Wisconsin Department of Safety and Professional Services
Division of Policy Development
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Tony Evers, Governor
Dan Hereth, Secretary

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
Virtual, 4822 Madison Yards Way, Madison
Contact: Tom Ryan (608) 266-2112
September 8, 2023

The following agenda describes the issues that the Board plans to consider at the meeting. At the time of the meeting, items may be removed from the agenda. Please consult the meeting minutes for a description of the actions and deliberations of the Board.

AGENDA

9:30 A.M.

OPEN SESSION – CALL TO ORDER – ROLL CALL

A. **Adoption of Agenda (1-3)**

B. **Approval of Minutes May 12, 2023 (4-5)**

C. Reminders: Conflicts of Interests, Scheduling Concerns

D. **Introductions, Announcements and Recognition**
   1) Introductions
      a. Cullen Eberhardy, AAG Representative (Succeeds: Sandy Koresch)
      b. Gregory Schmaling, Medical Examining Board Representative (Succeeds: Lemuel Yerby)
   2) Recognition
      a. Sandy Koresch, AAG Representative (Resigns: 7/14/2023)
      b. Lemuel Yerby, Medical Examining Board Representative (Resigns: 7/21/23)

E. Administrative Matters – Discussion and Consideration
   3) Department, Staff, and Board Updates
   4) Board Members – Term Expiration Dates
      a. Alton, Troy – Dentistry Examining Board Representative
      b. Barman, Subhadeep – 5/1/2019
      c. Bellay, Yvonne – DATCP Representative
      d. Bloom, Alan – 5/1/2020
      e. Eberhardy, Cullen – AAG Representative
      f. Englebert, Doug – DHS Representative
      g. Schmeling, Gregory – Medical Examining Board Representative
      h. Weinman, Robert – Board of Nursing Representative
      i. Weitekamp, John – Pharmacy Examining Board Representative
   5) Alternates
      a. Bistan, Matthew – Dentistry Examining Board Representative
      b. Ferguson, Kris – Medical Examining Board Representative
      c. McFarland, Rosalyn – Board of Nursing Representative
      d. Wasserman, Sheldon – Medical Examining Board Representative

F. **Administrative Rule Matters – Discussion and Consideration (6)**
   1) Adoption Order:
      a. CSB 2.92, Relating to Scheduling 35 Anabolic Steroids **(7-15)**
      b. CSB 2.93, Related to Scheduling Daridorexant **(16-22)**
      c. CSB 2.94, Related to Scheduling 7 Synthetic Benzimidazole-Opioids **(23-31)**
      d. CSB 2.95, Related to Scheduling Ganaxolone **(32-39)**
   2) Scope Statements
      a. CSB 2.001, Relating to Scheduling Methiopropamine **(40-41)**
      b. CSB 2.002, Relating to Excluding Fenfluramine **(42-43)**
   3) Affirmative Action Order:
      a. CSB. 2.003, Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances **(44-45)**
   4) Pending and Possible Rulemaking Projects
      a. Rule Projects Chart **(46-48)**

G. **Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration (49)**
   1) WI ePDMP Operations
      a. CSB PDMP Q2 2023 Report Completed
      b. Recent and Upcoming Releases **(50-51)**
      c. EHR Integration Status **(52-53)**
      d. Interstate Data Exchange **(54)**
   2) WI ePDMP Outreach **(55)**

H. **Board Member Reports – Discussion and Consideration**
   1) Medical Examining Board
   2) Dentistry Examining Board
   3) Board of Nursing
   4) Pharmacy Examining Board

I. **Fentanyl Adulterated or Associated with Xylazine Response Plan – Discussion and Consideration (56-70)**

J. **FDA updating warnings to improve safe use of prescription stimulants used to treat ADHD and other conditions– Discussion and Consideration**

K. Liaison Reports

L. **Report from the Referral Criteria Work Group – Discussion and Consideration**

M. Deliberation on Special Use Authorizations – Discussion and Consideration

N. Discussion and Consideration of Items Received After Preparation of the Agenda
   1) Introductions, Announcements, and Recognition
   2) Administrative Matters
   3) Election of Officers
   4) Appointment of Liaisons and Alternates
   5) Delegation of Authorities
   6) Informational Items
   7) Division of Legal Services and Compliance (DLSC) Matters
   8) Education and Examination Matters
   9) Credentialing Matters
   10) Practice Matters

11) Legislative and Administrative Rule Matters
12) Liaison Reports
13) Public Health Emergencies
14) Appearances from Requests Received or Renewed
15) Speaking Engagements, Travel, or Public Relations Requests, and Reports
16) Consulting with Legal Counsel

O. **Public Comments**

CONVENE TO CLOSED SESSION to deliberate on cases following hearing (s. 19.85(1)(a), Stats.); to consider licensure or certification of individuals (s. 19.85(1)(b), Stats.); to consider individual histories or disciplinary data (s. 19.85(1)(f), Stats.); and to confer with legal counsel (s. 19.85(1)(g), Stats.).

P. Deliberation on Special Use Authorizations – Discussion and Consideration

Q. Consulting with Legal Counsel

RECONVENE TO OPEN SESSION IMMEDIATELY FOLLOWING CLOSED SESSION

R. Vote on Items Considered or Deliberated Upon in Closed Session if Voting is Appropriate

S. Open Session Items Noticed Above Not Completed in the Initial Open Session

ADJOURNMENT

NEXT MEETING: November 10, 2023

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MEETINGS AND HEARINGS ARE OPEN TO THE PUBLIC, AND MAY BE CANCELLED WITHOUT NOTICE.

Times listed for meeting items are approximate and depend on the length of discussion and voting. All meetings are held virtually unless otherwise indicated. In-person meetings are typically conducted at 4822 Madison Yards Way, Madison, Wisconsin, unless an alternative location is listed on the meeting notice. In order to confirm a meeting or to request a complete copy of the board's agenda, please visit the Department website at https:\\dsps.wi.gov. The board may also consider materials or items filed after the transmission of this notice. Times listed for the commencement of disciplinary hearings may be changed by the examiner for the convenience of the parties. Requests for interpreters for the hard of hearing, or other accommodations, are considered upon request by contacting the Affirmative Action Officer, or the Meeting Staff at 608-267-7213.

VIRTUAL/TELECONFERENCE
CONTROLLED SUBSTANCES BOARD
MEETING MINUTES
MAY 12, 2023

PRESENT: Troy Alton, Alan Bloom, Doug Englebert, Sandy Koresch, Robert Weinman, Lemuel Yerby

EXCUSED: Subhadeep Barman, Yvonne Bellay, John Weitekamp

STAFF: Tom Ryan, Executive Director; Whitney DeVoe, Legal Counsel; Nilajah Hardin, Administrative Rules Coordinator; Katlin Schwartz, Bureau Assistant; and other DSPS Staff

CALL TO ORDER

Doug Englebert, Chairperson, called the meeting to order at 9:30 a.m. A quorum was confirmed with six (6) members present.

ADOPTION OF AGENDA

MOTION: Robert Weinman moved, seconded by Lemuel Yerby, to adopt the Agenda as published. Motion carried unanimously.

APPROVAL OF MINUTES OF MARCH 10, 2023

MOTION: Alan Bloom moved, seconded by Sandy Koresch, to adopt the Minutes of March 10, 2023 as published. Motion carried unanimously.

ADMINISTRATIVE RULE MATTERS

Adoption Order

MOTION: Alan Bloom moved, seconded by Troy Alton, to approve the Adoption Orders for the following rules:

- CSB 2.78, Relating to Scheduling Crotonyl Fentanyl
- CSB 2.79, Relating to Scheduling Remimazolam
- CSB 2.81, Relating to Scheduling Brorphine
- CSB 2.82, Relating to Scheduling Serdexmethylphenidate
- CSB 2.83, Relating to Scheduling 10 Fentanyl Related Substances
- CSB 2.84, Relating to Scheduling Alfaxalone
- CSB 2.85, Relating to Excluding 6-beta-naltrexol
- CSB 2.86, Relating to Scheduling Fospropofol
- CSB 2.87, Relating to Scheduling Embutramide
- CSB 2.88, Relating to Scheduling Lacosamide
- CSB 2.89, Relating to Scheduling Perampanel

- CSB 2.90, Relating to Transferring 1-phenycyclohexylamine and 1-piperidinoocyclohexanecarbonitrile, Immediate Precursors to Phencyclidine, Also Known as PCP
- CSB 2.91, Relating to Scheduling 4,4'-Dimethylaminorex.

Motion carried unanimously.

Scope Statements

MOTION: Sandy Koresch moved, seconded by Robert Weinman, to approve the following Scope Statements for submission to the Department of Administration and Governor's Office and for publication:

- CSB 2.96, Relating to Scheduling Amineptine
- CSB 2.97, Relating to Scheduling Zipeprol
- CSB 2.98, Relating to Excluding [18 F] FP-CIT
- CSB 2.99, Relating to Scheduling Mesocarb

Additionally, the Board authorizes the Chairperson to approve these Scope Statements for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on these Scope Statements, the Chairperson is authorized to approve the required notices of hearing.
Motion carried unanimously.

MOTION: Lemuel Yerby moved, seconded by Alan Bloom, to approve the Scope Statement revising CSB 4, relating to Monitored Prescription Drug History Reports, for submission to the Department of Administration and Governor's Office and for publication. Additionally, the Board authorizes the Chairperson to approve the Scope Statement for implementation no less than 10 days after publication. If the Board is directed to hold a preliminary public hearing on the Scope Statement, the Chairperson is authorized to approve the required notice of hearing. Motion carried unanimously.

ADJOURNMENT

MOTION: Alan Bloom moved, seconded by Troy Alton, to adjourn the meeting. Motion carried unanimously.

The meeting adjourned at 9:57 a.m.

State of Wisconsin
Department of Safety & Professional Services
AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Nilajah Hardin **Administrative Rules Coordinator**	**08/28/23** Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
09/08/23	☒ Yes ☐ No	**Administrative Rule Matters – Discussion and Consideration** 1. **Final Rule Draft:** a. **CSB 2.92, relating to Scheduling 35 Anabolic Steroids** b. **CSB 2.93, relating to Scheduling Daridorexant** c. **CSB 2.94, relating to Scheduling 7 Synthetic Benzimidazole-Opioids** d. **CSB 2.95, relating to Scheduling Ganaxolone** 2. **Scope Statement:** a. **CSB 2.001, relating to Scheduling Methiopropamine** b. **CSB 2.002, relating to Excluding Fenfluramine** 3. **Affirmative Action Order:** a. **CSB. 2003. Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances** 4. **Pending or Possible Rulemaking Projects** a. **Rule Projects Chart**

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete **Appearance Request** for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	**N/A**

10) Describe the issue and action that should be addressed:

Review and Take Action on Final Rule Drafts, Scope Statements, and an Affirmative Action Order.

Attachments:

- Final Rule Draft, Legislative Report, Economic Impact Analysis – CSB 2.92-2.95
- Public Comment – CSB 2.95
- Scope Statements – CSB 2.001 and 2.002
- Affirmative Action Order – CSB 2.003
- Rule Projects Chart

(All Board Rule Projects can be Viewed Here if Needed: https://dsps.wi.gov/Pages/RulesStatutes/PendingRules.aspx)

11) Authorization

Nilajah D. Hardin — 08/28/23

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:

1. **This form should be attached to any documents submitted to the agenda.**
2. **Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.**
3. **If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.**

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
CONTROLLED SUBSTANCES BOARD	**:**	**CR 23-018**

I. THE PROPOSED RULE:
The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA:
The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:
This rule adds thirty-five (35) anabolic steroids not previously scheduled in Wisconsin to schedule III under ch. 961, Stats.

The Controlled Substances Board did not receive an objection to similarly treating these thirty-five (35) anabolic steroids as schedule III under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating these thirty-five (35) anabolic steroids as controlled substances.

Therefore, pursuant to s. 961.11(4), Stats., the Controlled Substances Board by Affirmative Action similarly treated thirty-five (35) anabolic steroids under chapter 961, Stats and is now following up with a final rule.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, when it was published in the Administrative Register and expires upon promulgation of a final rule.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:
Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:
All of the recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-018)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.92 relating to scheduling thirty-five (35) anabolic steroids.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.18, Stats.

Statutory authority: s. 961.11 (1) and (4), Stats.

Explanation of agency authority:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

Related statute or rule: s. 961.18, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On December 16, 2005 and July 30, 2012, the Department of Justice, Drug Enforcement Administration published its final rules in the Federal Register placing a number of anabolic steroids into schedule III of the federal Controlled Substances Act. The scheduling actions are effective January 20, 2005 and August 29, 2012. Of the substances scheduled in these actions, thirty-five (35) have been determined to not have been previously scheduled in Wisconsin.

Plain language analysis:
This rule adds thirty-five (35) anabolic steroids not previously scheduled in Wisconsin to schedule III under ch. 961, Stats.

The Controlled Substances Board did not receive an objection to similarly treating these thirty-five (35) anabolic steroids as schedule III under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating these thirty-five (35) anabolic steroids as controlled substances.

Therefore, pursuant to s. 961.11(4), Stats., the Controlled Substances Board by Affirmative Action similarly treated thirty-five (35) anabolic steroids under chapter 961, Stats and is now following up with a final rule.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, when it was published in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: Illinois has included the thirty-five (35) anabolic steroids added in this rule as schedule III controlled substances [720 Illinois Compiled Statutes 570/102 (c-1) and 208 (f)].

Iowa: Iowa has included the thirty-five (35) anabolic steroids added in this rule as schedule III controlled substances [Iowa Code 124.208 (6)].

Michigan: Michigan has not included the thirty-five (35) anabolic steroids added in this rule as schedule III controlled substances [Michigan Compiled Laws s. 333.7201-7231].

Minnesota: Minnesota has included the thirty-five (35) anabolic steroids added in this rule as schedule III controlled substances [Minnesota Statutes 152.02 (4) (f) (1)].

Summary of factual data and analytical methodologies:
The methodology was to add thirty-five (35) anabolic steroids to schedule III of ch. 961, Stats. to conform with the federal Controlled Substances Act.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule adds thirty-five (35) anabolic steroids as Schedule III controlled substances which will not have any effect on small business.

Fiscal Estimate:
The proposed rule was posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by July 14, 2023 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.92 is created to read:

CSB 2.92 Addition of thirty-five (35) Anabolic Steroids to schedule III. Section 961.18 (7), Stats., is repealed and recreated to read:

961.18 (7) ANABOLIC STEROIDS. Unless specifically excepted or listed in another schedule, any material, compound, mixture, or preparation containing any quantity of any of the following anabolic steroids, including any of their esters, ethers, isomers, esters or ethers of isomers, salts and salts of esters or ethers, isomers and esters or ethers of isomers that are theoretically possible within the specific chemical designation. Except such terms do not include an anabolic steroid that is expressly intended for administration through implants to cattle or other nonhuman species and that has been approved by the Secretary of Health and Human Services for such administration. If any person prescribes, dispenses, or distributes such steroid for human use, the person shall be considered to have prescribed, dispensed, or distributed an anabolic steroid within the meaning of this section:

(a) 3beta,17-dihydroxy-5alpha-androstane.

(ag) 3alpha,17beta-dihydroxy-5alpha-androstane.
(ar) 5alpha-androstan-3,17-dione.
(b) 1-androstenediol (3beta,17beta-dihydroxy-5alpha-androst-1-ene; 3alpha,17beta-dihydroxy-5alpha-androst-1-ene).
(bg) 4-androstenediol.
(br) 5-androstenediol.
(c) 1-androstenedione.
(cg) 4-androstenedione.
(cr) 5-androstenedione.
(d) Bolasterone.
(dg) Boldenone.
(dr) Boldione.
(e) Calusterone.
(eg) 4-chlorotestosterone, which is also called clostebol.
(er) Dehydrochloromethyltestosterone.
(f) Desoxymethyltestosterone.
(fg) delta1-dihydrotestosterone.
(fr) 4-dihydrotestosterone, which is also called stanolone.
(g) Drostanolone.
(gg) Ethylestrenol.
(gr) Fluoxymesterone.
(h) Formebulone, which is also called fromebolone.
(hg) Furazabol.
(hr) 13beta-ethyl-17beta-hydroxygon-4-en-3-one.
(i) 4-hydroxytestosterone.
(ig) 4-hydroxy-19-nortestosterone.
(ir) Mestanolone.
(j) Mesterolone.
(jg) Methandienone, which is also called methandrostenolone.
(jr) Methandriol.
(k) Methasterone.
(kg) Methenolone.
(kr) 17alpha-methyl-3beta, 17beta-dihydroxy-5alpha-androstane.
(L) 17alpha-methyl-3alpha,17beta-dihydroxy-5alpha-androstane.
(Lg) 17alpha-methyl-3beta,17beta-dihydroxyandrost-4-ene.
(Lr) 17alpha-methyl-4-hydroxynandrolone.
(m) Methyldienolone.
(mg) Methyltrienolone.
(mr) Methyltestosterone.
(n) Mibolerone.
(ng) 17alpha-methyl-delta1-dihydrotestosterone, which is also called 17-alpha-methyl-1-testosterone.
(nr) Nandrolone.
(o) 19-nor-4-androstenediol (3beta, 17beta-dihydroxyestr-4-ene; 3alpha, 17beta-dihydroxyestr-4-ene).

(og) 19-nor-5-androstenediol (3beta, 17beta-dihydroxyestr-5-ene; 3alpha, 17beta-dihydroxyestr-5-ene).
(or) 19-nor-4,9(10)-androstadienedione.
(p) 19-nor-4-androstenedione (estr-4-en-3,17-dione).
(pg) 19-nor-5-androstenedione (estr-5-en-3,17-dione).
(pr) Norbolethone.
(q) Norclostebol.
(qg) Norethandrolone.
(qr) Normethandrolone.
(r) Oxandrolone.
(rg) Oxymesterone.
(rr) Oxymetholone.
(s) Prostanozol.
(sg) Stanozolol.
(sr) Stenbolone.
(t) Testolactone.
(tg) Testosterone.
(tr) Tetrahydrogestrinone.
(u) Trenbolone.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
04/26/23

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.92

4. Subject
Scheduling 38 Anabolic Steroids

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
s. 20.165 (1) (g) and (hg)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☒ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☒ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
On December 16, 2005 and July 30, 2012, the Department of Justice, Drug Enforcement Administration published its final rules in the Federal Register placing thirty-eight (38) anabolic steroids into schedule III of the federal Controlled Substances Act. The scheduling actions are effective January 20, 2005 and August 29, 2012.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule were poseted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
The rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole. The Department of Safety and Professional Services estimates a total of $2,500 in one-time costs. These estimated costs may not be absorbed in the agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that the federal and state controlled substances acts will be uniform to avoid confusion.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are that 38 anbolic steroids will be added to Wis. Stat. ch. 961 as schedule III controlled substances.

17. Compare With Approaches Being Used by Federal Government
The federal government has scheduled these 38 anabolic steroids as schedule III controlled substances.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Illinois: Illinois has included the thirty-eight (38) anabolic steroids listed in this rule as schedule III controlled substances [720 Illinois Compiled Statutes 570/102 (c-1) and 208 (f)].

Iowa: Iowa has included the thirty-eight (38) anabolic steroids listed in this rule as schedule III controlled substances [Iowa Code 124.208 (6)].

Michigan: Michigan has not included the thirty-eight (38) anabolic steroids listed in this rule as schedule III controlled substances [Michigan Compiled Laws s. 333.7201-7231].

Minnesota: Minnesota has included the thirty-eight (38) anabolic steroids listed in this rule as schedule III controlled substances [Minnesota Statutes 152.02 (4) (f) (1)].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

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STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
101 EAST WILSON STREET, 10TH FLOOR
P.O. BOX 7864
MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	: : : :	**REPORT TO THE LEGISLATURE CR 23-019**

I. THE PROPOSED RULE:
The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA: The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:
This rule schedules Daridorexant as a schedule IV controlled substance. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Daridorexant as a schedule IV controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Daridorexant under chapter 961, Stats. by creating the following:

CSB 2.93 Addition of Daridorexant to schedule IV. Section 961.20 (2) (cpm), Stats., is created to read:

961.20 (2) (cpm) Daridorexant.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, when it was published in the Administrative Register and expires upon promulgation of a final rule.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:
Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:
All of the recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-019)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.93 relating to scheduling Daridorexant.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.20, Stats.

Statutory authority: s. 961.11 (1) and (4), Stats.

Explanation of agency authority:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

Related statute or rule: s. 961.20, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On April 7, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Daridorexant into schedule IV of the federal Controlled Substances Act. The scheduling action is effective April 7, 2022.

Plain language analysis:
This rule schedules Daridorexant as a schedule IV controlled substance. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Daridorexant as a schedule IV controlled substance. Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Daridorexant under chapter 961, Stats. by creating the following:

CSB 2.93 Addition of Daridorexant to schedule IV. Section 961.20 (2) (cpm), Stats., is created to read:

961.20 (2) (cpm) Daridorexant.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, when it was published in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: Illinois has not scheduled Daridorexant as a schedule IV controlled substance [720 Illinois Compiled Statutes 570/210 (c)].

Iowa: Iowa has not scheduled Daridorexant as a schedule IV controlled substance [Iowa Code 124.210 (3)].

Michigan: Michigan has not scheduled Daridorexant as a schedule IV controlled substance [Michigan Compiled Laws s. 333.7218].

Minnesota: Minnesota has not scheduled Daridorexant as a schedule IV controlled substance [Minnesota Statutes 152.02 (5)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Daridorexant to conform with the federal Controlled Substances Act.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule schedules Daridorexant as a Schedule IV controlled substance which will not have any effect on small business.

Fiscal Estimate:
The proposed rule was posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by July 14, 2023 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.93 is created to read:

CSB 2.93 Addition of Daridorexant to schedule IV. Section 961.20 (2) (cpm), Stats., is created to read:

961.20 (2) (cpm) Daridorexant.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
04/26/23

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.93

4. Subject
Schedulinng Daridorexant

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
ss. 20.165 (1) (g) and (hg)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☒ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☒ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
On April 7, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Daridorexant into schedule IV of the federal Controlled Substances Act. The scheduling action is effective April 7, 2022.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
The rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole. The Department of Safety and Professional Services estimates a total of $2,500 in one-time costs. These estimated costs may not be absorbed in the agency budget

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that the federal and state controlled substances acts will be uniform to avoid confusion.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are that Daridorexant will be added to Wis. Stat. ch. 961 as a schedule IV controlled substance.

17. Compare With Approaches Being Used by Federal Government
The federal government has scheduled Daridorexant as schedule IV controlled substance.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Illinois: Illinois has not scheduled Daridorexant as a schedule IV controlled substance [720 Illinois Compiled Statutes 570/210 (c)].

Iowa: Iowa has not scheduled Daridorexant as a schedule IV controlled substance [Iowa Code 124.210 (3)].

Michigan: Michigan has not scheduled Daridorexant as a schedule IV controlled substance [Michigan Compiled Laws s. 333.7218].

Minnesota: Minnesota has not scheduled Daridorexant as a schedule IV controlled substance [Minnesota Statutes 152.02 (5)].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

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DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	**:** **:** **:** **:**	**REPORT TO THE LEGISLATURE CR 23-020**

I. THE PROPOSED RULE:
The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA: The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:
This rule adds seven (7) synthetic benzimidazole-opioid substances to schedule I under ch. 961, Stats. This rule also amends ss. 961.14 (2) (mm) and (pe), Stats. to add the scientific descriptions for two already scheduled synthetic benzimidazole-opioid substances and renumber them to group them with the seven new substances being added.

The Controlled Substances Board did not receive an objection to similarly treating the following seven (7) synthetic benzimidazole-opioid substances as schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating them as controlled substances:

- 2-(2-(4-butoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine (butonitazene),
- 2-(2-(4-ethoxybenzyl)-1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine (etodesnitazene; etazene),
- N,N-diethyl-2-(2-(4-fluorobenzyl)-5- nitro-1H-benzimidazol-1-yl)ethan-1- amine (flunitazene),
- N,N-diethyl-2-(2-(4- methoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (metodesnitazene),
- N,N-diethyl-2-(2-(4- methoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)ethan-1-amine (metonitazene),
- 2-(4-ethoxybenzyl)-5-nitro-1-(2- (pyrrolidin-1-yl)ethyl)-1Hbenzimidazole (N-pyrrolidino etonitazene; etonitazepyne), and
- N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (protonitazene).

Therefore, pursuant to s. 961.11(4), Stats., the Controlled Substances Board by Affirmative Action similarly treated the seven (7) synthetic benzimidazole-opioid substances listed above, under chapter 961, Stats and is now following up with a final rule.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, when it was published in the Administrative Register and expires upon promulgation of a final rule.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS:

All of the recommendations suggested in the Clearinghouse Report have been accepted in whole.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-020)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.94 relating to scheduling seven (7) synthetic benzimidazole-opioid substances.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.14, Stats.

Statutory authority: s. 961.11 (1) and (4), Stats.

Explanation of agency authority:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

Related statute or rule: s. 961.14, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On April 12, 2022, the Department of Justice, Drug Enforcement Administration published its temporary scheduling order in the Federal Register placing the following seven (7) synthetic benzimidazole-opioid substances into schedule I of the federal Controlled Substances Act. The scheduling action was effective immediately.

Plain language analysis:
This rule adds seven (7) synthetic benzimidazole-opioid substances to schedule I under ch. 961, Stats. This rule also amends ss. 961.14 (2) (mm) and (pe), Stats. to add the scientific descriptions for two already scheduled synthetic benzimidazole-opioid substances and renumber them to group them with the seven new substances being added.

The Controlled Substances Board did not receive an objection to similarly treating the following seven (7) synthetic benzimidazole-opioid substances as schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order designating them as controlled substances:

- 2-(2-(4-butoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine (butonitazene),
- 2-(2-(4-ethoxybenzyl)-1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine (etodesnitazene; etazene),
- N,N-diethyl-2-(2-(4-fluorobenzyl)-5- nitro-1H-benzimidazol-1-yl)ethan-1- amine (flunitazene),
- N,N-diethyl-2-(2-(4- methoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (metodesnitazene),
- N,N-diethyl-2-(2-(4- methoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)ethan-1-amine (metonitazene),
- 2-(4-ethoxybenzyl)-5-nitro-1-(2- (pyrrolidin-1-yl)ethyl)-1Hbenzimidazole (N-pyrrolidino etonitazene; etonitazepyne), and
- N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (protonitazene).

Therefore, pursuant to s. 961.11(4), Stats., the Controlled Substances Board by Affirmative Action similarly treated the seven (7) synthetic benzimidazole-opioid substances listed above, under chapter 961, Stats and is now following up with a final rule.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, when it was published in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:

Illinois: Illinois has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Iowa Code 124.204].

Michigan: Michigan has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Minnesota Statutes 152.02 (2)].

Summary of factual data and analytical methodologies:
The methodology was to schedule seven (7) synthetic benzimidazole-opioid substances to conform with the federal Controlled Substances Act.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:
The rule schedules seven (7) synthetic benzimidazole-opioid substances as Schedule III controlled substances which will not have any effect on small business.

Fiscal Estimate:
The proposed rule was posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by July 14, 2023 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.94 is created to read:

CSB 2.94 Addition of seven (7) synthetic benzimidazole-opioid substances to schedule I.
(1) Section 961.14 (2) (mm) and (pe), Stats. are renumbered to 961.14 (2) (xm) 3. and 5. And amended to read:

961.14 (2) (xm) 3. Etonitazene (2-(2-(4-ethoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1- amine).

961.14 (2) (xm) 5. Isotonitazene (N,N -diethyl-2-(2-(4-isopropoxybenzyl)-5-nitro-1H-benizimidazol-1-yl)ethan-1-amine).

(2) Section 961.14 (2) (xm) 1., 2., 4., and 6. to 9., Stats., are created to read:

961.14 (2) (xm) Synthetic Benzimidazole-opioid Substances, specifically including all of the following:

1. Butonitazene (2-(2-(4-butoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)-N,N-diethylethan-1-amine).

2. Etodesnitazene also known as Etazene (2-(2-(4-ethoxybenzyl)-1H-benzimidazol-1-yl)-N,N-diethylethan-1- amine).

4. Flunitazene (N,N-diethyl-2-(2-(4-fluorobenzyl)-5- nitro-1H-benzimidazol-1-yl)ethan-1-amine).

6. Metodesnitazene (N,N-diethyl-2-(2-(4- methoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine).

7. Metonitazene (N,N-diethyl-2-(2-(4- methoxybenzyl)-5-nitro-1H-benzimidazol-1-yl)ethan-1-amine).

8. N-pyrrolidino etonitazene also known as etonitazepyne (2-(4-ethoxybenzyl)-5-nitro-1-(2-(pyrrolidin-1-yl)ethyl)-1H-benzimidazole).

9. Protonitazene (N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine).

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

DIVISION OF EXECUTIVE BUDGET AND FINANCE
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FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
04/26/23

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.94

4. Subject
Schedulinng seven (7) synthetic benzimidazole-opioid substances

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
ss. 20.165 (1) (g) and (hg)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☒ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☒ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
On April 12, 2022, the Department of Justice, Drug Enforcement Administration published its temporary scheduling order in the Federal Register placing the following seven (7) synthetic benzimidazole-opioid substances into schedule I of the federal Controlled Substances Act. The scheduling action was effective immediately.

- 2-(2-(4-butoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine (butonitazene),
- 2-(2-(4-ethoxybenzyl)-1Hbenzimidazol-1-yl)-N,N-diethylethan-1- amine (etodesnitazene; etazene),
- N,N-diethyl-2-(2-(4-fluorobenzyl)-5- nitro-1H-benzimidazol-1-yl)ethan-1- amine (flunitazene),
- N,N-diethyl-2-(2-(4- methoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (metodesnitazene),
- N,N-diethyl-2-(2-(4- methoxybenzyl)-5-nitro-1Hbenzimidazol-1-yl)ethan-1-amine (metonitazene),
- 2-(4-ethoxybenzyl)-5-nitro-1-(2- (pyrrolidin-1-yl)ethyl)-1Hbenzimidazole (N-pyrrolidino etonitazene; etonitazepyne), and
- N,N-diethyl-2-(5-nitro-2-(4- propoxybenzyl)-1H-benzimidazol-1- yl)ethan-1-amine (protonitazene)

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals. No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
The rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole. The Department of Safety and Professional Services estimates a total of $2,500 in one-time costs. These estimated costs may not be absorbed in the agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule

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MADISON, WI 53707-7864
FAX: (608) 267-0372

ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

The benefit is that the federal and state controlled substances acts will be uniform to avoid confusion.

16. Long Range Implications of Implementing the Rule

The long range implications of implementing the rule are that seven (7) synthetic benzimidazole-opioid substances will be added to Wis. Stat. ch. 961 as a schedule I controlled substances.

17. Compare With Approaches Being Used by Federal Government

The federal government has scheduled these seven (7) synthetic benzimidazole-opioid substancesas as schedule I controlled substances.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

Illinois: Illinois has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [720 Illinois Compiled Statutes 570/204].

Iowa: Iowa has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Iowa Code 124.204].

Michigan: Michigan has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Michigan Compiled Laws s. 333.7212].

Minnesota: Minnesota has not included the seven (7) synthetic benzimidazole-opioid substances listed in this rule as schedule I controlled substances [Minnesota Statutes 152.02 (2)].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

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STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULEMAKING	**:**	
PROCEEDINGS BEFORE THE	**:**	**REPORT TO THE LEGISLATURE**
CONTROLLED SUBSTANCES BOARD	**:**	**CR 23-021**

I. THE PROPOSED RULE: The proposed rule, including the analysis and text, is attached.

II. REFERENCE TO APPLICABLE FORMS: N/A

III. FISCAL ESTIMATE AND EIA: The Fiscal Estimate and EIA is attached.

IV. DETAILED STATEMENT EXPLAINING THE BASIS AND PURPOSE OF THE PROPOSED RULE, INCLUDING HOW THE PROPOSED RULE ADVANCES RELEVANT STATUTORY GOALS OR PURPOSES:

This rule schedules Ganaxolone as a schedule V controlled substance.

The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Ganaxolone as a schedule V controlled substance.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Ganaxolone under chapter 961, Stats. by creating the following:

> **CSB 2.95 Addition of Ganaxolone to schedule V**. Section 961.22 (11), Stats., is created to read:
>
> 961.22 (11) Ganaxolone.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, when it was published in the Administrative Register and expires upon promulgation of a final rule.

V. SUMMARY OF PUBLIC COMMENTS AND THE BOARD'S RESPONSES, EXPLANATION OF MODIFICATIONS TO PROPOSED RULES PROMPTED BY PUBLIC COMMENTS:

Per s. 961.11(4), Stats., if no objection is made, the board shall promulgate a final rule for which notice of proposed rulemaking is omitted. Therefore, the Board did not hold a public hearing.

VI. RESPONSE TO LEGISLATIVE COUNCIL STAFF RECOMMENDATIONS: Legislative Council staff did not make any recommendations.

VII. REPORT FROM THE SBRRB AND FINAL REGULATORY FLEXIBILITY ANALYSIS: N/A

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING PROCEEDINGS BEFORE THE CONTROLLED SUBSTANCES BOARD	:	PROPOSED ORDER OF THE CONTROLLED SUBSTANCES BOARD ADOPTING RULES (CLEARINGHOUSE RULE 23-021)

PROPOSED ORDER

An order of the Controlled Substances Board to create CSB 2.95 relating to scheduling Ganaxolone.

Analysis prepared by the Department of Safety and Professional Services.

ANALYSIS

Statutes interpreted: s. 961.22, Stats.

Statutory authority: s. 961.11 (1) and (4), Stats.

Explanation of agency authority:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

Related statute or rule: s. 961.22, Stats.

Summary of, and comparison with, existing or proposed federal regulation:
On June 1, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Ganaxolone into schedule V of the federal Controlled Substances Act. The scheduling action is effective June 1, 2022.

Plain language analysis:
This rule schedules Ganaxolone as a schedule V controlled substance.

The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing Ganaxolone as a schedule V controlled substance.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Ganaxolone under chapter 961, Stats. by creating the following:

> **CSB 2.95 Addition of Ganaxolone to schedule V**. Section 961.22 (11), Stats., is created to read:
>
> 961.22 (11) Ganaxolone.

The Affirmative Action order, dated July 20, 2022, took effect on July 25, 2022, when it was published in the Administrative Register and expires upon promulgation of a final rule.

Summary of public comments received on statement of scope and a description of how and to what extent those comments and feedback were taken into account in drafting the proposed rule: N/A

Comparison with rules in adjacent states:
Illinois: Illinois has not listed Ganaxolone as a schedule V controlled substance [720 Illinois Compiled Statutes 570/212].

Iowa: Iowa has not listed Ganaxolone as a schedule V controlled substance [Iowa Code 124.212].

Michigan: Michigan has not listed Ganaxolone as a schedule V controlled substance [Michigan Compiled Laws s. 333.7220].

Minnesota: Minnesota has not listed Ganaxolone as a schedule V controlled substance [Minnesota Statutes 152.02 (6)].

Summary of factual data and analytical methodologies:
The methodology was to schedule Ganaxolone to conform with the federal Controlled Substances Act.

Analysis and supporting documents used to determine effect on small business or in preparation of economic impact analysis:

The rule schedules Ganaxolone as a Schedule V controlled substance which will not have any effect on small business.

Fiscal Estimate:
The proposed rule was posted for a period of 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.

Effect on small business:
These proposed rules do not have an economic impact on small businesses, as defined in s. 227.114 (1), Stats. The Department's Regulatory Review Coordinator may be contacted by email at Jennifer.Garrett@wisconsin.gov, or by calling (608) 266-6795.

Agency contact person:
Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, P.O. Box 8366, Madison, Wisconsin 53708; telephone 608-267-7139; email at DSPSAdminRules@wisconsin.gov.

Place where comments are to be submitted and deadline for submission:
Comments may be submitted to Nilajah Hardin, Administrative Rules Coordinator, Department of Safety and Professional Services, Division of Policy Development, 4822 Madison Yards Way, Madison, WI 53708-8366, or by email to DSPSAdminRules@wisconsin.gov. Comments must be received by July 14, 2023 to be included in the record of rulemaking proceedings.

TEXT OF RULE

SECTION 1. CSB 2.95 is created to read:

CSB 2.95 Addition of Ganaxolone to schedule V. Section 961.22 (11), Stats., is created to read:

961.22 (11) Ganaxolone.

SECTION 2. EFFECTIVE DATE. The rules adopted in this order shall take effect on the first day of the month following publication in the Wisconsin Administrative Register, pursuant to s. 227.22 (2) (intro.), Stats.

(END OF TEXT OF RULE)

This Proposed Order of the Controlled Substances Board is approved for submission to the Governor and Legislature.

Dated _____ Agency _____

Chairperson
Controlled Substances Board

STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

1. Type of Estimate and Analysis
☒ Original ☐ Updated ☐ Corrected

2. Date
04/26/23

3. Administrative Rule Chapter, Title and Number (and Clearinghouse Number if applicable)
CSB 2.95

4. Subject
Schedulinng Ganaxolone

5. Fund Sources Affected
☐ GPR ☐ FED ☒ PRO ☐ PRS ☐ SEG ☐ SEG-S

6. Chapter 20, Stats. Appropriations Affected
ss. 20.165 (1) (g) and (hg)

7. Fiscal Effect of Implementing the Rule
☐ No Fiscal Effect ☐ Increase Existing Revenues ☒ Increase Costs ☐ Decrease Costs
☒ Indeterminate ☐ Decrease Existing Revenues ☐ Could Absorb Within Agency's Budget

8. The Rule Will Impact the Following (Check All That Apply)
☐ State's Economy
☐ Local Government Units
☒ Specific Businesses/Sectors
☐ Public Utility Rate Payers
☐ Small Businesses **(if checked, complete Attachment A)**

9. Estimate of Implementation and Compliance to Businesses, Local Governmental Units and Individuals, per s. 227.137(3)(b)(1).
$0

10. Would Implementation and Compliance Costs Businesses, Local Governmental Units and Individuals Be $10 Million or more Over Any 2-year Period, per s. 227.137(3)(b)(2)?
☐ Yes ☒ No

11. Policy Problem Addressed by the Rule
On June 1, 2022, the Department of Justice, Drug Enforcement Administration published its interim final rule in the Federal Register listing Ganaxolone into schedule V of the federal Controlled Substances Act. The scheduling action is effective June 1, 2022.

12. Summary of the Businesses, Business Sectors, Associations Representing Business, Local Governmental Units, and Individuals that may be Affected by the Proposed Rule that were Contacted for Comments.
The rule was posted on the Department's website for 14 days to solicit public comment on economic impact, including how the proposed rules may affect businesses, local government units, and individuals.No comments were received.

13. Identify the Local Governmental Units that Participated in the Development of this EIA.
None.

14. Summary of Rule's Economic and Fiscal Impact on Specific Businesses, Business Sectors, Public Utility Rate Payers, Local Governmental Units and the State's Economy as a Whole (Include Implementation and Compliance Costs Expected to be Incurred)
The rule will not have an economic or fiscal impact on specific businesses, business sectors, public utility rate payers, local governmental units or the state's economy as a whole. The Department of Safety and Professional Services estimates a total of $2,500 in one-time costs. These estimated costs may not be absorbed in the agency budget.

15. Benefits of Implementing the Rule and Alternative(s) to Implementing the Rule
The benefit is that the federal and state controlled substances acts will be uniform to avoid confusion.

16. Long Range Implications of Implementing the Rule
The long range implications of implementing the rule are that Ganaxolone will be added to Wis. Stat. ch. 961 as a schedule V controlled substance.

17. Compare With Approaches Being Used by Federal Government
The federal government has scheduled Ganaxolone as schedule V controlled substance.

18. Compare With Approaches Being Used by Neighboring States (Illinois, Iowa, Michigan and Minnesota)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

Illinois: Illinois has not listed Ganaxolone as a schedule V controlled substance [720 Illinois Compiled Statutes 570/212].

Iowa: Iowa has not listed Ganaxolone as a schedule V controlled substance [Iowa Code 124.212].

Michigan: Michigan has not listed Ganaxolone as a schedule V controlled substance [Michigan Compiled Laws s. 333.7220].

Minnesota: Minnesota has not listed Ganaxolone as a schedule V controlled substance [Minnesota Statutes 152.02 (6)].

19. Contact Name	20. Contact Phone Number
Nilajah Hardin, Administrative Rules Coordinator	608-267-7139

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STATE OF WISCONSIN
DEPARTMENT OF ADMINISTRATION
DOA-2049 (R09/2016)

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ADMINISTRATIVE RULES
Fiscal Estimate & Economic Impact Analysis

ATTACHMENT A

1. Summary of Rule's Economic and Fiscal Impact on Small Businesses (Separately for each Small Business Sector, Include Implementation and Compliance Costs Expected to be Incurred)

2. Summary of the data sources used to measure the Rule's impact on Small Businesses

3. Did the agency consider the following methods to reduce the impact of the Rule on Small Businesses?
☐ Less Stringent Compliance or Reporting Requirements
☐ Less Stringent Schedules or Deadlines for Compliance or Reporting
☐ Consolidation or Simplification of Reporting Requirements
☐ Establishment of performance standards in lieu of Design or Operational Standards
☐ Exemption of Small Businesses from some or all requirements
☐ Other, describe:

4. Describe the methods incorporated into the Rule that will reduce its impact on Small Businesses

5. Describe the Rule's Enforcement Provisions

6. Did the Agency prepare a Cost Benefit Analysis (if Yes, attach to form)
☐ Yes ☐ No

From:	Software-Notification@legis.wisconsin.gov
To:	DSPS Admin Rules
Cc:	cheeseheadnate@gmail.com
Subject:	Public comment on CR 23-021
Date:	Saturday, July 8, 2023 12:29:05 AM

Name: Nathan Elliott
Address: 1401 Wisconsin St. , Oshkosh WI 54901
Email: cheeseheadnate@gmail.com

Organization: Wisconsin Citizen

Comments: I would like to register my opinion on CR 23-021 as it pertains to Wisconsin listing Ganaxolone as a Schedule V substance.

I would fully support and encourage that Ganaxolone be listed as a Schedule V substance, given that it can be abused and lead to dependence (according the manufacturer's own website at ztalmy.com under the section titled "What is Ztalmy").

thank you for your time and attention.

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2.001

Relating to: Scheduling Methiopropamine

Rule Type: Permanent

1. Finding/nature of emergency: N/A

2. Detailed description of the objective of the proposed rule:
The objective of the proposed rule is to schedule Methiopropamine as a schedule I controlled substance under s. 961.11 (4), Stats.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
On December 9, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding Methiopropamine to schedule I of the federal Controlled Substances Act. The scheduling action was effective January 9, 2023.

The Controlled Substances Board did not receive an objection to similarly listing Methiopropamine as a schedule I under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing Methiopropamine as a schedule I controlled substance.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Methiopropamine under chapter 961, Stats. by creating the following:

> **CSB 2.001 Addition of Methiopropamine to Schedule I**. Section 961.14 (7) (t), Stats., is created to read:
>
> **961.14 (7) (t)** N-methyl-1-(thiophen-2-yl)propan-2-amine, commonly known as Methiopropamine.

The Affirmative Action order, dated March 24, 2023, took effect on April 3, 2023, upon publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination

with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:
Approximately 80 hours.

6. List with description of all entities that may be affected by the proposed rule:
Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
On December 9, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register adding Methiopropamine to schedule I of the federal Controlled Substances Act. The scheduling action was effective January 9, 2023.

8. Anticipated economic impact of implementing the rule: None to minimal.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, DSPSAdminRules@wisconsin.gov

Approved for publication:

Authorized Signature

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

STATEMENT OF SCOPE

CONTROLLED SUBSTANCES BOARD

Rule No.: CSB 2.002

Relating to: Excluding Fenfluramine

Rule Type: Permanent

1. Finding/nature of emergency: N/A

2. Detailed description of the objective of the proposed rule:
The objective of the proposed rule is to remove Fenfluramine as a schedule IV controlled substance under s. 961.11 (4), Stats.

3. Description of the existing policies relevant to the rule, new policies proposed to be included in the rule, and an analysis of policy alternatives:
On December 23, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing Fenfluramine from schedule IV of the federal Controlled Substances Act. The scheduling action was effective on December 23, 2022.

The Controlled Substances Board did not receive an objection to similarly excluding Fenfluramine as a schedule IV controlled substance under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order removing Fenfluramine as a schedule IV controlled substance.

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Fenfluramine under chapter 961, Stats. by creating the following:

> **CSB 2.002 Excluding Fenfluramine from schedule IV**. Section 961.20 (4) (am), Stats. is repealed.

The Affirmative Action order, dated April 7, 2023, took effect on April 17, 2023, upon publication in the Administrative Register and expires upon promulgation of a final rule.

4. Detailed explanation of statutory authority for the rule:
Section 961.11 (1), Stats. provides that "[t]he controlled substances board shall administer this subchapter and may add substances to or delete or reschedule all substances listed in the schedules in ss. 961.14, 961.16, 961.18, 961.20 and 961.22 pursuant to the rule-making procedures of ch. 227."

Section 961.11(4), Stats. provides that "[i]f a substance is designated, rescheduled or deleted as a controlled substance under federal law and notice thereof is given to the controlled substances board, the board by affirmative action shall similarly treat the substance under this chapter after the expiration of 30 days from the date of publication in the federal register of a final order designating the substance as a controlled substance or rescheduling or deleting the substance or from the date of issuance of an order of temporary scheduling under 21 USC 811 (h), unless within that 30−day period, the board or an interested party objects to the treatment of the substance. If no objection is made, the board shall promulgate, without making the determinations or findings required by subs. (1), (1m), (1r) and (2) or s. 961.13, 961.15, 961.17, 961.19 or 961.21, a final rule, for which notice of proposed rulemaking is omitted, designating, rescheduling, temporarily scheduling or deleting the substance. If an objection is made the board shall publish notice of receipt of the objection and the reasons for objection and afford all interested parties an opportunity to be heard. At the conclusion of the hearing, the board shall make a determination with respect to the treatment of the substance as provided in subs. (1), (1m), (1r) and (2) and shall

publish its decision, which shall be final unless altered by statute. Upon publication of an objection to the treatment by the board, action by the board under this chapter is stayed until the board promulgates a rule under sub. (2)."

5. Estimate of amount of time that state employees will spend developing the rule and of other resources necessary to develop the rule:
Approximately 80 hours.

6. List with description of all entities that may be affected by the proposed rule:
Law enforcement, district attorney offices, Dept of Justice, state courts and the Controlled Substances Board.

7. Summary and preliminary comparison with any existing or proposed federal regulation that is intended to address the activities to be regulated by the proposed rule:
On December 23, 2022, the Department of Justice, Drug Enforcement Administration published its final rule in the Federal Register removing Fenfluramine from schedule IV of the federal Controlled Substances Act. The scheduling action was effective on December 23, 2022.

8. Anticipated economic impact of implementing the rule: None to minimal.

Contact Person: Nilajah Hardin, Administrative Rules Coordinator, DSPSAdminRules@wisconsin.gov

Approved for publication:

Authorized Signature

Date Submitted

Approved for implementation:

Authorized Signature

Date Submitted

STATE OF WISCONSIN
CONTROLLED SUBSTANCES BOARD

IN THE MATTER OF RULE-MAKING	:	AFFIRMATIVE ACTION
PROCEEDINGS BEFORE THE	:	ORDER OF THE
CONTROLLED SUBSTANCES BOARD	:	CONTROLLED SUBSTANCES BOARD

FINDINGS

1. On July 26, 2023, the Department of Justice, Drug Enforcement Administration published its temporary amendment and scheduling order in the Federal Register adding the following 5 synthetic benzodiazepine substances to schedule I of the federal Controlled Substances Act:

- Etizolam
- Flualprazolam
- Clonazolam
- Flubromazolam
- Diclazepam

The scheduling action is effective July 26, 2023.

2. The Controlled Substances Board did not receive an objection to similarly listing the above 5 synthetic benzodiazepine substances as schedule I controlled substances under ch. 961, Stats. within 30 days of the date of publication in the federal register of the final order listing the above 5 synthetic benzodiazepine substances as schedule I controlled substances.

3. The Controlled Substances Board will promulgate a final rule, without making the determinations or findings required by ss. 961.11(1), (1m), (1r) and (2) or s. 961.19 and omitting the notice of proposed rulemaking, listing the above 5 synthetic benzodiazepine substances as schedule I controlled substances.

ORDER

Pursuant to s. 961.11(4), Stats., the Controlled Substances Board by affirmative action similarly treats Methiopropamine under chapter 961, Stats. by creating the following:

CSB 2.003 Transfer of Flualprazolam and Addition of 4 Other Synthetic Benzodiazepine Substances to Schedule I. **(1)** Section 961.20 (2) (ef), Stats. is repealed.

(2) Section 961.14 (5) (aa), (ab), (ac), (ad), and (ae) Stats., are created to read:

961.14 (5) (aa) Clonazolam (6-(2-chlorophenyl)-1-methyl-8-nitro-4 *H* -benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ab) Diclazepam (7-chloro-5-(2-chlorophenyl)-1-methyl-1,3-dihydro-2 *H* -benzo[*e*][1,4]diazepin-2-one).

(ac) Etizolam (4-(2-chlorophenyl)-2-ethyl-9-methyl-6 *H* -thieno[3,2-*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ad) Flualprazolam (8-chloro-6-(2-fluorophenyl)-1-methyl-4 *H* -benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

(ae) Flubromazolam.(8-bromo-6-(2-fluorophenyl)-1-methly-4 *H* -benzo[*f*][1,2,4]triazolo[4,3-*a*][1,4]diazepine).

This order shall become effective upon publication in the Administrative Register. The order expires upon promulgation of a final rule.

Dated _____ _____

Doug Englebert, Chair
Controlled Substances Board

Controlled Substances Board
Rule Projects (updated 08/28/23)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
22-011	070-21	02/29/2024	CSB 2.78	Scheduling Crotonyl Fentanyl	Effective 07/01/2023	N/A
22-014	071-21	02/29/2024	CSB 2.79	Scheduling Remimazolam	Effective 07/01/2023	N/A e
22-016	072-21	02/29/2024	CSB 2.81	Scheduling Brorphine	Effective 07/01/2023	N/A
22-032	088-21	04/18/2024	CSB 2.82	Scheduling Serdexmethylphenidate	Effective 07/01/2023	N/A
22-033	089-21	04/18/2024	CSB 2.83	Scheduling 10 Fentanyl Related Substances	Effective 07/01/2023	N/A
22-034	090-21	04/18/2024	CSB 2.84	Scheduling Alfaxalone	Effective 07/01/2023	N/A
22-035	091-21	04/18/2024	CSB 2.85	Excluding 6-beta-Naltrexol	Effective 07/01/2023	N/A
22-036	092-21	04/18/2024	CSB 2.86	Scheduling Fospropofol	Effective 07/01/2023	N/A
22-037	093-21	04/18/2024	CSB 2.87	Scheduling Embutramide	Effective 07/01/2023	N/A
22-039	094-21	04/18/2024	CSB 2.88	Scheduling Lacosamide	Effective 07/01/2023	N/A
22-038	095-21	04/18/2024	CSB 2.89	Scheduling Perampanel	Effective 07/01/2023	N/A
22-040	096-21	04/18/2024	CSB 2.90	Transferring 1-phenylcyclohexylamine and 1-piperidinocyclohexanecarbonitrile, Immediate Precursors to Phencyclidine, Also Known as PCP	Effective 07/01/2023	N/A e
22-054	015-22	08/28/2024	CSB 2.91	Scheduling 4,4'-Dimethylaminorex	Effective 07/01/2023	N/A

Controlled Substances Board
Rule Projects (updated 08/28/23)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
23-018	091-22	05/21/2025	CSB 2.92	Scheduling 35 Anabolic Steroids	Board Review of Final Rule Draft and Legislative Report at 09/08/23 Meeting	Submission to the Governor's Office and Legislature for Review
23-019	092-22	05/21/2025	CSB 2.93	Scheduling Daridorexant	Board Review of Final Rule Draft and Legislative Report at 09/08/23 Meeting	Submission to the Governor's Office and Legislature for Review
23-020	093-22	05/21/2025	CSB 2.94	Scheduling 7 Synthetic Benzimidazole-Opioids	Board Review of Final Rule Draft and Legislative Report at 09/08/23 Meeting	Submission to the Governor's Office and Legislature for Review
23-021	094-22	05/21/2025	CSB 2.95	Scheduling Ganaxolone	Board Review of Final Rule Draft and Legislative Report at 09/08/23 Meeting	Submission to the Governor's Office and Legislature for Review t
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.96	Scheduling Amineptine	Scope Statement Pending Implementation	Drafting
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.97	Scheduling Zipeprol	Scope Statement Pending Implementation	Drafting
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.98	Excluding [^{18} F] FP-CIT	Scope Statement Pending Implementation	Drafting
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.99	Scheduling Mesocarb	Scope Statement Pending Implementation	Drafting
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.001	Scheduling Methiopropamine	Scope Statement Reviewed at 09/08/23 Meeting	Scope Submitted for Governor Approval and Publication
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.002	Excluding Fenfluramine	Scope Statement Reviewed at 09/08/23 Meeting	Scope Submitted for Governor Approval and Publication
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 2.003	Transferring Flualprazolam and Scheduling 4 Other Synthetic Benzodiazepine Substances	Affirmative Action Order Reviewed at 09/08/23 Meeting	Affirmative Action Order Submitted for Publication

Controlled Substances Board
Rule Projects (updated 08/28/23)

CH Rule Number	Scope Number	Scope Expiration Date	Code Chapter Affected	Relating Clause	Stage of Rule Process	Next Step
Not Assigned Yet	095-22	05/21/2025	CSB 4	National Provider Identifier Requirement	Drafting	Board Review of Preliminary Rule Draft
Not Assigned Yet	Not Assigned Yet	Not Assigned Yet	CSB 4	Monitored Prescription Drug History Reports	Scope Statement Pending Implementation	Drafting

State of Wisconsin
Department of Safety & Professional Services

AGENDA REQUEST FORM

1) Name and title of person submitting the request:	2) Date when request submitted:
Marjorie Liu **Program Lead, PDMP**	08/282023 Items will be considered late if submitted after 12:00 p.m. on the deadline date which is 8 business days before the meeting

3) Name of Board, Committee, Council, Sections:

Controlled Substances Board

4) Meeting Date:	5) Attachments:	6) How should the item be titled on the agenda page?
09/08/2023	☒ Yes ☐ No	Prescription Drug Monitoring Program (PDMP) Updates – Discussion and Consideration

7) Place Item in:	8) Is an appearance before the Board being scheduled? *(If yes, please complete Appearance Request for Non-DSPS Staff)*	9) Name of Case Advisor(s), if required:
☒ Open Session ☐ Closed Session	☐ Yes ☒ No	

10) Describe the issue and action that should be addressed: Type text here

1. WI ePDMP Operations
    a. CSB PDMP Q2 2023 Report Completed
    b. Recent and Upcoming Releases
    c. EHR Integration Status
    d. Interstate Data Exchange
2. WI ePDMP Outreach

11) Authorization

Marjorie Liu — 08/28/2023

Signature of person making this request — **Date**

Supervisor (if required) — **Date**

Executive Director signature (indicates approval to add post agenda deadline item to agenda) — **Date**

Directions for including supporting documents:
1. This form should be attached to any documents submitted to the agenda.
2. Post Agenda Deadline items must be authorized by a Supervisor and the Policy Development Executive Director.
3. If necessary, provide original documents needing Board Chairperson signature to the Bureau Assistant prior to the start of a meeting.

2021-2023 Development and Release Summary

Updated 08.25.2023

Release Date	Description
Pending	
Harold Rogers Grant 2020 Component 3 Release date TBD	Automation of top prescribing reports Site reskin/redesign Ability for users to change the order in which the sections of the patient report are presented. Adding a Buprenorphine Naïve Alert section to the patient report.
Harold Rogers Grant 2020 Component 2 Release date TBD	Infrastructure and Technology stack changes to improve performance in the following areas: • Patient Matching • Dispensing Matching • Reporting Statistics
Completed	
R30 February 2023	Iframe support Prescriber Practice Metric UI Text updates Maintenance Updates
R29 October 2022	Updated mapping tool Adjusted language for expired temporary licenses Modified file processing
R28 July 2022	Adding language related to Buprenorphine Alert Override • Minor text changes to submission error emails • Minor language changes around alert messaging Maintenance Updates
Harold Rogers Grant 2021 Promotional Materials May 2022	Promotional Materials for free EHR Integrations Maintenance Updates
R26 April 2022	Buprenorphine Alert Override • Ability to override prescriber facing alerts, metrics, and MME calculations for certain drugs. Maintenance Updates RxCheck 3.0 Upgrades
Harold Rogers Grant 2020 Component 1 December 2021	Security Enhancements • Two-Factor Authentication • Compromised Email Address Check Patient Report and other User Experience Updates

R25 **November 2021**	Maintenance Updates • Adjustments to triggering Annual Terms and Conditions prompt • Enhanced EHR Integration Testing capabilities Chatbot display changes
R24 **August 2021**	Text Updates • Gabapentin related text changes to the Submitter Error Email. Security-Related Enhancements
R23 **July 2021**	Text Updates • Gabapentin related text changes to the Submitter Error Email.
R22 **July 2021**	Pharmacy-Related Enhancements • Missing DEA Number Error Process Updates Administrative-Related Enhancements
R21 **May 2021**	New Design Enhancements • Proactive MC/HCP linkage renewals • Search enhancements Administrative-Related Enhancements Additional administrator tools
R20 **March 2021**	WI DOJ-Medical College of Wisconsin DataShare Project • Automatically send data extracts to DOJ-MCW • Automatically receive data extracts from DOJ-MCW Administrative-Related Enhancements • Additional improvements to query process • Additional administrator tools

WI ePDMP Integration Services Summary

Current as of 08.25.2023

Pending Health Systems and EHR Platforms	Status			Notes
Allina Health	Implementation in progress			
QuadMed, LLC	Implementation in progress			
CompuGroup Medical	Initial stages			
Connected Health Systems (approx. 57% of monthly patient queries)	**Free Pricing Model**	**Implementation Date**	**Est. Total # of Users**	**Notes**
Advent Health	Y	03/05/2023		
Ascension Wisconsin				
Aspirus Health Care				
Aurora Health Care				
Children's Hospital of Wisconsin	Y	09/01/2022	300	
Clark County	Y			
Clean Slate	Y	09/01/2022	26	
DrFirst				
Froedtert & the Medical College of Wisconsin				Pending signed Free agreement
GHC of South Central Wisconsin				
Gundersen Health System				Pending signed Free agreement
HealthPartners				
HSHS / Prevea Health	Y	01/01/2023		
M Health Fairview	Y	08/01/2022	30	
Marshfield Clinic	Y	09/01/2022	100	
Mayo Clinic				
Mercy Health	Y	08/01/2022	766	
Monroe Clinic				
NOVO Health Technology Group	Y	02/01/2023		
Ochin	Y	12/21/2022	100	Epic
ProHealth Care				

SSM Health				
Thedacare				Pending signed Free agreement
UnityPoint				
UW Health				
Wisconsin Statewide Health Information Network	Y	09/01/2022	3500	

DrFirst Facilities	
Alay Health Team	Wauwatosa Children's Clinic
ASSOCIATED MENTAL HEALTH CONSULTANTS	Watertown Regional Medical Center
Behavioral Health Svcs of Racine Co.	
Door County Memorial Hospital	
Dr. Colleen Worth, DNP, APNP	
FAMILY PSYCHIATRIC CARE, LLC	
Fort Healthcare	
GI Associates LLC	
Heartland Hospice	
Lake Superior Community Health Center	
Lifestance Health WI	
Marshfield Clinic Health System	
Mile Bluff Medical Center	
Mindful Healing and Wellness LLC	
Oak Medical	
Oral Surgery Associates of Milwaukee	
Orthopedic Hospital of Wisconsin	
PAIN MANAGEMENT AND TREATMENT CTR	
Reka Furedi MD	
Richland Hospital	
Watertown Rainbow Hospice	
Red Oak Counseling	
Regional Medical Center	
Rogers Memorial Hospital	
Sauk Prairie Memorial Hospital	

Interstate Data Sharing

RxCheck/EHR	PMPi
Connected	
IL, MD, NE, PA, UT, WA, ME	AZ, CO, DE, FL, HI, IA, ID, IN, MI, MN, MT, NC, ND, NM, NV, NY, OH, PR, SC, SD, TN, WV, Military Health System

2023 WI PDMP Outreach Calendar

MONTH	EVENT	DESCRIPTION	DATES	NOTES
January	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	1/12/2023	Virtual; Quarterly Meeting
February				
March	RxCheck Governance Board Bi-Annual Meeting	Participant; bi-annual meeting for state PDMP administrators	3/9/2023	Virtual
April	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	4/13/2023	Virtual; Quarterly Meeting
May	MOU- St. Croix Chippewa Indians of WI	MOU fully executed to enable PDMP participation of the St. Croix tribal nation	5/22/2023	
June	WI NADDI Conference (National Association of Drug Diversion Investigators)	Presenter; NADDI annual training for WI healthcare professionals and law enforcement agents who focus on drug diversion prevention and detection	6/16/2023	Wauwatosa, WI
	TTAC North and East Region PDMP Meeting	Participant; regional meeting for state PDMP administrators organized by PDMP Training & Technical Assistance Center - attendance is required for BJA HR PDMP Grant recipients.	6/27-29/2023	Kansas City, MO
July	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	7/13/2023	Virtual; Quarterly Meeting
August	2023 PMP InterConnect Steering Committee Meeting	Participant; Annual national meeting for PDMP administrators organized by National Association of Boards of Pharmacy (NABP)	8/15-16/2023	Mount Prospect, IL
	2023 Comprehensive Opioid, Stimulant, and Substance Use Program (COSSUP) National	Participant; Annual national meeting organized by US DOJ; attendance is required for BJA HR PDMP Grant recipients.	8/29-31/2023	Washington DC
September				
October	NASCSA Conference (National Association of State Controlled Substances Authorities)	Participant; annual national meeting for government controlled substances authority, PDMP and healthcare professionals organized by NASCSA	10/23-10/26/2023	Minneapolis, MN
	Overdose Fatality Review (OFR) State Advisory Group	DSPS Representative; inter-agency advisory board for OFR participating local sites	10/12/2023	Virtual; Quarterly Meeting
November				
December				

FENTANYL ADULTERATED OR ASSOCIATED WITH XYLAZINE RESPONSE PLAN

JULY 2023

THE WHITE HOUSE
EXECUTIVE OFFICE OF THE PRESIDENT
OFFICE OF NATIONAL DRUG CONTROL POLICY

Table of Contents

Background

On April 12, 2023, Dr. Rahul Gupta, Director of the Office of National Drug Control Policy (ONDCP), formally designated fentanyl adulterated or associated with xylazine as an emerging drug threat, pursuant to 21 U.S.C. § 1708. According to authorities provided to ONDCP by Congress in 2018, such a designation triggers a number of follow-on federal actions, outlined below.

The non-opioid drug xylazine is being distributed illicitly for human use in combination with fentanyl and is associated with significant and rapidly worsening negative health consequences, including fatal overdoses and severe morbidity (including deep flesh wounds). Xylazine is the active ingredient in an approved animal drug (xylazine hydrochloride), which the Food and Drug Administration (FDA) originally approved in 1972 for use in animals as a sedative and analgesic. Xylazine is not approved for use in humans. The Drug Enforcement Administration (DEA) reports that between 2020 and 2021, forensic laboratory identifications of xylazine rose in all four U.S. census regions, most notably in the South (193%) and the West (112%). The DEA also reports that xylazine-positive overdose deaths increased by 1,127% in the South and over 100% in all other regions.[1] For both laboratory identifications and xylazine-positive overdose deaths, the highest overall numbers (not percentage increases) were in the Northeast and Southern United States. These levels of geographic distribution and rapid increase in negative health outcomes meet the Emerging Threats Criteria used by ONDCP to judge when the novel use of a substance should be considered an emerging threat to the nation.

In addition, data from the Centers for Disease Control and Prevention's State Unintentional Drug Overdose Reporting System (SUDORS) shows that in 2021, 23 states and the District of Columbia[2] reported 41,224 overdose deaths to SUDORS. Xylazine was detected in 2,171 (5.3%) postmortem toxicology analyses and was listed as a cause of death in 1,717 (79.0%) deaths in which it was detected. This represents an increase from 2019, when the same jurisdictions reported 29,125 overdose deaths to SUDORS, and 667 (2.3%) overdose deaths with xylazine detected in postmortem toxicology analyses, and xylazine was listed as a cause of death in 427 (64.0%) of deaths in which it was detected. In 2021, 99.5% of xylazine-involved deaths also involved illicitly manufactured fentanyl or fentanyl analogues.

In deliberating this decision, Dr. Gupta consulted with the ONDCP-led Evolving and Emerging Threats Committee, representatives from the National Drug Control Program Agencies, the U.S. Emerging Threats Coordinator, and other governmental and non-governmental experts (including leaders in law enforcement and other first responders and frontline service providers, state and local officials, subject matter experts on the ground, and public health officials). During the Evolving and Emerging Threats Committee's January 17, 2023 meeting, the group expressed acute concern for the safety of those consuming both xylazine and fentanyl. Because xylazine is not an opioid and is therefore not impacted by the opioid reversal agent naloxone, persons using fentanyl adulterated with xylazine may be less responsive to naloxone—which should still be

[1] The Growing Threat of Xylazine and its Mixture with Illicit Drugs (dea.gov)

[2] Jurisdictions with sufficient toxicology report coverage and deaths with a toxicology report.

administered due to its lifesaving actions on fentanyl effects should an overdose occur. Those who develop dependence on these drugs also experience severe withdrawal symptoms requiring skilled, simultaneous treatment for both fentanyl and xylazine. Dr. Gupta noted in a statement:

> The United States today faces the most dangerous illicit drug supply in the history of the country. The deadly drug fentanyl is sold on its own and in combination with street drugs trafficked as heroin, cocaine, and methamphetamine, and it is contained in fraudulent prescription medications sold as opioid pain killers, sedatives, and stimulants. To make matters worse, the country now faces a severe challenge from xylazine, especially when combined with fentanyl. There is an urgent need to determine the source of xylazine and how to reduce the illicit supply; to develop evidence-based testing and overdose response protocols; and to determine how to treat those who have become dependent on the dangerous fentanyl and xylazine combination.

The emerging threat designation, made under the authority provided by *The Substance Use-Disorder Prevention that Promotes Opioid Recovery and Treatment (SUPPORT) for Patients and Communities Act of 2018* (P.L. 115-271), requires the Executive Branch to take several steps:

- First, ONDCP, in collaboration with relevant federal agencies, must draft and publicly issue a fentanyl adulterated or associated with xylazine Response Plan (within 90 days of designation).
- Second, ONDCP must issue Implementation Guidance to agencies (120 days after designation).
- Third, agencies must provide a specific Agency Implementation Report to ONDCP (180 days after designation).
- Fourth, ONDCP must publish a National Implementation Report on the Response Plan (in February 2024, with other ONDCP annual reports).

The response plan presented here fulfills the first of these requirements and addresses urgent public health and safety needs. The SUPPORT Act also requires that the ONDCP Director decide whether a stand-alone national media campaign would be effective in addressing the emerging threat. In the case of xylazine-adulterated fentanyl, Director Gupta has determined that it will be productive to include such public messaging on fentanyl adulterants in existing campaigns and other federal messaging on fentanyl, in lieu of establishing a new stand-alone campaign focused solely on xylazine.

The SUPPORT Act requires that an emerging threat response plan include evidence-based prevention, treatment, and supply reduction action steps, in addition to establishing goals and performance measures informed by comprehensive data. In the plan outlined below, we apply those requirements to the case of fentanyl adulterated or associated with xylazine and describe critically important and urgent next action steps.

Actions

Testing

Xylazine testing is being conducted in community and law enforcement settings for the purpose of detecting xylazine in drug products and postmortem toxicology settings, and the results of such tests can provide important information about this emerging threat. However, the use of such testing for xylazine is uneven across the United States, impeding the development of a full national threat picture. With respect to clinical testing, FDA has not authorized any in vitro diagnostic products (IVDs) intended to detect xylazine in human specimens.

The federal government will pursue the following xylazine-related testing action steps outlined below. Some of these efforts will more broadly focus on the class of α_2-adrenergic agonists, potentially on other drug classes, and on detecting other compounds of concern in the drug supply.

Standardize Forensic Testing Practices

There is a need to standardize practices across drug analysis laboratories, medical examiners and coroners, and public health laboratories, and to scale up forensic testing and postmortem toxicology testing to better estimate population level usage of or exposure to xylazine, alone or in combination with other drugs (especially fentanyl).

Develop New Tests for Clinical Settings

Develop, validate, authorize marketing of, and deploy, as appropriate, rapid tests for xylazine and fentanyl intended for real time clinical care (point of care testing).

Deploy Testing in Community Settings

Further develop, validate, and deploy, as appropriate, a test to detect xylazine in drug samples at all levels in the supply chain, from wholesale seizure quantities to retail levels within communities (including harm reduction services).

Target Testing to Those In-Need

During the development of the above-referenced tests, devise a statistical and clinical algorithm for predicting whether a patient has used xylazine based on epidemiological information, such as background community prevalence and clinical indicators, including flesh wounds. Validate the clinical algorithm and obtain any applicable FDA marketing authorization, as appropriate.

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Epidemiology and Comprehensive Data System

The SUPPORT Act and public health and public safety best practices require comprehensive, accurate, and timely data systems to address an emerging threat. The increases in samples from drug seizures testing positive for xylazine and drug poisoning deaths involving xylazine demonstrate that xylazine exposure is increasing rapidly. Accordingly, fentanyl adulterated with xylazine meets ONDCP's central criteria to determine whether a substance is an "emerging threat." Additional information is needed to inform, implement, and evaluate a comprehensive and coordinated public health and public safety response. Examples of such additional information might include xylazine sourcing and determining to what degree persons are encountering xylazine alone or xylazine-adulterated products. To advance this work, the federal government will pursue the following steps:

Epidemiological System Enhancement, Coordination, and Development

Enhance and coordinate data systems to develop a comprehensive epidemiologic data system, including utilization of new testing strategies noted above; standardize medical examiner and coroner reports regarding the presence and role of xylazine in fatalities; create a central repository of key data; develop and publish a timely "dashboard" of the spread and impact of xylazine-adulterated fentanyl on counties across the country; and, as needed, develop and utilize novel data collection strategies such as wastewater testing.

Standardize Use of Diagnostic Codes

Develop recommendations for ICD-10-CM and ICD-10 coding of xylazine to optimize precision in data systems.

Develop an Impact Assessment

Develop an assessment of the differential impact of xylazine-adulterated fentanyl on communities (where disparities are defined broadly and as described in recent federal reports on best-practices in equitable data collection and analysis), as well as an assessment of key social determinants of health that may be related to xylazine use.

Evidence-Based Prevention, Harm Reduction, and Treatment Implementation and Capacity Building

Xylazine-adulterated fentanyl poses a number of unique health challenges, including but not limited to: (a) insufficient responses to the naloxone required to address fentanyl overdoses but that doesn't impact xylazine effects; (b) severe breathing difficulty given xylazine's analgesic and central nervous system depressant effects, requiring intensive breathing assistance; (c) the development of "dual" dependence on both fentanyl and xylazine associated with extremely severe withdrawal symptoms; (d) difficulty initiating addiction treatment, including medication for opioid use disorder, for people using both fentanyl and xylazine given lack of consensus on the best treatment protocols, and because severe withdrawal symptoms may cause a patient to leave treatment against medical advice; and (e) development of serious wounds, the severity of

some requiring limb amputation. To address these and other concerning health challenges, the federal government will:

Develop and Deploy a Treatment Framework

Develop and disseminate best practices based on emerging clinical efforts with patients exposed to xylazine to identify the most promising clinical stabilization, withdrawal management (detoxification), and treatment protocols. Relatedly, utilize or establish efficient mechanisms for sharing and regularly updating current best practices information, using both federal and non-federal channels of communication such as health departments. Information about withdrawal management, treatment initiation, treatment retention, and re-engagement strategies will be particularly important.

Develop and Deploy Overdose Treatment and Other Harm Reduction Strategies

Rapidly evaluate potential xylazine overdose reversal strategies (including reversal agents) and inform educational and capacity-building efforts for persons who use drugs, community bystanders witnessing drug poisonings, persons leaving carceral settings, healthcare providers, harm reduction staff, and first responders on best practices to address overdoses due to xylazine, including overdoses involving xylazine and fentanyl (focused on the use of assisted breathing, hands-only CPR, and naloxone). These constituencies should be involved in message development to maximize credibility.

Capacity Building Among First Responders and Other Service Providers

Prioritize efforts to educate and equip healthcare providers, harm reduction staff, health-sector payers, and first responders on best practices to treat flesh wounds associated with xylazine. This should include explicitly encouraging federal grantees to utilize grant monies to address xylazine-related challenges, e.g., the purchasing of wound care kits and other resources needed for wound healing, or other validated intervention tools and strategies to coordinate care across a number of types of necessary services. These efforts may involve a variety of channels of communication.

Educate the Public

Collaborate with private and nonprofit sector partners to integrate adulterant information into existing national media campaign efforts related to fentanyl or toxicity of the drug supply more broadly, and continually gauge the need for xylazine-specific messaging.

Source and Supply Information and Intelligence; and Supply Reduction Actions

Xylazine is the active ingredient in an animal drug approved for veterinary use, but not human use. It is not a controlled substance, and public health and public safety officials need to know more about the sources of xylazine in the illicit drug supply chain and markets in the United States. This information will be critical when considering effective actions to take to disrupt the supply of xylazine destined for human use. The federal government will:

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Identify the Illicit Supply Chain

Identify sources of xylazine and determine whether it is diverted from legitimate supplies and/or synthesized for illicit use, including who may be synthesizing it (including the development of analytic protocols to identify such sources), and identify points and methods of illicit drug supply adulteration to disrupt and reduce the supply and trafficking of the illicit supply.

Enhance Regulation Capabilities

Enhance ability and jurisdiction to regulate the supply chain (e.g., from active pharmaceutical ingredient (API) producer, finished dosage form manufacturer, to the veterinarian) while maintaining availability for its legitimate uses in animals and research, and, separately, to restrict the unlawful entry of xylazine active pharmaceutical ingredients and finished dosage form drug products into the country.

Develop Interdiction Tactics

Identify and develop additional targeted and coordinated law enforcement actions and efforts to reduce the illicit supply of xylazine and the precursor chemicals associated with the production of illicit xylazine, and disrupt trafficking of fentanyl adulterated or associated with xylazine. Identify whether other substances may supplant xylazine as a fentanyl additive in the future.

Regulatory Control and Monitoring Options

As part of this action plan, the U.S. government should assess regulatory options to disrupt the production, distribution, illegal sale and trafficking (even if not scheduled), and exposure to illicit xylazine. The particular chemical nature of this non-opioid tranquilizer may pose challenges for traditional methods of testing drugs in scheduling decisions. The federal government will:

Explore Scheduling and Other Regulatory Options

Progress toward decisions on possible regulatory actions under the Controlled Substances Act, including scheduling of xylazine while simultaneously maintaining the legitimate supply of xylazine in veterinary medicine, and prioritizing facilitation of access to xylazine for research purposes. The government will also consider other potential avenues for prosecuting those who manufacture, import, export, sell, or distribute xylazine in order to support fentanyl trafficking.

Investigate Scope of Scheduling

Discuss whether any potential regulatory actions should be xylazine-specific or for a broader class of drugs or pharmacologically similar substances that could replace xylazine as a fentanyl adulterant.

Support Interdiction Efforts

Identify opportunities to enhance importation oversight, prevent diversion throughout the legitimate supply chain, and to further enable both civil and criminal actions by authorities to effectively interdict and reduce illicit supply.

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Basic and Applied Research

As noted above, there are multiple areas that require further knowledge for the comprehensive, optimal prevention and treatment of fentanyl-adulterated xylazine use and poisoning (i.e., identification of the most impactful treatment protocol for overdoses caused by fentanyl adulterated or associated with xylazine). Below are further areas of needed basic and applied research (though the topics may shift as this fast-moving area unfolds):

Treatment Development

Conduct research to evaluate as quickly as possible potential xylazine antidotes in humans, and identify the most promising clinical stabilization, detoxification, and treatment protocols.

Investigate How Xylazine Impacts Humans Physiology and Behavior

Conduct basic research on drug-drug interactions to understand the pharmacology, chemistry, biology and toxicology of how xylazine and fentanyl interact in humans and the behavioral consequences. Examine whether any of these effects vary across modes of xylazine administration (e.g., injecting, smoking, or inhalation). Include research on the effects of fentanyl adulterated with xylazine used during pregnancy.

Research Social Outcomes of Xylazine Use in Humans

Conduct applied research on population-level health, social, equity, and economic drivers and consequences of exposure to fentanyl adulterated with xylazine.

Research on Use Motivations

Conduct research on awareness of and motivations for use of xylazine-containing products, strategies people use to reduce harm, how motivations related to use are changing over time, as well as the recovery process for those who have been able to stop use after a sustained period of consumption of xylazine-adulterated fentanyl.

Goals

Pursuant to the SUPPORT Act and the Criteria for Designating Evolving and Emerging Drug Threats (Dir. No. 2022-002), the Director of National Drug Control Policy is establishing a national goal that, if met, would lead to the termination of fentanyl adulterated or associated with xylazine as an emerging threat. The goal is:

A 15% reduction (compared to 2022 as the baseline year) of xylazine positive drug poisoning deaths in at least three of four U.S. census regions by 2025.

Key shorter-term actions include the following by the end of fiscal year (FY) 2024 (*additional FY24 action objectives may be provided by National Drug Control Program agencies in their emerging threat implementation report due to ONDCP 180 days after fentanyl adulterated with xylazine is designated an emerging threat, and other important action steps are listed in the plan above*):

- Development, validation, marketing authorization, and deployment, as appropriate, of tests for xylazine and/or fentanyl intended for real-time clinical care (point of care testing). [Measured dichotomously on each of the four stages listed here.]
- Development and rapid evolution of best practices for initiating and maintaining treatment of fentanyl adulterated or associated with xylazine in healthcare settings. [Measured dichotomously and evidenced by publicly-available best practices document.]
- Development and rapid evolution of wound care best practices for successfully treating flesh wounds associated with fentanyl adulterated or associated with xylazine in community-based and other situations. [Measured dichotomously and evidenced by publicly-available best practices document.]
- Implementation of capacity-building programs focused on fentanyl adulterated or associated with xylazine treatment and wound care to be available (virtually) to all healthcare providers (including harm reduction service providers) in the United States. [Measured dichotomously and evidenced by publicly available capacity building materials online.]
- Identification and commencement of implementation strategies to identify the sources and to reduce the diversion and/or illicit supply of xylazine, especially focused on xylazine being used as an adulterant with fentanyl. [Measured dichotomously by actions described in briefing materials to ONDCP Director and which may or may not be publicly-available depending on sensitivity of information.]

Conclusions and Key Federal Leadership Responsibilities

Xylazine is a substance not meant for human consumption and is particularly harmful in combination with fentanyl. All those who may use fentanyl adulterated with xylazine are encouraged to seek medical care as well as behavioral health services. Although more information is necessary to develop the most effective testing and treatment protocols, medical professionals possess enough information to improve the health and safety of those exposed to xylazine and facing serious negative health consequences. Partnering with the community, especially community-based programs with experience working with individuals actively using fentanyl adulterated with xylazine, will be critical for maximum impact.

While this plan outlines action steps the federal government will pursue to address this threat, we need a whole-of-society effort to save lives. Healthcare providers are encouraged to be on the alert for signs and symptoms of patients' exposure to fentanyl adulterated with xylazine and to provide effective care for overdose and wounds, and initiate or transfer care to opioid use disorder treatment services wherever these patients are encountered. State, county, and city health authorities are encouraged to proactively seek out those believed to be consuming fentanyl adulterated with xylazine to offer mobile, low-threshold care before their conditions worsen. Addiction treatment and emergency responders should consult with experts on xylazine detoxification methods to understand emerging practices. Law enforcement and elected officials must coordinate with their public health colleagues in order to enhance the efficacy of their efforts to reduce and disrupt the illicit supply chain and go after traffickers. Community-based programs will be amongst the first to interface with individuals vulnerable to fentanyl adulterated with xylazine and will be key partners in these efforts. These are urgently needed, practical steps that can help mitigate the harmful impacts of xylazine as the elements of the response plan described above come to fruition.

As further actions are taken on this response plan, multiple federal agencies and many partners will have important roles to play. In the table below, some initial key areas of federal department-level leadership are noted; as each agency develops an implementation strategy to enact this response plan, this list of departmental-level leadership and partnership may evolve.

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Key Department-level Leadership and Partnership Roles, by Activity Area

Testing	Department of Health and Human Services, Department of Justice, Department of Veterans Affairs
Standardize Forensic Testing Practices	Centers for Disease Control and Prevention
Develop New Tests for Clinical Settings	Food and Drug Administration, Centers for Disease Control and Prevention
Deploy Testing in Community Settings	Substance Abuse and Mental Health Services Administration, Health Resources Services Administration, Centers for Disease Control and Prevention
Target Testing to Those In-Need	Centers for Disease Control and Prevention, Food and Drug Administration
Epidemiology and Comprehensive Data	Department of Health and Human Services, Department of Justice, Department of Transportation
Epidemiological System Enhancement, Coordination, and Development	Centers for Disease Control and Prevention, Substance Abuse and Mental Health Services Administration, Drug Enforcement Administration
Standardize Use of Diagnostic Codes	Centers for Disease Control and Prevention
Develop an Impact Assessment	Substance Abuse and Mental Health Services Administration, Health Resources Services Administration
Evidence-based Prevention, Harm Reduction, and Treatment Implementation and Capacity Building	Department of Health and Human Services, Department of Veterans Affairs, Department of Transportation
Develop and Deploy a Treatment Framework	Substance Abuse and Mental Health Services Administration, National Institute on Drug Abuse, Veterans Health Administration, Health Resources and Services Administration, Centers for Medicare and Medicaid Services

Develop and Deploy Overdose Treatment and Other Harm Reduction Strategies	Substance Abuse and Mental Health Services Administration, Veterans Health Administration, National Institute on Drug Abuse, Centers for Disease Control and Prevention
Capacity Building Among First Responders and Other Service Providers	Substance Abuse and Mental Health Services Administration, Centers for Disease Control and Prevention, National Highway Traffic Safety Administration
Educate the Public	Centers for Disease Control and Prevention
Source and Supply Information and Intelligence; and Supply Reduction Actions	Department of Justice, Department of Homeland Security, Department of State, Department of Health and Human Services
Identify the Illicit Supply Chain	Food and Drug Administration, Drug Enforcement Administration
Enhance Regulation Capabilities	Food and Drug Administration, Drug Enforcement Administration
Develop Interdiction Tactics	Bureau of International Narcotics and Law Enforcement, Drug Enforcement Administration, Food and Drug Administration
Regulatory Control and Other Regulatory Options	Department of Health and Human Services, Department of Justice
Explore Scheduling and Other Regulatory Options	Food and Drug Administration, Drug Enforcement Administration
Investigate Scope of Scheduling	Food and Drug Administration, Drug Enforcement Administration, National Institute on Drug Abuse
Support Interdiction Efforts	Drug Enforcement Administration, Food and Drug Administration
Basic and Applied Research	Department of Health and Human Services, Department of Justice, Department of Veterans Affairs
Treatment Development	National Institute on Drug Abuse, Food and Drug Administration

Investigate How Xylazine Impacts Humans Physiology and Behavior	National Institute on Drug Abuse
Research Social Outcomes of Xylazine Use in Humans	Centers for Disease Control and Prevention, National Institute on Drug Abuse
Research on Use Motivations	Substance Abuse and Mental Health Services Administration, National Institute on Drug Abuse
Oversight and Coordination	White House Office of National Drug Control Policy