister of Mental Health and Addiction, 2022

## Ontario

[September 2023 Report by The Ontario Drug Policy Research Network and Public Health Ontario](#): Characteristics of Substance-Related Toxicity Deaths in Ontario - Stimulant, Opioid, Benzodiazepine and Alcohol-Related Deaths,

The report notes:

- Opioid toxicity deaths increased two-fold from 1,290 in 2018 to 2,547 in 2021. The majority of opioid toxicity deaths were caused by non-pharmaceutical opioids in 2021 (90.4%, N=2,303). When only considering opioid toxicity deaths that involved other substances, deaths increased from 795 in 2018 to 1,734 in 2021. The proportion of opioid toxicity deaths that directly involved other substances increased from 61.6% in 2018 to 68.1% in 2021.

## Toronto Drug Checking Services

Toronto’s Drug Checking Service offers people who use drugs timely and detailed information on the contents of their drugs, helping them to make more informed decisions. This service also helps to uncover the [makeup of Toronto’s unregulated drug supply](#), which includes illegal drugs, as well as legal drugs diverted from regulated markets. It is another source demonstrating the volatility of the unregulated drug supply.

## The harms of drugs versus the harms of prohibition

It is important to note that fentanyl is not inherently dangerous – it is used widely in human medicine (Trade names Abstral®, Duragesic®, Onsolis®). However, in the unregulated market, dosage and purity are never assured - prohibition and unregulated drugs are killing people.

People are now consuming drugs that unknowingly contain multiple substances. Fentanyl analogues, novel opioids, and nitazine and benzodiazepines type compounds widely contaminate the supply, increasing toxicity. Beyond the deaths, there are thousands of hospitalizations, a growing cohort of people surviving with brain damage after non-fatal overdoses, and traditional opioid therapies, such as methadone, are less effective due to increased drug tolerance.

The diversification of drugs has caused [unprecedented mortality, negative health outcomes and social impacts](#), creating an untenable situation. Solutions to Canada’s toxic drug crisis require a shift away from the various harms of prohibition.

## Other costs of prohibition

Making certain drugs illegal does not stop people from using substances. Criminalization of substance use further [stigmatizes people who use drugs](#), making it more difficult to engage them in health care, [exacerbates many of the factors that negatively impact health and wellbeing](#), and negatively impacts educational, employment, travel and other future prospects of individuals convicted for drug charges. Criminalization also fosters social marginalization and encourages high-risk behaviours, such as injecting in unhygienic, unsupervised environments, poly-drug use, and binge use.

Scheduling drugs and precursors [creates incentives](#) for underground chemists to create new substances that may be even more dangerous. Scheduling each new substance, precursor, or class of substances increases costs related to enforcement strategies and social costs to people who use these drugs. Resources spent on enforcement mean less resources for the provision of health and social supports that would be more effective in reducing drug use.

Banning drugs and relying on enforcement based supply-side approaches to discourage their use has not stemmed drug use or stopped the drug supply. Despite Canada's significant investment in drug control efforts, drugs or more dangerous substitutes are just as available as ever. There is a [growing consensus among international experts](#) that drug prohibition has failed to deliver its intended outcomes and has been counterproductive.

## Creation of unregulated drug markets

Rather than reducing the supply of drugs, prohibition abdicates the regulation of drugs to criminal markets. This approach has several negative effects.

Drug policies that prohibit substances eliminate age restrictions on them by abandoning controls to an unregulated market. In addition, when we prohibit rather than regulate substances, it becomes impossible to control the purity and strength of drugs. Illegally produced and supplied drugs are of unknown strength and purity, increasing the risk of overdose, poisoning, and infections.

### *Substance displacement*

If the use of one drug is controlled by reducing supply, suppliers and users may move on to another drug with similar psychoactive effects, but less stringent controls. An example of this was emergence and subsequent banning of a novel synthetic cathinone (mephedrone) in the United Kingdom in 2010. People started using (unscheduled) mephedrone because drug enforcement efforts had negatively impacted the availability and quality of other stimulants such as cocaine and MDMA. However, people who used mephedrone before the ban either continued their use or switched back to already prohibited and unregulated substances after the ban. Research showed that prohibiting mephedrone did not have the intended effect of reducing substance

use; rather it [displaced drug use](#) to either new substances or older illegal substances of unknown purity or dose.

In a 2010 article by David Nutt titled *New psychoactive substances: Pharmacology influencing UK practice, policy and the law*, he writes, “Many might say “so what, surely banning a drug couldn't do any harm?” But it soon transpired that banning it was associated with an increase in harms from other stimulant drugs. Because mephedrone was legal it took a lot of the cocaine and amphetamine markets. This led to a remarkable fall in deaths from these 2 more toxic stimulants. Overall, the emergence of mephedrone was associated with a reduction in over 300 deaths from these other 2 stimulants. Since this was not a controlled trial, it is not possible to be certain that the rise of mephedrone use led directly to the fall in deaths from other stimulants but it seems almost certainly to have been a significant factor. In hindsight, one could speculate that mephedrone turned out to be the most effective intervention to reduce cocaine deaths ever known. Further evidence for a causative effect of mephedrone is the fact that since it was banned cocaine deaths have risen to their highest ever levels.”

[Research](#) also suggests that the ban on mephedrone displaced provision of this substance from Internet and “head shop” supplies to street-level drug dealers, thus involving more people in this illegal activity, and the price increased.

#### *Market disruption*

A [recent US study](#) also demonstrated that law enforcement efforts to disrupt local drug markets by seizing opioids or stimulants are associated with increased spatiotemporal clustering of overdose events in the surrounding geographic area.

#### *Increasing challenges and costs for law enforcement*

As noted in the “Illegal drug supply innovations and synthetic drugs” section of the [Executive Summary](#) of the United Nations Office on Drugs and Crime [2023 World Drug Report](#):

- Synthetic drugs offer criminals several advantages, namely lower operational costs, fewer production impediments, and reduced risks of detection, interdiction and prosecution because they can be produced closer to destination. Supply reduction efforts may be increasingly challenged, as criminals employ new means of manufacture that are easier to conceal, use chemicals that fall outside of existing controls or access inputs within expanding chemical and pharmaceutical sectors where it becomes easier to conceal diversion. Synthesis of drugs offers additional flexibility in terms of having no fixed geography and much shorter production times. Interdiction of drugs may be less effective, as illegal manufacture can be relocated and product quickly replaced.
- Consumers face growing challenges from synthetic drugs owing to the unknown pharmacology and harms of the drugs, lack of pharmacological



treatments, therapies or antagonists, and an increasingly dangerous mix in retail markets, as shown by the growing numbers of tranquilizers, including novel benzodiazepines, found in the drug supply.

- The opioid crisis in North America has not been associated with a sizeable increase in the number of opioid users but driven by overdose deaths, mainly attributed to the use of fentanyl.

A November 18, 2023 [CBC News article](#) quoted Mathieu Bertrand, head of the RCMP unit responsible for fighting organized crime, “Sadly, Canada is a producing country of fentanyl and synthetic opioids. Not only are we a producing country, we're an exporting country. One of the challenges is that a lot of these precursors are not illegal”.

CDPC notes that while this may appear to be a challenge from a law enforcement perspective, the unintended consequences of never-ending scheduling and prohibition are a far greater challenge.

A November 26, 2023 [CBC News article](#) states:

- “Canada Border Services Agency (CBSA) is in a constant game of cat-and-mouse with criminal organizations that are trying to import dangerous narcotics as well as the ingredients for fentanyl — sometimes through “creative” means, says a senior border official. “It's an ever-evolving game where we're constantly looking at new and different tactics to smuggle drugs into the country or out of the country.” - Aaron McCrorie, vice-president of intelligence and enforcement, CBSA

CDPC believes a drug free world is an unattainable world. It is time to consider a new approach that eliminates the negative effects of drug prohibition, provides a variety health and social supports and harm reduction services, and avoids criminalizing those who choose to use drugs.

### **Alternative policy options**

Clearly all drugs, whether legal or illegal, can pose risks. The [2019 Canadian Alcohol and Drugs Survey \(CADS\)](#) asked about five harms people may have experienced in the past 12 months due to alcohol consumption. Types of harm include being unable to stop drinking once started, failing to do what was normally expected from you because of drinking, needing a first drink in the morning to get yourself going after a heavy drinking session, being unable to remember what happened the night before because of your drinking, or having a feeling of guilt or remorse after drinking.

Of those who reported past-year alcohol use, 21% (4.8 million) experienced at least one alcohol-related harm in the past year due to alcohol use. These data demonstrate that alcohol, a regulated substance, can still be harmful. However, alcohol is subject to regulatory controls including, pricing, age restrictions and dose that help to

contain the negative public health and public safety effects avoiding the negative effects of complete prohibition - people do not die from a toxic alcohol supply.

CDPC supports calls for regulation, not prohibition, of all substances so they are manufactured under safe and sanitary conditions and can be subject to penalties for sale in adulterated and/or unlabeled forms. A key benefit of regulation is that it allows appropriate controls to be put in place over price and availability (location, times of opening and age restrictions) as well as controls over advertising and promotion. It is precisely because unregulated drugs pose risks that they need to be appropriately regulated to ensure that dosing and conditions of manufacture protect the safety and health of Canadians. Allowing people reasonable access to substances of known quality and purity would:

- Significantly reduce unintentional fatal and non-fatal overdose or poisoning.
- Remove the control of drugs from the criminal market and its associated corruption and violence.
- Reduce criminal market enterprising in incentivization to produce new or novel substances to skirt scheduling and enforcement.
- Free-up resources wasted on ineffective and harmful prohibition and law enforcement that could be directed to myriad health and social programs.

## Recommendations

CDCP recommends stopping the endless and harmful cycle of scheduling and prohibition and to follow recommendations and calls found in:

- The August 2023 Report of the Office of the United Nations High Commissioner for Human Rights, [Human rights challenges in addressing and countering all aspects of the world drug problem](#) (A/HRC/54/53), specifically recommendations:
  - 
  - (a) Adopt alternatives to criminalization, “zero tolerance” and elimination of drugs, by considering decriminalization of usage; and take control of illegal drug markets through responsible regulation, to eliminate profits from illegal trafficking, criminality and violence;
  - (c) Consider developing a regulatory system for legal access to all controlled substances;
- The Global Commission on Drug Policy 2021 report, [Time to End Prohibition](#), which notes:
  - The Global Commission argues that options for legal regulation should be explored for all psychoactive substances. Regulation means not only

protecting the health and safety of the end-consumer, but also creating a supply chain with strict controls for potency, quality and access. Regulation ultimately requires the boldness to build a world that does not yet exist.

- Consider different models of legal regulation such as those outlined by the UK's [Transform Drug Policy Foundation](#) and [CDPC](#).



## Appendix A - Types of opioids

Category	Includes (but are not limited to):
<b>Fentanyl and fentanyl analogues</b>	3-methylfentanyl acetylfentanyl acrylfentanyl butyrylfentanyl carfentanil crotonyl fentanyl cyclopropyl fentanyl despropionyl-fentanyl fentanyl fluoroisobutyrylfentanyl (FIBF) furanylfentanyl methoxyacetylfentanyl norfentanyl
<b>Non-fentanyl opioids</b>	2-methyl AP-237 AH-7921 AP-237 brorphine buprenorphine metabolites codeine desomorphine dihydrocodeine etodesnitazene heroin hydrocodone hydromorphone isopropyl-U-47700 isotonitazene loperamide meperidine methadone metonitazene mitragynine monoacetylmorphine morphine MT-45 normeperidine oxycodone tapentadol tramadol U-47700 U-49900 U-50488