SB

20

<TARGET><BILL>SB 20</BILL><SUBJECT>SB
20</SUBJECT><COMM>SHSS30</COMM></TARGET>

ALASKA STATE LEGISLATURE

Interim:
1500 West Benson Blvd.
Anchorage, Alaska 99503
Phone: (907) 269-0199
Fax (907) 269-0197
Senator.Kevin.Meyer@akleg.gov

Session:
Alaska State Capitol
Juneau, Alaska 99801-1182
Phone: (907) 465-4945
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SENATOR KEVIN MEYER
SENATE DISTRICT M

SPONSOR STATEMENT FOR SB 20

"An Act classifying U-47700 as a schedule IA controlled substance; and providing for an effective date."

SB 20 would classify U-47700, a synthetic opioid commonly known as pink or U4, a schedule IA controlled substance.

U-47700 was a research chemical created and patented in the United States in the 1970's. It was never tested on humans and was not manufactured for public consumption. Drug labs in China are now producing this drug and selling it online where people purchase this inexpensive, lethal alternative to purchasing opioid drugs on the street.

This synthetic opioid is eight times more potent than morphine and according to the Drug Enforcement Administration (DEA) it has been associated with at least 46 deaths in 2015 and 2016. The State of Alaska Epidemiology Bulletin has attributed U-47700 to three drug overdose deaths in Alaska.

U-47700 is abused many ways. Similar to oxycodone or heroin, some users experience a feeling of euphoric relaxation along with tolerance and dependence on the drug. Users may also experience severe adverse reactions such as nerve damage, seizures and death.

Several states have already banned this drug and last November the DEA issued a final order to temporarily schedule U-47700 as a schedule I controlled substance. Should SB 20 pass, it will be unlawful to sell, use, purchase, possess, manufacture, transport or deliver this synthetic opioid in the State of Alaska.

ALASKA STATE LEGISLATURE

Interim:
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SENATOR KEVIN MEYER
SENATE DISTRICT M

TO: Senator David Wilson, Chairman
Senate Health & Social Services Committee

RECEIVED FEB 01 2017

FROM: Senator Kevin Meyer

DATE: February 1, 2017

RE: Senate H&SS Committee Request for Hearing SB 20

This is a request for the Senate Health and Social Services Committee to schedule a bill hearing for SB 20, "An act classifying U-47700 as a schedule IA controlled substance; and providing for an effective date."

The following documents are attached and will be sent electronically:

- Latest version of the bill: 30-LS0319\A
- Sponsor Statement
- Supporting Documents
  - Federal Register, Vol. 81, No. 219, Monday, November 14, 2016, Rules and Regulations, Department of Justice Drug Enforcement Administration, Docket No. DEA-440, "Schedules of Controlled Substances: Temporary Placement of U-47700 into Schedule I"
  - State of Alaska Epidemiology Bulletin, No. 28, November 7, 2016, "Overview of Recent Synthetic Opioid Overdose Deaths."
- News Articles
  - Wall Street Journal, "This Is U-47700, Once a Lab Experiment, Now a Killer Opioid," November 4, 2016.
  - NBC News, "Pink: Stronger Than Heroin, But Legal in Most States," October 15, 2016.
- Letter of Support: Department of Health & Social Services, Jay Butler Chief Medical Officer and Director, Division of Public Health
- Witness/Testimony:
  - Department of Health and Social Services
  - Department of Public Safety
- Staff member assigned to the bill:
  - Christine R. Marasigan, christine.marasigan@akleg.gov, 465-6876

This bill would make it unlawful to sell, use, purchase, possess, manufacture transport or deliver a U-47700, a synthetic opioid.

Fiscal Note

State of Alaska
2017 Legislative Session

Bill Version: SB 20
Fiscal Note Number:
() Publish Date:

Identifier: SB020-DPS-SDAEU-02-03-17
Title: LIST U-47700 AS A CONTROLLED SUBSTANCE
Sponsor: MEYER
Requester: (S) HSS

Department: Department of Public Safety
Appropriation: Alaska State Troopers
Allocation: Statewide Drug and Alcohol Enforcement Unit
OMB Component Number: 3052

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2018 Appropriation Requested	Included in Governor's FY2018 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2018**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Fund Source (Operating Only)

None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Positions

Full-time							
Part-time							
Temporary							

Change in Revenues

None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimated SUPPLEMENTAL (FY2017) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2018) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed?

Why this fiscal note differs from previous version:

Not applicable, initial version.

Prepared By: Kelly Howell Phone: (907)465-4336
Division: Administrative Services Date: 02/03/2017 02:00 PM
Approved By: Walt Monegan Date: 02/03/17
Agency: Public Safety

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2017 LEGISLATIVE SESSION

BILL NO. SB 20

Analysis

This legislation adds U-47700, a synthetic opioid, to the Schedule IA list of statutorily controlled substances.

Passage of this legislation is not expected to significantly impact the enforcement efforts of the Alaska State Troopers. Therefore, a zero fiscal note is being submitted.

(Revised 8/12/16 OMB/LFD)

Fiscal Note

State of Alaska
2017 Legislative Session

Bill Version: SB 20
Fiscal Note Number:
() Publish Date:

Identifier: SB020-DPS-LAB-02-03-17
Title: LIST U-47700 AS A CONTROLLED SUBSTANCE
Sponsor: MEYER
Requester: (S) HSS

Department: Department of Public Safety
Appropriation: Statewide Support
Allocation: Laboratory Services
OMB Component Number: 527

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2018 Appropriation Requested	Included in Governor's FY2018 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2018**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Fund Source (Operating Only)							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Positions							
Full-time							
Part-time							
Temporary							
Change in Revenues							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimated SUPPLEMENTAL (FY2017) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2018) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed?

Why this fiscal note differs from previous version:

Not applicable, initial version.

Prepared By: Kelly Howell Phone: (907)465-4336
Division: Administrative Services Date: 02/03/2017 02:00 PM
Approved By: Walt Monegan Date: 02/03/17
Agency: Public Safety

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2017 LEGISLATIVE SESSION

BILL NO. SB 20

Analysis

This legislation adds U-47700, a synthetic opioid, to the Schedule IA list of statutorily controlled substances.

The Scientific Crime Detection Laboratory (crime lab) provides analysis of suspected controlled substances, issues reports, and provides expert testimony for the State of Alaska.

Passage of this legislation is not expected to result in a significant increase in the controlled substance analysis workload. Therefore, no fiscal impact to the crime lab is anticipated.

Fiscal Note

State of Alaska
2017 Legislative Session

Bill Version: SB 20
Fiscal Note Number:
() Publish Date:

Identifier: SB020-DOC-IDO-02-03-17
Title: LIST U-47700 AS A CONTROLLED SUBSTANCE
Sponsor: MEYER
Requester: (S) HSS

Department: Department of Corrections
Appropriation: Population Management
Allocation: Institution Director's Office
OMB Component Number: 1381

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2018 Appropriation Requested	Included in Governor's FY2018 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2018**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Fund Source (Operating Only)							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Positions							
Full-time							
Part-time							
Temporary							
Change in Revenues							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimated SUPPLEMENTAL (FY2017) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2018) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed?

Why this fiscal note differs from previous version:

Not applicable, initial version.

Prepared By: April Wilkerson — Phone: (907)465-3460
Division: Administrative Services - Department of Corrections — Date: 02/03/2017 04:30 PM
Approved By: Dean Williams, Commissioner — Date: 02/03/17
Agency: Department of Corrections

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2017 LEGISLATIVE SESSION

BILL NO. SB 20

Analysis

This legislation adds U-47700 to Alaska's list of schedule IA substances and will also allow law enforcement to stop those who are distributing the substance. Violation of this section of statute is misconduct involving a controlled substance and could increase the number of offenders placed under the department's custody.

Potential financial impacts to the Department could range anywhere from $0.00 (no time served) to $149.62 (per day) for each offender incarcerated under this legislation; however, there is not sufficient data at this time to determine the full impact to the prison population of this legislation.

The Department will continue to monitor the financial impacts of this legislation if passed.

Fiscal Note

State of Alaska
2017 Legislative Session

Bill Version: SB 20
Fiscal Note Number:
() Publish Date:

Identifier: SB020-LAW-CRIM-02-03-17
Title: LIST U-47700 AS A CONTROLLED SUBSTANCE
Sponsor: MEYER
Requester: (S) HSS

Department: Department of Law
Appropriation: Criminal Division
Allocation: Criminal Justice Litigation
OMB Component Number: 2202

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2018 Appropriation Requested	Included in Governor's FY2018 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2018**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Fund Source (Operating Only)							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Positions							
Full-time							
Part-time							
Temporary							
Change in Revenues							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimated SUPPLEMENTAL (FY2017) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2018) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed?

Why this fiscal note differs from previous version:

Not applicable, initial version.

Prepared By:	Valerie Rose, Budget Analyst	Phone:	(907)465-3674
Division:	Administrative Services	Date:	02/03/2017 08:38 AM
Approved By:	Jahna Lindemuth, Attorney General	Date:	02/03/17
Agency:	Department of Law		

STATE OF ALASKA
2017 LEGISLATIVE SESSION

BILL NO. SB 20

Analysis

This legislation schedules U-47700 as a IA controlled substance.

The Department of Law does not anticipate a fiscal impact.

Fiscal Note

State of Alaska
2017 Legislative Session

Bill Version: SB 20
Fiscal Note Number:
() Publish Date:

Identifier: SB020-DHSS-PHA-1-23-17
Title: LIST U-47700 AS A CONTROLLED SUBSTANCE
Sponsor: MEYER
Requester: (S) HSS

Department: Department of Health and Social Services
Appropriation: Public Health
Allocation: Public Health Administrative Services
OMB Component Number: 292

Expenditures/Revenues

Note: Amounts do not include inflation unless otherwise noted below. (Thousands of Dollars)

	FY2018 Appropriation Requested	Included in Governor's FY2018 Request	Out-Year Cost Estimates				
OPERATING EXPENDITURES	**FY 2018**	**FY 2018**	**FY 2019**	**FY 2020**	**FY 2021**	**FY 2022**	**FY 2023**
Personal Services							
Travel							
Services							
Commodities							
Capital Outlay							
Grants & Benefits							
Miscellaneous							
Total Operating	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Fund Source (Operating Only)							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**
Positions							
Full-time							
Part-time							
Temporary							
Change in Revenues							
None							
Total	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**	**0.0**

Estimated SUPPLEMENTAL (FY2017) cost: 0.0 *(separate supplemental appropriation required)*
(discuss reasons and fund source(s) in analysis section)

Estimated CAPITAL (FY2018) cost: 0.0 *(separate capital appropriation required)*
(discuss reasons and fund source(s) in analysis section)

ASSOCIATED REGULATIONS

Does the bill direct, or will the bill result in, regulation changes adopted by your agency? No
If yes, by what date are the regulations to be adopted, amended or repealed?

Why this fiscal note differs from previous version:

Not applicable; initial version.

Prepared By:	Jay C. Butler, MD, Chief Medical Officer/Director	Phone:	(907)269-6680
Division:	Public Health	Date:	01/23/2017 08:00 AM
Approved By:	Shawnda O'Brien, Acting Asst. Commissioner	Date:	01/23/17
Agency:	Health and Social Services		

FISCAL NOTE ANALYSIS

STATE OF ALASKA
2017 LEGISLATIVE SESSION

BILL NO. SB 20

Analysis

SB020 version "A" adds the synthetic opioid U-47700 (commonly known as "pink") as a Schedule IA controlled substance under AS 11.71.140(c).

This bill has zero fiscal impact for the Department of Health and Social Services. The department provides ongoing public education to prevent and reduce opioid misuse and abuse. Informing the public of the dangers of U-47700 can be accomplished within budgeted resources and does not require an appropriation.

State of Alaska Epidemiology **Bulletin**

Department of Health and Social Services
Valerie J. Davidson, Commissioner

3601 C Street, Suite 540
Anchorage, Alaska 99503 http://dhss.alaska.gov/dph/Epi

Division of Public Health
Jay C. Butler, MD, Chief Medical Officer and Director
Local (907) 269-8000
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Editors:
Joe McLaughlin, MD, MPH
Louisa Castrodale, DVM, MPH

Bulletin No. 28 November 7, 2016

Overview of Recent Synthetic Opioid Overdose Deaths

Introduction

In 2015, the U.S. Drug Enforcement Agency (DEA) and the Centers for Disease Control and Prevention (CDC) issued alerts concerning an increase in the number of fentanyl-related overdose deaths in multiple states, which was subsequently attributed to illicitly manufactured fentanyl (IMF) or "novel synthetic opioid" analogs.[1] These IMF analogs are commonly mixed with or sold as heroin. Depending on the type and manufacturing, IMFs can be many times more potent than prescription opioids. This *Bulletin* provides updated information about drug overdose deaths in Alaska due to heroin, fentanyl, and other synthetic opioids and presents four recent case reports of synthetic opioid overdoses.

Methods

The Alaska Violent Death Reporting System (AKVDRS) and the Alaska Bureau of Vital Statistics databases were queried to quantify the number of deaths due to heroin and synthetic opioid poisoning using the International Classification of Disease 10th Revision (ICD-10) Codes for drug poisoning and key words contained in text fields. Drug categories queried by ICD-10 codes included the following: 1) underlying causes for intentional, unintentional, and undetermined drug overdose (X40–44, X60–64, X85, and Y10–14), and 2) contributory causes for illicit drug overdose (T40.1 heroin, and T40.4 fentanyl and other synthetic opioids, other than methadone). Four of the cases were selected to highlight as case reports.

Results

From January 1, 2014 through September 15, 2016, 122 drug overdose deaths due to heroin and synthetic opioids were entered into the Alaska mortality database. Of the 122 drug overdose decedents, 78 (64%) were White, 15 (12%) were Asian/Pacific Islander, 4 (3%) were Alaska Native, and 4 (3%) were other races. The median age was 33 years (range: 18–73 years) and 71 (59%) were male. Most drug overdose deaths occurred in Anchorage/Mat-Su (61, 50%), followed by the Gulf Coast (19, 16%), and the Southeast (8, 7%).

Case Reports

- In November 2015, a young adult male was found unresponsive at his residence in the presence of recreational drug paraphernalia and a baggie of white powder. Initial postmortem toxicology testing was reported as negative. Additional testing indicated the presence of U-47700, a synthetic opioid.
- In May 2016, a male in his 30s was found unresponsive at his residence and was transported to emergency department (ED), where he died. Postmortem toxicology indicated the presence of etizolam, an illicit benzodiazepine-like drug, and U-47700.
- In August 2016, three people in a small community were found unresponsive due to apparent drug overdoses; of which, one victim died. Postmortem toxicology testing indicated the presence of heroin and fentanyl.
- In September 2016, a young adult male was found unresponsive at his residence and pronounced dead by EMS. Postmortem toxicology indicated the presence of U-47700.

Discussion

Three of the confirmed drug overdose death case reports involved U-47700, an opioid analog characterized as a "novel psychoactive substance" (NPS). Numerous overdose deaths nationwide have been caused by U-47700.[2] On September 7, 2016, the Drug Enforcement Administration issued a notice of intent to temporarily schedule U-47700 into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act.[3] While popular media outlets have drawn considerable attention to the emerging health threats of synthetic narcotics (e.g., fentanyl), synthetic cannabinoids (e.g., spice), and cathinones (e.g., bath salts), many additional NPS have been developed and are circulating on the black markets, sometimes without the customer's knowledge of what they are buying.[4]

Despite dedicated work to classify new synthetic opioids, many remain uncharacterized. Overdose deaths involving such uncategorized drugs are coded under a generic classification, "other ill-defined and unspecified causes of mortality".[5] When an overdose with an NPS is suspected, clinicians should consult with Alaska Poison Control Center (AKPCC) for the most current clinical information and with their reference laboratory for appropriate specimen collection. The Alaska State Public Health Laboratory (ASPHL) can provide additional analytical support for testing.

Table. Drug Overdose Deaths due to Heroin and Synthetic Opioids — Alaska, Jan. 1, 2014 through Sept. 15, 2016

Drug Overdose Categories	2014	2015	YTD* 2016	Total
Fentanyl or synthetic opioids other than methadone (with no other drugs)	1	3	2	6
Fentanyl or synthetic opioids other than methadone (with other drugs, excluding heroin)	13	11	4	28
Heroin (with no other drugs)	3	5	0	8
Heroin (with other drugs)	23	32	23	78
Heroin + fentanyl or synthetic opioids other than methadone (with no other drugs)	0	1	1	2
Total	40	52	30	122

**YTD = year to date (note: the number of deaths to date for 2016 will likely increase, as several pending cases are still under review)*

Recommendations

1. Health care providers should keep informed of the new types of synthetic opioids emerging nationally and current guidelines on emergency naloxone administration for overdoses. In some cases, greater than expected or repeated doses of naloxone may be required for reversal.
2. Report opioid poisoning to the AKPCC at 800-222-1222.
3. For more information on heroin and opioids in Alaska, see: http://dhss.alaska.gov/dph/Director/Pages/heroin-opioids/default.aspx

References

1. Peterson AB, Gladden RM, Delcher C, et al. Increases in fentanyl-related overdose deaths — Florida and Ohio, 2013–2015. *MMWR Morb Mortal Wkly Rep* 2016;65(33):844-849.
2. NMS. Toxicological Confirmation of Hundreds of Deaths Involving Novel Designer Opioids in the U.S. *Business Wire*. Available at: http://www.businesswire.com/news/home/20160914005894/en/NMS-Labs-Announces-Toxicological-Confirmation-Hundreds-Deaths
3. DEA. Schedules of Controlled Substances: Temporary Placement of U-47700 Into Schedule I. Available at: https://www.deadiversion.usdoj.gov/fed_regs/rules/2016/fr0907.htm
4. CDC. Injury Prevention & Control: Opioid Overdose. Available at: http://www.cdc.gov/drugoverdose/opioids/index.html
5. Section of Epidemiology. *Bulletin*. "Drug Overdose Deaths in Alaska, 2009–2015." No. 6, March 23, 2016. Available at: http://www.epi.alaska.gov/bulletins/docs/b2016_06.pdf

(Contributed by Christine Andrews, RN, MPH, and Deborah Hull-Jilly, MPH, Injury Surveillance Program, Section of Epidemiology; David Gibson, BS, Bureau of Vital Statistics; and David Verbrugge, BS, ASPHL Analytical Toxicology.)

Certification Office (ACO), FAA; or the Boeing Commercial Airplanes Organization Designation Authorization (ODA) that has been authorized by the Manager, Seattle ACO, to approve the part.

(ii) The replacement MOV actuator must be fully interchangeable with the part specified in Boeing Service Bulletin 777–28A0034, Revision 3, dated September 25, 2015.

(j) Credit for Previous Actions

(1) This paragraph provides credit for the requirements of paragraph (g) of this AD, if those actions were performed before the effective date of this AD using Boeing Special Attention Service Bulletin 777–28–0061, dated October 25, 2010; or Boeing Special Attention Service Bulletin 777–28–0061, Revision 1, dated January 26, 2012; as applicable. These documents are not incorporated by reference in this AD.

(2) This paragraph provides credit for the requirements of paragraph (i) of this AD, if those actions were performed before April 25, 2013 (the effective date of AD 2013–05–03, Amendment 39–17375 (78 FR 17290, March 21, 2013), "AD 2013–05–03"), using Boeing Alert Service Bulletin 777–28A0034, dated August 2, 2007; or Boeing Alert Service Bulletin 777–28A0034, Revision 1, dated May 20, 2010; except that the replacement of MOV actuators of the left and right engine fuel spar valves must also include cap sealing the bonding jumper, as described in Boeing Service Bulletin 777–28A0034, Revision 2, dated September 20, 2010; and provided that the replacement is an MOV actuator identified in paragraph (j)(2)(i) or (j)(2)(ii) of this AD. Boeing Alert Service Bulletin 777–28A0034, dated August 2, 2007, and Boeing Alert Service Bulletin 777–28A0034, Revision 1, dated May 20, 2010, are not incorporated by reference in this AD. Boeing Service Bulletin 777–28A0034, Revision 2, dated September 20, 2010, is incorporated by reference in AD 2013–05–03.

(i) An MOV actuator that has P/N MA30A1001, MA30A1017, or MA20A2027.

(ii) An MOV actuator that has a part number other than P/N MA20A1001–1 and meets the criteria specified in paragraphs (i)(2)(i) and (i)(2)(ii) of this AD.

(3) This paragraph provides credit for the requirements of paragraph (i) of this AD, if those actions were performed before the effective date of this AD using Boeing Service Bulletin 777–28A0034, Revision 2, dated September 20, 2010, which was incorporated by reference in AD 2013–05–03.

(k) Alternative Methods of Compliance (AMOCs)

(1) The Manager, Seattle ACO, FAA, has the authority to approve AMOCs for this AD, if requested using the procedures found in 14 CFR 39.19. In accordance with 14 CFR 39.19, send your request to your principal inspector or local Flight Standards District Office, as appropriate. If sending information directly to the manager of the ACO, send it to the attention of the person identified in paragraph (l)(1) of this AD. Information may be emailed to: *9-ANM-Seattle-ACO-AMOC-Requests@faa.gov.*

(2) Before using any approved AMOC, notify your appropriate principal inspector, or lacking a principal inspector, the manager of the local flight standards district office/certificate holding district office.

(3) An AMOC that provides an acceptable level of safety may be used for any repair, modification, or alteration required by this AD if it is approved by the Boeing Commercial Airplanes ODA that has been authorized by the Manager, Seattle ACO, to make those findings. To be approved, the repair method, modification deviation, or alteration deviation must meet the certification basis of the airplane and the approval must specifically refer to this AD.

(l) Related Information

(1) For more information about this AD, contact Brendan Shanley, Aerospace Engineer, Systems and Equipment Branch, ANM–130S, FAA, Seattle Aircraft Certification Office, 1601 Lind Avenue SW., Renton, WA 98057–3356; telephone: 425–917–6492; fax: 425–917–6590; email: *brendan.shanley@faa.gov.*

(2) Service information identified in this AD that is not incorporated by reference is available at the addresses specified in paragraphs (m)(3) and (m)(4) of this AD.

(m) Material Incorporated by Reference

(1) The Director of the Federal Register approved the incorporation by reference (IBR) of the service information listed in this paragraph under 5 U.S.C. 552(a) and 1 CFR part 51.

(2) You must use this service information as applicable to do the actions required by this AD, unless the AD specifies otherwise.

(i) Boeing Special Attention Service Bulletin 777–28–0061, Revision 2, dated May 4, 2015.

(ii) Boeing Service Bulletin 777–28A0034, Revision 3, dated September 25, 2015.

(3) For Boeing service information identified in this AD, contact Boeing Commercial Airplanes, Attention: Data & Services Management, P.O. Box 3707, MC 2H–65, Seattle, WA 98124–2207; telephone 206–544–5000, extension 1; fax 206–766–5680; Internet *https://www.myboeingfleet.com.*

(4) You may view this service information at FAA, Transport Airplane Directorate, 1601 Lind Avenue SW., Renton, WA. For information on the availability of this material at the FAA, call 425–227–1221.

(5) You may view this service information that is incorporated by reference at the National Archives and Records Administration (NARA). For information on the availability of this material at NARA, call 202–741–6030, or go to: *http://www.archives.gov/federal-register/cfr/ibr-locations.html.*

Issued in Renton, Washington, on October 7, 2016.

Michael Kaszycki,

Acting Manager, Transport Airplane Directorate, Aircraft Certification Service.

[FR Doc. 2016–25491 Filed 11–10–16; 8:45 am]

BILLING CODE 4910–13–P

DEPARTMENT OF JUSTICE

Drug Enforcement Administration

21 CFR Part 1308

[Docket No. DEA–440]

Schedules of Controlled Substances: Temporary Placement of U–47700 Into Schedule I

AGENCY: Drug Enforcement Administration, Department of Justice.

ACTION: Final order.

SUMMARY: The Administrator of the Drug Enforcement Administration is issuing this final order to temporarily schedule the synthetic opioid, 3,4-dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide (also known as U–47700), and its isomers, esters, ethers, salts and salts of isomers, esters and ethers, into schedule I pursuant to the temporary scheduling provisions of the Controlled Substances Act. This action is based on a finding by the Administrator that the placement of U–47700 into schedule I of the Controlled Substances Act is necessary to avoid an imminent hazard to the public safety. As a result of this order, the regulatory controls and administrative, civil, and criminal sanctions applicable to schedule I controlled substances will be imposed on persons who handle (manufacture, distribute, reverse distribute, import, export, engage in research, conduct instructional activities or chemical analysis, or possess), or propose to handle, U–47700.

DATES: This final order is effective on November 14, 2016.

FOR FURTHER INFORMATION CONTACT: Michael J. Lewis, Diversion Control Division, Drug Enforcement Administration; Mailing Address: 8701 Morrissette Drive, Springfield, Virginia 22152; Telephone: (202) 598–6812.

SUPPLEMENTARY INFORMATION:

Legal Authority

The Drug Enforcement Administration (DEA) implements and enforces titles II and III of the Comprehensive Drug Abuse Prevention and Control Act of 1970, as amended. 21 U.S.C. 801–971. Titles II and III are referred to as the "Controlled Substances Act" and the "Controlled Substances Import and Export Act," respectively, and are collectively referred to as the "Controlled Substances Act" or the "CSA" for the purpose of this action. The DEA publishes the implementing regulations

for these statutes in title 21 of the Code of Federal Regulations (CFR), chapter II. The CSA and its implementing regulations are designed to prevent, detect, and eliminate the diversion of controlled substances and listed chemicals into the illicit market while ensuring an adequate supply is available for the legitimate medical, scientific, research, and industrial needs of the United States. Controlled substances have the potential for abuse and dependence and are controlled to protect the public health and safety.

Under the CSA, every controlled substance is classified into one of five schedules based upon its potential for abuse, its currently accepted medical use in treatment in the United States, and the degree of dependence the drug or other substance may cause. 21 U.S.C. 812. The initial schedules of controlled substances established by Congress are found at 21 U.S.C. 812(c), and the current list of all scheduled substances is published at 21 CFR part 1308.

Section 201 of the CSA, 21 U.S.C. 811, provides the Attorney General with the authority to temporarily place a substance into schedule I of the CSA for two years without regard to the requirements of 21 U.S.C. 811(b) if she finds that such action is necessary to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h)(1). In addition, if proceedings to control a substance are initiated under 21 U.S.C. 811(a)(1), the Attorney General may extend the temporary scheduling for up to one year. 21 U.S.C. 811(h)(2).

Where the necessary findings are made, a substance may be temporarily scheduled if it is not listed in any other schedule under section 202 of the CSA, 21 U.S.C. 812, or if there is no exemption or approval in effect for the substance under section 505 of the Federal Food, Drug, and Cosmetic Act (FDCA), 21 U.S.C. 355. 21 U.S.C. 811(h)(1). The Attorney General has delegated her scheduling authority under 21 U.S.C. 811 to the Administrator of the DEA. 28 CFR 0.100.

Background

Section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), requires the Administrator to notify the Secretary of the Department of Health and Human Services (HHS) of his intention to temporarily place a substance into schedule I of the CSA.[1] The Administrator transmitted the notice of intent to place U–47700 into schedule I on a temporary basis to the Assistant Secretary by letter dated April 18, 2016. The Assistant Secretary responded to this notice by letter dated April 28, 2016, and advised that based on review by the Food and Drug Administration (FDA), there are currently no investigational new drug applications or approved new drug applications for U–47700. The Assistant Secretary also stated that the HHS has no objection to the temporary placement of U–47700 into schedule I of the CSA. The DEA has taken into consideration the Assistant Secretary's comments as required by 21 U.S.C. 811(h)(4). U–47700 is not currently listed in any schedule under the CSA, and no exemptions or approvals are in effect for U–47700 under section 505 of the FDCA, 21 U.S.C. 355. The DEA has found that the control of U–47700 in schedule I on a temporary basis is necessary to avoid an imminent hazard to the public safety, and as required by 21 U.S.C. 811(h)(1)(A), a notice of intent to temporarily schedule U–47700 was published in the **Federal Register** on September 7, 2016. 81 FR 61636.

To find that placing a substance temporarily into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety, the Administrator is required to consider three of the eight factors set forth in section 201(c) of the CSA, 21 U.S.C. 811(c): The substance's history and current pattern of abuse; the scope, duration and significance of abuse; and what, if any, risk there is to the public health. 21 U.S.C. 811(h)(3). Consideration of these factors includes actual abuse, diversion from legitimate channels, and clandestine importation, manufacture, or distribution. 21 U.S.C. 811(h)(3).

A substance meeting the statutory requirements for temporary scheduling may only be placed into schedule I. 21 U.S.C. 811(h)(1). Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. 21 U.S.C. 812(b)(1). Available data and information for U–47700, summarized below, indicate that this synthetic opioid has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. The DEA's updated three-factor analysis, and the Assistant Secretary's April 28, 2016, letter, are available in their entirety under the tab "Supporting Documents" of the public docket of this action at *www.regulations.gov* under FDMS Docket ID: DEA–2016–0016 (Docket Number DEA–440).

Factor 4. History and Current Pattern of Abuse

The recreational abuse of novel opioids continues to be a significant concern. These substances are distributed to users with often unpredictable outcomes. The novel synthetic opioid U–47700 has recently been encountered by law enforcement and public health officials and the adverse health effects and outcomes are documented in the scientific literature. Self-reporting by users describes the effects of U–47700 to be similar to other opioids. The negative effects documented in the scientific literature are also consistent with other opioids. The National Forensic Laboratory Information System (NFLIS) is a national drug forensic laboratory reporting system that systematically collects results from drug chemistry analyses conducted by participating Federal, State, and local forensic laboratories across the country. The DEA utilizes NFLIS to monitor for drug trends. The first laboratory submission of U–47700 was recorded in October 2015; a total of 88 records were reported from State and local forensic laboratories between October 2015—September 2016 according to NFLIS (query date: October 24, 2016).

On October 1, 2014, the DEA implemented STARLiMS (a web-based, commercial laboratory information management system) as its laboratory drug evidence data system of record. DEA laboratory data submitted after September 30, 2014, are reposited in STARLiMS; data from STARLiMS were queried on November 1, 2016. STARLiMS registered 45 reports containing U–47700 in 2016 from California, Connecticut, Florida, Maryland, Montana, North Dakota, New Jersey, New York, Tennessee, Texas, Virginia, West Virginia, and the District of Columbia. Through information collected from NFLIS, law enforcement reports, and email communications, the DEA is aware of the identification of U–47700 from toxicology reports and submitted evidence to forensic laboratories in several states, including Arkansas, California, Colorado, Connecticut, Florida, Georgia, Iowa, Kentucky, Missouri, Montana, New

[1] As discussed in a memorandum of understanding entered into by the Food and Drug Administration (FDA) and the National Institute on Drug Abuse (NIDA), the FDA acts as the lead agency within the HHS in carrying out the Secretary's scheduling responsibilities under the CSA, with the concurrence of NIDA. 50 FR 9518, Mar. 8, 1985. The Secretary of the HHS has delegated to the Assistant Secretary for Health of the HHS the authority to make domestic drug scheduling recommendations. 58 FR 35460, July 1, 1993.

Hampshire, New Jersey, New York, North Carolina, North Dakota, Ohio, Oklahoma, Oregon, Pennsylvania, Texas, and Wisconsin. These identifications occurred in 2015 and 2016.

Evidence suggests that the pattern of abuse of U–47700 parallels that of heroin, prescription opioid analgesics, and other novel opioids. Seizures of U–47700 have been encountered in powder form and in counterfeit tablets that mimic pharmaceutical opioids. U–47700 has also been encountered in glassine bags and envelopes and knotted corners of plastic bags. These clandestine forms of distribution demonstrate the abuse of this substance as a replacement for heroin or other opioids, either knowingly or unknowingly. Further, U–47700 has been encountered as a single substance as well as in combination with other substances, including heroin, fentanyl, and furanyl fentanyl in drug exhibits.

The scientific literature and information collected by DEA demonstrate U–47700 is being abused for its opioid properties. The distribution of U–47700 and the increased prevalence of abuse remain deeply concerning to the DEA.

Factor 5. Scope, Duration and Significance of Abuse

The scientific literature and reports collected by the DEA demonstrate U–47700 is being abused for its opioid properties. This abuse of U–47700 has resulted in morbidity and mortality (see updated DEA 3-Factor Analysis for full discussion). The DEA has received reports for at least 46 confirmed fatalities [2] associated with U–47700. The information on these deaths occurring in 2015 and 2016 was collected from email communications and toxicology and medical examiner reports and was reported from New Hampshire (1), New York (31), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1). The scientific literature notes additional fatal overdoses connected to U–47700. The population likely to abuse U–47700 appears to overlap with the populations abusing prescription opioid analgesics, other "designer opioids," and heroin, as evidenced by drug use history documented in U–47700 fatal overdose cases. This observation is further supported by U–47700 being sold on the illicit market in glassine bags, some of which are marked with stamped logos, imitating the sale of heroin.

[2] Due to a proofreading error, the number of fatalities listed in the U–47700 NOI, which was 15, is incorrect. The correct number, 46, has been added to this Final Order.

Additionally, U–47700 has been found in counterfeit pills. Because abusers of U–47700 are likely to obtain this substance through non-regulated sources (*i.e.*, on-line purchases or drug dealers), the identity, purity, and quantity are uncertain and inconsistent, thus posing significant adverse health risks to the end user. Individuals who initiate (*i.e.*, use a drug for the first time) U–47700 abuse are likely to be at risk of developing substance use disorder, overdose, and death similar to that of other opioid analgesics (*e.g.*, fentanyl, morphine, etc.).

STARLiMS contains 45 reports in which U–47700 was identified in drug exhibits submitted in 2016. A query of NFLIS returned 88 records of U–47700 being identified in exhibits submitted to State and local forensic laboratories between October 2015—September 2016. The DEA is not aware of any laboratory analyses of drug evidence identifying U–47700 prior to 2015, indicating that this synthetic opioid only recently became available as a replacement for other opioids that are commonly abused (*i.e.* oxycodone, heroin, fentanyl). U–47700 is available over the Internet and is marketed as a "research chemical." The on-line sale and marketing of U–47700 are similar to other new psychoactive substances that have rapidly appeared on the recreational drug market and also resulted in negative consequences for the user.

Factor 6. What, if Any, Risk There Is to the Public Health

U–47700 exhibits pharmacological profiles similar to that of morphine and other mu-opioid receptor agonists. Cases of intoxication are reported in the literature with morbidity and mortality associated with U–47700 use. The toxic effects of U–47700 in humans are demonstrated by overdoses and overdose fatalities associated with this substance, as reported in the scientific literature. Abusers of U–47700 may not know the origin, identity, or purity of this substance, thus posing significant adverse health risks when compared to abuse of pharmaceutical preparations of opioid analgesics, such as morphine and oxycodone. Additionally, the potent opioid U–47700 may serve as a precursor to problematic opioid use and dependence.

Based on reports in the scientific literature and information received by the DEA, the abuse of U–47700 leads to the same qualitative public health risks as heroin, fentanyl and other opioid analgesic substances. As with any non-medically approved opioid, the health and safety risks for users are great. The public health risks attendant to the abuse of heroin and opioid analgesics are well established and have resulted in large numbers of drug treatment admissions, emergency department visits, and fatal overdoses.

U–47700 has been associated with a number of fatalities and non-fatal overdoses as detailed in the scientific literature. The DEA has received information connecting U–47700 to at least 46 confirmed overdose deaths, occurring in 2015 and 2016 in New Hampshire (1), New York (31), North Carolina (10), Ohio (1), Texas (2), and Wisconsin (1).

Finding of Necessity of Schedule I Placement To Avoid Imminent Hazard to Public Safety

In accordance with 21 U.S.C. 811(h)(3), based on the data and information summarized above, the continued uncontrolled manufacture, distribution, importation, exportation, and abuse of U–47700 pose an imminent hazard to the public safety. The DEA is not aware of any currently accepted medical uses for this substance in the United States. A substance meeting the statutory requirements for temporary scheduling, 21 U.S.C. 811(h)(1), may only be placed into schedule I. Substances in schedule I are those that have a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. Available data and information for U–47700 indicate that this substance has a high potential for abuse, no currently accepted medical use in treatment in the United States, and a lack of accepted safety for use under medical supervision. As required by section 201(h)(4) of the CSA, 21 U.S.C. 811(h)(4), the Administrator, through a letter dated April 18, 2016, notified the Assistant Secretary of the DEA's intention to temporarily place this substance into schedule I.

Conclusion

In accordance with the provisions of section 201(h) of the CSA, 21 U.S.C. 811(h), the Administrator considered available data and information, herein sets forth the grounds for his determination that it is necessary to temporarily schedule U–47700 into schedule I of the CSA, and finds that placement of this synthetic opioid into schedule I of the CSA is necessary to avoid an imminent hazard to the public safety. Because the Administrator hereby finds it necessary to temporarily place this synthetic opioid into schedule I to avoid an imminent hazard

to the public safety, this final order temporarily scheduling U–47700 will be effective on the date of publication in the **Federal Register**, and will be in effect for a period of two years, with a possible extension of one additional year, pending completion of the regular (permanent) scheduling process. 21 U.S.C. 811(h) (1) and (2).

The CSA sets forth specific criteria for scheduling a drug or other substance. Permanent scheduling actions in accordance with 21 U.S.C. 811(a) are subject to formal rulemaking procedures done "on the record after opportunity for a hearing" conducted pursuant to the provisions of 5 U.S.C. 556 and 557. 21 U.S.C. 811. The permanent scheduling process of formal rulemaking affords interested parties with appropriate process and the government with any additional relevant information needed to make a determination. Final decisions that conclude the permanent scheduling process of formal rulemaking are subject to judicial review. 21 U.S.C. 877. Temporary scheduling orders are not subject to judicial review. 21 U.S.C. 811(h)(6).

Requirements for Handling

Upon the effective date of this final order, U–47700 will become subject to the regulatory controls and administrative, civil, and criminal sanctions applicable to the manufacture, distribution, reverse distribution, importation, exportation, engagement in research, and conduct of instructional activities or chemical analysis with, and possession of schedule I controlled substances including the following:

1. *Registration.* Any person who handles (manufactures, distributes, reverse distributes, imports, exports, engages in research, or conducts instructional activities or chemical analysis with, or possesses), or who desires to handle, U–47700 must be registered with the DEA to conduct such activities pursuant to 21 U.S.C. 822, 823, 957, and 958 and in accordance with 21 CFR parts 1301 and 1312, as of November 14, 2016. Any person who currently handles U–47700, and is not registered with the DEA, must submit an application for registration and may not continue to handle U–47700 as of November 14, 2016, unless the DEA has approved that application for registration pursuant to 21 U.S.C. 822, 823, 957, 958, and in accordance with 21 CFR parts 1301 and 1312. Retail sales of schedule I controlled substances to the general public are not allowed under the CSA. Possession of any quantity of this substance in a manner not authorized by the CSA on or after November 14, 2016 is unlawful and those in possession of any quantity of this substance may be subject to prosecution pursuant to the CSA.

2. *Disposal of stocks.* Any person who does not desire or is not able to obtain a schedule I registration to handle U–47700, must surrender all quantities of currently held U–47700.

3. *Security.* U–47700 is subject to schedule I security requirements and must be handled and stored pursuant to 21 U.S.C. 821, 823, 871(b), and in accordance with 21 CFR 1301.71–1301.93, as of November 14, 2016.

4. *Labeling and packaging.* All labels, labeling, and packaging for commercial containers of U–47700 must be in compliance with 21 U.S.C. 825, 958(e), and be in accordance with 21 CFR part 1302. Current DEA registrants shall have 30 calendar days from November 14, 2016, to comply with all labeling and packaging requirements.

5. *Inventory.* Every DEA registrant who possesses any quantity of U–47700 on the effective date of this order must take an inventory of all stocks of this substance on hand, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all inventory requirements. After the initial inventory, every DEA registrant must take an inventory of all controlled substances (including U–47700) on hand on a biennial basis, pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR 1304.03, 1304.04, and 1304.11.

6. *Records.* All DEA registrants must maintain records with respect to U–47700 pursuant to 21 U.S.C. 827 and 958, and in accordance with 21 CFR parts 1304, and 1312, 1317 and § 1307.11. Current DEA registrants shall have 30 calendar days from the effective date of this order to be in compliance with all recordkeeping requirements.

7. *Reports.* All DEA registrants who manufacture or distribute U–47700 must submit reports pursuant to 21 U.S.C. 827 and in accordance with 21 CFR parts 1304, and 1312 as of November 14, 2016.

8. *Order Forms.* All DEA registrants who distribute U–47700 must comply with order form requirements pursuant to 21 U.S.C. 828 and in accordance with 21 CFR part 1305 as of November 14, 2016.

9. *Importation and Exportation.* All importation and exportation of U–47700 must be in compliance with 21 U.S.C. 952, 953, 957, 958, and in accordance with 21 CFR part 1312 as of November 14, 2016.

10. *Quota.* Only DEA registered manufacturers may manufacture U–47700 in accordance with a quota assigned pursuant to 21 U.S.C. 826 and in accordance with 21 CFR part 1303 as of November 14, 2016.

11. *Liability.* Any activity involving U–47700 not authorized by, or in violation of the CSA, occurring as of November 14, 2016, is unlawful, and may subject the person to administrative, civil, and/or criminal sanctions.

Regulatory Matters

Section 201(h) of the CSA, 21 U.S.C. 811(h), provides for a temporary scheduling action where such action is necessary to avoid an imminent hazard to the public safety. As provided in this subsection, the Attorney General may, by order, schedule a substance in schedule I on a temporary basis. Such an order may not be issued before the expiration of 30 days from (1) the publication of a notice in the **Federal Register** of the intention to issue such order and the grounds upon which such order is to be issued, and (2) the date that notice of the proposed temporary scheduling order is transmitted to the Assistant Secretary. 21 U.S.C. 811(h)(1).

Inasmuch as section 201(h) of the CSA directs that temporary scheduling actions be issued by order and sets forth the procedures by which such orders are to be issued, the DEA believes that the notice and comment requirements of the Administrative Procedure Act (APA) at 5 U.S.C. 553, do not apply to this temporary scheduling action. In the alternative, even assuming that this action might be subject to 5 U.S.C. 553, the Administrator finds that there is good cause to forgo the notice and comment requirements of 5 U.S.C. 553, as any further delays in the process for issuance of temporary scheduling orders would be impracticable and contrary to the public interest in view of the manifest urgency to avoid an imminent hazard to the public safety.

Further, the DEA believes that this temporary scheduling action is not a "rule" as defined by 5 U.S.C. 601(2), and, accordingly, is not subject to the requirements of the Regulatory Flexibility Act. The requirements for the preparation of an initial regulatory flexibility analysis in 5 U.S.C. 603(a) are not applicable where, as here, the DEA is not required by the APA or any other law to publish a general notice of proposed rulemaking.

Additionally, this action is not a significant regulatory action as defined by Executive Order 12866 (Regulatory Planning and Review), section 3(f), and, accordingly, this action has not been

reviewed by the Office of Management and Budget (OMB).

This action will not have substantial direct effects on the States, on the relationship between the national government and the States, or on the distribution of power and responsibilities among the various levels of government. Therefore, in accordance with Executive Order 13132 (Federalism) it is determined that this action does not have sufficient federalism implications to warrant the preparation of a Federalism Assessment.

As noted above, this action is an order, not a rule. Accordingly, the Congressional Review Act (CRA) is inapplicable, as it applies only to rules. However, if this were a rule, pursuant to the Congressional Review Act, "any rule for which an agency for good cause finds that notice and public procedure thereon are impracticable, unnecessary, or contrary to the public interest, shall take effect at such time as the federal agency promulgating the rule determines." 5 U.S.C. 808(2). It is in the public interest to schedule this substance immediately because it poses a public health risk. This temporary scheduling action is taken pursuant to 21 U.S.C. 811(h), which is specifically designed to enable the DEA to act in an expeditious manner to avoid an imminent hazard to the public safety. 21 U.S.C. 811(h) exempts the temporary scheduling order from standard notice and comment rulemaking procedures to ensure that the process moves swiftly. For the same reasons that underlie 21 U.S.C. 811(h), that is, the DEA's need to move quickly to place this substance into schedule I because it poses an imminent hazard to the public safety and it would be contrary to the public interest to delay implementation of the temporary scheduling order. Therefore, this order shall take effect immediately upon its publication. The DEA has submitted a copy of this final order to both Houses of Congress and to the Comptroller General, although such filing is not required under the Small Business Regulatory Enforcement Fairness Act of 1996 (Congressional Review Act), 5 U.S.C. 801–808, because, as noted above, this action is an order, not a rule.

List of Subjects in 21 CFR Part 1308

Administrative practice and procedure, Drug traffic control, Reporting and recordkeeping requirements.

For the reasons set out above, the DEA amends 21 CFR part 1308 as follows:

PART 1308—SCHEDULES OF CONTROLLED SUBSTANCES

■ 1. The authority citation for part 1308 continues to read as follows:

Authority: 21 U.S.C. 811, 812, 871(b), unless otherwise noted.

■ 2. Amend § 1308.11 by adding paragraph (h)(18) to read as follows:

§ 1308.11 Schedule I.

* * * * *

(h) * * *

(18) 3,4-Dichloro-*N*-[2-(dimethylamino)cyclohexyl]-*N*-methylbenzamide, its isomers, esters, ethers, salts and salts of isomers, esters and ethers (Other name: U–47700) ..... (9547)

* * * * *

Dated: November 7, 2016.

Chuck Rosenberg,

Acting Administrator.

[FR Doc. 2016–27357 Filed 11–10–16; 8:45 am]

BILLING CODE 4410–09–P

DEPARTMENT OF HOMELAND SECURITY

Coast Guard

33 CFR Part 117

[Docket No. USCG–2016–1008]

Drawbridge Operation Regulation; Great Channel, New Jersey Intracoastal Waterway, Stone Harbor, NJ

AGENCY: Coast Guard, DHS.

ACTION: Notice of deviation from drawbridge regulation.

SUMMARY: The Coast Guard has issued a temporary deviation from the operating schedule that governs the Stone Harbor Boulevard (CR657) Bridge across the Great Channel, mile 102.0, New Jersey Intracoastal Waterway, at Stone Harbor, NJ. This deviation is necessary to avoid bridge failure and perform emergency bridge repairs. This deviation allows the bridge to remain in the closed-to-navigation position.

DATES: This deviation is effective without actual notice from November 14, 2016 through 4 p.m. on December 2, 2016. For the purposes of enforcement, actual notice will be used from November 8, 2016, until November 14, 2016.

ADDRESSES: The docket for this deviation, [USCG–2016–1008] is available at *http://www.regulations.gov.* Type the docket number in the "SEARCH" box and click "SEARCH". Click on Open Docket Folder on the line associated with this deviation.

FOR FURTHER INFORMATION CONTACT: If you have questions on this temporary deviation, call or email Mr. Hal R. Pitts, Bridge Administration Branch Fifth District, Coast Guard, telephone 757–398–6222, email *Hal.R.Pitts@uscg.mil.*

SUPPLEMENTARY INFORMATION: The County of Cape May, NJ, that owns and operates the Stone Harbor Boulevard (CR657) Bridge across the Great Channel, mile 102.0, New Jersey Intracoastal Waterway, at Stone Harbor, NJ, has requested a temporary deviation from the current operating regulations to avoid bridge failure and perform emergency repairs to the bridge, due to a serious crack in one of two main bridge girders, causing the bridge to be unsafe for vehicular traffic and movement of the bascule spans. The bridge is a bascule drawbridge and has a vertical clearance in the closed position of 10 feet above mean high water.

The current operating schedule is set out in 33 CFR 117.733(h). Under this temporary deviation, the bridge will remain in the closed-to-navigation position until 4 p.m. on December 2, 2016.

The Great Channel, New Jersey Intracoastal Waterway is used by a variety of vessels including small public vessels, small commercial vessels, tug and barge traffic, and recreational vessels. The Coast Guard has carefully considered the nature and volume of vessel traffic on the waterway in publishing this temporary deviation.

Vessels able to safely pass through the bridge in the closed position may do so at any time. The bridge will not be able to open for emergencies and there is no immediate alternate route for vessels to pass. The Coast Guard will also inform the users of the waterways through our Local and Broadcast Notices to Mariners of the change in operating schedule for the bridge so that vessel operators can arrange their transit to minimize any impact caused by the temporary deviation.

In accordance with 33 CFR 117.35(e), the drawbridge must return to its regular operating schedule immediately at the end of the effective period of this temporary deviation. This deviation from the operating regulations is authorized under 33 CFR 117.35.

Dated: November 8, 2016.

Hal R. Pitts,

Bridge Program Manager, Fifth Coast Guard District.

[FR Doc. 2016–27281 Filed 11–10–16; 8:45 am]

BILLING CODE 9110–04–P

NEWS AMERICA'S HEROIN EPIDEMIC OCT 15 2016, 5:05 AM ET

Pink: Stronger Than Heroin, But Legal In Most States

by ANDREW BLANKSTEIN

Editor's Note: *An earlier version of this story included a photo of Ryan Ainsworth's brother and mistakenly identified him as Ryan, who is deceased. NBC News has removed the photo and regrets the error.*

Two 13-year-old boys in the ski town of Park City, Utah died within 48 hours of each other in September, likely overdosing on a powerful heroin substitute that had been delivered — legally — to their homes by the U.S. mail, and is now turning up in cities across the nation.

Ryan Ainsworth was found dead on his couch two days after his best friend Grant Seaver passed away. "I wish I had been better warned," sang one of their friends at a massive memorial service. "But now it's too late."

The death toll could have been worse, say investigators, since as many as 100 Park City students had apparently been discussing the drug "Pink" on SnapChat and other social media.

"This stuff is so powerful that if you touch it, you could go into cardiac arrest," Park City Police Chief Wade Carpenter told NBC News. "The problem is if you have a credit card and a cell phone, you have access to it."

One toxicology lab has linked 80 deaths to the synthetic opioid known as Pink. DEA

Pink, better known by chemists as U-47700, is eight times stronger than heroin, and is part of a family of deadly synthetic opioids, all of them more powerful than heroin, that includes ifentanyl, carfentanil and furanyl fentanyl. By themselves or mixed with other drugs, in forms ranging from pills to powder to mists, they're killing thousands of people across the country, say law enforcement and health officials. The powerful, ersatz opioids are part of a surge of synthetic drugs,

including bath salts and mock-ups of ecstasy, being shipped into the U.S. from China and other nations.

So far, however, only four states have made Pink illegal. It can still be ordered legally on-line and delivered to your home. The internet has many websites a Google search away where the drug is available for as little as $5 plus shipping.

Melissa Davidson, mother of a Park City teen who had friends in common with the dead boys, showed NBC News on her home computer screen how easy it was to find the drug for sale with just a few keystrokes. "Look! There are like pages and pages that you can buy this stuff online."

According to the U.S. Centers for Disease Control, total opioid overdose deaths nearly quadrupled between 1999 and 2014, rising from 8,050 to 28,647. The portion of those deaths caused by synthetic opioids, however, rose almost twice as fast, from just 730 in 1999 to 5,544 in 2014.

Because of the surge in opioid-related deaths, and the regular appearance of new synthetics on the market, there is a time lag in toxicology reports from coroners, and the possibility that some deaths are mistakenly linked to other, better known substances. But Pink, a relative newcomer among the synthetics, has been implicated in 80 deaths across the country in just the past nine months, according to Pennsylvania-based NMS Labs, which conducts forensic toxicology tests.

The Drug Enforcement Administration said it is aware of confirmed fatalities associated with U-47700 in New Hampshire, North Carolina, Ohio, Texas, and Wisconsin. Though its own tally is only 15 deaths, an agency spokesperson said the number was probably higher because of challenges and delays in reporting.

On Sept. 7, the DEA took initial steps toward banning the drug nationally by giving notice of its intent to schedule the synthetic opioid temporarily as a Schedule 1 substance under the federal Controlled Substances Act.

Some states aren't waiting for a permanent federal ban. In late September, Florida Attorney General Pam Bondi signed an emergency order outlawing the drug after it was tied to eight deaths in recent months.

Melissa Davidson and her daughter Jane Moyes of Park City, Utah. NBC News

Florida joins Ohio, Wyoming and Georgia in outlawing the compound and other states are looking to do the same.

In some states, law enforcement is just learning about a threat that is especially challenging because so many transactions are done by computer and through the mail. And the chemists who manufacture the drugs can invent new variants as fast as the states can outlaw them.

"The hardest part is when something new comes up, and no one in the country or world has seen it in a forensic setting yet and trying to decide what that actual structure or drug is," said Bryan Holden, senior forensic scientist with the Utah Department of Public Safety. "Sometimes we have had cases where the substance sat for months and months -- no one had ever seen it before, and until someone else sees it or manufactures it then we kind of know what it is."

The DEA has been using so-called temporary bans more and more often to combat designer synthetic drugs have made their way into the U.S. from China and other parts of the world. The U47700 ban allows them three years to research whether something should be permanently controlled or whether it should revert back to non-controlled status.

But experts say the most effective prevention may start in the home, at the computer and the mailbox.

"I'm worried about you," Melissa Davidson told her 17-year-old daughter Jane.

Jane, however, was worried about her friends at school. "I can't imagine the kids I'm in math class with, just not being there one day. One bad decision can have permanent consequences."

This Is U-47700, Once a Lab Experiment, Now a Killer Opioid

The synthetic drug, born of pharmaceutical research, has been co-opted by overseas laboratories to feed America's addiction—and evade U.S. law enforcement

By Jon Kamp and Arian Campo-Flores

PITTSBURGH—Ray and Christine Henney grew anxious when their 25-year-old son, R.J., didn't respond to text messages late one April night.

Mr. Henney drove to his son's apartment near the University of Pittsburgh, where R.J. studied chemistry, early the next morning. The front door was locked, so he climbed a fire escape and jimmied open R.J.'s third-floor window.

He found R.J.'s lifeless body slumped over a desk, face down on a laptop keyboard. Scattered nearby were several syringes and powdery substances. A toxicology test later found that R.J. died of a drug cocktail that included an obscure synthetic opioid called U-47700, a relic of 1970s pharmaceutical research that was never brought to market.

"It was crushing," the father says. "It was the saddest thing I ever saw."

It was also a legal gray area. The narcotics found in R.J.'s system included compounds so novel that the Drug Enforcement Administration didn't move to ban them until five months after his death.

In a high-stakes game of cat-and-mouse, overseas labs are churning out new synthetic drugs at a furious pace, often staying a step ahead of authorities and helping to fuel America's rampant opioid crisis.

R.J. Henney in family photos. *PHOTO: JEFF SWENSEN FOR THE WALL STREET JOURNAL*

The United Nations Commission on Narcotic Drugs estimates that "new psychoactive substances"—a broad list that includes synthetic opioids—are emerging globally at an average rate of one a week. As with U-47700, rogue chemists sometimes piggyback on research by legitimate scientists that was abandoned before making it to the legal market.

"We're seeing a whole unknown group of poisons being sold as potent opiate drugs or as heroin substitutes," says James Hall, an epidemiologist at the Center for Applied Research on Substance Use and Health Disparities in Miami. Most are chemical spinoffs of the powerful painkiller fentanyl.

Synthetic opioids are often more deadly than other kinds of common designer drugs, such as artificial cannabinoids or stimulants known as bath salts. Some opioids have flared up before—fentanyl variants caused problems on the West Coast in the late 1970s and 1980s—and they are roaring back at a perilous time.

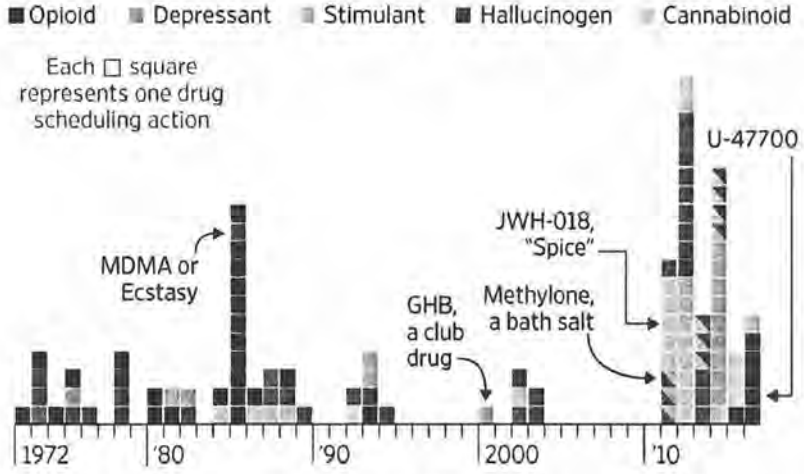
"What makes this more dangerous and more concerning is the already widespread abuse of opioids in the United States," says Jill Head, supervisory chemist at the DEA. "It just adds to an already-saturated market."

Heroin, painkillers and other opioids killed more than 28,000 people in the U.S. in 2014, the most recent year for which nationwide data is available, according to the

Dangerous Recipes

Drugs added to Schedule I, the most restrictive U.S. category, by the DEA and Congress since passage of the 1970 Controlled Substances Act

Scheduling actions by type of drug



Note: Drugs can fall under multiple categories; i.e. Methylone is a stimulant and hallucinogen
Actions are in chronological order from top to bottom.
Source: WSJ analysis of Drug Enforcement Administration data and federal legislation
THE WALL STREET JOURNAL.

Centers for Disease Control and Prevention. Data from many hard-hit states show the overdose problem, already at record levels, continues to worsen.

The designer opioids mainly come from Chinese labs, the DEA says, and many labs sell them openly in online drug bazaars. On online forums, people compare notes on their experiences using the synthetics. The web "really develops the market for this stuff in the U.S.," says Gary Tuggle, special agent in charge of the DEA's Philadelphia division.

The U.S. surveillance system for these chemicals is a largely informal network of crime labs, medical examiners and law-enforcement authorities who share clues and alert each other when they find something new. It can be a laborious task, slowed in part by the challenge of finding something they didn't know they were looking for.

The U.S. government—including Congress and the DEA—has added more than 100 drugs to Schedule I, the category for chemicals the DEA says don't have a medical purpose and pose a significant abuse risk, since passing the Controlled Substances Act in 1970. This has long been largely reactive, fueled by drug producers intent on evading the law.

"That's the challenge here for the DEA," says Larry Cote, a former associate chief counsel in the DEA's Diversion and Regulatory Litigation Section, who is now a

partner with law firm Quarles & Brady LLP. "The bad guys, I hate to say it, are smart. They always seem to be a step ahead of the regulators."

The Opioid Crisis

Continuing coverage of how synthetic painkillers became a global menace

- Hooked: One Family's Ordeal With Fentanyl
- The Chinese Connection Fueling America's Fentanyl Crisis
- For Small-Town Cops, Opioid Scourge Hits Close to Home
- The Pill Makers Next Door: How America's Opioid Crisis Is Spreading
- Tramadol: The Opioid Crisis for the Rest of the World
- This Is U-47700, Once a Lab Experiment, Now a Killer Opioid
- Fentanyl Billionaire Comes Under Fire as Death Toll Mounts From Prescription Opioids
- The Children of the Opioid Crisis
- Vermont's Radical Experiment to Break the Addiction Cycle
- The VA Hooked Veterans on Opioids, Then Failed Them Again

At least six states specifically banned U-47700 before the DEA announced plans in September to make the drug illegal. DEA spokesman Rusty Payne said the agency's scheduling actions are subject to "exhaustive reviews," which take time.

So far this year through September, NMS Labs, a major

private lab outside Philadelphia that works with states around the U.S., has tallied 105 overdose deaths related to U-47700 and 265 fatalities related to furanyl fentanyl—an analog, or chemical compound that is closely related to fentanyl—which also was detected in R.J. Henney's blood. Axis Forensic Toxicology, a private lab firm in Indianapolis, has seen another 20 deaths linked to U-47700.

"It's hard to keep track of what's killing people," says Karl Williams, chief medical examiner in Allegheny County, which includes Pittsburgh.

The DEA on Sept. 27 announced plans to put furanyl fentanyl on a list of controlled substances in coming weeks.

The U-47700-related fatalities span at least 31 states from Alaska to Utah to Florida. At least four users, including Mr. Henney, have died in the Pittsburgh area.

Christopher DeKleva was discovered dead in his Pittsburgh home in January by his mother. A toxicology test found the 28-year-old had ingested substances including U-47700 and 4-methoxy-butyryl fentanyl, a fentanyl analog that hasn't been placed on the controlled-substances list.

Denny DeKleva goes through an album of photos of his son Christopher, who died in January. *PHOTO: JEFF SWENSEN FOR THE WALL STREET JOURNAL*

His mother, Karen DeKleva Rebottini, a psychologist who was staying with him out of concern for his well-being, knew he was ordering drugs online. On the day he overdosed, she intercepted a package with markings suggesting it came from overseas. She tossed it out but fears he retrieved it.

"He would try to find the things that could get you high but were 'legal,' " says his stepfather, Rick Rebottini. "When one became listed, he gave it up and went to another one."

A U.S. and Chinese crackdown last year on a fentanyl variant known as acetyl fentanyl may have primed the market for other synthetic opioids, including U-47700. The DEA issued an order scheduling acetyl fentanyl in July 2015, and China added that drug and 115 other chemicals to a controlled-substances list three months later.

Angel Hao of Wuhan, China-based synthetics vendor Dharmachems said in an email to The Wall Street Journal that these moves boosted the popularity of both U-47700 and furanyl fentanyl.

The origins of U-47700 date to 1973, when Upjohn Co. asked its scientist Jacob Szmuszkovicz to create a drug with the pain-relieving power of morphine, but without the risk, according to a chapter he wrote for a 1999 book on drug research. Researchers wanted to find the Holy Grail that is elusive to this day: potent pain relievers that don't have dangerous side effects, such as addiction and a potentially fatal slowdown in breathing.

By about 1974, Dr. Szmuszkovicz created a chemical Upjohn dubbed U-47700 at a company lab in Kalamazoo, Mich. Researchers knew it was a morphine-like drug when it triggered erect tails in mice, a reaction known as a Straub tail, says Phil von Voigtlander, a retired Upjohn research director who worked on the project. Dr. Szmuszkovicz died in mid-October at age 92.

Another test, which involved shining a hot light on mice's tails to judge how long it took them to move, helped measure U-47700's potency, says Dr. von Voigtlander. He learned the compound worked on the same receptor as morphine with roughly 7.5 times the strength.

A 1984 Upjohn Co. annual report photo shows Phil von Voigtlander, far right, who worked on U-47700, and Jacob Szmuszkovicz, far left, who invented the chemical. *PHOTO: PFIZER*

Further rodent testing also revealed a downside. "Once we saw that it just caused tolerance and dependence like opioids and had opioid side effects, we thought, well, that's just another morphine and that's not what we're looking for," Dr. von Voigtlander says.

He calls U-47700 an important research steppingstone, and Upjohn patented the chemical. The company never tested U-47700 on people.

These kinds of pharmaceutical research efforts leave behind copious patents and scientific papers, which can serve as recipes for today's enterprising chemists. Some researchers, such as Mr. Hall, the Miami epidemiologist, believe Chinese labs are scouring patent literature for new synthetic compounds to produce, before selling them.

"That's the scary thing," says Dr. von Voigtlander, who lamented that a company's quest to develop a less-addictive painkiller instead created ammunition for abuse. "We tried vitally to produce alternatives."

Foreign labs began making U-47700 and offering it for sale online by late 2014, according to a forum on the social-media website Reddit devoted to discussion of chemical vendors and frequented by drug users. Buyers can choose from an array of online vendors selling synthetic drugs, including opioids, dubbed "research chemicals."

The websites typically carry warnings that the chemicals they sell are "not for human consumption"—an attempt to gain legal cover, authorities say—and that buyers are responsible for complying with their home countries' laws.

Mr. Hao, from the China-based U-47700 vendor, wrote, "I don't sell illegal products to U.S." and "I sell for lab research only." The DEA spokesman said the term "research chemical" "only exists to evade law-enforcement scrutiny."

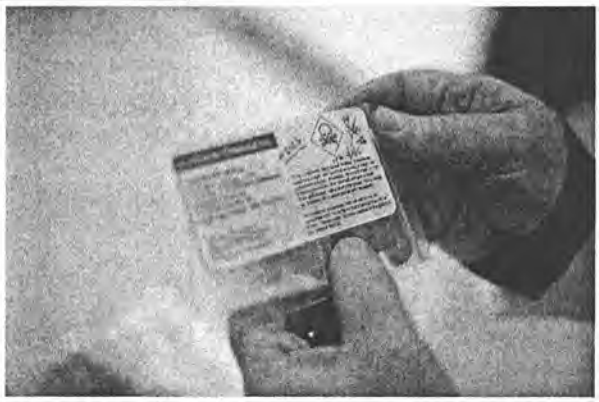
LS Research Chem Lab, a five-year-old company registered in Jiangsu province in China, recently offered U-47700 online for $120 a gram, or $290 for 10 grams. It promised fast shipment and offered various payment options, including PayPal. The company, as well as six others that list synthetic drugs for sale, didn't respond to emails seeking comment.

Several people who claim they used U-47700 told The Wall Street Journal they were drawn to the drug because it was cheap, readily available and allowed them to avoid interacting with street dealers. One user estimated he would have to spend 15 times as much to get the same high from oxycodone, the narcotic prescription pill.

On message boards, users described snorting, injecting or "plugging" the drug in their anus. They lauded U-47700's euphoric high, but complained it wears off fast and fuels near-obsessive cravings. Many recounted suffering nasal or rectal bleeding.

U-47700 began claiming lives in the U.S. by May 2015, when a 28-year-old man overdosed in Knox County, Tenn. The medical examiner there initially pegged his death to oxycodone, which was in his system. It took many more months to discover U-47700 was also there.

First, labs had to figure out what the drug was. NMS Labs detected U-47700 in November 2015 while testing blood samples from four different states at its facility outside Philadelphia.



Scientists test samples at NMS Labs in Willow Grove, Pa. NMS detected the synthetic opioid U-47700 in November 2015. *PHOTOS: MARK MAKELA FOR THE WALL STREET JOURNAL*

"We actually found it by accident," says Barry Logan, chief scientist there. U-47700 closely resembles a synthetic opioid called AH-7921—another research relic—which NMS had started watching for last year.

NMS, which is now rushing to create new tests to screen for 21 different designer opioids, eventually linked U-47700 to the Knox County case.

The Society of Forensic Toxicologists' newsletter for March and April cited two 2015 deaths in Texas linked to the drug. Axis, the private lab in Indianapolis, saw its first case this spring, according to Kevin Shanks, a forensic toxicologist there.

Growing worries triggered actions to outlaw the drug in states like Georgia and Idaho.

Ohio, a hotbed for opioid abuse and fatal overdoses, was among the first states to take action by placing U-47700 on its controlled-substances list in May. The move came a month after Douglas Rohde, a toxicologist in Lake County, confirmed that an overdose death from January involved U-47700, and a local news program aired a report about it. Authorities in nearby Lorain County also blamed a spate of springtime overdoses on the drug.

The DEA on April 18 told the secretary of the Department of Health and Human Services it planned to make U-47700 a Schedule I drug on an emergency basis. A bulletin in May from the agency's Philadelphia division cited R.J. Henney's overdose, without naming him, while warning that deaths linked to the drug were on the rise. The bulletin included a picture of Mr. Henney's head on his drug-strewn desk.

This spring, R.J. Henney showed his mother how he could access the darknet, a restricted part of the internet and a known drug market, she said. A drug shipment his parents later discovered arrived in what looked like a greeting card, with calligraphy on the envelope. Another came in a cellophane-wrapped DVD case for "Lord of the Dance," an Irish musical.

Ray, Christine and Megan Henney listen to a recording of R.J. Henney talking about helping an addict he met at a gas station. *PHOTO: JEFF SWENSEN FOR THE WALL STREET JOURNAL*

His parents, Ray, a civil engineer, and Christine, a bank director, say he had been a bright child and insatiable reader, though he later struggled with clinical depression and borderline personality disorder. As a teen, he tried a raft of drugs, some illegal. By 2013, he was using heroin. They enrolled their son in treatment programs.

R.J. hated being an addict, and the impact his addiction had on his family, his parents say. A fluid writer, he was open about his struggles.

"Those you love begin to fall away, Replaced by a synthetic narcotic bouquet," he wrote in one poem about addiction posted on Facebook.

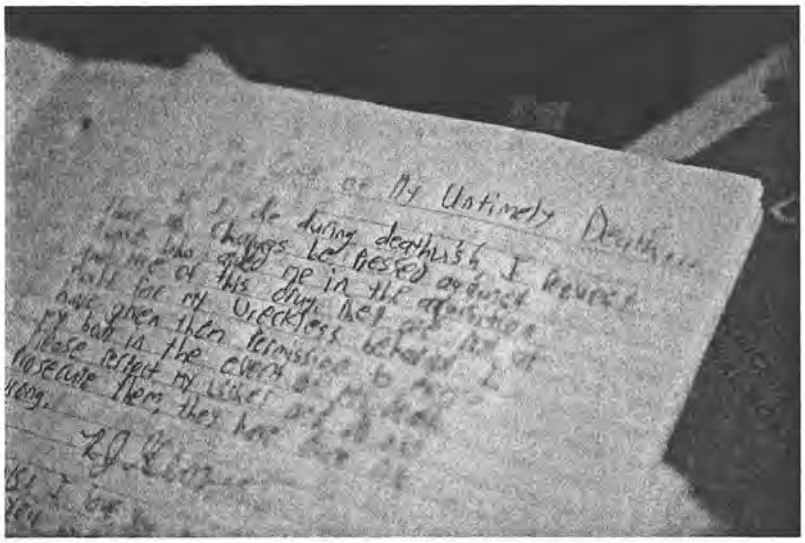
On April 10, R.J. posted on the message board drugs-forum.com about his desire to inject fentanyl, which the medical examiner also found in his blood. Some members sought to dissuade him. "Worried about you," one wrote. "These chems are more powerful. Seriously, don't f—ing die."

In an April 11 post, the day before his parents believe he overdosed, R.J. wrote, "I can't get the needle out of my mind." Later that night, he sent a text message to a friend in Germany that his parents still have on his phone. "I made some really bad decisions man and just scared the f— out of myself," he wrote.

A week later, his father introduced himself on drugs-forum.com. "I found his posts looking at his computer after I found his body...dead from an accidental overdose," he wrote. "Such a tragic waste of a brilliant mind...I encourage anyone with addictions to get the help they need."

On Sept. 7, the DEA moved to add U-47700 to Schedule I. The agency spokesman noted that U-47700 is an analog of AH-7921, which the DEA scheduled in the spring. The DEA has the authority to treat analogs of controlled substances as illegal drugs.

Some people scrambled to stock up on the drug after the DEA's scheduling announcement, according to interviews with users and comments some users posted online. Others discussed potential alternatives, including more castoffs from Upjohn's research with similar "U" names.



A will in R.J. Henney's notebook, found after his death. *PHOTO: JEFF SWENSEN FOR THE WALL STREET JOURNAL*

Chinese labs "have a backup list a mile long," a 26-year-old former U-47700 user said in an interview, adding: "If [the DEA doesn't] think there are entire communities analyzing and making and testing new chemical structures every day, then they have no idea how our world works."

Write to Jon Kamp at jon.kamp@wsj.com and Arian Campo-Flores at arian.campo-flores@wsj.com

This Is U-47700, Once a Lab Experiment, Now a Killer Opioid
By JON KAMP and ARIAN CAMPO-FLORES
Nov. 4, 2016 10:24 a.m. ET

THE STATE
of ALASKA
GOVERNOR BILL WALKER

Department of Health and Social Services

OFFICE OF THE COMMISSIONER

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January 19, 2016

Senator Kevin Meyer
State Capitol Room 103
Juneau, AK 99801

Dear Senator Meyer,

As Chief Medical Officer for the Department of Health and Social Services and a member of the Department of Law's Controlled Substances Advisory Committee, I would like to offer strong support for adding the drug U-47700 (sometimes known as "pink" or "pinkie") to schedule IA of Alaska Controlled Substances list. Under AS 11.71.140, schedule IA substances are deemed "to have the highest degree of danger or probable danger to a person or the public."

U-47700 is a synthetic opioid nearly eight times more potent than morphine and has been linked to numerous deaths nationwide. It has also been linked to the deaths of at least three Alaskans since November 2015. U-47700 has not been approved by the Food and Drug Administration (FDA) for any medical use. U-47700 is sometimes mixed with other powerful drugs such as heroin and fentanyl. It can be easy to obtain, and is often purchased directly over the internet. Because this substance is both unregulated and very potent, a user is at serious risk of overdosing or suffering other adverse effects.

In response to this emerging public health threat, the U.S. Drug Enforcement Agency (DEA) recently designated U-47700 as a schedule I controlled substance on the Federal Controlled Substances schedule, through emergency regulations. The Alaska Division of Public Health has notified the medical community and the public of the use and risks of U-47700 in Alaska in an *Epidemiology Bulletin* issued on November 7, 2016 (enclosed). However, the lack of state law on U-47700 leaves law enforcement with few tools to combat its continued distribution in Alaska. U-47700 poses a serious danger to Alaskans. By making this drug a schedule IA controlled substance, Alaska would be better positioned to address and mitigate the growing problem of opioid misuse.

Please feel free to contact me if I can provide additional information. Thank you for your consideration.

Sincerely,

Jay C. Butler, MD, FAAP, FACP, FIDSA
Chief Medical Officer and Director, Division of Public Health

Alaska Mental Health Board
Advisory Board on Alcoholism and Drug Abuse
431 N. Franklin St. Suite 200
Juneau, Alaska, 99801

ABADA Advisory Board on Alcoholism and Drug Abuse
AMHB Alaska Mental Health Board

January 25, 2017

Senator Kevin Meyer
Alaska State Capitol, Room 103
Juneau, Alaska 99801

BY HAND-DELIVERY

Re: Letter of Support for SB 20

Senator Meyer,

The Advisory Board on Alcohol and Drug Abuse and the Alaska Mental Health Board support the addition of the synthetic opioid U-47700 to the controlled substances schedule IA.

Deaths due to synthetic opioids and designer drugs have grown since 2015. The U.S. Drug Enforcement Agency noted the increase in deaths due to illicitly manufactured fentanyl and synthetic opioids in 2015, and then acted to regulate U-47700 by adding it to the federal controlled substances schedule I in November, 2016.

Of the opioid-related overdose deaths in Alaska since January 1, 2014, 29% involved fentanyl or synthetic opioids. The Division of Public Health reports that three of this deaths involved U-47700. Designer drugs like U-47700, like other opioids, pose a significant threat to the public health and safety of Alaskans. Acting to regulate U-47700 now, before greater impact occurs, is wise policymaking. The Boards appreciate your leadership in sponsoring SB 20.

Sincerely,

J. Kate Burkhart
Executive Director

cc: Philip Licht, Chairperson, ABADA
Charlene Tautfest, Chairperson, AMHB
Dr. Jay Butler, Chief Medical Office, DHSS

THE STATE
of ALASKA
GOVERNOR BILL WALKER

Department of Law

Office of the Attorney General
1031 West 4th Avenue, Suite 200
Anchorage, Alaska 99501-5903
Main: 907-269-5100
Fax: 907-269-5110

February 2, 2017

The Honorable Kevin Meyer
State Senate
State Capitol, Rm 103
Juneau, AK 99801

Re: Support for SB 20

Dear Senator Meyer:

The Department of Law would like to express its support for SB 20 which schedules U-47700 as a schedule IA controlled substance. SB 20 mirrors the actions that the U.S. Drug Enforcement Administration took in November of 2016 when it scheduled this substance as a schedule I controlled substance.

In recent months, the dangerousness of U-47700 has become evident. U-47700 is a synthetic opioid which has no known medical utility and is several times more potent than morphine or fentanyl. Its previously unregulated status allowed the public to purchase it in large quantities and states across the nation have seen numerous overdoses due to this substance.

Scheduling U-47700 as a schedule IA controlled substance in Alaska will allow state law enforcement to stop those who are distributing the drug, and assist the medical community in identifying those who may be struggling with addictions to these substances.

U-47700 poses a serious danger to all Alaskans. The Department of Law thanks you for introducing this important piece of legislation.

Sincerely,

Jahna Lindemuth
Attorney General

30-LS0319\D
Martin
2/8/17

CS FOR SENATE BILL NO. 20(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTIETH LEGISLATURE - FIRST SESSION

BY THE SENATE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered:
Referred:

Sponsor(s): SENATOR MEYER

A BILL

FOR AN ACT ENTITLED

"An Act classifying U-47700 as a schedule IA controlled substance; classifying tramadol and related substances as schedule IVA controlled substances; and providing for an effective date."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* **Section 1.** AS 11.71.140(c) is amended to read:

(c) Schedule IA includes, unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan excepted:

(1) acetylmethadol;

(2) allylprodine;

(3) alphacetylmethadol;

(4) alphameprodine;

(5) alphamethadol;
(6) alphaprodine;
(7) anileridine;
(8) benzethidine;
(9) betacetylmethadol;
(10) betameprodine;
(11) betamethadol;
(12) betaprodine;
(13) bezitramide;
(14) clonitazene;
(15) dextromoramide;
(16) diampromide;
(17) diethylthiambutene;
(18) difenoxin;
(19) dihydrocodeine;
(20) dimenoxadol;
(21) dimepheptanol;
(22) dimethylthiambutene;
(23) dioxaphetyl butyrate;
(24) diphenoxylate;
(25) dipipanone;
(26) ethylmethythiamutene;
(27) etonitazene;
(28) etoxeridine;
(29) fentanyl;
(30) furethidine;
(31) hydroxpethidine;
(32) isomethadone;
(33) ketobemidone;
(34) levomethorphan;
(35) levomoramide;

(36) levorphanol;

(37) levophenacylmorphan;

(38) meperidine, also known as pethidine;

(39) metazocine;

(40) methadone;

(41) methadone-intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

(42) moramide-intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid;

(43) morpheridine;

(44) noracymethadol;

(45) norlevorphanol;

(46) normethadone;

(47) norpipanone;

(48) pethidine, also known as merperidine;

(49) pethidine-intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;

(50) pethidine-intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;

(51) pethidine-intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(52) phenadoxone;

(53) phenampromide;

(54) phenazocine;

(55) phenomorphan;

(56) phenoperidine;

(57) piminodine;

(58) piritramide;

(59) propheptazine;

(60) properidine;

(61) propiram;

(62) racemethorphan;

(63) racemoramide;

(64) racemorphan;

(65) trimeperidine;

(66) alfentanil;

(67) alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)- ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4(N-propanilido) piperidine);

(68) bulk dextropropoxyphene (non-dosage form);

(69) carfentanil;

(70) sufentanil;

(71) tilidine;

(72) para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl] propanamide);

(73) 3-methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide);

(74) acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenetnyl)-4-piperidinyl]-N-phenylacetamide);

(75) alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl) ethyl-4-piperidinyl]-N-phenylpropanamide);

(76) beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropan amide);

(77) beta-hydroxy-3-methylfentanyl (N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

(78) 3-methylthiofentanyl (N-[(3-methyl-l-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

(79) thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

(80) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

(81) PEPAP (1-(-2-pheynethyl)-4-phenyl-4-acetoxypiperidine)**;**

(82) 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide, also known as U-47700.

*** Sec. 2.** AS 11.71.170 is amended by adding a new subsection to read:

(g) Schedule IVA includes, unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substance or its salts calculated as the free anhydrous base or alkaloid: 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers, including tramadol.

*** Sec. 3.** This Act takes effect immediately under AS 01.10.070(c).

SENATE COMMITTEE REPORT
First Committee of Referral

DATE: 1/18/17

FURTHER: Judiciary

DATE TURNED IN TO OFFICE: 2/10/17

Health and Social Services Committee considered SENATE BILL NO. 20

SB 20-LIST U-47700 AS A CONTROLLED SUBSTANCE

"An Act classifying U-47700 as a schedule IA controlled substance; and providing for an effective date."

and recommends:

[ ] be **replaced** with **CS** SB 20 (HSS) *[ ] Same Title [✓] New Title*

[ ] adopt **previous CS** _____ (_____) *[ ] Same Title [ ] New Title*

[ ] attached amendment(s)

[ ] adopt _____ Letter of Intent

[ ] further referral to _____ Committee

Dept Abbr.	
ADM	LWF
CED	LAW
COR	LEG
EED	MVA
DEC	DNR
DFG	DPS
GOV	REV
DHS	DOT
AJS	UA

NEW FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #
DPS			1	1
DPS			1	2
COR			1	3
LAW			1	4
DHS			1	5

PREVIOUS FISCAL NOTE(S)				
Dept.	Fiscal	Indet.	Zero	FN #

[ ] **APPROPRIATION - no fiscal note**

SIGNATURES AND RECOMMENDATIONS:	PRINTED LAST NAME	DO PASS	DO NOT PASS	NO REC	AMEND
Do Pass	Begich	✓			
	VonImhof	✓			
	Micciche	✓			
	Giessel	✓			
CHAIR:	Wilson	✓			

CS FOR SENATE BILL NO. 20(HSS)

IN THE LEGISLATURE OF THE STATE OF ALASKA

THIRTIETH LEGISLATURE - FIRST SESSION

BY THE SENATE HEALTH AND SOCIAL SERVICES COMMITTEE

Offered:
Referred:

Sponsor(s): SENATOR MEYER

A BILL

FOR AN ACT ENTITLED

"An Act classifying U-47700 as a schedule IA controlled substance; classifying tramadol and related substances as schedule IVA controlled substances; and providing for an effective date."

BE IT ENACTED BY THE LEGISLATURE OF THE STATE OF ALASKA:

* **Section 1.** AS 11.71.140(c) is amended to read:

(c) Schedule IA includes, unless specifically excepted or unless listed in another schedule, any of the following opiates, including their isomers, esters, ethers, salts, and salts of isomers, esters, and ethers, whenever the existence of these isomers, esters, ethers, and salts is possible within the specific chemical designation, dextrorphan excepted:

(1) acetylmethadol;

(2) allylprodine;

(3) alphacetylmethadol;

(4) alphameprodine;

(5) alphamethadol;
(6) alphaprodine;
(7) anileridine;
(8) benzethidine;
(9) betacetylmethadol;
(10) betameprodine;
(11) betamethadol;
(12) betaprodine;
(13) bezitramide;
(14) clonitazene;
(15) dextromoramide;
(16) diampromide;
(17) diethylthiambutene;
(18) difenoxin;
(19) dihydrocodeine;
(20) dimenoxadol;
(21) dimepheptanol;
(22) dimethylthiambutene;
(23) dioxaphetyl butyrate;
(24) diphenoxylate;
(25) dipipanone;
(26) ethylmethythiamutene;
(27) etonitazene;
(28) etoxeridine;
(29) fentanyl;
(30) furethidine;
(31) hydroxpethidine;
(32) isomethadone;
(33) ketobemidone;
(34) levomethorphan;
(35) levomoramide;

(36) levorphanol;

(37) levophenacylmorphan;

(38) meperidine, also known as pethidine;

(39) metazocine;

(40) methadone;

(41) methadone-intermediate, 4-cyano-2-dimethylamino-4, 4-diphenyl butane;

(42) moramide-intermediate, 2-methyl-3-morpholino-1, 1-diphenyl-propane-carboxylic acid;

(43) morpheridine;

(44) noracymethadol;

(45) norlevorphanol;

(46) normethadone;

(47) norpipanone;

(48) pethidine, also known as merperidine;

(49) pethidine-intermediate-A, 4-cyano-1-methyl-4-phenylpiperidine;

(50) pethidine-intermediate-B, ethyl-4-phenylpiperidine-4-carboxylate;

(51) pethidine-intermediate-C, 1-methyl-4-phenylpiperidine-4-carboxylic acid;

(52) phenadoxone;

(53) phenampromide;

(54) phenazocine;

(55) phenomorphan;

(56) phenoperidine;

(57) piminodine;

(58) piritramide;

(59) propheptazine;

(60) properidine;

(61) propiram;

(62) racemethorphan;

(63) racemoramide;

(64) racemorphan;

(65) trimeperidine;

(66) alfentanil;

(67) alpha-methylfentanyl (N-[1-(alpha-methyl-beta-phenyl)- ethyl-4-piperidyl] propionanilide; 1-(1-methyl-2-phenylethyl)-4(N-propanilido) piperidine);

(68) bulk dextropropoxyphene (non-dosage form);

(69) carfentanil;

(70) sufentanil;

(71) tilidine;

(72) para-fluorofentanyl (N-(4-fluorophenyl)-N-[1-(2-phenethyl)-4-piperidinyl] propanamide);

(73) 3-methylfentanyl (N-[3-methyl-1-(2-phenylethyl)-4-piperidyl]-N-phenylpropanamide);

(74) acetyl-alpha-methylfentanyl (N-[1-(1-methyl-2-phenetnyl)-4-piperidinyl]-N-phenylacetamide);

(75) alpha-methylthiofentanyl (N-[1-methyl-2-(2-thienyl) ethyl-4-piperidinyl]-N-phenylpropanamide);

(76) beta-hydroxyfentanyl (N-[1-(2-hydroxy-2-phenethyl)-4-piperidinyl]-N-phenylpropan amide);

(77) beta-hydroxy-3-methylfentanyl (N-[1-(2-hydroxy-2-phenethyl)-3-methyl-4-piperidinyl]-N-phenylpropanamide);

(78) 3-methylthiofentanyl (N-[(3-methyl-l-(2-thienyl)ethyl-4-piperidinyl]-N-phenylpropanamide);

(79) thiofentanyl (N-phenyl-N-[1-(2-thienyl)ethyl-4-piperidinyl]-propanamide);

(80) MPPP (1-methyl-4-phenyl-4-propionoxypiperidine);

(81) PEPAP (1-(-2-pheynethyl)-4-phenyl-4-acetoxypiperidine)**;**

(82) 3,4-dichloro-N-[2-(dimethylamino)cyclohexyl]-N-methylbenzamide, also known as U-47700.

* **Sec. 2.** AS 11.71.170 is amended by adding a new subsection to read:

(g) Schedule IVA includes, unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substance or its salts calculated as the free anhydrous base or alkaloid: 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers, including tramadol.

* **Sec. 3.** This Act takes effect immediately under AS 01.10.070(c).

30-LS0319\A.1
Martin
2/7/17

AMENDMENT

OFFERED IN THE SENATE

TO: SB 20

Page 1, line 1, following "**substance;**":

Insert "**classifying tramadol and related substances as schedule IVA controlled substances;**"

Page 4, following line 29:

Insert a new bill section to read:

"* Sec. 2. AS 11.71.170 is amended by adding a new subsection to read:

(g) Schedule IVA includes, unless specifically excepted or unless listed in another schedule, any material, compound, mixture, or preparation which contains any quantity of the following substance or its salts calculated as the free anhydrous base or alkaloid: 2-[(dimethylamino)methyl]-1-(3-methoxyphenyl)cyclohexanol, its salts, optical and geometric isomers, and salts of these isomers, including tramadol."

Renumber the following bill section accordingly.