



Regulatory Approaches to Confront Chemical Workarounds

Drug and Chemical Evaluation Section
Diversion Control Division
U.S. Drug Enforcement Administration

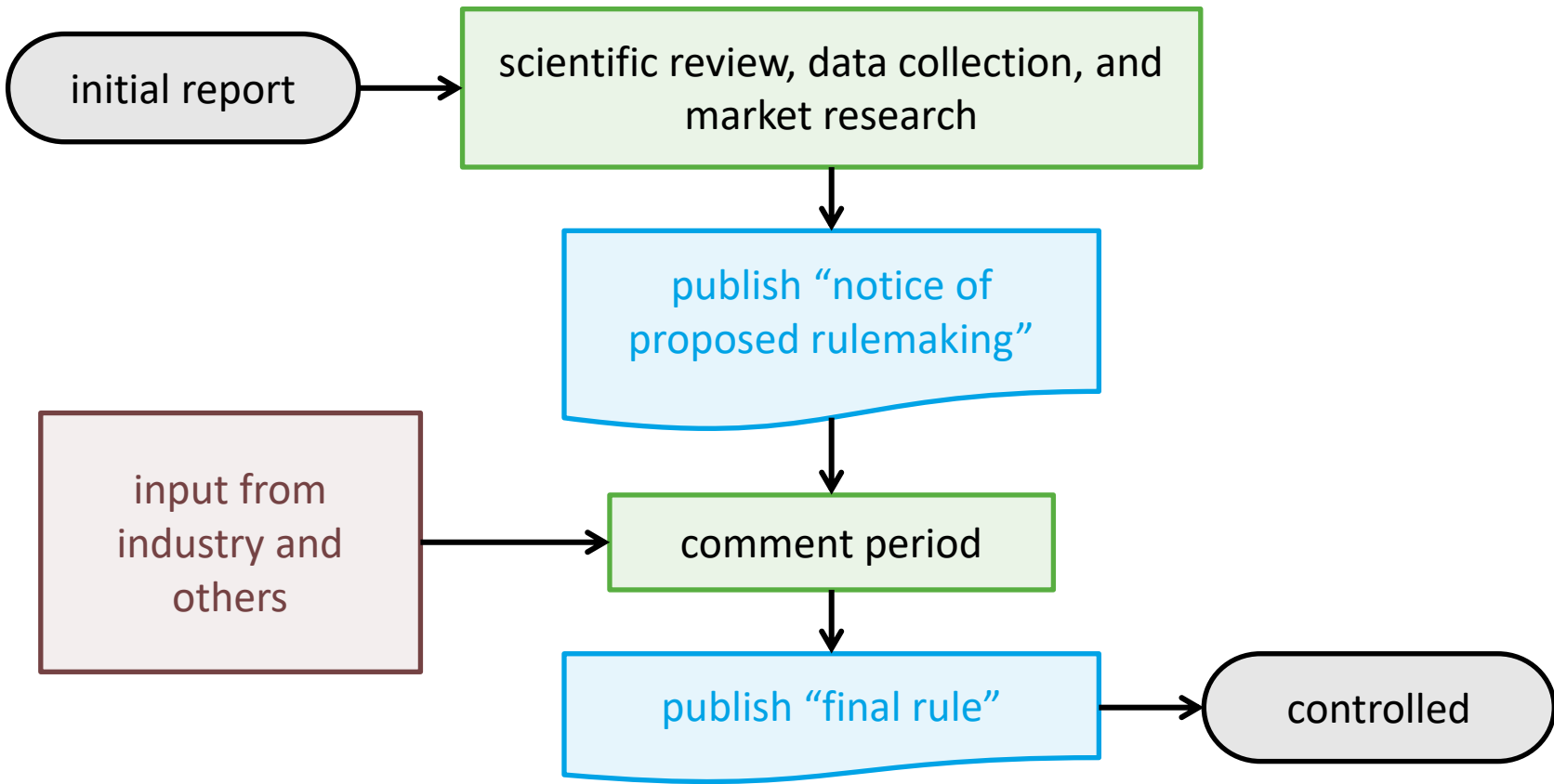
Diversion Control Division

The contents of this document do not have the force and effect of law and are not meant to bind the public or DEA in any way. This document is intended only to provide clarity to the public regarding existing requirements under the law or agency policies.

I have no financial relationships to disclose.



Enacting a New Chemical Control Authority delegated to DEA





Registration for handlers of List I chemicals

- Handlers include manufacturers, distributors, importers, and exporters
- Registration considerations:
 - Effective controls against diversion of listed chemicals?
 - Compliance with applicable Federal, State, and local law?
 - Prior convictions relating to controlled substances or listed chemicals?
 - Past experience in the manufacture and distribution of chemicals?
 - Other factors relevant to and consistent with the public health and safety.
- Separate registration for different groups of activities
- Separate registration for separate locations
- Registrations are renewed annually



On site inspection required for every new List I chemical registration:

1. Review of the completed DEA application to verify the information is complete and accurate.
2. Obtain a description of the company's planned activity with the List I chemical(s).
3. Obtain information on the principals of the firm as well as those responsible for handling List I chemicals to include, but not limited to, date of birth, home address, and home phone number.
4. Review of State and Federal licenses and certificates.
5. Obtain supplier list and customer list.
6. Review of the firm's business practices and procedures including procedures for identifying suspicious orders of listed chemicals.
7. Inspection of the firm's physical security and its procedures for employee screening/background checks.



Requirements for handlers of List I chemicals

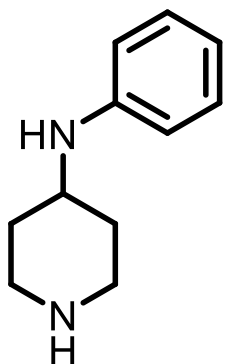
For manufacturers, distributors, importers, and exporters:

- Recordkeeping
- Reporting
- “Know Your Customer” Policy:
 - Must verify the identity of their customers and understand the normal and expected transactions typically conducted by those customers.
 - Detect and report suspicious transactions.
- Tools to address unauthorized activities involving listed chemicals:
 - Suspension or revocation of DEA registration
 - Violations may result in civil fines and criminal penalties

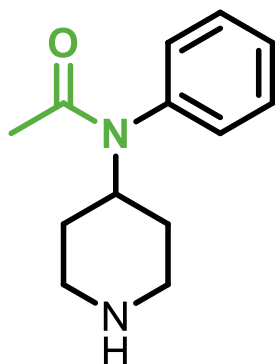


2020 Chemical Control

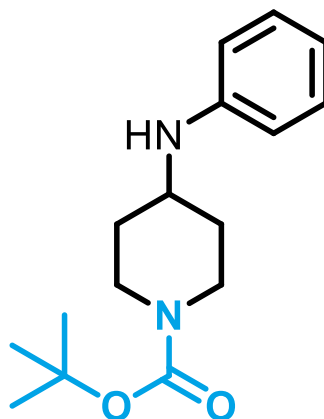
4-Anilinopiperidine (4-AP), its **amides**, its **carbamates**, and its salts



4-AP



acetyl
norfentanyl



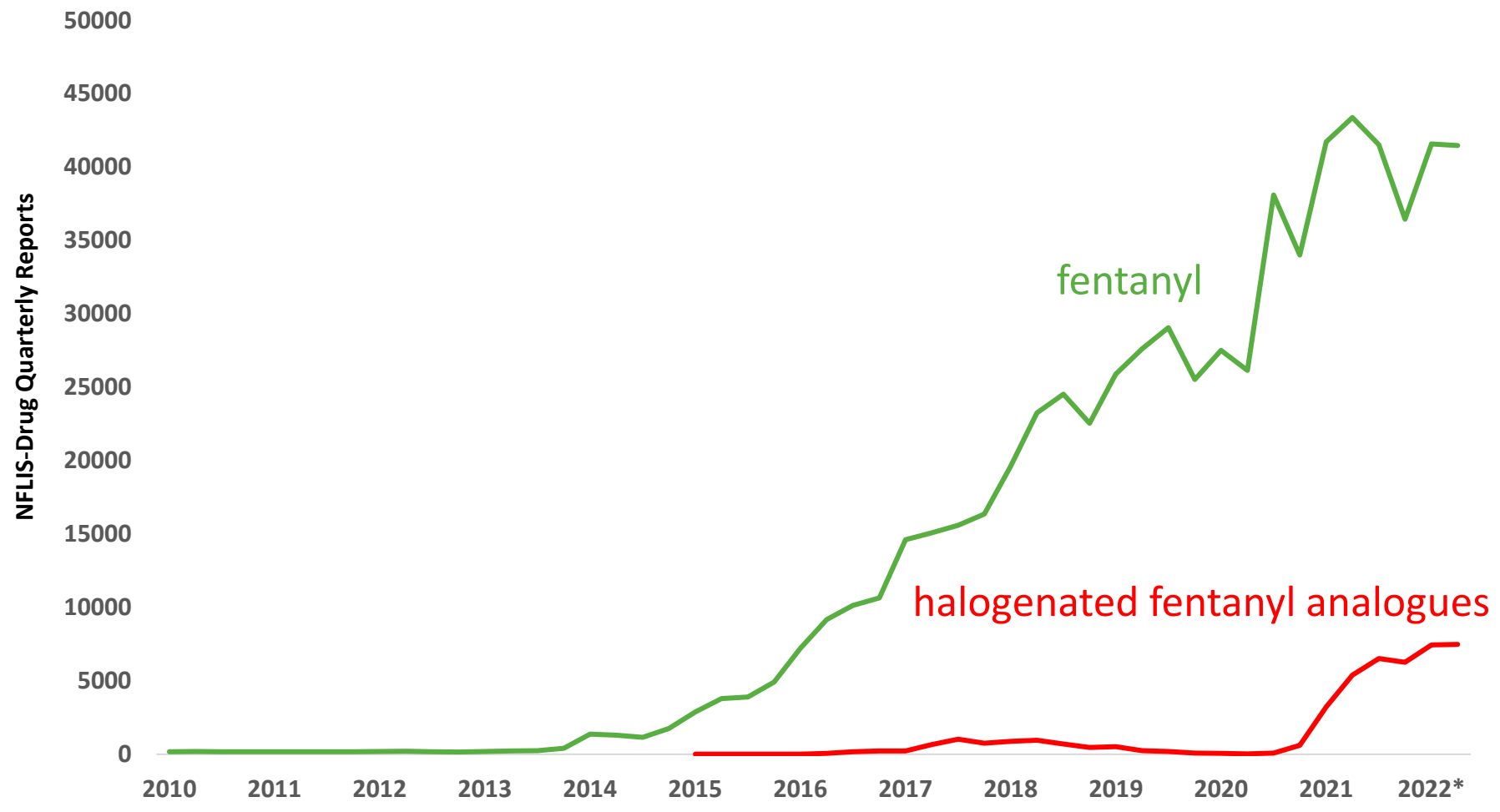
1-Boc-4-AP

Others captured:

- ethyl 4-AP-1-carboxylate
- 1-Cbz-4-AP
- furanyl norfentanyl
- butyryl norfentanyl
- cyclopropyl norfentanyl
- valeryl norfentanyl
- isobutyryl norfentanyl



NFLIS-Drug

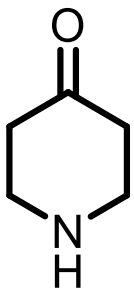


Source: DEA, National Forensic Laboratory Information System (NFLIS-Drug), queried on 15 May 2023.
*Reports still pending for 2022.

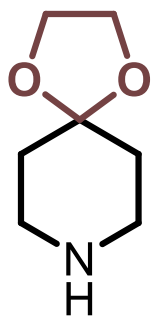


2023 Chemical Control

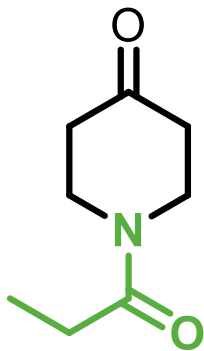
4-Piperidone, its **acetals**, its **amides**, its **carbamates**, its salts, and salts of its acetals, its amides, and its carbamates



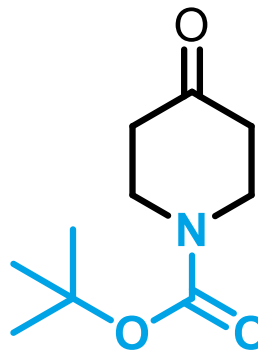
4-piperidone



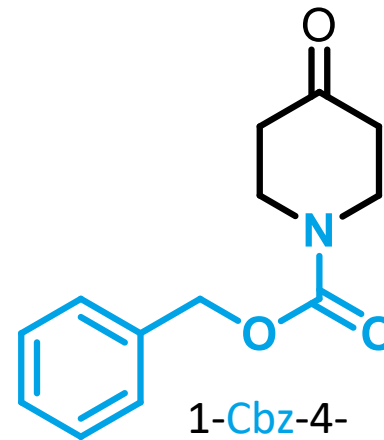
4-piperidone
ethylene ketal



1-propionyl-
4-piperidone



1-Boc-4-
piperidone

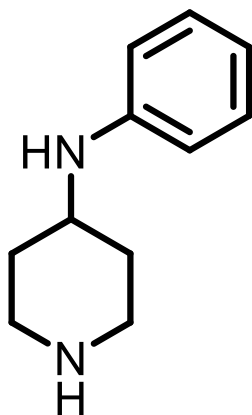


1-Cbz-4-
piperidone

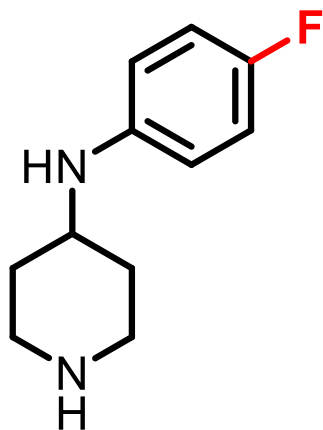


Proposed Change to 2020 Control

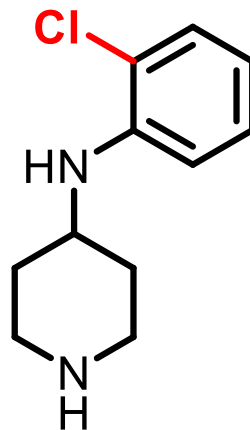
4-Anilinopiperidine (4-AP), its **amides**, its **carbamates**, its salts, its **halides**, and any combination thereof



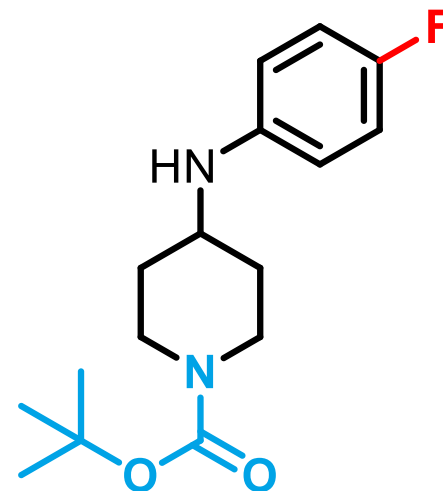
4-AP



para-**fluoro** 4-AP



ortho-**chloro** 4-AP



para-**fluoro** 1-**Boc** 4-AP



Thank You



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